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Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

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Abstract

Objective: Surgical complications may affect patients psychologically due to challenges such as prolonged recovery or long-lasting disability. Psychological distress could further delay patients' recovery as stress delays wound healing and compromises immunity. This review investigates whether surgical complications adversely affect patients' post-operative wellbeing and the duration of this impact.

Methods: The primary data sources were 'PsychINFO', 'Embase' and 'MEDLINE' through OvidSP (year 2000 to May 2012). The reference lists of eligible articles were also reviewed. Studies were eligible if they measured the association of surgical complications after cardiac, thoracic, gastro-intestinal or vascular surgery with adult patients' post-operative psychosocial wellbeing using validated tools or psychological assessment. 13,605 articles were identified. Two researchers independently extracted information from the included articles on study aims, participants' characteristics, study designs, surgical procedures, surgical complications, wellbeing outcomes and findings. The studies were synthesised qualitatively. Supplementary meta-analyses of the impact of surgical complications on patients' wellbeing were also conducted.

Results: 50 studies were included. Two thirds of the studies found that patients who suffered surgical complications had significantly lower levels of post-operative psychosocial wellbeing even after controlling for patients' pre-operative wellbeing, clinical and demographic factors. There were significant and clinically meaningful differences between patients with complications and patients without on aspects of quality of life including 'problems with daily activities due to emotional problems' (p<.01), 'interference with social activities due to physical and emotional problems' (p<.001), and 'feelings of nervousness and depression' (p<.001). Half of the studies with significant findings reported significant adverse effects of complications on patients' wellbeing at 12 months (or more) post-surgery.



Strengths and weaknesses of this study

- This is, to our knowledge, the first systematic review of the literature assessing the impact of surgical complications on patients' psychosocial wellbeing.
- The validity of the findings is reinforced by the fact that only studies that used validated selfreport measures for the assessment of patients' wellbeing were included in the review, as well as by the use of a very comprehensive search strategy for the identification of relevant literature.
- Caution should be taken when interpreting these findings to other specialties as the review was limited in four surgical specialties.
- A limitation of this review was the very small number of studies with sufficient data for
 quantitative synthesis, which did not also permit certain types of sensitivity analyses such as by
 surgical specialty or type of surgery.

Introduction

Surgical complications pose significant challenges for surgical patients. Complications may vary from very minor events that can be resolved relatively quickly without the need for pharmacological treatment or other intervention, to more serious events which can be life-threatening, require multiple interventions (e.g. return to theatre), delay patient's discharge and may lead to multi-organ failure or even death. ¹ A recent review of the literature found that post-operative complications contribute to increased mortality, length of stay and an increased level of care at discharge. ²

Other than the complications' impact on patients' post-operative recovery, they may also affect patients psychologically. They may contribute to the development of severe psychological distress such as depression or anxiety due to the challenges that are inherent to them in terms of prolonged recovery or long-lasting disability (e.g. severe post-operative pain, permanent disfigurement). An early study found that patients who experienced serious adverse events after surgery reported higher levels of distress than people who had experienced serious accidents or bereavements and psychosocial adjustment worse than in patients with serious medical conditions. ³ Moreover, the authors of an interview study on patients' experiences of cardio-thoracic surgery reported that a small number of patients who had a long and complicated post-operative hospital stay expressed intense feelings of hopelessness and depression. ⁴ Psychological distress resulting from the experience of surgical complications could further delay patients' recovery from surgery as increased levels of stress delay wound healing ^{5,6} and compromise immunity. ^{7,9}

This review aims to critically review and synthesize the existing literature on the psychosocial impact of surgical complications on adult surgical patients and to estimate the types and duration of this impact. For this purpose, quantitative studies which assessed the association of surgical complications with adult patients' psycho-social wellbeing post-surgery were reviewed. Our hypothesis was that the occurrence of surgical complications adversely affects patients' psychosocial wellbeing. More specifically, the research questions that this systematic review aims to answer are:

- Do surgical complications impact on patients' psychosocial wellbeing?
- Is the psychosocial impact transitory or long-lasting?

Methods

Search strategy

The following databases were searched through OvidSP: 'PsychINFO' (1967 to 25th May 2012), 'Embase' (1947 to 25th May 2012) and 'Medline' (1948 to 25th May 2012). A search strategy was developed specific to each database. The three facets of the search strategy were:

A. Adult surgical patients

Terms such as patients, inpatients, outpatients, men, women were used for this facet.

B. Patient psychosocial outcomes

Key psychosocial outcomes that are commonly used to assess patients' wellbeing include anxiety, depression and quality of life. Terms for post-traumatic stress were also included due to the relevance of this psychological outcome in situations where a person is exposed to extreme stress. ¹⁰ Generic terms such as wellbeing and emotions were also used.

C. Surgical complications

Surgical complications were defined as any adverse event in relation to the surgical procedure including search terms for complications (e.g. adverse events, untoward incidents) and terms about the surgical setting (e.g. surgical, post-operative).

Each of the facets was expanded into a list of search terms truncated and combined with each other using Boolean operators, and also by mapping those to their relevant MeSH headings and sub-

headings in each database (through explosion of each MeSH heading). The search was restricted to titles and abstracts, and the results were limited to studies that used human participants and were written in English. The search strategies are presented as supplementary material. Database searching was complemented by reviewing the reference lists of eligible articles.

Eligibility criteria

Studies were included in the review if they met the following criteria:

- Any quantitative study that measured the association of surgical complications with adult
 patients' psychosocial wellbeing after surgery, either as a primary or secondary aim. Specific
 types of complications were not pre-defined as this review was interested in the impact of
 any surgical complications on patients' wellbeing. Psychosocial wellbeing was assessed with
 validated self-report tools or psychological assessment.
- Studies of surgical complications after cardiac, thoracic, gastro-intestinal or vascular surgery
 where complications are more likely to occur. ¹¹ Studies of neuropsychological complications
 (e.g. delirium) and studies of transplantation procedures were excluded.

Conference proceedings, non-empirical data and articles that were published before the year 2000 or with the majority of their participants recruited before the year 2000 were excluded. This current approach in the selection of literature was expected to reduce bias resulting from studies of outdated surgical practices.

Study selection

A total of 50% of the abstracts were reviewed independently by two researchers (AP and RD) and disagreements were resolved by consensus. The remaining half of the retrieved abstracts were

reviewed by the primary researcher (AP) based on the consensus that was achieved for the first half. After excluding ineligible articles at abstract and title level, the remaining articles were assessed in full text. The eligibility criteria were applied again on each article. Reasons for exclusion were coded. Articles for which there was uncertainty were discussed between the primary researcher (AP), a researcher with background in psychology (RD) and a researcher with background in surgery (AA). Any disagreements were resolved by consensus.

Data extraction and quality assessment

The primary researcher (AP) and a researcher with a background in surgery (AA) independently extracted data from 20 articles, which they reviewed for any disagreements. Disagreements were resolved by consensus or referral to a third senior researcher (OF). Data were extracted from the remaining articles by the primary researcher and were later checked by the second reviewer (AA). A total of 10 authors were contacted by email to provide information that was not included in the manuscript. Three articles were excluded from the analysis as their authors did not respond to our requests for further information. Information was extracted from each article on study aims, participants' characteristics, study design, surgical procedure, surgical complications (i.e. types, definitions and method of recording, where available), wellbeing outcomes (including scales and time-points of measurement) and relevant findings.

The quality of the included studies was assessed with the Newcastle Ottawa scales (NOS). ¹² The scales were modified in order to reflect the research questions of the review and to also incorporate the assessment of cross-sectional studies.

Data synthesis

The included studies were first synthesised narratively. In order to quantify the degree of the impact of surgical complications on patients' wellbeing quantitative procedures were also used. A meta-analysis was conducted on each extracted wellbeing outcome using Review Manager (version 5.2).

1² was used to calculate the heterogeneity present in the meta-analyses. Heterogeneity was considered low when it was below 25% and high above 50%.

1⁴ A random effects approach was chosen, as a degree of heterogeneity between studies should always be assumed in social sciences.

1⁵ Where multiple assessments were conducted in one single study, only the one furthest from the participants' surgery was included in the meta-analysis.

Results

18,585 articles were retrieved in total across the three databases. After removing duplicate references, a total of 13,605 papers were reviewed at abstract and title level. 994 articles remained to be assessed in full text. A total of 51 articles (50 studies) were eligible for inclusion in the final stage of the review (see Figure 1).

-Figure 1 -

Study characteristics

Details of the included studies are presented in Tables 1-3. A total of 28 studies were conducted in Europe, 14 in the US, three in Australia, two in Turkey, one in Egypt, one in Japan, and one in Taiwan. There were 29 studies in gastro-intestinal, ¹⁶⁻⁴⁴ 17 in cardio-thoracic, ⁴⁵⁻⁶² and four in vascular surgery. ⁶³⁻⁶⁶ The majority of the included studies (40 studies) assessed major procedures. The most common indications for surgery were heart conditions, followed by different types of cancer.

Twenty-three studies examined the association between surgical complications and patients' wellbeing as a primary research aim. ^{17, 19, 28, 30-38, 43, 47, 48, 50-53, 55, 62, 64, 66} The remaining examined this relationship as part of an exploration of the association of different clinical factors with patients' postoperative wellbeing. The majority of the studies were cohort studies. There were four case-control and 20 cross-sectional studies.

Quality of life was the main psychosocial outcome. Three studies assessed anxiety, ^{30, 40, 62} four studies assessed depression, ^{31, 41, 49, 62} and one study assessed mood states. ⁴¹ No other psychosocial outcomes were studied. The SF-36 (and its associated versions, i.e. SF-12, SF-20) was the most commonly used scale for the assessment of quality of life. ^{18, 25-31, 36-38, 42, 43, 45, 46, 48, 51-55, 57-59, 61, 63}

The vast majority of the studies used a-priori definitions of complications. For example, Bloemen et al. recorded only severe complications based on a grading system of surgical operations. ¹⁹ Dasgupta et al., also recorded major complications which were defined as "those associated with systemic illness requiring transfer to a higher level of care or requiring relaparotomy, or complications needing interventional radiology". ²³ Others used pre-defined categories of complications such as infections, respiratory complications, chronic postoperative pain or perioperative myocardial infarctions. A total of 14 studies did not define or describe the complications that were recorded. The majority of the studies recorded a range of post-operative complications. 18 studies focused on a single category of complications (e.g. anastomotic leaks, peri-operative myocardial infarctions, wound complications, atrial fibrillation). Complications were mostly recorded through medical records review, clinical examinations and review of administrative databases.

Study quality varied. The scores of the included studies ranged from 2 to 8, with a mean score of 5.9. Points were deducted for the following reasons: lack of information on how complications were defined or on the methods that were used for their recording, ^{16-18, 21-23, 25, 29, 35, 37, 40-42, 46, 51, 55-57, 61, 63} lack of information on response rates, ^{16, 21, 22, 25-27, 29, 37, 40, 50, 52, 54, 55, 57, 60, 61} patients' baseline wellbeing was not measured or controlled for in the analysis, ^{17, 19, 20, 25, 27, 30-36, 38-40, 43-45, 47, 49, 53, 63} and

 demographic or clinical factors were not controlled for. ^{20, 25, 27, 31, 32, 34, 40, 43, 45, 51, 56, 61, 63} Only 7 studies scored exceptionally low (i.e. below 4).

-Tables 1,2,3-

The impact of surgical complications on patients' wellbeing

The majority of studies (n=32) found that patients who suffered surgical complications had significantly lower post-operative wellbeing than patients with uncomplicated recovery. 16-20, 22, 24, 25, ^{28, 30, 31, 33, 35-37, 39, 41-48, 50-52, 54, 57, 60, 62, 65} This was the case not only after major surgical procedures but also after relatively minor operations such as hernia repairs. 30, 18, 28, 31, 43 The vast majority (n=25, 78%,) were of high quality (i.e. quality assessment score greater than 6 out of 8). For instance, more than half of the studies with significant findings had measured and controlled for patients' baseline wellbeing (n=18) 16, 18, 22, 24, 28, 37, 41, 42, 46, 48, 50-52, 54, 57, 60, 62, 65 and used multivariate analyses (n=21), 16, 18, 19, 22, 24, 25, 28, 35, 37, 39, 41, 42, 44, 46, 47, 50, 52, 54, 60, 62, 65 suggesting that complications remained a significant independent predictor of patients' postoperative wellbeing even after controlling for a range of clinical and demographic factors. Domains of patients' wellbeing that were significantly negatively affected by surgical complications included physical, emotional, and social aspects of patients' quality of life as well as anxiety and depression levels (see Table 4). Complications that were found to be significantly associated with low levels of patient wellbeing included both major events such as perioperative myocardial infarctions after CABG, 50 severe incontinence after internal sphincterectomy ³¹ or graft-related events after vascular surgery, ⁶⁵ and minor complications such as wound infections after hepatic resection, ²⁰ or new cardiac arrhythmias after CABG. ⁵⁴ The complications that were significantly associated with patients' post-operative wellbeing are presented in Tables 1-3.

Six studies reported a confounding association between surgical complications and patients' wellbeing (i.e. complications were significantly associated with worse wellbeing only under certain

conditions) ^{21, 32, 40} or complications were significantly associated with patients' wellbeing at univariate but not at multivariate analysis. ^{49, 59, 64} A total of 12 studies did not find a significant association of surgical complications with patients' postoperative wellbeing. ^{23, 26, 27, 29, 34, 38, 53, 55, 56, 61, 63, 66} The majority of them (n=7) scored below 6 on quality assessment. For example, four studies suffered from very small sample sizes. ^{26, 27, 34, 38}

-Table 4 -

Meta-analyses

 A series of supplementary meta-analyses were conducted on each extracted outcome (i.e. quality of life, anxiety, depression). For a meta-analysis on Quality of life only studies that used the SF-scales were considered, as they were the most commonly used quality of life assessment tools. There were three studies with sufficient data on the physical and mental quality of life component scores, 28, 31, 45 and three studies with data on 'physical functioning' (i.e. limitations in performing physical activities), 'bodily pain' (i.e. limitations due to pain), 'role -physical' (i.e. problems with daily activities as a result of physical health), and 'role -emotional' (i.e. problems with daily activities as a result of emotional health), 36, 37, 48 Moreover, there were four studies with sufficient data on 'general health' (i.e. evaluations of overall health), 'social role functioning' (i.e. interference with normal social activities due to physical and emotional problems), 'mental health' (i.e. feelings of nervousness and depression), and 'vitality' (i.e. feeling tired). 31, 36, 37, 48 The pooled mean differences between the two groups were significant for each quality of life sub-domain. The pooled differences were more than 5 points (on a scale from 0 to 100) for most of the sub-domains, indicating clinically meaningful 67 adverse effects of complications on the different quality of life domains (see supplementary materials). Two studies provided sufficient data for a meta-analysis on anxiety. 30,62 The pooled SMD was not significant. A meta-analysis on depression was not possible as only one study provided sufficient data. 30

For a more detailed report of the meta-analyses see the supplementary materials.

The duration of the impact of surgical complications on patients' wellbeing

Eighteen out of the 38 studies which reported significant associations (including the six studies which reported confounding findings) found a significant relationship of the presence of post-operative complications with lower levels of wellbeing at 12 months post-surgery or later. ^{16, 19-22, 25, 28, 30-33, 36, 37, 47, 48, 50, 51, 65} Twenty studies reported a significant association of complications with lower levels of patient wellbeing less than 12 months post-surgery. ^{17, 18, 24, 35, 39-46, 49, 52, 54, 57, 59, 60, 62, 64}

Discussion

This is, to our knowledge, the first systematic review of the literature assessing the impact of surgical complications on patients' psychosocial wellbeing. In line with our hypothesis, two thirds of the included studies found a significant negative association between the occurrence of surgical complications and patients' postoperative wellbeing. The vast majority of those studies were of high quality. For instance, more than half of the studies with significant findings found that complications were an independent predictor of patients' postoperative wellbeing after controlling for pre-existing differences on patients' wellbeing, clinical and demographic variables.

Significant associations were reported between surgical complications and lower scores not only on physical but also on emotional and social dimensions of the various quality of life measures. A meta-analysis of the studies that used the SF-scales confirmed the existence of significant and clinically meaningful adverse effects of complications on various domains of patients' quality of life including patients' mental health, social functioning and problems with daily activities as a result of emotional problems. These findings confirm earlier preliminary findings on the psychological burden that surgical adverse events often cause on patients. ^{3, 4} Surgical complications were also significantly associated with higher post-operative anxiety and depression in individual studies, even though a

population effect could not be shown in meta-analysis due to the very small number of studies that assessed anxiety and depression in relation to surgical complications. Despite the fact that quality of life is a useful screening outcome offering a general picture of a person's physical health and psychological state, ⁶⁸ future studies on the psychosocial impact of surgical complications should focus more on outcomes such as anxiety and depression as they offer a more accurate picture of a person's psychological wellbeing. Highly relevant psychological outcomes such as post-traumatic stress that were not assessed in any of the included studies would also be of relevance for future research in this area.

Complications that were found to significantly contribute to patients' low post-operative wellbeing ranged from severe adverse events such as anastomotic leaks after gastro-intestinal surgery or perioperative myocardial infarctions after cardiac surgery to relatively minor complications such as wound infections or atrial fibrillation. It is not therefore only severe post-operative events that cause emotional distress and disruption during patients' convalescence but also less serious complications. Wound complications for instance may affect patients' satisfaction with their body image which may in turn affect their quality of life and psychological wellbeing. ⁶⁹ Moreover, this finding shows that the severity of complications as judged by clinicians does not always relate to how patients experience complications or how severely they are affected by them. Similarly, complications were found to be negatively associated with patients' post-operative wellbeing not only after major surgical procedures but also after relatively minor operations, ^{30, 18, 28, 31, 43} which suggests a potential independence of the magnitude of initial surgery with the development of significant effect of complications on patients' wellbeing. Further research on how complications affect patients' wellbeing after different types of surgery will help elucidate the role of this factor.

A considerable number of studies also found a significant negative contribution of surgical complications to patients' psychosocial wellbeing more than a year post-operatively, suggesting that patients may suffer psychologically due to the experience of surgical complications for an extensive

period of time after their surgery. The above findings hold important implications for surgical patients' recovery. There is growing evidence on the role of psychological stress in compromising the function of the immune system and slowing down wound healing. ⁷⁻⁹ The emotional distress that surgical complications inflict on patients is likely to further compromise their recovery in almost a reciprocal cycle of distress and decreased immune function. The exact relationships between the occurrence of surgical complications, psychological distress and speed of recovery warrant further investigation.

It is noteworthy that a smaller number of studies did not find a significant association between complications and patients' postoperative wellbeing or found significant univariate associations which were not replicated in multivariate models. Even in studies showing a significant impact there will be many patients who largely maintain their psychological health and quality of life in the aftermath of complications. Other than clinical factors, factors such as patients' ways of coping with stress, their appraisals of surgery and their condition as well as their perceptions of support from their loved ones and the healthcare professionals may also explain under which conditions complications affect patients' psychosocial wellbeing, as suggested by wider literature on patients' adjustment after surgical treatment. 70-72 The contribution of psychological factors in ameliorating the psychological impact of surgical complications needs to be further explored.

Overall the quality of the included studies was good as indicated by their relatively high quality assessment scores and the small number of studies that scored exceptionally low. A substantial number of studies with significant findings accounted not only for patients' pre-operative wellbeing but also for a host of other clinical and demographic factors in multivariate analyses confirming that surgical complications were an independent predictor of low levels of postoperative wellbeing above and beyond any pre-existing differences. The validity of the findings is also reinforced by the fact that all the included studies used validated self-report measures for the assessment of patients'

wellbeing, as well as by the use of a very comprehensive search strategy for the identification of relevant literature.

Limitations

A few caveats should be borne in mind when interpreting the above findings. Firstly, even though the majority of the included studies used predefined lists or definitions of complications one third of them did not define or describe the complications that were recorded, nor did they explain their methods of complications recording. Moreover, almost one third of the studies did not describe their response rates, which does not permit inferences about the representativeness of their samples. With regards to the methodology of the systematic review, studies that were published before the year 2000 or with the majority of patients recruited before the year 2000 were excluded. However, limiting this review to literature that was published in the last decade is more reflective of current surgical practices and their associated complications. Caution should also be taken when interpreting these findings to other specialties as the clinical setting in which complications occur may affect their impact on patients' wellbeing. Another limitation was the very small number of studies with sufficient data for quantitative synthesis and the difficulty of synthesising data from different quality of life measures, which resulted in restricting the meta-analyses on data collected only with the SF scales. The small number of studies with available data did not also permit certain types of sensitivity analyses such as by surgical specialty, type of surgery (i.e. minor versus major surgery) or underlying disease (e.g. cancer versus other conditions). These factors may be significant determinants of the extent to which complications negatively impact on patients' post-operative wellbeing. Future studies on the association of surgical complications with outcomes such as anxiety, depression and post-traumatic stress, other than allowing a more accurate investigation of the complications' psychological impact, would also permit fuller meta-analyses of these effects. Lastly,

 there is always the potential for publication bias where studies with significant results and big effect sizes are more easily published. ⁷³⁻⁷⁵

Implications of findings

The results highlight the importance of considering patients' psychological needs in the aftermath of complicated surgical recovery. Surgical and nursing staff need to be aware of the challenges of surgical complications for patients' wellbeing and ensure that their psychological needs are not neglected. Screening patients who suffer post-operative complications for symptoms of psychological distress could help clinical staff identify those patients who need psychological support. Facilitating patients' access to psychological support during their hospital stay and arrangements for follow-up support could also be of great value for patients' post-operative wellbeing. For example, early referral to psychological services and early psychological interventions could prevent long-term psychological distress and may also mitigate the negative effects of stress on patients' recovery. Primary care practitioners and carers need also to be aware of the psychological burden that surgical complications impose on patients' lives in order to recognise their distress in time and to provide the support that patients need.

Conclusions

This is the first systematic review of the literature on the impact of surgical complications on patients' psychosocial wellbeing. The findings of this review strongly suggest that surgical complications are a significant independent predictor of patients' impaired post-operative psychosocial wellbeing often for a very long time post-surgery. It is not only major complications that may compromise patients' psychosocial wellbeing but also relatively minor adverse events,

which implies that the clinical severity of complications does not always indicate how seriously patients will be affected by them. Patients who experience surgical complications report lower levels of different aspects of quality of life than patients with uncomplicated recovery, often more than a year after their operation. The ways in which complications are managed (e.g. reoperation versus conservative management), the type of surgery (e.g. minor versus major), the underlying disease (e.g. cancer versus other conditions), psychological mechanisms (e.g. patients' perceptions of support, illness perceptions, coping strategies) or cultural influences may be key factors that moderate the impact of surgical complications on patients' psychosocial wellbeing. Future research should try to disentangle the contribution of the above factors on the impact of surgical complications on patients' post-operative wellbeing. Lastly, future studies should try to understand the impact of surgical complications on psychological outcomes such as anxiety, depression and traumatic stress and how to better support patients who experience a complicated post-operative recovery.

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Competing interests: None

Contributions: All co-authors contributed to the study design and reviewed drafts of the article. The first author screened all the articles for inclusion in this review, extracted and synthesised the data, and appraised the study quality. RD screened a sample of these at title/abstract and full text, and AA extracted data and scored the quality of a sample of the included articles.

Data sharing: No additional unpublished data

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Table 1: Key characteristics of gastro-intestinal surgery studies (n=29)

4	First author's name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per timepoint, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of surgical complications with patients' wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
2										Quality of life			
					Nt1=71/?	Colorectal cancer,			Morbidity was defined as any event that resulted	(QOL)/at time of			1
3					Nt2=63	male patients who	Observational,	Open surgical	in the need for additional therapy or readmission	diagnosis and 12			İ '
4						underwent open	cohort,	therapy for colorectal	to the hospital within 30 days of initial	months after		Any complications/12	1
	Anthony	2003	US	Secondary	Nc=16	surgical therapy	prospective	cancer	discharge/Method not specified	surgery/FACT-C ¹	YES*	months post- surgery	6
5						Patients with			A major complication was defined as reoperation,				1
6						esophageal or		Upper gastro-	readmission to the high-dependency or intensive				1
7						gastric cancer who		intestinal surgical	care unit, readmission to the hospital within 30	QOL/39.6days after			1
					N=139/162	underwent upper		treatment for	days of operation, or death within 30 days of	treatment (range,6-		Any complications/39.6	1
8				D.C.	N . 27	gastro-intestinal	Observational,	esophageal or gastric	operation or later if the patient did not leave the	105)/EORTC QLQ-C30	YES	days after treatment	1
9 🗠	Avery	2006	UK	Primary	Nc=37	surgical treatment	cross-sectional	cancer	hospital/Method not specified		163	(range: 6–105)	5
2					Nt1=151/205 Nt2=130 (86.1%)								İ '
0					N(2=130 (86.1%)								İ '
1					Nc(complaints)=49								1
2					Nc(wound infection)=5					QOL/14 days pre-op,			1
4					Nc(seroma)=13	Patients	Observational.		Retrospective list: Any complaint, Wound	14 days post-op, and			1
3					Nc(pneumonia)=1	undergoing	cohort,		infection, Seroma, Pneumonia, other	6 months post-op/SF-		Any complications/6	1
1	Bitzer	2008	Germany	Secondary	Nc(other)=28	cholecystectomy	prospective	Cholecystectomy	complaints/Patient reports	36	YES*	months post-surgery	İ '
	DILZEI	2008			(р. очровито		Only severe complications were considered: Grade				
5									III or IV complications (according to Dindo's				1
6								Surgical treatment	model) were defined as severe, whereas absence	QOL/36 (16-51)		Severe post-operative	1
7					N=121/170			for adenocarcinoma	of complications or Grade I and II complications	months post-op		complications/Median	1
'	DI	2009	Netherlands	Primary	Nc=33	Rectal cancer patients	Observational, cross-sectional	of the rectum	were defined as absent or mild complications/patient records	/EORTC QLQ-C30 & CR38 ³	YES	of 36 (range, 16–51)	6
8⊢	Bloemen	2009	Netherianus	rilliary	INC-33	Patients who	CIOSS-SECTIONAL	the rectum	complications/patient records	CNOO	11.3	months post-surgery	
9						underwent							Í '
						curative hepatic							1
0						resection for			Surgical (e.g. bile leak or biloma, pneumothorax,				1
1					N 06/400	malignant or non			wound infection, liver abscess, bleeding, and				1
-					N=96/188	malignant diseases, disease			surgical dehiscence) and medical (e.g. pleural effusion, renal failure, hepatic failure, pneumonia,				1
2					Nc(any morbidity)=30	free at time of	Observational,		cardiac insufficiency, and cholangitis)/patient	QOL/ 3-36 months		Wound infections/3-36	1
3	Bruns	2010	Germany	Secondary	Nc(wound infections)=10	assessment	cross-sectional	Hepatectomy	records	post-op /SF-12	YES	months post-surgery	5

¹ Functional assessment of cancer therapy questionnaire with the colorectal module

 $^{^2}$ European Organisation for Research and Treatment of Cancer core 3 European Organisation for Research and Treatment of colorectal cancer

Retrospective list: pulmonary atelectasis or pneumonia, prolonged ileus, minor wounds

								problems and urinary retention. Slippage with a peak incidence during the second postoperative				
								year. Band erosion with penetration into the				
								stomach. Access port problems (infection,			Band removal for	
				Nt1=152/?	Consecutive			hematoma, leak, disconnection), bands			complications such as	
				Nt(4)=139	patients operated	Observational,	Laparoscopic	explanted, associated with erosion, obstruction,	QOL/pre-op, 1, 3		erosion, slippage,	
1					on for morbid	cohort,	placement	immediate intolerance, and recurrent tubing	months & 2 years		intolerance/2 year post-	
Champaul	t 2006	France	Secondary	Nc=(unclear)	obesity.	prospective	of a gastric band	break/Method not specified	post-op/GIQLI ⁴	CONFOUNDING*	surgery	6
				N=102/218								
<u>'</u>				Nc(anastomotic								
				stricture)=12								
				Nc(gastrojejunal				On anation related as a climation of inclination				
				anastomotic ulcer) =9 Nc(upper gastro-intestinal	Patients	Observational,		Operation related complications, including gastrojejunal anastomotic stricture, gastrojejunal	QOL/pre-op, 1, 3, 6		Any complications/1, 3,	
				bleeding) =1	undergoing	case-control,		anastomotic ulcer, upper gastro-intestinal	and 12 months post-		6, 12 months post-	
Chang	2010	Taiwan	Secondary	N(GORD)=2	bariatric surgery.	longitudinal	Roux-en-Y bypass	bleeding and GORD/Method not specified	op/WHOQOL-BREF ⁵	YES*	surgery	5
Chang	2010	1		Nt1=102/122					ор,о до 2		20.00.7	-
				·				Major complications were defined as those				
				Nt2=87	Consecutive,			associated with systemic illness requiring transfer				
				Nt3=80	patients			to a higher level of care (high-dependency or				
				Nt4=33	undergoing liver	Observational,		intensive care unit) or requiring relaparotomy, or	QOL/pre-op, 6, 12,			
					surgery for liver	prospective,	Liver resection for	complications needing interventional	36-48 months post-			
Dasgupta	2008	UK	Secondary	Nc=44	cancer	cohort	hepatic malignancies	radiology/Method not specified	op/EORTC QLQ-C30	NO*	N/A	6
				Nt1=109/109				Retrospectively listed complications: anastomotic				
				Nt2=82/109				leak, intraabdominal abscess, bleeding, venous				
						Observational,	Surgery for CD	thrombosis, renal failure, and pneumonia,				
		US	Secondary	Nc(any)=19	Patients with Crohn's Disease	cohort,	(abdominal perineal, loop or end stoma)	dehydration, intraabdominal abscess, small bowel obstruction and wound infection/Database review	QOL/pre-op & 30 days post-op/CGQL ⁶	YES*	Any complications/30	_
Delaney	2003	03	Secondary	Nc(major)=9	Cronin's Disease	prospective	100p or end storna)	Obstruction and would infection/ batabase review	QOL/0 to >10 years	TES	days post-op	7
									post-op/SF-36,			
									EORTC-QLQ-			
									C38,Social			
				N=296/?	296 patients with		Surgery for familial		Functioning subscale			
					FAP who had been	Observational,	adenomatous	Surgery-related complications/Self-reports +	of the Dutch version		Any complications/0 to	
Douma	2011	Netherlands	Secondary	Nc=?	surgically treated	cross-sectional	polyposis (FAP)	medical records	of IBDQ ⁷	YES	>10 years post-surgery	2
					Women with			Retrospectively listed complications: rectovaginal				
•					colorectal			fistulae, vessel injury of the protective colostomy				
					endometriosis			treated by laparoscopic coagulation,				
				Nt1=58/?	who underwent a		Laparoscopic	uroperitoneum requiring a ureteral stent for 6				
		1		Nt2=58	segmental	Observational,	segmentalcolorectal	weeks and an abscess behind colorectal	OOL/pro % post			
	2006	France	Secondary	Nc=9	colorectal resection	cohort,	resection for endometriosis	anastomosis requiring a laparoscopic drainage/Patient observations	QOL/pre & post- op/SF-36	NO*	N/A	
Dubernare	d 2006	Tance	Secondary	140-3	resection	prospective	Chadinethosis	aramage, radent observations	ορ _/ 31 - 30	140	1975	6
		1		N=40/?		Observational,	Anterior open	Postoperative complications: seroma,	QOL/pre-op, 3, 6 &12			
		1		1	Patients with	prospective,	Lichtenstein tension	haematoma, 2ry infection, neuralgia and	months post-op/SF-			
El-Awady	2009	Egypt	Secondary	Nc=14	inguinal hernia	cohort	free hernioplasty	anaesthesia/patient observations	36	NO	N/A	4

⁴ Gastrointestinal Quality of Life index

⁵World Health Organization Quality of Life – Brief

⁶ Cleveland Global Quality of Life

⁷Inflammatory Bowel Disease Questionnaire

8 Hospital Anxiety and Depression Scale	

: Г					Nt1=1983/3518								
'					·								
3					Nt2=1526 (77%)				Complications were summarized by 4 categories:				
,					Nt3=1603 (81%)				(1) hematoma/seroma, (2) orchitis, (3) neuralgia				
′ I									of the leg or groin, and (4) other. Complications				
ιl					Nc(neuralgia t1)=94				classified as "other" included: (1) early				
.					Nc(hematoma t1)=51				postoperative complications (urinary tract				
)					Nc(orchitis t1)=13				infection, urinary retention, and hematuria); (2)				
10					Nc(recurrence t1)=76				life-threatening complications (respiratory				
					Nc(other t1)=124				insufficiency, myocardial ischemia, cardiac				
11									arrhythmia, intraoperative hypotension, and				
2					Nc(neuralgia t2)=105				stroke); and (3) long-term complications (4 weeks				
					Nc(hematoma t2)=55		Observational,		or more postoperative)/Patient reports for				
13					Nc(orchitis t2)=18	Men who received	cohort,	Inguinal	neuralgia & orchitis + Expert consensus for life-	QOL/pre-op, 1 &2		Neuralgia, orchitis/2	
14	Hawn	2006	US	Primary	Nc(other t2)=150	a hernia repair.	prospective	herniorrhaphy	threatening complications	years post-op/SF-36	YES*	years post-surgery	8
		2000		. ,		Patients who	r r		0 to 1 to 1	7	-	,,,	
15						underwent							
6						colorectal							
- 1					Nt1=?/568	resection for							
17					Nt2=166	benign and	Observational,						
18					1412=100			Lanarossonis		OOI /pro on Awaaks			
			US	Secondary	Nc=?	malignant diseases.	cohort, retrospective	Laparoscopic colorectal resection	No reference	QOL/pre-op, 4weeks post-op/SF-36	NO*	N/A	_
19	Ince	2011	03	Secondary	140-:		retrospective	colorectarresection	NO TETETETICE	post-op/31-30	NO	N/A	3
						Patients who had							
20						been operated on							
21						for groin hernia.							
						Controls matched							
22						for age, gender							
23						and method of							
24						surgical repair							
						were allotted from			Persistent postoperative pain (patients with pain	QOL, anxiety,			
25					N(total)=184/423	the group of			of Grade 3, i.e. pain that could not be ignored but	depression/(on			
26						persons without	Observational,		did not interfere with everyday activities, or	average 4.9 years		Persistent post-	
20					N1=92 (cases)	persisting pain	case-control,		higher on IPQ)/Patient reports (Inguinal Pain	post-op, range > 7		op/Mean of 4.9 years	
27	Kalliomaki	2009	Sweden	Primary	N2=92 (controls)	(Grade 1 in IPQ)	cross-sectional	Hernia repair	Questionnaire) & clinical examination	years)/SF-36, HADS ⁸	YES	post-surgery	5
28						Consecutive							
					N=253/351	patients with						_	
29						chronic anal						Severe	
30					N(incontinence)=28	fissure who			Anal incontinence/Patient reports: Wexner	QOL/23.3 +/- 7.1		incontinence/23.3 (SD ±	
וטכ					N(severe incont)=9	underwent open	Observational,	Open lateral internal	Incontinence Score system (WIS) + Clinical	months post-op/SF-		7.1) months post-	
31 <u> </u>	Kement	2011	Turkey	Primary	N(mild incont)=19	LIS.	cross-sectional	sphincterotomy	examination	36	YES	surgery	5
32						Consecutive							
						patients under the							
33						care of three							
34					N=92/112	consultant							
						surgeons who							
35					Nc(leaks)=23	underwent							
36					Nc(clinical leaks)=13	procedures with	Observational,	Low rectal	Anastomotic leaks (clinical & subclinical)/Patient	QOL/10-18 months		Anastomotic leaks/10-	
Ξ[Lim	2006	UK	Primary	Nc(sub-clinical leaks)=10	LRA	cross-sectional	anastomosis (LRA)	observations, CT scans, WCE	post-op/EORTC QOL	CONFOUNDING	18 months post-op	5

28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	

					N=679/1308								
0	Liu	2010	US	Primary	Nc(early comps/anast)=54 Nc(late comps/anast)=126 Nc(early comps/anast/rectal cancer only)=42 Nc(late comps/ostom/rectal cancer only)=105 Nt1=253/302	Long-term Colorectal Cancer patients Patients who	Observational, cross-sectional	Colorectal cancer surgery	-Digestive, skin, genitourinary, surgical, medical, immediate indirect complications -Early complications: those that were first recorded within 30 days of the surgery. Late complications: occurring 31 days after surgery/Patient computerised data	QOL/ 5-15 years post-op/mCOH-QOL- Ostomy ³	YES	Enterocutaneous fistula for all patients & any late complications for ostomy patients>5 years post-surgery	6
1					Nt1=233/302 Nt2=244	underwent Lateral							
2					1102-244	internal		Lateral internal		QOL/pre-op	UNCLEAR (due to		
3					Nc(anal fistula/abscess)=3	sphincterotomy	Observational,	sphincterotomy (LIS)		(admission) & 12	small number of		
7					Nc(FISI>0)=7	(LIS) for chronic	cohort,	for chronic anal		months post-	patients with		
4	Mentes	2006	Turkey	Primary	Nc(FISI, 0->4, 21, 7)=3	anal fissure (CAF)	prospective	fissure (CAF)	Anal Incontinence/Patient examination+ FISI score	op/GIQLI & FIQL ¹⁰	complications)	N/A	6
5						Veterans with an			Ostomy complications: skin problems, leakage,				
6						ostomy after			and difficulty with adjustment (i.e. leakage,				
						major gastro-			peristomal irritant dermitis, pain, bleeding, stomal			Ostomy complications	
7					N=239/322	intestinal surgery	Observational,	Gastro-intestinal	necrosis, prolapse, stenosis, herniation, retraction,	QOL/6months post-		(skin problems,	
8						requiring an	case-control,	surgery requiring an	infection, mucotaneous separation, difficulty	op/mCOH-QOL-		leakage)/ 6 months	
<u> </u>	Pittman	2008	US	Primary	Nc=56	intestinal stoma	cross-sectional	intestinal stoma	adjusting)/Patient reports	Ostomy	YES	post-surgery	6
0 1 2 3 4					N=147/211 Nc(anastomotic	Patients who underwent elective left colonic or rectal resection and colorectal anastomosis for neoplastic or inflammatory	Observational,	Left colonic or rectal resection and colorectal		QOL/mean 58 (SD ± 31) months		Anastomotic stenosis/58 (SD ± 31) months post-	
5	Polese	2012	Italy	Primary	stenoses)=22	disease.	cross-sectional	anastomosis	Anastomotic stenosis/Clinical examination	post-op/SF-36	YES	surgery	6
6 7 8 9	i viese	2012		,	Nt1=505/? Nt2=237 Nt3=106 Nc(t2)=41	Patients who underwent LRYGB by one surgeon	Observational,	LRYGB for morbid obesity without conversion to an	Postoperative complications requiring	QOL/baseline, 1 & 2		Complications requiring intervention/1 & 2 years	
- ا	Rea	2007	US	Primary	Nc(t3)=23	for morbid obesity	prospective	open procedure.	intervention/Method not specified	years post-op/SF-36	YES*	post-surgery	6
0 1 2 3 4 5										1			

⁹ City of Hope Quality of Life for Ostomates questionnaire 10 Fecal Incontinence Quality of Life Instrument

Cases: patients

						cases, patients							
						operated for							
						rectal cancer and							
						developed							
						anastomotic leak.							
						Controls: Patients							
						operated for							
0						rectal cancer at							
						the same time							
1						period and had an							
2						uneventful							
						postoperative			Anastomotic leakage: Defined as grade A (no				
3						course matched			change in patient's management), grade B				
4						by sex, age (±5			(requires active therapeutic intervention but is				
5						years), type of		Rectal resection for	managed without relaparotomy) and grade C				
						resection, and	Observational,	malignancies on	(requires relaparotomy)/Review of the	QOL/106.8 months			
6					N1=16/36 (cases)	neoadjuvant	case-control,	overall pelvic organ	institutional colorectal database and individual	post-op (32.4-			
7L	Riss	2011	Austria	Primary	N2=16/? (controls)	therapy.	cross-sectional	function	chart reviews	170.4)/SF-12	NO	N/A	7
′						Patients			Technical surgical complications, including				
8						diagnosed with an			postoperative bleed exceeding 2000 ml or				
9						oesophageal or			requiring a reoperation, anastomotic insufficiency,				
						cardia cancer who			necrosis of the substitute, damage to the				
0						underwent			recurrent nerve, thoracic duct damage or gastric				
1						macroscopically			perforation/Prospective scrutiny of medical and				
ا '					N=355/ 446 (79·6 %)	and			histopathological records, operation charts,	QOL/6months post-		Technical	
2						microscopically	Observational,	Oesophageal	extensive study protocol with predefined	op/EORT QLQ-C30, &		complications/6 months	
3	Rutegard	2008	Sweden	Secondary	Nc=56	radical resection	cross-sectional	resection	exposure alternatives	QLQ-0ES1812 11	YES	post-surgery	7
4								Bowel resection					
4								through midline laparotomy or with	Medical and surgical complications and need of				
5						Patients admitted		laparoscopic	reoperation (2 anastomotic leaks, 3 intestinal				
6					N=47/?	for intestinal		assistance, end	obstructions, 2 intestinal bleeding, and a wound				
O					·	surgery for	Observational,	ileostomy,	infection were recorded and two re-	QOL/3 months post-		Any complications/3	
7 _	Scarpa	2009	Italy	Secondary	Nc=?	Crohn's Disease	cross-sectional	stricturoplasty	laparotomies)/Method not specified	op/CGQLI	CONFOUNDING	months post-surgery	3
0										QOL, anxiety,			
8										depression, positive			
9						Consecutive				vs. negative			
0						patients with				affectivity, mood			
						newly diagnosed				states/pre-op (5-12			
1						colorectal			Wound, urinary tract and chest infections, cardiac	days pre-op) & 6-8			
2					Nt1=104 /110	cancer scheduled			and respiratory complications, deep venous	weeks post-op/FACT-			
					Nt2=92	for elective open	Observational,		thrombosis, pulmonary embolism and	C, EuroQOL (EQ-5D),		Complications within 30	
3						resection in one	cohort,	Elective resection	complications related to anastomotic	HADS, PANAS ¹² ,		days of operation/6-8	
4	Sharma	2007	UK	Secondary	Nc=41	hospital trust	prospective	for colorectal cancer	breakdown/Method not specified	MRS ¹³	YES*	weeks post-surgery	6
5						Patients							
					N+1=02/112	undergoing							
6					Nt1=93/113 Nt2,t3=79	colorectal surgery for benign and	Observational,	Resection of the	Postoperative complications (anastomotic leak,	QOL/pre-op, 3 & 12			
7					N(2,t3-73	malignant	prospective,	sigmoid	wound infection, delayed food intake, fever, and	months post-op/SF-		Any complications/3	

¹¹ Oesophageal cancer-specific questionnaire

¹² Positive and negative affect schedule

¹³ Mood rating scale

¹⁴ Gastrointestinal Quality of Life Index

						Patients							
						diagnosed with							
						paraesophageal or							
						mixed hiatal			Hernia recurrence (any migration of the cardia to				
						hernia (types II, III,			chest level or evidence of a new paraesophageal	QOL/>=6 months			
' I					N=37/46	and IV) with >50%		Laparoscopic repair	sac)/A barium swallow was given to all patients to	post-op (median, 24;		Clinically recurrent	
'						of the stomach in	Observational,	of paraesophageal	rule out an anatomic recurrence. An independent	range, 6-50)/SF-36,		hernias/>=6 months	
ol	Targarona	2004	Spain	Primary	Nc(recurrent hernias)=3	the chest.	cross-sectional	hiatal hernia	radiologist evaluated all the explorations.	GDSS ¹⁵ and GIQLI	YES	post-surgery	5
4						Patients newly							
'						diagnosed with a							
2						histologically							
3						verified							
						adenocarcinoma							
4						or squamous-cell carcinoma of the							
5					·	esophagus or							
6						adenocarcinoma							
						of the gastric							
7						cardia that			Anastomotic leakage , infections, respiratory			Any complications,	
8						underwent			insufficiency, cardiac complications, technical			anastomotic leakage,	
						macroscopically			complications, anastomotic strictures, and others			infection, respiratory	
9						and			(intervention needed to treat embolus, deep			insufficiency, cardiac	
0					N=100/146	microscopically			venous thrombosis, rupture of the wound,	QOL/6 months post-		complications, technical	
4						radical tumor	Observational,	Esophageal resection	intestinal obstruction, stroke, renal failure, or liver	discharge/QLQ-C30 &		complications/6 months	
	Viklund	2005	Sweden	Secondary	Nc=44	resection.	cross-sectional	surgery for cancer	failure)/Patient records	OES-24 ¹⁶	YES	post-discharge	7
2									,	010 2 1	1.25		
_		*Study co	ntrolled for patie	ents' preoperative w	ellbeing					0.521	123	,	,
		*Study co	ntrolled for pation	ents' preoperative w	ellbeing			(8)		0.021		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
3		*Study co	ntrolled for pation	ents' preoperative w	ellbeing					0.021	1.00		•
3		*Study co	ntrolled for patio	ents' preoperative w	ellbeing			CI		0.02.	1.00		,
3 4 5		*Study co	ntrolled for pation	ents' preoperative w	ellbeing					0.021		,	•
3 4 5		*Study co	ntrolled for pation	nts' preoperative w	ellbeing				76.	00021		,	
3 4 5 6		*Study co	ntrolled for pation	ents' preoperative w	ellbeing			O.	/e/_	0.021			,
3 4 5 6		*Study con	ntrolled for pation	nts' preoperative w	ellbeing			. GT	ieu.	0.021			,
3 4 5 6 7		*Study co	ntrolled for pation	ents' preoperative w	ellbeing			67	ie _h	0.021	140		,
3 4 5 6 7 8		*Study co	ntrolled for patio	ents' preoperative w	ellbeing			61	ioh.	0.021	140		,
3 4 5 6 7 8 9		*Study co	ntrolled for patie	ents' preoperative w	ellbeing			61	ioh o	0.021	140		,
3 4 5 6 7 8 9		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			67	ieh, o.	0.021	155		,
3 4 5 6 7 8 9		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			67	ion on		100		
3 4 5 6 7 8 9 0 1		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			67	ieh on		140		
3 4 5 6 7 8 9 0 1 2		*Study co	ntrolled for patie	ents' preoperative w	ellbeing			67	10h-0h		140		
3 4 5 6 7 8 9 0 1 2		*Study co	ntrolled for patio	ents' preoperative w	ellbeing			61	10/1/O/1		140		
3 4 5 6 7 8 9 0 1 2 3		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			67	10/1/O/1		1.00		
3 4 5 6 7 8 9 0 1 2 3 4		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			6/	10h on				
3 4 5 6 7 8 9 0 1 2 3		*Study co	ntrolled for patio	nts' preoperative w	ellbeing			6/	failure)/Patient records				

*Study controlled for patients' preoperative wellbeing

¹⁵ Glasgow Dyspepsia Severity Score

Table 2: Key characteristics of cardio-thoracic surgery studies (n=17)

	First author name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
					Nt1= 317/442 Nt2=270	Patients with documented T2DM	Observational, cohort,		Infection of the leg, thorax, sternum, bloodstream or urinary tract; central neurological deficit (stroke or transient ischemia, coma); pneumonia, pulmonary insufficiency with prolonged ventilation or reintubation, pulmonary embolism; renal failure; arrhythmias requiring treatment; prolonged inotropic support or use of intra-aortic balloon pump; reoperation for bleeding or tamponade/Patient	QOL/ 3 months post-		Any complications/3	
	Deaton	2009	US	Secondary	Nc=44% (130)	undergoing CABG	prospective	CABG	records	op/SF-36	YES	months post-surgery	6
- 1	il Baz	2008	Netherlands	Secondary	Nt1=198/256 Nt2=168 Nc=?	Consecutive patients who were scheduled for CABG following a coronary angiography Prospective patients	Observational, cohort, prospective	CABG Major lung resection for early stage lung cancer	Postoperative events such as use of inotropes, atrial arrhythmias, or ventricular arrhythmias, sternal resuturing, re-exploration for bleeding, and time spent on mechanical ventilation/Registry database, medical notes, outpatient notes and intensive therapy unit charts Complications were categorized as pulmonary (pneumonia, prolonged intubation, reintubation, air leak more than 7 days, lobar collapse requiring intervention), cardiovascular (pulmonary embolism, myocardial infarction, new postoperative arrhythmia,	QOL/pre-op & 6 months post-op/SF- 36 QOL/average of 2.6 years post-op (3 months to 6.4 years)/EORTC QLQ-	YES*	Re-exploration for bleeding and sternal resuturing/6 months post-surgery	8
					N=124/221	who underwent major lung resection for early	Observational,	(lobectomy, bilobectomy,	need for intravenous inotropic agents), other, and any complication/Administrative database, hospital	C30, EORTC QLQLC13 ¹⁷ and DASS-		complications/2.6 years	
	erguson	2009	US	Primary	Nc=22	stage lung cancer.	cross-sectional	pneumonectomy)	medical records, office shadow files	21 ¹⁸	YES	post-surgery (Range: 3 months-6.4 years)	6
	Sjeilo	2010	Norway	Primary	Nt1=534/631 Nt2=462 Nt3=465 Nc(t2)=52	Patients undergoing cardiac surgery	Observational, cohort, prospective	Midline sternotomy	Chronic pain (pain arising after surgery and persisting either continuously or intermittently for 3 months or more/BPI (Brief Pain Inventory)	QOL/pre-op, 6 & 12 months post-op/SF- 36	YES*	Chronic post-surgical pain/12 months post-surgery	6
	Hata	2006	Japan	Secondary	N=452/452 Nc=?	Consecutive adult patients who underwent open heart surgery	Observational, cross-sectional	CABG	Postoperative morbidity (minor stroke, infection, pneumonia, haemodialysis, paraplesis)/Patient records	Depression/5-7 days post-op/Interviewed by a psychiatrist and CES-D ¹⁹	CONFOUNDING	Post-operative minor stroke and pneumonia/5-7 days post-surgery	6
,					L			ı				, , ,	

BMJ Open

¹⁷ EORTC Lung Cancer Questionnaire

¹⁸ Short version of the Depression Anxiety Stress Scales

¹⁹ Center for Epidemiological Studies Depression Scale

		1						CABG [89% via					
								sternotomy					
								incision with					
								cardiopulmonary					
					Nt1=501/1128			bypass (CPB; on-					
					Nt2=485		Observational,	pump) and 11%	Perioperative myocardial infarctions/Clinical	QOL/pre-op & 12		Perioperative myocardial	
	Jarvinen	2004	Finland	Primary	Nc=80	Patients who underwent CABG	cohort,	without CPB (off-	examination + clinical tests (ECGs, echocardiography,	months post- op/RAND-36	YES*	infarctions /12 months	7
	Jarvilleli	2004	riillallu	rilliary	INC-OU	-Cases: patients who	prospective	pump)]	laboratory tests)	OP/KAND-30	TES	post-surgery	,
						developed sternal							
						wound infection (SWI)							
						after cardiopulmonary							
						bypass.							
						-Controls: patients prior							
						to CABG and evaluated							
						1 year postoperative and matched for time of	Observational,		Serious wound infections (SWIs: deep infection	QOL/20 months post-		Serious wound infections	
					N1=73/84 (cases)	the operation, age and	case-control,	Cardiopulmonary	involving retrosternal tissue and/or the sternal	op (range 7-40)/SF-		/20 (Range: 7-40) months	
	Jideus	2009	Sweden	Primary	N2=42/? (controls)	sex	cross-sectional	bypass	bone)/Clinical examination	36	YES*	post-surgery	4
					N=99								
								Serratus-sparing					
					Nt1=120/?			posterolateral					
					Nt2=99	Patients aged 45 to 75	Observational,	thoracotomy or				Chronic post-thoracotomy	
						years undergoing	cohort,	limited	Chronic post-thoracotomy pain/Leeds Assessment of	QOL/pre-op, 3 moths		pain/3 months post-	
	Kinney	2012	US	Primary	Nc=75	elective thoracotomy	prospective	thoracotomy	Neuropathic Symptoms and Signs + self-reports	post-op/SF-36	YES*	surgery	7
						-Cases: patients who							
						underwent cardiac							
						surgery and developed							
						ARF requiring RRT and							
						left the hospital aliveControls: matched							
						controls who did not	Observational,	Cardiac surgery	ARF (acute renal failure) requiring RRT (renal				
					N1=22/42 (cases)	develop ARF and did not	case-control,	(procedures not	replacement therapy)/Administrative database,	QOL/23-42 months			
L	Landoni	2006	Italy	Primary	N2=40/42 (controls)	receive RRT.	cross-sectional	specified)	registry	post-op/SF-36	NO	N/A	`6
					Nt1=182/444								
					Nt2=128							New cardiac arrhythmia	
					Nt3=114		Observational,			QOL/pre-op, 2 & 6		post-surgery, atrial	
						Adults on the waiting	cohort,		Post-surgical complications such as cardiac	months post-op/SF-		fibrillation/ 6 months post-	
	Le Grande	2006	Australia	Secondary	Nc=?	list for CABG	prospective	CABG	arrhythmias, stroke and infections/Medical records	36	YES*	surgery	7
								Open heart					
								surgery (133 valve procedure; 620					
								CABG; 67 CABG	Perioperative myocardial infarction, mediastinitis,				
								plus valve	superficial wound infection, septicemia, permanent				
								procedure; 15	stroke, transient ischemic attack, continuous coma,				
								CABG plus other	prolonged intubation, ventilator-associated				
					Nt1=836/2,007	Bartan danata	01	cardiac procedure;	pneumonia, cardiac tamponade, atrial fibrillation,				
					Nt2=2.007	Patients undergoing	Observational,	and 1 closure of	reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method	001/pre-on 1 year			
	Martin	2008	US	Primary	Nc=189	elective open heart surgery	cohort, prospective	an atrial septal defect)	not specified	QOL/pre-op, 1 year post-op/SF-20	NO*	N/A	6
ı				,		0~1	1. yeli		Retrospective list of complications: Atrial fibrillation,	P > = P	-	,	-
						All patients over 65			re-exploration for bleeding, low cardiac output				
					Nt1=63/63	presenting a 1, 2 or 3			syndrome, acute respiratory failure, sternal wound	QOL/pre-op, 4 & 12			
					Nt2=59	vessel disease treated			infection, neurological dysfunction, mild problems	months post-			
					Nt3=56	with CABG without	Observational,		related to leg incision healing or swelling, chest	op/MacNew Heart			
	Merkouris	2009	Greece	Secondary	Nc=42	concurrent procedures (e.g. valve replacement)	cohort, prospective	CABG	incision discomfort and medications/Method not specified	Disease HRQOL questionnaire	NO*	N/A	5
_		_003				(2.6. varve replacement)	p. sopective	50	ab asas	430001110110		1	

Complication was defined as any of the following postoperative complications: new onset atrial

Nt1=249/? Nt2=213 Prospective patients scheduled for lung surgery Moller 2012 Sweden Secondary Nc=? Nt2=213 Prospective patients scheduled for lung surgery Sweden Secondary Nc=? Nc=? Nc=? Nc=? Nt2=213 Prospective patients scheduled for lung surgery Sweden Secondary Nc=? N	6
Sweden Secondary Nc=? Sweden Secondary Nc=. Sweden Secondary Nc=.	6
Moller 2012 Sweden Secondary Nc=? surgery for lung cancer prospective Lung surgery more/Method not specified 36 YES* months post-surgery 1. Respiratory: postoperative mechanical ventilation for more than 24 h or pneumonia, defined as pulmonary infiltrea with positive microbial cultures; 2. Cardiac: arrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	6
Moller 2012 Sweden Secondary Nc=? surgery for lung cancer prospective Lung surgery more/Method not specified 36 YES* months post-surgery 1. Respiratory: postoperative mechanical ventilation for more than 24 h or pneumonia, defined as pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twite normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	6
1. Respiratory: postoperative mechanical ventilation for more than 24 h or pneumonia, defined as pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmia requiring treatment with antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt1=120/125 Nt2=120 (days 1,2,3) Nt3=108 1. Respiratory: postoperative mechanical ventilation for more than 24 h or pneumonia, defined as a pulmonary infiltration of preamma; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
for more than 24 h or pneumonia, defined as pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmia requiring treatment with antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-NB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt1=120/125 Nt2=120 (days 1,2,3) Nt3=108 for more than 24 h or pneumonia, defined as a pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary edema; 2. Cardiac: arrhythmia requiring treatment with high pulmonary endors or requiring treatment with high pulmonary endors or requiring treatment with high pu	
pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmia requiring treatment with antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt2=120 (days 1,2,3) Nt3=108 Nt3=108 Nt3=108	
2. Cardiac: arrhythmia requiring treatment with antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt3=108 Nt3=108 Nt3=108 Nt3=108	
antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt1=120/125 Nt2=120 (days 1,2,3) Nt3=108 antiarrhythmic medication or electrical cardioversion reversion; radiologic edicites, or myocardial infarction, redefined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt2=120 (days 1,2,3) Nt3=108 reversion; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardine greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt2=120 (days 1,2,3) Nt3=108 or myocardial infarction, defined by new Q waves on electrocarding concentration greater than 200 m; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; Nt2=120 (days 1,2,3) Nt3=108 electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine connectmentation greater than 200 M; Nt2=120 (days 1,2,3) Nt3=108 concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine connectmentation greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
Nt1=120/125 Nt2=120 (days 1,2,3) Nt3=108 Nt1=120/125 creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit;	
Nt2=120 (days 1,2,3) Nt3=108 4. Neurologic: stroke, defined as a new central neurologic deficit;	
Nt3=108 neurologic deficit;	
Nt4=94 5. Sepsis: wound infection requiring excision of tissue	
Cardiac surgery or antibiotic therapy, or positive microbial culture	
2001 Observational, (specific (other than pneumonia) QOL/pre-op, 1 & 3	
Adult cardiac surgical cohort, procedures not Clinical and laboratory tests (microbial cultures, months, 3 years post-months, 3 years p	
Myles 2006 Australia Secondary Nc=69 patients prospective specified) radiologic data, electrocardiograms etc.) op/SF-36 CONFOUNDING* months post-surgery	8
Retrospective list of complications: low cardiac	
output (cardiac index lower than 2 L/min/m2), mechanical ventilation longer than 24 hours,	
reoperation of the bleeding, sternal wound infection,	
perioperative myocardial infarction, pericardial QOL/pre-op, 6	
Nt1=208/? effusion, arrhythmic complications (atrial fibrillation, months post-	
Nt2=192 Consecutive patients Observational, ventricular tachycardia, ventricular fibrillation), op/Nottingham	
Serbia & who underwent elective cohort, abdominal complications, and other/Observations, Health Profile Any complications/6	
Peric 2008 Montenegro Secondary Nc=60 CABG prospective CABG ECGs, echocardiography, laboratory tests Questionnaire (NHP) YES* months post-surgery	7
-Compensatory sweating (CS): Excessive sweating	
considered abnormal in other parts of the body after	
Nt1=397/?	
Nt2=? Thoracoscopic -Gustatory sweating: Facial sweating after eating	
Nt3=? sympathectomy foods QOL/pre-op,	
Nt4=? Patients diagnosed with Observational, for palmar and -Excessive dryness: Dryness affecting the hands and discharge, 6 & 12	
upper extremity HH cohort, axillary requiring hydration months post-op/sf-	
	3
Rodriguez 2008 US Secondary Nc=23 treated with TS. prospective hyperhidrosis -Method not specified 36 NO* N/A New-onset atrial fibrillation (AF) between the	3
patient's day of admission to the intensive care unit Anxiety, Depression,	1
and the median day of discharge (day 5) after CABG Stress/pre-op	
Nt1=226/238 during the index hospitalization/ECGs, transthoracic (mean=2 days, SD=2	1
Nt2=222 Observational, echocardiographs reviewed by technicians and days) & post-op	
Patients undergoing cohort, reviewers blinded to patients' psychological distress (mean=6 days, SD=2 Atrial fibrillation/6 days	
Tully 2011 Australia Primary Nc=56 first-time CABG surgery prospective CABG scores days)/ DASS ²⁰ YES* (SD=2 days) post-surgery	
*Study controlled for patients' preoperative wellbeing	7

²⁰ Depression Anxiety Stress Scales

Table 3: Key characteristics of studies in vascular surgery (n=4)

3	First author name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome & timepoints	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
7									Retrospective list: Postoperative				
ч									bleeding, Myocardial infarction,				
2						Consecutive patients			Stroke, Pneumonia, Respiratory	QOL/36.4 ± 15.5			
3					N=110/124	who received a			insufficiency, Acute renal dysfunction,	months post-op			
3						replacement of the	Observational,	Ascending aorta	Sepsis, Lung fistula/Method not	(11–58			
4	Lohse	2009	Germany	Secondary	Nc=?	dilated ascending aorta.	cross-sectional	replacement	specified (MG)	months)/SF-36	NO	N/A	4
5					•				Wound complications (WC): patients				
6						Patients who			having infection, necrosis, hematoma- haemorrhage, or seroma-lymphocele				
_						underwent IB for			at the surgical incision or harvest site				
7					Nt1=1296/1404	Critical Limb Ischaemia			within 30 days of the bypass				
8					Nt2=862	(CLI) in community and		Lower extremity vein	surgery/Adverse events clinical trial				
					Nt3=732	university hospitals	Observational,	bypass for limb salvage	documentation with reference to	QOL/baseline, 3 &			
9						across the US and	cohort,	in critical limb ischemia	source documentation (hospital notes	12 months post-		Wound complications/3	
n	Nguyen ^a	2007	US & Canada	Primary	Nc=543	Canada	prospective	(CLI) patients	etc.)	op/VascuQol ²¹	CONFOUNDING*	months post-surgery	8
34	11647211	2007	os a canada	,				, ,,	Graft-related events (GREs):			, ,	
۱۱ ک									development of a >70% graft stenosis				
22						Patients who			or having undergone a percutaneous				
23						underwent IB for			or surgical revision or a major				
					N1=1296/1404 (92.3%)	Critical Limb Ischaemia			amputation/Clinical tests				
24					N2=862 (61.4%)	(CLI) in community and		Infrainguinal vein	(angiography, ultrasonography etc.),				
25					N3=732 (52.1%)	university hospitals	Observational,	grafting for limb salvage	source documentation (hospital notes,	QOL/pre-op, 3 &			
06						across the US and	cohort,	in critical limb ischemia	discharge notes, operative and	12 months post-		Graft-related events/12	
20	Nguyen ^b	2006	US & Canada	Secondary	Nc=?	Canada	prospective	(CLI) patients	procedural notes etc.)	op/VascuQol	YES*	months post-surgery	8
27						Patients with varicose							
28						veins, either							
						symptomatic or with							
29						skin changes, resulting							
30						from incompetence of							
1					Nt1=70/70	the LSV as confirmed by handheld Doppler							
1					Nt2=59	examination or duplex				QOL/pre-op,			
32					Nt3=62	ultrasonography or			-Bruising/Tracing method	discharge & 6			
33					1413-02	both and requiring			-Sensory abnormalities, both	weeks post-			
<u> </u>					Nc(sensory abnormalities)=25	surgical intervention	Observational,		subjective (paresthesia and	op/Aberdeen			
34					Nc(bruising at t1)=58	(both day cases and	cohort,	Conventional LSV	dysesthesia) and objective/Patient	Varicose Vein			
35	Subramonia	2005	UK	Primary	Nc(bruising at t2)=16	inpatients).	prospective	stripping	reports, sensory testing	Questionnaire 2	NO*	N/A	7
			rolled for natients' r			•	-		· -				

^{*}Study controlled for patients' preoperative wellbein

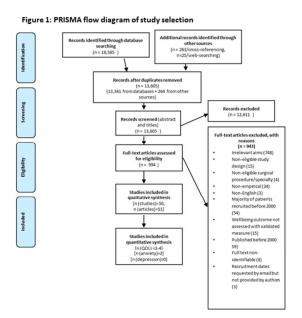
 $^{^{21}\,\}text{A validated instrument assessing pain, symptoms, activities, social life and emotional state in patients with vascular disease}$

Table 4: Domains of patients' wellbeing that were significantly affected by surgical complications

																	St	udies															
Mea	asures	Bruns	niu	Bloemen	Siassi	Rutegard	Pittman	Sharma	Avery	Le Grande	_q uəƙnßN	Viklund	Delaney	Kalliomaki	Hawn	Anthony	Chang	Douma	Kement	Targarona	Peric	El Baz	Deaton	Ferguson	Tully	Gjeilo	Jideus	Kinney	Polese	Rea	Bitzer	Jarvinen	Moller
	Physical- Component	✓			✓					✓					~	_		>	>		_		✓									>	
	Mental Component									*					~				✓				~										
	Physical functioning													✓												✓	✓	✓				✓	✓
	Bodily pain													✓					✓							✓		✓	✓	✓	✓		
Short Form scales (e.g. SF-36, SF-12	Role physical													✓												✓			✓	✓	✓	~	
RAND-36)	Role emotional													~															>				
	General health													✓					>				_			~	✓		✓	✓		>	✓
	Mental health													>								✓				✓			>	✓			
	Social functioning													✓		_			>							✓	✓		✓	✓			
	Vitality													✓					✓			✓				✓		✓		✓			✓
	Physical Functioning			~		✓			✓	~	ı	✓						✓						✓									
	Global QOL					✓				√		✓																					
EORTC QLQ-	Social Functioning								✓																								
C30+	Fatigue			✓		✓																											
	Role functioning					✓			✓																								
	Pain			✓																													
	Weight loss			<u> </u>																													

	Dyspnea				✓																			
	Nausea- Vomiting				✓			✓																$\overline{\Box}$
	Coughing					✓																		
	Defecation														✓									
VascuQOL	Total QOL								✓															
GIQLI	Total QOL															√								
	Total QOL		✓																					
mCOH-QOL	Physical QOL					✓		7																
	Social QOL					✓																		
	Total QOL												√											
FACT-C	Physical wellbeing						✓						✓											
FACT-C	Social wellbeing											<i>^</i>	✓											
	Cancer concerns	_		 						 			✓				L							
CGQL	Total QOL									✓														
	Physical domain													✓										
WHOQOL- BREF	Pain & discomfort													~										
	Activities of daily living								_					~										
IBDQ	Social functioning														√)					
	Social isolation									 			L				✓							
NHP	Sleep																✓							
	Pain																✓							
HADS & DASS	Anxiety						√				√									✓				
	Depression Negative						✓				✓													
PANAS	affect						✓																	
MRS	Negative mood						✓																	38





254x190mm (96 x 96 DPI)

Supplementary materials for manuscript entitled:

Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

Supplementary material 1: Search strategies

Embase

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- 1. exp mental stress/
- 2. exp emotion/
- 3. exp depression/
- 4. exp ANXIETY/
- 5. exp posttraumatic stress disorder/
- 6. exp "quality of life"/
- 7. exp wellbeing/
- 8. 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9. exp surgery/
- 10. exp complication/
- 11. 9 and 10
- 12. exp surgery/co [Complication]
- 13. exp perioperative complication/
- 14. exp peroperative complication/
- 15. exp postoperative complication/
- 16. exp preoperative complication/
- 17. exp surgical error/
- 18. exp iatrogenic disease/su [surgery]
- 19. exp anesthesia complication/
- 20. exp ANESTHESIA/co [Complication]
- 21. exp anesthesia/
- 22. exp complication/
- 23. 21 and 22
- 24. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 23
- 25. exp patient/
- 26. adult/
- 27. female/
- 28. male/
- 29. 25 or 26 or 27 or 28
- 30. 8 and 24 and 29
- 31. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or awareness or iatrogen* or ((adverse or unfavourable or unfavorable or untoward or undesired) adj (outcome*1 or effect*1 or event*1 or incident*1 or reaction*1))),ti,ab.
- 32. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-oper
- 33. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 34. 31 and 32 and 33
- 35. 30 or 34
- 36. limit 35 to (human and English language)

MEDLINE

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Stress, Psychological/
- 9. exp Emotions/
- 10. exp Depression/
- 11. exp Anxiety/
- 12. exp Stress Disorders, Post-Traumatic/
- 13. exp "Quality of Life"/
- 14. 8 or 9 or 10 or 11 or 12 or 13
- 15. exp Medical Errors/
- 16. exp Postoperative Complications/
- 17. exp iatrogenic disease/su [surgery]
- 18. exp Anesthesia/ae, co [Adverse Effects, Complications]
- 19. 15 or 16 or 17 or 18
- 20. 14 and 19
- 21. exp Patients/
- 22. exp adult/
- 23. exp women/
- 24. exp men/
- 25. exp research subjects/
- 26. 21 or 22 or 23 or 24 or 25
- 27. 14 and 19 and 26
- 28. 7 or 27
- 29. limit 28 to (English language and humans)

PsycINFO

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Psychological Stress/
- 9. exp emotions/
- 10. exp "depression (emotion)"/
- 11. exp Anxiety/
- 12. exp posttraumatic stress disorder/
- 13. exp "Quality of Life"/
- 14. exp well being/
- 15. 8 or 9 or 10 or 11 or 12 or 13 or 14
- 16. exp postsurgical complications/
- 17. exp patients/
- 18. exp Human Females/
- 19. exp human males/
- 20. 17 or 18 or 19
- 21. 15 and 16 and 20
- 22. 7 or 21
- 23. limit 22 to (human and English language)

Supplementary material 2:

Detailed report of meta-analyses on the impact of complications on patients' psychosocial wellbeing

Quality of life

Due to the different measurement tools that were used for the assessment of QOL as well as the different domains that each tool assesses, a meta-analysis was conducted only on the studies that used the SF-tools. These were the most commonly used tools for the assessment of QoL, they are not condition-specific and they use the same measurement scale. Moreover, all of them yield the same summary scores (i.e. physical and mental) and the sub-scores (i.e. Physical functioning, Bodily pain, Role limitations due to physical health problems, Role limitations due to emotional health problems, General health, Mental health, Social functioning, Vitality). A meta-analysis was conducted on each sub-score. The effect sizes are expressed as mean differences (MD) on a scale ranging from 0 to 100.

Only three studies provided sufficient data for a meta-analysis on the physical and mental component scores of quality of life between patients with complications and patients without complications. ²⁻⁴ The pooled mean differences for the physical and mental summary scores between the two groups indicated significantly lower levels of physical and mental quality of life in patients who suffered complications compared to patients without complications (see eTable1).

Three studies ⁵⁻⁷ provided sufficient data for a quantitative synthesis on 'physical functioning' (i.e. limitations in performing physical activities), 'bodily pain' (i.e. limitations experienced due to pain), 'role -physical ' (i.e. problems with work/daily activities as a result of physical health), and 'role -emotional' (i.e. problems with work/ daily activities as a result of emotional health). The pooled mean differences between the two groups were significant and more than 5 points, indicating clinically meaningful ¹ adverse effects of complications on each of the above domains of quality of life (see eTable1). Four studies ⁴⁻⁷ provided sufficient data for a meta-analysis of the differences on 'general health' (i.e. evaluations of overall health), 'social role functioning' (i.e. degree of interference with normal social activities due to physical and emotional problems), 'mental health' (i.e. feelings of nervousness and depression vs. feeling peaceful and happy), and 'vitality' (i.e. feeling tired vs. feeling full of energy). The pooled mean differences between the two groups were again significant and clinically meaningful on each sub-domain (i.e. more than 5 points) (see eTable1).

The estimates of heterogeneity (I²) were low for the majority of the SF scores (<25%). High heterogeneity was observed only for mental health (78%), bodily pain (70%), and general health (81%). A sensitivity analysis by the methodological quality of the included studies revealed that when a study that scored low in quality assessment was excluded, ⁴ the pooled mean differences for mental health and general health increased indicating even higher adverse effects of complications on these two domains.

Anxiety and Depression

Two studies provided sufficient data for a meta-analysis on anxiety levels. ^{8,9} Each study used a different scale, therefore the effect sizes are expressed as standardised mean differences (SMD). The pooled SMD for anxiety was not significant indicating a lack of population effect in terms of the complications' impact on patients' anxiety levels. The estimate of heterogeneity was high (I²=81%), however a sensitivity analysis by the methodological quality of the included studies did not alter the results. A meta-analysis on depression was not possible as only one study provided sufficient data. ⁸

Supplementary material 3

Table: Results of meta-analyses on the impact of complications on patients' psychosocial wellbeing

Wellbeing outcome	Sub-score	Comparison	k	N	z	P	MD (SMD/anxiety)	95% CI	l ²
Quality of life (SF-scales)	Physical component	Complications vs.	3	244	4.51	0.00001	-3.28	-4.71, -1.86	20%
,	, , , , , , , , , , , , , , , , , , ,	No complications		1638					
	Mental component	Complications vs.	3	244	6.52	0.00001	-3.82	-4.97, -2.67	0%
	·	No complications		1638					
	Physical functioning	Complications vs.	3	97	2.34	0.02	-5.26	-9.67, -0.85	20%
		No complications		610					
	Bodily pain	Complications vs.	3	97	3.70	0.0002	-15.05	-23.04, -7.07	70%
		No complications		610					
	Role physical	Complications vs.	3	97	2.58	0.010	-11.56	-20.33, -2.78	48%
		No complications		610					
	Role emotional	Complications vs.	3	97	2.65	0.008	-8.63	-15.00, -2.25	25%
		No complications		610	0.54	0.04	42.74	24.40.000	000/
	General health	Complications vs.	4	106	2.51	0.01	-13.71	-24.40, -3.02	82%
		No complications		629					

	Mental health	Complications vs.	4	106 629	5.01	0.00001	-9.33	-12.97, -5.68	0%
	Social	Complications vs.	4	106	6.93	0.00001	-9.95	-12.76, -7.14	0%
	functioning	No complications		629					
	Vitality	Complications vs.	4	106	5.15	0.00001	-10.63	-14.67, -6.58	0%
		No complications		629					
Anxiety		Complications vs.	2	148	1.12	0.26	0.27	-0.21, 0.75	81%
		No complications		262					
						1/2 C			

Supplementary material 4:

Forest plots of meta-analyses on the impact of complications on patients' wellbeing

SF Physical summary score (SF PCS)

Study or Subgroup	Co	mplicatio	ns	No	complicat	ions	Weight	Mean Difference	Mean Difference
otady of odbyfodp	Mean	SD	Total	Mean	SD	Total	vveigni	IV, Random, 95% CI	IV, Random, 95% CI
20-Hawn	41.2	16.0186	105	45.7	52.9351	1479	11.3%	-4.50 [-8.58, -0.42]	
28-Kement	53.97	2.22	9	57.91	1.63	19	51.5%	-3.94 [-5.57, -2.31]	-
39-Deaton	41	9	130	43	8	140	37.2%	-2.00 [-4.04, 0.04]	- -
Total (95% CI)			244			1638	100.0%	-3.28 [-4.71, -1.86]	•
Heterogeneity: Tau ² = 0.34; Chi ² = 2.49, df = 2 (P = 0.29); I ² = 20%									
Test for overall effect: Z = 4.51 (P < 0.00001)									-20 -10 0 10 20 Favours No complications Favours Complications

SF Mental summary score (SF MCS)

Study or Subgroup	C	omplicatio	ins	No	complicat	ions	Weight	Mean Difference	Mean Difference
Study of Subgroup	Mean	SD	Total	Mean	SD	Total	weight	IV, Random, 95% CI /	IV, Random, 95% CI
39-Deaton	43	11	130	48	10	140	20.9%	-5.00 [-7.51, -2.49]	_ - -
28-Kement	47.17	1.96	9	50.79	2.09	19	52.3%	-3.62 [-5.21, -2.03]	- I
20-Hawn	47.1	10.3346	105	50.4	19.6056	1479	26.9%	-3.30 [-5.51, -1.09]	- - -
Total (95% CI)			244			1638	100.0%	-3.82 [-4.97, -2.67]	• I
Heterogeneity: Tau ² = 0.00; Chi ² = 1.12, df = 2 (P = 0.57); I ² = 0%									
Test for overall effect: Z = 6.52 (P < 0.00001)									-20 -10 0 10 20 Favours No complications Favours Complications

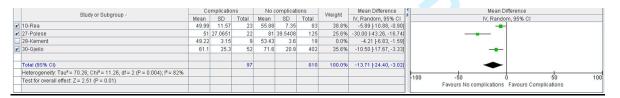
SF physical functioning (SF PF)

Study or Subgroup	Co	mplicatio	ns	No c	complicat	ions	Weight	Mean Difference	1	Mean D	ifference	
olddy of Sabgroup	Mean	SD	Total	Mean	SD	Total	vveigni	IV, Random, 95% CI		IV, Rando	m, 95% CI	
30-Gjeilo	67.9	28.9	52	78.3	23.1	402	24.2%	-10.40 [-18.57, -2.23]	8			
10-Rea	50.3	9.66	23	53.37	7.03	83	61.6%	-3.07 [-7.30, 1.16]			-	
27-Polese	79	22.5543	22	85	33.6097	125	14.2%	-6.00 [-17.11, 5.11]		-		
Total (95% CI)			97			610	100.0%	-5.26 [-9.67, -0.85]		•		
Heterogeneity: Tau ² = 3.58; Chi ² = 2.49, df = 2 (P = 0.29); I ² = 20%										1.	<u>.</u>	
Test for overall effect: Z = 2.34 (P = 0.02)									-100	-50 Favours No complications	Favours Complications	100

SF vitality (SF VT)



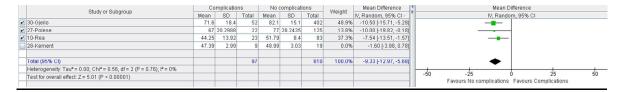
SF general health (SF GH)



SF bodily pain (SF BP)

Study or Subgroup	Co	mplication	ns	No c	omplicat	ions	Weight	Mean Difference	Mean Difference	
Study of Subgroup	Mean	SD	Total	Mean	SD	Total	vveigni	IV, Random, 95% CI	IV, Random, 95% CI	
10-Rea	44.99	12.92	23	53.66	10.47	83	38.5%	-8.67 [-14.41, -2.93]	I	
27-Polese	77	22.5545	22	94	11.6697	125	28.3%	-17.00 [-26.64, -7.36]		
30-Gjeilo	58.2	26.9	52	79	24.8	402	33.2%	-20.80 [-28.50, -13.10]	<u></u>	
Total (95% CI)			97			610	100.0%	-15.05 [-23.04, -7.07]	◆	
Heterogeneity: Tau ² = 34.52; Chi ² = 6.66, df = 2 (P = 0.04); I ² = 70%									l)	
Test for overall effect: Z = 3.70 (P = 0.0002)									100 -50 0 50 Favours No complications Favours Complications	100

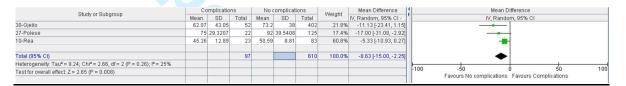
SF mental health (SF MH)



SF role physical (SF RP)

Study or Subgroup	Co	omplicatio	ns	No	complicat	ions	Weight	Mean Difference	Mean Difference
Study of Subgroup	Mean	SD	Total	Mean	SD	Total	weight	IV, Random, 95% CI	IV, Random, 95% CI
30-Gjeilo	40.2	44.7	52	56.2	42.8	402	27.5%	-16.00 [-28.85, -3.15]	
10-Rea	47.02	13.05	23	53.14	7.46	83	52.9%	-6.12 [-11.69, -0.55]	_ _ _
27-Polese	68	33.8314	22	88	50.8382	125	19.6%	-20.00 [-36.71, -3.29]	-
Total (95% CI)			97			610	100.0%	-11.56 [-20.33, -2.78]	•
Heterogeneity: Tau2 = 29.85; Chi2 = 3.82, df = 2 (P = 0.15); I2 = 48%									
Test for overall effect: Z = 2.58 (P = 0.010)									-100 -50 0 50 11 Favours No complications Favours Complications

SF role emotional (SF RE)



SF social functioning (SF SF)

Study or Subgroup	C	omplicatio	ins	No:	complicat	ions	Weight	Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	vveignt	IV, Random, 95% CI	IV, Random, 95% CI
30-Gjeilo	7.4	26.8	52	86.8	20.2	402	13.9%	-12.80 [-20.35, -5.25]	
10-Rea	40.14	16.56	23	51.91	9.53	83	15.8%	-11.77 [-18.84, -4.70]	I
27-Polese	82	20.2988	22	93	28.2435	125	8.2%	-11.00 [-20.82, -1.18]	
28-Kement	48.1	5.4	9	56.81	1.21	19	62.1%	-8.71 [-12.28, -5.14]	—
Total (95% CI)			106			629	100.0%	-9.95 [-12.76, -7.14]	•
Heterogeneity: Tau ² = 0.00; Chi ² = 1.31, df = 3 (P = 0.73); I ² = 0%									1. J. J. J.
Test for overall effect: Z = 6.93 (P < 0.00001)									-50 -25 0 25 50 Favours No complications Favours Complications

Anxiety



References

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- 3. Hawn MT, Itani KM, Giobbie-Hurder A, McCarthy Jr M, Jonasson O, Neumayer LA. Patient-reported outcomes after inguinal herniorrhaphy. *Surgery* 2006; **140(2)**: 198-205.
- 4. Kement M, Karabulut M, Gezen FC, Demirbas S, Vural S, Oncel M. Mild and severe anal incontinence after lateral internal sphincterotomy: Risk factors, postoperative anatomical findings and quality of life. *Eur Surg Res* 2011; **47**(1): 26-31.
- 5. Gjeilo KH, Klepstad P, Wahba A, Lydersen S, Stenseth R. Chronic pain after cardiac surgery: A prospective study. *Acta Anaesth Scand* 2010; **54(1)**: 70-8.
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- 7. Rea JD, Yarbrough DE, Leeth RR, Leath TD, Clements RH. Influence of complications and extent of weight loss on quality of life after laparoscopic Roux-en-Y gastric bypass. *Surg Endosc* 2007; **21(7)**: 1095-100.
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- 9. Tully PJ, Bennetts JS, Baker RA, McGavigan AD, Turnbull DA, Winefield HR. Anxiety, depression, and stress as risk factors for atrial fibrillation after cardiac surgery. Heart Lung 2011; 40(1): 4-11.



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary 3	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
9 Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6
METHODS			
3 Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not available
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search 2	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Suppl. Materials
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7-8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Suppl. Materials

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17-18



45 Conclusions

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Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	8-9
		Page 1 of 2	-1
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9 & Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1-
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Tables 1-
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Suppl. Materials and Tables 1- 3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Suppl. Materials
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	16
0 1 1			4- 4-

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Provide a general interpretation of the results in the context of other evidence, and implications for future research.



PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	18

For more infon. From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and metaanalysis

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Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

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Abstract

Objective: Surgical complications may affect patients psychologically due to challenges such as prolonged recovery or long-lasting disability. Psychological distress could further delay patients' recovery as stress delays wound healing and compromises immunity. This review investigates whether surgical complications adversely affect patients' post-operative wellbeing and the duration of this impact.

Methods: The primary data sources were 'PsychINFO', 'Embase' and 'MEDLINE' through OvidSP (year 2000 to May 2012). The reference lists of eligible articles were also reviewed. Studies were eligible if they measured the association of surgical complications after cardiac, thoracic, gastro-intestinal or vascular surgery with adult patients' post-operative psychosocial wellbeing using validated tools or psychological assessment. 13,605 articles were identified. Two researchers independently extracted information from the included articles on study aims, participants' characteristics, study designs, surgical procedures, surgical complications, wellbeing outcomes and findings. The studies were synthesised qualitatively. Supplementary meta-analyses of the impact of surgical complications on patients' wellbeing were also conducted.

Results: 50 studies were included. Two thirds of the studies found that patients who suffered surgical complications had significantly lower levels of post-operative psychosocial wellbeing even after controlling for patients' pre-operative wellbeing, clinical and demographic factors. There were significant and clinically meaningful differences between patients with complications and patients without on aspects of quality of life including 'problems with daily activities due to emotional problems' (p<.01), 'interference with social activities due to physical and emotional problems' (p<.001), and 'feelings of nervousness and depression' (p<.001). Half of the studies with significant findings reported significant adverse effects of complications on patients' wellbeing at 12 months (or more) post-surgery.

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Strengths and weaknesses of this study

- This is, to our knowledge, the first systematic review of the literature assessing the impact of surgical complications on patients' psychosocial wellbeing.
- The validity of the findings is reinforced by the fact that only studies that used validated selfreport measures for the assessment of patients' wellbeing were included in the review, as well as by the use of a very comprehensive search strategy for the identification of relevant literature.
- Caution should be taken when interpreting these findings to other specialties as the review was limited in four surgical specialties.
- A limitation of this review was the very small number of studies with sufficient data for
 quantitative synthesis, which did not also permit certain types of sensitivity analyses such as by
 surgical specialty or type of surgery.

Introduction

Surgical complications pose significant challenges for surgical patients. Complications may vary from very minor events that can be resolved relatively quickly without the need for pharmacological treatment or other intervention, to more serious events which can be life-threatening, require multiple interventions (e.g. return to theatre), delay patient's discharge and may lead to multi-organ failure or even death. ¹ A recent review of the literature found that post-operative complications contribute to increased mortality, length of stay and an increased level of care at discharge. ²

Other than the complications' impact on patients' post-operative recovery, they may also affect patients psychologically. They may contribute to the development of severe psychological distress such as depression or anxiety due to the challenges that are inherent to them in terms of prolonged recovery or long-lasting disability (e.g. severe post-operative pain, permanent disfigurement). An early study found that patients who experienced serious adverse events after surgery reported higher levels of distress than people who had experienced serious accidents or bereavements and psychosocial adjustment worse than in patients with serious medical conditions. ³ Moreover, the authors of an interview study on patients' experiences of cardio-thoracic surgery reported that a small number of patients who had a long and complicated post-operative hospital stay expressed intense feelings of hopelessness and depression. ⁴ Psychological distress resulting from the experience of surgical complications could further delay patients' recovery from surgery as increased levels of stress delay wound healing ^{5,6} and compromise immunity. ^{7,9}

This review aims to critically review and synthesize the existing literature on the psychosocial impact of surgical complications on adult surgical patients and to estimate the types and duration of this impact. For this purpose, quantitative studies which assessed the association of surgical complications with adult patients' psycho-social wellbeing post-surgery were reviewed. Our hypothesis was that the occurrence of surgical complications adversely affects patients' psychosocial wellbeing. More specifically, the research questions that this systematic review aims to answer are:

- Do surgical complications impact on patients' psychosocial wellbeing?
- Is the psychosocial impact transitory or long-lasting?

Methods

Search strategy

The following databases were searched through OvidSP: 'PsychINFO' (1967 to 25th May 2012), 'Embase' (1947 to 25th May 2012) and 'Medline' (1948 to 25th May 2012). A search strategy was developed specific to each database. The three facets of the search strategy were:

A. Adult surgical patients

Terms such as patients, inpatients, outpatients, men, women were used for this facet.

B. Patient psychosocial outcomes

Key psychosocial outcomes that are commonly used to assess patients' wellbeing include anxiety, depression and quality of life. Terms for post-traumatic stress were also included due to the relevance of this psychological outcome in situations where a person is exposed to extreme stress. ¹⁰ Generic terms such as wellbeing and emotions were also used.

C. Surgical complications

Surgical complications were defined as any adverse event in relation to the surgical procedure including search terms for complications (e.g. adverse events, untoward incidents) and terms about the surgical setting (e.g. surgical, post-operative).

Each of the facets was expanded into a list of search terms truncated and combined with each other using Boolean operators, and also by mapping those to their relevant MeSH headings and sub-

headings in each database (through explosion of each MeSH heading). The search was restricted to titles and abstracts, and the results were limited to studies that used human participants and were written in English. The search strategies are presented in supplementary material 1. Database searching was complemented by reviewing the reference lists of eligible articles.

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Eligibility criteria

Studies were included in the review if they met the following criteria:

- Any quantitative study that measured the association of surgical complications with adult
 patients' psychosocial wellbeing after surgery, either as a primary or secondary aim. Specific
 types of complications were not pre-defined as this review was interested in the impact of
 any surgical complications on patients' wellbeing. Psychosocial wellbeing was assessed with
 validated self-report tools or psychological assessment.
- Studies of surgical complications after cardiac, thoracic, gastro-intestinal or vascular surgery
 where complications are more likely to occur. ¹¹ Studies of neuropsychological complications
 (e.g. delirium) and studies of transplantation procedures were excluded.

Conference proceedings, non-empirical data and articles that were published before the year 2000 or with the majority of their participants recruited before the year 2000 were excluded. This current approach in the selection of literature was expected to reduce bias resulting from studies of outdated surgical practices.

Study selection

A total of 50% of the abstracts were reviewed independently by two researchers (AP and RD) and disagreements were resolved by consensus. The remaining half of the retrieved abstracts were

reviewed by the primary researcher (AP) based on the consensus that was achieved for the first half. After excluding ineligible articles at abstract and title level, the remaining articles were assessed in full text. The eligibility criteria were applied again on each article. Reasons for exclusion were coded. Articles for which there was uncertainty were discussed between the primary researcher (AP), a researcher with background in psychology (RD) and a researcher with background in surgery (AA). Any disagreements were resolved by consensus.

Data extraction and quality assessment

The primary researcher (AP) and a researcher with a background in surgery (AA) independently extracted data from 20 articles, which they reviewed for any disagreements. Disagreements were resolved by consensus or referral to a third senior researcher (OF). Data were extracted from the remaining articles by the primary researcher and were later checked by the second reviewer (AA). A total of 10 authors were contacted by email to provide information that was not included in the manuscript. Three articles were excluded from the analysis as their authors did not respond to our requests for further information. Information was extracted from each article on study aims, participants' characteristics, study design, surgical procedure, surgical complications (i.e. types, definitions and method of recording, where available), wellbeing outcomes (including scales and time-points of measurement) and relevant findings.

The quality of the included studies was assessed with the Newcastle Ottawa scales (NOS). ¹² The scales were modified in order to reflect the research questions of the review and to also incorporate the assessment of cross-sectional studies.

Data synthesis

The included studies were first synthesised narratively. In order to quantify the degree of the impact of surgical complications on patients' wellbeing quantitative procedures were also used. A meta-analysis was conducted on each extracted wellbeing outcome using Review Manager (version 5.2).

1² was used to calculate the heterogeneity present in the meta-analyses. Heterogeneity was considered low when it was below 25% and high above 50%.

1⁴ A random effects approach was chosen, as a degree of heterogeneity between studies should always be assumed in social sciences.

1⁵ Where multiple assessments were conducted in one single study, only the one furthest from the participants' surgery was included in the meta-analysis.

Results

18,585 articles were retrieved in total across the three databases. After removing duplicate references, a total of 13,605 papers were reviewed at abstract and title level. 994 articles remained to be assessed in full text. A total of 51 articles (50 studies) were eligible for inclusion in the final stage of the review (see Figure 1).

-Figure 1 -

Study characteristics

Details of the included studies are presented in Tables 1-3. A total of 28 studies were conducted in Europe, 14 in the US, three in Australia, two in Turkey, one in Egypt, one in Japan, and one in Taiwan. There were 29 studies in gastro-intestinal, ¹⁶⁻⁴⁴ 17 in cardio-thoracic, ⁴⁵⁻⁶² and four in vascular surgery. ⁶³⁻⁶⁶ The majority of the included studies (40 studies) assessed major procedures. The most common indications for surgery were heart conditions, followed by different types of cancer.

Quality of life was the main psychosocial outcome. Three studies assessed anxiety, 30, 40, 62 four studies assessed depression, 31, 41, 49, 62 and one study assessed mood states. 41 No other psychosocial outcomes were studied. The SF-36 (and its associated versions, i.e. SF-12, SF-20) was the most commonly used scale for the assessment of quality of life. 18, 25-31, 36-38, 42, 43, 45, 46, 48, 51-55, 57-59, 61, 63

The vast majority of the studies used a-priori definitions of complications. For example, Bloemen et al. recorded only severe complications based on a grading system of surgical operations. ¹⁹ Dasgupta et al., also recorded major complications which were defined as "those associated with systemic illness requiring transfer to a higher level of care or requiring relaparotomy, or complications needing interventional radiology". ²³ Others used pre-defined categories of complications such as infections, respiratory complications, chronic postoperative pain or perioperative myocardial infarctions. A total of 14 studies did not define or describe the complications that were recorded. The majority of the studies recorded a range of post-operative complications. 18 studies focused on a single category of complications (e.g. anastomotic leaks, peri-operative myocardial infarctions, wound complications, atrial fibrillation). Complications were mostly recorded through medical records review, clinical examinations and review of administrative databases.

Study quality varied. The scores of the included studies ranged from 2 to 8, with a mean score of 5.9. Points were deducted for the following reasons: lack of information on how complications were defined or on the methods that were used for their recording, ^{16-18, 21-23, 25, 29, 35, 37, 40-42, 46, 51, 55-57, 61, 63} lack of information on response rates, ^{16, 21, 22, 25-27, 29, 37, 40, 50, 52, 54, 55, 57, 60, 61} patients' baseline wellbeing was not measured or controlled for in the analysis, ^{17, 19, 20, 25, 27, 30-36, 38-40, 43-45, 47, 49, 53, 63} and

 demographic or clinical factors were not controlled for. ^{20, 25, 27, 31, 32, 34, 40, 43, 45, 51, 56, 61, 63} Only 7 studies scored exceptionally low (i.e. below 4).

-Tables 1,2,3-

The impact of surgical complications on patients' wellbeing

The majority of studies (n=32) found that patients who suffered surgical complications had significantly lower post-operative wellbeing than patients with uncomplicated recovery. 16-20, 22, 24, 25, ^{28, 30, 31, 33, 35-37, 39, 41-48, 50-52, 54, 57, 60, 62, 65} This was the case not only after major surgical procedures but also after relatively minor operations such as hernia repairs. 30, 18, 28, 31, 43 The vast majority (n=25, 78%,) were of high quality (i.e. quality assessment score greater than 6 out of 8). For instance, more than half of the studies with significant findings had measured and controlled for patients' baseline wellbeing (n=18) 16, 18, 22, 24, 28, 37, 41, 42, 46, 48, 50-52, 54, 57, 60, 62, 65 and used multivariate analyses (n=21), 16, 18, 19, 22, 24, 25, 28, 35, 37, 39, 41, 42, 44, 46, 47, 50, 52, 54, 60, 62, 65 suggesting that complications remained a significant independent predictor of patients' postoperative wellbeing even after controlling for a range of clinical and demographic factors. Domains of patients' wellbeing that were significantly negatively affected by surgical complications included physical, emotional, and social aspects of patients' quality of life as well as anxiety and depression levels (see Table 4). Complications that were found to be significantly associated with low levels of patient wellbeing included both major events such as perioperative myocardial infarctions after CABG, 50 severe incontinence after internal sphincterectomy ³¹ or graft-related events after vascular surgery, ⁶⁵ and minor complications such as wound infections after hepatic resection, ²⁰ or new cardiac arrhythmias after CABG. ⁵⁴ The complications that were significantly associated with patients' post-operative wellbeing are presented in Tables 1-3.

Six studies reported a confounding association between surgical complications and patients' wellbeing (i.e. complications were significantly associated with worse wellbeing only under certain

conditions) ^{21, 32, 40} or complications were significantly associated with patients' wellbeing at univariate but not at multivariate analysis. ^{49, 59, 64} A total of 12 studies did not find a significant association of surgical complications with patients' postoperative wellbeing. ^{23, 26, 27, 29, 34, 38, 53, 55, 56, 61, 63, 66} The majority of them (n=7) scored below 6 on quality assessment. For example, four studies suffered from very small sample sizes. ^{26, 27, 34, 38}

-Table 4 -

Meta-analyses

 A series of supplementary meta-analyses were conducted on each extracted outcome (i.e. quality of life, anxiety, depression). For a meta-analysis on Quality of life only studies that used the SF-scales were considered, as they were the most commonly used quality of life assessment tools. There were three studies with sufficient data on the physical and mental quality of life component scores, 28, 31, 45 and three studies with data on 'physical functioning' (i.e. limitations in performing physical activities), 'bodily pain' (i.e. limitations due to pain), 'role -physical' (i.e. problems with daily activities as a result of physical health), and 'role -emotional' (i.e. problems with daily activities as a result of emotional health), 36, 37, 48 Moreover, there were four studies with sufficient data on 'general health' (i.e. evaluations of overall health), 'social role functioning' (i.e. interference with normal social activities due to physical and emotional problems), 'mental health' (i.e. feelings of nervousness and depression), and 'vitality' (i.e. feeling tired). 31, 36, 37, 48 The pooled mean differences between the two groups were significant for each quality of life sub-domain. The pooled differences were more than 5 points (on a scale from 0 to 100) for most of the sub-domains, indicating clinically meaningful 67 adverse effects of complications on the different quality of life domains (see supplementary materials). Two studies provided sufficient data for a meta-analysis on anxiety. 30,62 The pooled SMD was not significant. A meta-analysis on depression was not possible as only one study provided sufficient data. 30

For a more detailed report of the meta-analyses see supplementary materials 2-4.

The duration of the impact of surgical complications on patients' wellbeing

Eighteen out of the 38 studies which reported significant associations (including the six studies which reported confounding findings) found a significant relationship of the presence of post-operative complications with lower levels of wellbeing at 12 months post-surgery or later. ^{16, 19-22, 25, 28, 30-33, 36, 37, 47, 48, 50, 51, 65} Twenty studies reported a significant association of complications with lower levels of patient wellbeing less than 12 months post-surgery. ^{17, 18, 24, 35, 39-46, 49, 52, 54, 57, 59, 60, 62, 64}

Discussion

This is, to our knowledge, the first systematic review of the literature assessing the impact of surgical complications on patients' psychosocial wellbeing. In line with our hypothesis, two thirds of the included studies found a significant negative association between the occurrence of surgical complications and patients' postoperative wellbeing. The vast majority of those studies were of high quality. For instance, more than half of the studies with significant findings found that complications were an independent predictor of patients' postoperative wellbeing after controlling for pre-existing differences on patients' wellbeing, clinical and demographic variables.

Significant associations were reported between surgical complications and lower scores not only on physical but also on emotional and social dimensions of the various quality of life measures. A meta-analysis of the studies that used the SF-scales confirmed the existence of significant and clinically meaningful adverse effects of complications on various domains of patients' quality of life including patients' mental health, social functioning and problems with daily activities as a result of emotional problems. These findings confirm earlier preliminary findings on the psychological burden that surgical adverse events often cause on patients. ^{3, 4} Surgical complications were also significantly associated with higher post-operative anxiety and depression in individual studies, even though a

population effect could not be shown in meta-analysis due to the very small number of studies that assessed anxiety and depression in relation to surgical complications. Despite the fact that quality of life is a useful screening outcome offering a general picture of a person's physical health and psychological state, ⁶⁸ future studies on the psychosocial impact of surgical complications should focus more on outcomes such as anxiety and depression as they offer a more accurate picture of a person's psychological wellbeing. Highly relevant psychological outcomes such as post-traumatic stress that were not assessed in any of the included studies would also be of relevance for future research in this area.

Complications that were found to significantly contribute to patients' low post-operative wellbeing ranged from severe adverse events such as anastomotic leaks after gastro-intestinal surgery or perioperative myocardial infarctions after cardiac surgery to relatively minor complications such as wound infections or atrial fibrillation. It is not therefore only severe post-operative events that cause emotional distress and disruption during patients' convalescence but also less serious complications. Wound complications for instance may affect patients' satisfaction with their body image which may in turn affect their quality of life and psychological wellbeing. ⁶⁹ Moreover, this finding shows that the severity of complications as judged by clinicians does not always relate to how patients experience complications or how severely they are affected by them. Similarly, complications were found to be negatively associated with patients' post-operative wellbeing not only after major surgical procedures but also after relatively minor operations, ^{30, 18, 28, 31, 43} which suggests a potential independence of the magnitude of initial surgery with the development of significant effect of complications on patients' wellbeing. Further research on how complications affect patients' wellbeing after different types of surgery will help elucidate the role of this factor.

A considerable number of studies also found a significant negative contribution of surgical complications to patients' psychosocial wellbeing more than a year post-operatively, suggesting that patients may suffer psychologically due to the experience of surgical complications for an extensive

period of time after their surgery. The above findings hold important implications for surgical patients' recovery. There is growing evidence on the role of psychological stress in compromising the function of the immune system and slowing down wound healing. ⁷⁻⁹ The emotional distress that surgical complications inflict on patients is likely to further compromise their recovery in almost a reciprocal cycle of distress and decreased immune function. The exact relationships between the occurrence of surgical complications, psychological distress and speed of recovery warrant further investigation.

It is noteworthy that a smaller number of studies did not find a significant association between complications and patients' postoperative wellbeing or found significant univariate associations which were not replicated in multivariate models. Even in studies showing a significant impact there will be many patients who largely maintain their psychological health and quality of life in the aftermath of complications. Other than clinical factors, factors such as patients' ways of coping with stress, their appraisals of surgery and their condition as well as their perceptions of support from their loved ones and the healthcare professionals may also explain under which conditions complications affect patients' psychosocial wellbeing, as suggested by wider literature on patients' adjustment after surgical treatment. ⁷⁰⁻⁷² The contribution of psychological factors in ameliorating the psychological impact of surgical complications needs to be further explored.

Overall the quality of the included studies was good as indicated by their relatively high quality assessment scores and the small number of studies that scored exceptionally low. A substantial number of studies with significant findings accounted not only for patients' pre-operative wellbeing but also for a host of other clinical and demographic factors in multivariate analyses confirming that surgical complications were an independent predictor of low levels of postoperative wellbeing above and beyond any pre-existing differences. The validity of the findings is also reinforced by the fact that all the included studies used validated self-report measures for the assessment of patients'

wellbeing, as well as by the use of a very comprehensive search strategy for the identification of relevant literature.

Limitations

A few caveats should be borne in mind when interpreting the above findings. Firstly, even though the majority of the included studies used predefined lists or definitions of complications one third of them did not define or describe the complications that were recorded, nor did they explain their methods of complications recording. Moreover, almost one third of the studies did not describe their response rates, which does not permit inferences about the representativeness of their samples. With regards to the methodology of the systematic review, studies that were published before the year 2000 or with the majority of patients recruited before the year 2000 were excluded. However, limiting this review to literature that was published in the last decade is more reflective of current surgical practices and their associated complications. Caution should also be taken when interpreting these findings to other specialties as the clinical setting in which complications occur may affect their impact on patients' wellbeing. Another limitation was the very small number of studies with sufficient data for quantitative synthesis and the difficulty of synthesising data from different quality of life measures, which resulted in restricting the meta-analyses on data collected only with the SF scales. The small number of studies with available data did not also permit certain types of sensitivity analyses such as by surgical specialty, type of surgery (i.e. minor versus major surgery) or underlying disease (e.g. cancer versus other conditions). These factors may be significant determinants of the extent to which complications negatively impact on patients' post-operative wellbeing. Future studies on the association of surgical complications with outcomes such as anxiety, depression and post-traumatic stress, other than allowing a more accurate investigation of the complications' psychological impact, would also permit fuller meta-analyses of these effects. Lastly,

 there is always the potential for publication bias where studies with significant results and big effect sizes are more easily published. ⁷³⁻⁷⁵

Implications of findings

The results highlight the importance of considering patients' psychological needs in the aftermath of complicated surgical recovery. Surgical and nursing staff need to be aware of the challenges of surgical complications for patients' wellbeing and ensure that their psychological needs are not neglected. Screening patients who suffer post-operative complications for symptoms of psychological distress could help clinical staff identify those patients who need psychological support. Facilitating patients' access to psychological support during their hospital stay and arrangements for follow-up support could also be of great value for patients' post-operative wellbeing. For example, early referral to psychological services and early psychological interventions could prevent long-term psychological distress and may also mitigate the negative effects of stress on patients' recovery. Primary care practitioners and carers need also to be aware of the psychological burden that surgical complications impose on patients' lives in order to recognise their distress in time and to provide the support that patients need.

Conclusions

This is the first systematic review of the literature on the impact of surgical complications on patients' psychosocial wellbeing. The findings of this review strongly suggest that surgical complications are a significant independent predictor of patients' impaired post-operative psychosocial wellbeing often for a very long time post-surgery. It is not only major complications that may compromise patients' psychosocial wellbeing but also relatively minor adverse events,

which implies that the clinical severity of complications does not always indicate how seriously patients will be affected by them. Patients who experience surgical complications report lower levels of different aspects of quality of life than patients with uncomplicated recovery, often more than a year after their operation. The ways in which complications are managed (e.g. reoperation versus conservative management), the type of surgery (e.g. minor versus major), the underlying disease (e.g. cancer versus other conditions), psychological mechanisms (e.g. patients' perceptions of support, illness perceptions, coping strategies) or cultural influences may be key factors that moderate the impact of surgical complications on patients' psychosocial wellbeing. Future research should try to disentangle the contribution of the above factors on the impact of surgical complications on patients' post-operative wellbeing. Lastly, future studies should try to understand the impact of surgical complications on psychological outcomes such as anxiety, depression and traumatic stress and how to better support patients who experience a complicated post-operative recovery.

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Competing interests: None

Contributions: All co-authors contributed to the study design and reviewed drafts of the article. The first author screened all the articles for inclusion in this review, extracted and synthesised the data, and appraised the study quality. RD screened a sample of these at title/abstract and full text, and AA extracted data and scored the quality of a sample of the included articles.

Data sharing: No additional unpublished data

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Table 1: Key characteristics of gastro-intestinal surgery studies (n=29)

0	First author's name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per timepoint, N=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of surgical complications with patients' wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
2										Quality of life			
					Nt1=71/?	Colorectal cancer,			Morbidity was defined as any event that resulted	(QOL)/at time of			
3					Nt2=63	male patients who	Observational,	Open surgical	in the need for additional therapy or readmission	diagnosis and 12			
4						underwent open	cohort,	therapy for colorectal	to the hospital within 30 days of initial	months after		Any complications/12	
.	Anthony	2003	US	Secondary	Nc=16	surgical therapy	prospective	cancer	discharge/Method not specified	surgery/FACT-C ¹	YES*	months post- surgery	6
5						Patients with			A major complication was defined as reoperation,				
6						esophageal or		Upper gastro-	readmission to the high-dependency or intensive				
7						gastric cancer who		intestinal surgical	care unit, readmission to the hospital within 30	QOL/39.6days after			
					N=139/162	underwent upper		treatment for	days of operation, or death within 30 days of	treatment (range,6-		Any complications/39.6	
8						gastro-intestinal	Observational,	esophageal or gastric	operation or later if the patient did not leave the	105)/EORTC QLQ-C30		days after treatment	
aL	Avery	2006	UK	Primary	Nc=37	surgical treatment	cross-sectional	cancer	hospital/Method not specified	*	YES	(range: 6–105)	5
2					Nt1=151/205								
0					Nt2=130 (86.1%)								
1					Na/aaaaalainta\-40								
١.					Nc(complaints)=49 Nc(wound infection)=5					QOL/14 days pre-op,			
4					Nc(seroma)=13	Patients	Observational.		Retrospective list: Any complaint, Wound				
3					, ,					14 days post-op, and		A	
			Cormany	Cocondany	Nc(pneumonia)=1 Nc(other)=28	undergoing	cohort,	Cholecystectomy	infection, Seroma, Pneumonia, other complaints/Patient reports	6 months post-op/SF- 36	YES*	Any complications/6	_
4	Bitzer	2008	Germany	Secondary	Nc(other)=28	cholecystectomy	prospective	Cholecystectomy		30	152.	months post-surgery	7
5									Only severe complications were considered: Grade III or IV complications (according to Dindo's				
6								Surgical treatment	model) were defined as severe, whereas absence	QOL/36 (16-51)		Severe post-operative	
					N=121/170			for adenocarcinoma	of complications or Grade I and II complications	months post-op		complications/Median	
7						Rectal cancer	Observational,	of	were defined as absent or mild	/EORTC QLQ-C30 &		of 36 (range, 16–51)	
8	Bloemen	2009	Netherlands	Primary	Nc=33	patients	cross-sectional	the rectum	complications/patient records	CR38 ³	YES	months post-surgery	6
٦						Patients who underwent							
9						curative hepatic							
0						resection for			Surgical (e.g. bile leak or biloma, pneumothorax,				
						malignant or non			wound infection, liver abscess, bleeding, and				
1					N=96/188	malignant			surgical dehiscence) and medical (e.g. pleural				
2						diseases, disease			effusion, renal failure, hepatic failure, pneumonia,	7, 10,00			
2	Bruns	2010	Germany	Secondary	Nc(any morbidity)=30 Nc(wound infections)=10	free at time of assessment	Observational, cross-sectional	Hepatectomy	cardiac insufficiency, and cholangitis)/patient records	QOL/ 3-36 months post-op /SF-12	YES	Wound infections/3-36 months post-surgery	_
J∟	Diulis	2010	Germany	Secondary	NC(WOUNG IMPECTIONS)=10	assessment	CIO33-3ECLIOIIdi	перасессопу	records	μοσι-ομ / στ-12	ILJ	months post-surgery	,

¹ Functional assessment of cancer therapy questionnaire with the colorectal module

 $^{^2}$ European Organisation for Research and Treatment of Cancer core 3 European Organisation for Research and Treatment of colorectal cancer

: г									Retrospective list: pulmonary atelectasis or				
'									pneumonia, prolonged ileus, minor wounds				
;													
,									problems and urinary retention. Slippage with a				
									peak incidence during the second postoperative				
}									year. Band erosion with penetration into the				
١l									stomach. Access port problems (infection,			Band removal for	
'					Nt1=152/?	Consecutive			hematoma, leak, disconnection), bands			complications such as	
01					Nt(4)=139	patients operated	Observational,	Laparoscopic	explanted, associated with erosion, obstruction,	QOL/pre-op, 1, 3		erosion, slippage,	
4						on for morbid	cohort,	placement	immediate intolerance, and recurrent tubing	months & 2 years		intolerance/2 year post-	
1	Champault	2006	France	Secondary	Nc=(unclear)	obesity.	prospective	of a gastric band	break/Method not specified	post-op/GIQLI ⁴	CONFOUNDING*	surgery	6
2					N=102/218								
3													
					Nc(anastomotic								
4					stricture)=12								1
5					Nc(gastrojejunal								
					anastomotic ulcer) =9				Operation related complications, including				
6					Nc(upper gastro-intestinal	Patients	Observational,		gastrojejunal anastomotic stricture, gastrojejunal	QOL/pre-op, 1, 3, 6		Any complications/1, 3,	
7					bleeding) =1	undergoing	case-control,		anastomotic ulcer, upper gastro-intestinal	and 12 months post-		6, 12 months post-	
<u>'</u> [Chang	2010	Taiwan	Secondary	N(GORD)=2	bariatric surgery.	longitudinal	Roux-en-Y bypass	bleeding and GORD/Method not specified	op/WHOQOL-BREF ⁵	YES*	surgery	5
8					Nt1=102/122								
9									Major complications were defined as those				
- 1					Nt2=87	Consecutive,			associated with systemic illness requiring transfer				
201					Nt3=80	patients			to a higher level of care (high-dependency or				
1					Nt4=33	undergoing liver	Observational,		intensive care unit) or requiring relaparotomy, or	QOL/pre-op, 6, 12,			
۱۱.						surgery for liver	prospective,	Liver resection for	complications needing interventional	36-48 months post-			
2	Dasgupta	2008	UK	Secondary	Nc=44	cancer	cohort	hepatic malignancies	radiology/Method not specified	op/EORTC QLQ-C30	NO*	N/A	6
3					Nt1=109/109				Retrospectively listed complications: anastomotic				
					Nt2=82/109				leak, intraabdominal abscess, bleeding, venous				
4							Observational,	Surgery for CD	thrombosis, renal failure, and pneumonia,				
5					Nc(any)=19	Patients with	cohort,	(abdominal perineal,	dehydration, intraabdominal abscess, small bowel	QOL/pre-op & 30		Any complications/30	
	Delaney	2003	US	Secondary	Nc(major)=9	Crohn's Disease	prospective	loop or end stoma)	obstruction and wound infection/Database review	days post-op/CGQL ⁶	YES*	days post-op	7
6										QOL/0 to >10 years			
7										post-op/SF-36,			
										EORTC-QLQ-			
8										C38,Social			
9					N=296/?	296 patients with		Surgery for familial	The state of the s	Functioning subscale			
- 1						FAP who had been	Observational,	adenomatous	Surgery-related complications/Self-reports +	of the Dutch version		Any complications/0 to	
80	Douma	2011	Netherlands	Secondary	Nc=?	surgically treated	cross-sectional	polyposis (FAP)	medical records	of IBDQ ⁷	YES	>10 years post-surgery	2
11						Women with			Retrospectively listed complications: rectovaginal				
ار						colorectal			fistulae, vessel injury of the protective colostomy				
2						endometriosis			treated by laparoscopic coagulation,				
3					Nt1=58/?	who underwent a		Laparoscopic	uroperitoneum requiring a ureteral stent for 6				
4					Nt2=58	segmental	Observational,	segmentalcolorectal	weeks and an abscess behind colorectal				
-						colorectal	cohort,	resection for	anastomosis requiring a laparoscopic	QOL/pre & post-			
5	Dubernard	2006	France	Secondary	Nc=9	resection	prospective	endometriosis	drainage/Patient observations	op/SF-36	NO*	N/A	6
6													
_					N=40/?		Observational,	Anterior open	Postoperative complications: seroma,	QOL/pre-op, 3, 6 &12			
7	El Awady	2000	Equat	Cocondon	Nc=1.4	Patients with	prospective,	Lichtenstein tension	haematoma, 2ry infection, neuralgia and	months post-op/SF-	NO	NI/A	
٦.	El-Awady	2009	Egypt	Secondary	Nc=14	inguinal hernia	cohort	free hernioplasty	anaesthesia/patient observations	36	NO	N/A	4

⁴ Gastrointestinal Quality of Life index

⁵World Health Organization Quality of Life – Brief

⁶ Cleveland Global Quality of Life

⁷Inflammatory Bowel Disease Questionnaire

3	Hospital	Anxiety	and	Depression	Scal

								1					
)					Nt1=1983/3518								
:					Nt2=1526 (77%)				Complications were summarized by 4 categories:				
					Nt3=1603 (81%)				(1) hematoma/seroma, (2) orchitis, (3) neuralgia				
									of the leg or groin, and (4) other. Complications				
.					Nc(neuralgia t1)=94				classified as "other" included: (1) early				
•					Nc(hematoma t1)=51				postoperative complications (urinary tract				
)					Nc(orchitis t1)=13				infection, urinary retention, and hematuria); (2)				
					Nc(recurrence t1)=76				life-threatening complications (respiratory				
0					Nc(other t1)=124				insufficiency, myocardial ischemia, cardiac				
1					110(001101 (1) 12)				arrhythmia, intraoperative hypotension, and				
					Nc(neuralgia t2)=105				stroke); and (3) long-term complications (4 weeks				
2					Nc(hematoma t2)=55		Observational,						
3						No. be and a		to a dead	or more postoperative)/Patient reports for	001/		No	
					Nc(orchitis t2)=18	Men who received	cohort,	Inguinal	neuralgia & orchitis + Expert consensus for life-	QOL/pre-op, 1 &2		Neuralgia, orchitis/2	
4	Hawn	2006	US	Primary	Nc(other t2)=150	a hernia repair.	prospective	herniorrhaphy	threatening complications	years post-op/SF-36	YES*	years post-surgery	8
5						Patients who							
						underwent							
6						colorectal							
7					Nt1=?/568	resection for							
					Nt2=166	benign and	Observational,						
8						malignant	cohort,	Laparoscopic		QOL/pre-op, 4weeks			
9	Ince	2011	US	Secondary	Nc=?	diseases.	retrospective	colorectal resection	No reference	post-op/SF-36	NO*	N/A	3
- 1						Patients who had							
20						been operated on							
1						for groin hernia.							
						Controls matched							
2						for age, gender							
23						and method of							
						surgical repair							
4						were allotted from			Persistent postoperative pain (patients with pain	QOL, anxiety,			
					N(total)=184/423	the group of			of Grade 3, i.e. pain that could not be ignored but	depression/(on			
25						persons without	Observational,		did not interfere with everyday activities, or	average 4.9 years		Persistent post-	
26					N1=92 (cases)	persisting pain	case-control,		higher on IPQ)/Patient reports (Inguinal Pain	post-op, range > 7		op/Mean of 4.9 years	
7	Kalliomaki	2009	Sweden	Primary	N2=92 (controls)	(Grade 1 in IPQ)	cross-sectional	Hernia repair	Questionnaire) & clinical examination	years)/SF-36, HADS ⁸	YES	post-surgery	5
<u>'</u>						Consecutive							
8					N=253/351	patients with							
9					•	chronic anal						Severe	
					N(incontinence)=28	fissure who			Anal incontinence/Patient reports: Wexner	QOL/23.3 +/- 7.1		incontinence/23.3 (SD ±	
80					N(severe incont)=9	underwent open	Observational,	Open lateral internal	Incontinence Score system (WIS) + Clinical	months post-op/SF-		7.1) months post-	
1	Kement	2011	Turkey	Primary	N(mild incont)=19	LIS.	cross-sectional	sphincterotomy	examination	36	YES	surgery	5
<u>`</u>				,	,	Consecutive		•				- /	-
32						patients under the							
3						care of three							
					N=92/112	consultant							
4					- ,===	surgeons who							
55					Nc(leaks)=23	underwent							
					Nc(clinical leaks)=13	procedures with	Observational,	Low rectal	Anastomotic leaks (clinical & subclinical)/Patient	QOL/10-18 months		Anastomotic leaks/10-	
6	Lim	2006	UK	Primary	Nc(sub-clinical leaks)=10	LRA	cross-sectional	anastomosis (LRA)	observations, CT scans, WCE	post-op/EORTC QOL	CONFOUNDING	18 months post-op	5
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_													
					N=679/1308								
					Nc(early comps/anast)=54								
					Nc(late comps/anast)=126				Standard Standard Standard Standard				
					Nc(early				-Digestive, skin, genitourinary, surgical, medical,			5.1	
					comps/anast/rectal cancer only)=42				immediate indirect complications -Early complications: those that were first			Enterocutaneous fistula for all patients & any	
					Nc(late	Long-term			recorded within 30 days of the surgery. Late	QOL/ 5-15 years		late complications for	
_					comps/ostom/rectal	Colorectal Cancer	Observational,	Colorectal cancer	complications: occurring 31 days after	post-op/mCOH-QOL-		ostomy patients>5 years	
U	Liu	2010	US	Primary	cancer only)=105	patients	cross-sectional	surgery	surgery/Patient computerised data	Ostomy ⁹	YES	post-surgery	6
1 İ				, , , ,	Nt1=253/302	Patients who		87	9 N			p e e e e e e e e e e e e e e e e e e e	_
<u>'</u>					Nt2=244	underwent Lateral							
2						internal		Lateral internal		QOL/pre-op	UNCLEAR (due to		
3					Nc(anal fistula/abscess)=3	sphincterotomy	Observational,	sphincterotomy (LIS)		(admission) & 12	small number of		
J					Nc(FISI>0)=7	(LIS) for chronic	cohort,	for chronic anal		months post-	patients with		
4			Turkey	Primary			prospective		Anal Incontinuous (Dationt associantino : FISI acces	op/GIQLI & FIQL ¹⁰	· .	N/A	
5	Mentes	2006	Turkey	Primary	Nc(FISI, 0->4, 21, 7)=3	anal fissure (CAF)	prospective	fissure (CAF)	Anal Incontinence/Patient examination+ FISI score	op/GIQLI & FIQL	complications)	N/A	6
_						Veterans with an			Ostomy complications: skin problems, leakage,				
6						ostomy after			and difficulty with adjustment (i.e. leakage,			0.1	
7						major gastro-	Q		peristomal irritant dermitis, pain, bleeding, stomal			Ostomy complications	
′					N=239/322	intestinal surgery	Observational,	Gastro-intestinal	necrosis, prolapse, stenosis, herniation, retraction,	QOL/6months post-		(skin problems,	
8						requiring an	case-control,	surgery requiring an	infection, mucotaneous separation, difficulty	op/mCOH-QOL-		leakage)/ 6 months	
9	Pittman	2008	US	Primary	Nc=56	intestinal stoma	cross-sectional	intestinal stoma	adjusting)/Patient reports	Ostomy	YES	post-surgery	6
- 1						Patients who							
0						underwent							
1						elective left	·						
						colonic or rectal							
2						resection and							
3						colorectal							
- 1					N=147/211	anastomosis for		Left colonic or rectal					
4						neoplastic or		resection and		QOL/mean 58		Anastomotic stenosis/58	
_					Nc(anastomotic	inflammatory	Observational,	colorectal		(SD ± 31) months		(SD ± 31) months post-	
5	Polese	2012	Italy	Primary	stenoses)=22	disease.	cross-sectional	anastomosis	Anastomotic stenosis/Clinical examination	post-op/SF-36	YES	surgery	6
6		_			Nt1=505/?								
7					Nt2=237								
٠,					Nt3=106	Patients who		LRYGB for morbid					
8						underwent LRYGB	Observational,	obesity without				Complications requiring	
9					Nc(t2)=41	by one surgeon	cohort,	conversion to an	Postoperative complications requiring	QOL/baseline, 1 & 2		intervention/1 & 2 years	
- 1	Rea	2007	US	Primary	Nc(t3)=23	for morbid obesity	prospective	open procedure.	intervention/Method not specified	years post-op/SF-36	YES*	post-surgery	6
0				- 11			l .	l.		l.	l .		
1													
1													
2													
3													
4													
5													

⁹ City of Hope Quality of Life for Ostomates questionnaire 10 Fecal Incontinence Quality of Life Instrument

						Cases: patients							
:						operated for							
.						rectal cancer and							
						developed							
≀						anastomotic leak.							
						Controls: Patients							
)						operated for							
0						rectal cancer at							
-						the same time							
1						period and had an							
2						uneventful							
						postoperative			Anastomotic leakage: Defined as grade A (no				
3						course matched			change in patient's management), grade B				
4						by sex, age (±5			(requires active therapeutic intervention but is				
						years), type of		Rectal resection for	managed without relaparotomy) and grade C				
5						resection, and	Observational,	malignancies on	(requires relaparotomy)/Review of the	QOL/106.8 months			
6					N1=16/36 (cases)	neoadjuvant	case-control,	overall pelvic organ	institutional colorectal database and individual	post-op (32.4-			
7	Riss	2011	Austria	Primary	N2=16/? (controls)	therapy.	cross-sectional	function	chart reviews	170.4)/SF-12	NO	N/A	7
1						Patients			Technical surgical complications, including				
8						diagnosed with an			postoperative bleed exceeding 2000 ml or				
9						oesophageal or			requiring a reoperation, anastomotic insufficiency,				
9						cardia cancer who			necrosis of the substitute, damage to the				
20						underwent			recurrent nerve, thoracic duct damage or gastric				
						macroscopically	*		perforation/Prospective scrutiny of medical and				
21					N=355/ 446 (79·6 %)	and			histopathological records, operation charts,	QOL/6months post-		Technical	
22						microscopically	Observational,	Oesophageal	extensive study protocol with predefined	op/EORT QLQ-C30, &		complications/6 months	
2	Rutegard	2008	Sweden	Secondary	Nc=56	radical resection	cross-sectional	resection	exposure alternatives	QLQ-0ES1812 11	YES	post-surgery	7
								Bowel resection					
24								through midline	Market and a control or confirming and a second of				
25						Patients admitted		laparotomy or with	Medical and surgical complications and need of				
- 1					N=47/?	for intestinal		laparoscopic assistance, end	reoperation (2 anastomotic leaks, 3 intestinal obstructions, 2 intestinal bleeding, and a wound				
26					14-477:	surgery for	Observational,	ileostomy,	infection were recorded and two re-	QOL/3 months post-		Any complications/3	
7	Scarpa	2009	Italy	Secondary	Nc=?	Crohn's Disease	cross-sectional	stricturoplasty	laparotomies)/Method not specified	op/CGQLI	CONFOUNDING	months post-surgery	3
0					_			_		QOL, anxiety,			
28										depression, positive			
29						Consecutive				vs. negative			
30						patients with				affectivity, mood			
						newly diagnosed				states/pre-op (5-12			
31						colorectal			Wound, urinary tract and chest infections, cardiac	days pre-op) & 6-8			
32					Nt1=104 /110	cancer scheduled			and respiratory complications, deep venous	weeks post-op/FACT-			
- 1					Nt2=92	for elective open	Observational,		thrombosis, pulmonary embolism and	C, EuroQOL (EQ-5D),		Complications within 30	
33						resection in one	cohort,	Elective resection	complications related to anastomotic	HADS, PANAS ¹² ,		days of operation/6-8	
14	Sharma	2007	UK	Secondary	Nc=41	hospital trust	prospective	for colorectal cancer	breakdown/Method not specified	MRS ¹³	YES*	weeks post-surgery	6
, - [Patients							\neg
35						undergoing							
36					Nt1=93/113	colorectal surgery	01	December of the	Bodowski sameline (sameline in the sameline in	001/			
, ,					Nt2,t3=79	for benign and malignant	Observational,	Resection of the sigmoid	Postoperative complications (anastomotic leak, wound infection, delayed food intake, fever, and	QOL/pre-op, 3 & 12 months post-op/SF-		Any complications/3	
5/	Siassi	2009	Germany	Secondary	Nc=26	disease	prospective, cohort	colon or rectum	bladder dysfunction)/Method not specified	36 & GLQI ¹⁴	YES*	months post-surgery	7

¹¹ Oesophageal cancer-specific questionnaire

¹² Positive and negative affect schedule

¹³ Mood rating scale

¹⁴ Gastrointestinal Quality of Life Index

•													
5						Patients							
١ :						diagnosed with							
,						paraesophageal or							
'						mixed hiatal			Hernia recurrence (any migration of the cardia to				
3						hernia (types II, III,			chest level or evidence of a new paraesophageal	QOL/>=6 months			
,					N=37/46	and IV) with >50%		Laparoscopic repair	sac)/A barium swallow was given to all patients to	post-op (median, 24;		Clinically recurrent	
'			C	8.5	N. (4 b	of the stomach in	Observational,	of paraesophageal	rule out an anatomic recurrence. An independent	range, 6–50)/SF-36,	VEC	hernias/>=6 months	
0	Targarona	2004	Spain	Primary	Nc(recurrent hernias)=3	the chest.	cross-sectional	hiatal hernia	radiologist evaluated all the explorations.	GDSS ¹⁵ and GIQLI	YES	post-surgery	5
11 l						Patients newly diagnosed with a							
						histologically							
2						verified							
13						adenocarcinoma							
4						or squamous-cell							
						carcinoma of the							
5						esophagus or							
6						adenocarcinoma							
7						of the gastric							
						cardia that			Anastomotic leakage , infections, respiratory			Any complications,	
8						underwent			insufficiency, cardiac complications, technical			anastomotic leakage,	
9						macroscopically			complications, anastomotic strictures, and others			infection, respiratory	
						and			(intervention needed to treat embolus, deep			insufficiency, cardiac	
20					N=100/146	microscopically	Observational	F. Alexandra	venous thrombosis, rupture of the wound,	QOL/6 months post-		complications, technical	
21	veri	2005	Sweden	Secondary	Nc=44	radical tumor resection.	Observational, cross-sectional	Esophageal resection surgery for cancer	intestinal obstruction, stroke, renal failure, or liver failure)/Patient records	discharge/QLQ-C30 & OES-24 ¹⁶	YES	complications/6 months post-discharge	l <u>-</u>
22	Viklund	2005 *Study.cor		nts' preoperative we		resection.	cross-sectional	surgery for cancer	ranure//radent records	UE3-24	153	post-discharge	7
		July Col	icioneu ioi patiei	is picoperative we	ocnig								
23													
24													
25													
26													
27													
28													
29													
30													
31													
32													
33													
,,,													
34									failure)/Patient records				

^{*}Study controlled for patients' preoperative wellbeing

¹⁵ Glasgow Dyspepsia Severity Score

Table 2: Key characteristics of cardio-thoracic surgery studies (n=17)

Firs auth nam	or	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
Deato		2009	US	Secondary	Nt1= 317/442 Nt2=270 Nc=44% (130)	Patients with documented T2DM undergoing CABG	Observational, cohort, prospective	CABG	Infection of the leg, thorax, sternum, bloodstream or urinary tract; central neurological deficit (stroke or transient ischemia, coma); pneumonia, pulmonary insufficiency with prolonged ventilation or reintubation, pulmonary embolism; renal failure; arrhythmias requiring treatment; prolonged inotropic support or use of intra-aortic balloon pump; or reoperation for bleeding or tamponade/Patient records	QOL/ 3 months post- op/SF-36	YES	Any complications/3 months post-surgery	6
El Baz		2009	Netherlands	Secondary	Nt1=198/256 Nt2=168 Nc=?	Consecutive patients who were scheduled for CABG following a coronary angiography	Observational, cohort, prospective	CABG	Postoperative events such as use of inotropes, atrial arrhythmias, or ventricular arrhythmias, sternal resuturing, re-exploration for bleeding, and time spent on mechanical ventilation/Registry database, medical notes, outpatient notes and intensive therapy unit charts	QOL/pre-op & 6 months post-op/SF- 36	YES*	Re-exploration for bleeding and sternal resuturing/6 months post-surgery	8
Fergus	son 2	2009	US	Primary	N=124/221 Nc=22	Prospective patients who underwent major lung resection for early stage lung cancer.	Observational,	Major lung resection for early stage lung cancer (lobectomy, bilobectomy, pneumonectomy)	Complications were categorized as pulmonary (pneumonia, prolonged intubation, reintubation, air leak more than 7 days, lobar collapse requiring intervention), cardiovascular (pulmonary embolism, myocardial infarction, new postoperative arrhythmia, need for intravenous inotropic agents), other, and any complication/Administrative database, hospital medical records, office shadow files	QOL/average of 2.6 years post-op (3 months to 6.4 years)/EORTC QLQ- C30, EORTC QLQLC13 ¹⁷ and DASS- 21 ¹⁸	YES	Pulmonary complications/2.6 years post-surgery (Range: 3 months-6.4 years)	6
Gjeilo		2010	Norway	Primary	Nt1=534/631 Nt2=462 Nt3=465 Nc(t2)=52	Patients undergoing cardiac surgery	Observational, cohort, prospective	Midline sternotomy	Chronic pain (pain arising after surgery and persisting either continuously or intermittently for 3 months or more/BPI (Brief Pain Inventory)	QOL/pre-op, 6 & 12 months post-op/SF- 36	YES*	Chronic post-surgical pain/12 months post-surgery	6
Hata	2	2006	Japan	Secondary	N=452/452 Nc=?	Consecutive adult patients who underwent open heart surgery	Observational, cross-sectional	CABG	Postoperative morbidity (minor stroke, infection, pneumonia, haemodialysis, paraplesis)/Patient records	Depression/5-7 days post-op/Interviewed by a psychiatrist and CES-D ¹⁹	CONFOUNDING	Post-operative minor stroke and pneumonia/5-7 days post-surgery	6

¹⁷ EORTC Lung Cancer Questionnaire

¹⁸ Short version of the Depression Anxiety Stress Scales

¹⁹ Center for Epidemiological Studies Depression Scale

							CABG [89% via					
							sternotomy					
							incision with cardiopulmonary					
				Nt1=501/1128			bypass (CPB; on-					
				Nt2=485		Observational,	pump) and 11%	Perioperative myocardial infarctions/Clinical	QOL/pre-op & 12		Perioperative myocardial	
					Patients who	cohort,	without CPB (off-	examination + clinical tests (ECGs, echocardiography,	months post-		infarctions /12 months	
Jarvinen	2004	Finland	Primary	Nc=80	underwent CABG	prospective	pump)]	laboratory tests)	op/RAND-36	YES*	post-surgery	7
					-Cases: patients who							
					developed sternal							
					wound infection (SWI)							
					after cardiopulmonary							
					bypass.							
					 Controls: patients prior to CABG and evaluated 							
					1 year postoperative							
					and matched for time of	Observational,		Serious wound infections (SWIs: deep infection	QOL/20 months post-		Serious wound infections	
				N1=73/84 (cases)	the operation, age and	case-control,	Cardiopulmonary	involving retrosternal tissue and/or the sternal	op (range 7-40)/SF-		/20 (Range: 7-40) months	
Jideus	2009	Sweden	Primary	N2=42/? (controls)	sex	cross-sectional	bypass	bone)/Clinical examination	36	YES*	post-surgery	4
				N=99								
							Serratus-sparing					
				Nt1=120/?	\		posterolateral					
				Nt2=99	Patients aged 45 to 75	Observational,	thoracotomy or				Chronic post-thoracotomy	
					years undergoing	cohort,	limited	Chronic post-thoracotomy pain/Leeds Assessment of	QOL/pre-op, 3 moths		pain/ 3 months post-	
Kinney	2012	US	Primary	Nc=75	elective thoracotomy	prospective	thoracotomy	Neuropathic Symptoms and Signs + self-reports	post-op/SF-36	YES*	surgery	7
					-Cases: patients who							
					underwent cardiac							
					surgery and developed ARF requiring RRT and							
					left the hospital alive.							
					-Controls: matched							
					controls who did not	Observational,	Cardiac surgery	ARF (acute renal failure) requiring RRT (renal				
				N1=22/42 (cases)	develop ARF and did not	case-control,	(procedures not	replacement therapy)/Administrative database,	QOL/23-42 months			
Landoni	2006	Italy	Primary	N2=40/42 (controls)	receive RRT.	cross-sectional	specified)	registry	post-op/SF-36	NO	N/A	`6
				Nt1=182/444								
				Nt2=128							New cardiac arrhythmia	
				Nt3=114		Observational,			QOL/pre-op, 2 & 6		post-surgery, atrial	
					Adults on the waiting	cohort,		Post-surgical complications such as cardiac	months post-op/SF-		fibrillation/ 6 months post-	
Le Grande	2006	Australia	Secondary	Nc=?	list for CABG	prospective	CABG	arrhythmias, stroke and infections/Medical records	36	YES*	surgery	7
							Open heart					
							surgery (133 valve procedure; 620					
				ĺ	ĺ		CABG; 67 CABG	Perioperative myocardial infarction, mediastinitis,				
							plus valve	superficial wound infection, septicemia, permanent				
							procedure; 15	stroke, transient ischemic attack, continuous coma,				
							CABG plus other	prolonged intubation, ventilator-associated				
				Nt1=836/2,007			cardiac procedure;	pneumonia, cardiac tamponade, atrial fibrillation,				
				Nt2=2.007	Patients undergoing	Observational,	and 1 closure of	reoperation for bleeding, renal failure, renal failure				
Martin	2008	US	Primary	Nc=189	elective open heart	cohort,	an atrial septal defect)	which required dialysis, and length of stay/Method not specified	QOL/pre-op, 1 year post-op/SF-20	NO*	N/A	6
iviai tiii	2000	03	Filliary	INC-103	surgery	prospective	uerett)	Retrospective list of complications: Atrial fibrillation,	μοσι-υμ/ στ- Ζυ	INU	N/A	,
					All patients over 65			re-exploration for bleeding, low cardiac output				
				Nt1=63/63	presenting a 1, 2 or 3			syndrome, acute respiratory failure, sternal wound	QOL/pre-op, 4 & 12			
				Nt2=59	vessel disease treated			infection, neurological dysfunction, mild problems	months post-			
				Nt3=56	with CABG without	Observational,		related to leg incision healing or swelling, chest	op/MacNew Heart			
	2000		C d	N: 42	concurrent procedures	cohort,	CARC	incision discomfort and medications/Method not	Disease HRQOL	NO*		_
Merkouris	2009	Greece	Secondary	Nc=42	(e.g. valve replacement)	prospective	CABG	specified	questionnaire	NO*	N/A	5

Complication was defined as any of the following

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								Complication was defined as any of the following				
								postoperative complications: new onset atrial				
				Nt1=249/?				fibrillation, prolonged air leak (chest tubes in place				
				Nt2=213	Prospective patients	Observational,		for more than 5 days), pneumonia, re-intubation,	QOL/pre-op, 6			
					scheduled for lung	cohort,		reoperation, or hospital stay of 8 days or	months post-op/SF-		Any complications/6	
Moller	2012	Sweden	Secondary	Nc=?	surgery for lung cancer	prospective	Lung surgery	more/Method not specified	36	YES*	months post-surgery	6
								Respiratory: postoperative mechanical ventilation				
								for more than 24 h or pneumonia, defined as				
								pulmonary infiltrate with positive microbial cultures;				
								Cardiac: arrhythmia requiring treatment with				
								antiarrhythmic medication or electrical cardioversion				
								reversion; radiologic evidence of pulmonary edema;				
								or myocardial infarction, defined by new Q waves on				
								electrocardiogram or creatine kinase-MB isoenzyme				
								concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum				
				Nt1=120/125				creatinine concentration greater than 200 M;				
				Nt2=120 (days 1,2,3)				Neurologic: stroke, defined as a new central				
				Nt3=108				neurologic deficit;				
				Nt4=94				5. Sepsis: wound infection requiring excision of tissue				
							Cardiac surgery	or antibiotic therapy, or positive microbial culture				
	2001					Observational,	(specific	(other than pneumonia)	QOL/pre-op, 1 & 3			
	&				Adult cardiac surgical	cohort,	procedures not	-Clinical and laboratory tests (microbial cultures,	months, 3 years post-		Any complications/3	
Myles	2006	Australia	Secondary	Nc=69	patients	prospective	specified)	radiologic data, electrocardiograms etc.)	op/SF-36	CONFOUNDING*	months post-surgery	8
								Retrospective list of complications: low cardiac output (cardiac index lower than 2 L/min/m2),				
								mechanical ventilation longer than 24 hours,				
								reoperation for bleeding, sternal wound infection,				
								perioperative myocardial infarction, pericardial	QOL/pre-op, 6			
				Nt1=208/?				effusion, arrhythmic complications (atrial fibrillation,	months post-			
				Nt2=192	Consecutive patients	Observational,		ventricular tachycardia, ventricular fibrillation),	op/Nottingham			
		Serbia &			who underwent elective	cohort,		abdominal complications, and other/Observations,	Health Profile		Any complications/6	
Peric	2008	Montenegro	Secondary	Nc=60	CABG	prospective	CABG	ECGs, echocardiography, laboratory tests	Questionnaire (NHP)	YES*	months post-surgery	7
								-Compensatory sweating (CS): Excessive sweating				
								considered abnormal in other parts of the body after				
				Nt1=397/?				TS.				
				Nt2=?			Thoracoscopic	-Gustatory sweating: Facial sweating after eating				
				Nt3=?			sympathectomy	foods	QOL/pre-op,			
				Nt4=?	Patients diagnosed with	Observational,	for palmar and	-Excessive dryness: Dryness affecting the hands and	discharge, 6 & 12			
					upper extremity HH	cohort,	axillary	requiring hydration	months post-op/SF-			
Rodriguez	2008	US	Secondary	Nc=23	treated with TS.	prospective	hyperhidrosis	-Method not specified	36	NO*	N/A	3
								New-onset atrial fibrillation (AF) between the				
								patient's day of admission to the intensive care unit	Anxiety, Depression,			
								and the median day of discharge (day 5) after CABG	Stress/pre-op			
				Nt1=226/238				during the index hospitalization/ECGs, transthoracic	(mean=2 days, SD=2			
				Nt2=222		Observational,		echocardiographs reviewed by technicians and	days) & post-op			
					Patients undergoing	cohort,		reviewers blinded to patients' psychological distress	(mean=6 days, SD=2		Atrial fibrillation/6 days	
Tully	2011	Australia	Primary	Nc=56	first-time CABG surgery	prospective	CABG	scores	days)/ DASS ²⁰	YES*	(SD=2 days) post-surgery	7
,												

²⁰ Depression Anxiety Stress Scales

Table 3: Key characteristics of studies in vascular surgery (n=4)

3	First author name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome & timepoints	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
7									Retrospective list: Postoperative				
ч									bleeding, Myocardial infarction,				
2						Consecutive patients			Stroke, Pneumonia, Respiratory	QOL/36.4 ± 15.5			
3					N=110/124	who received a			insufficiency, Acute renal dysfunction,	months post-op			
3						replacement of the	Observational,	Ascending aorta	Sepsis, Lung fistula/Method not	(11–58			
4	Lohse	2009	Germany	Secondary	Nc=?	dilated ascending aorta.	cross-sectional	replacement	specified (MG)	months)/SF-36	NO	N/A	4
5					•				Wound complications (WC): patients				
6						Patients who			having infection, necrosis, hematoma- haemorrhage, or seroma-lymphocele				
_						underwent IB for			at the surgical incision or harvest site				
7					Nt1=1296/1404	Critical Limb Ischaemia			within 30 days of the bypass				
8					Nt2=862	(CLI) in community and		Lower extremity vein	surgery/Adverse events clinical trial				
					Nt3=732	university hospitals	Observational,	bypass for limb salvage	documentation with reference to	QOL/baseline, 3 &			
9						across the US and	cohort,	in critical limb ischemia	source documentation (hospital notes	12 months post-		Wound complications/3	
n	Nguyen ^a	2007	US & Canada	Primary	Nc=543	Canada	prospective	(CLI) patients	etc.)	op/VascuQol ²¹	CONFOUNDING*	months post-surgery	8
34	11647211	2007	os a canada	,				, ,,	Graft-related events (GREs):			, ,	
۱۱ ک									development of a >70% graft stenosis				
22						Patients who			or having undergone a percutaneous				
23						underwent IB for			or surgical revision or a major				
					N1=1296/1404 (92.3%)	Critical Limb Ischaemia			amputation/Clinical tests				
24					N2=862 (61.4%)	(CLI) in community and		Infrainguinal vein	(angiography, ultrasonography etc.),				
25					N3=732 (52.1%)	university hospitals	Observational,	grafting for limb salvage	source documentation (hospital notes,	QOL/pre-op, 3 &			
06						across the US and	cohort,	in critical limb ischemia	discharge notes, operative and	12 months post-		Graft-related events/12	
20	Nguyen ^b	2006	US & Canada	Secondary	Nc=?	Canada	prospective	(CLI) patients	procedural notes etc.)	op/VascuQol	YES*	months post-surgery	8
27						Patients with varicose							
28						veins, either							
						symptomatic or with							
29						skin changes, resulting							
30						from incompetence of							
1					Nt1=70/70	the LSV as confirmed by handheld Doppler							
1					Nt2=59	examination or duplex				QOL/pre-op,			
32					Nt3=62	ultrasonography or			-Bruising/Tracing method	discharge & 6			
33					1413-02	both and requiring			-Sensory abnormalities, both	weeks post-			
<u> </u>					Nc(sensory abnormalities)=25	surgical intervention	Observational,		subjective (paresthesia and	op/Aberdeen			
34					Nc(bruising at t1)=58	(both day cases and	cohort,	Conventional LSV	dysesthesia) and objective/Patient	Varicose Vein			
35	Subramonia	2005	UK	Primary	Nc(bruising at t2)=16	inpatients).	prospective	stripping	reports, sensory testing	Questionnaire 2	NO*	N/A	7
			rolled for natients' r			•	-		· -				

^{*}Study controlled for patients' preoperative wellbein

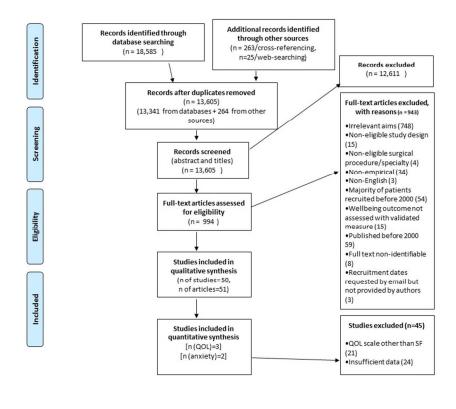
 $^{^{21}\,\}text{A validated instrument assessing pain, symptoms, activities, social life and emotional state in patients with vascular disease}$

Table 4: Domains of patients' wellbeing that were significantly affected by surgical complications

																	St	udies															
Mea	asures	Bruns	Liu	Bloemen	Siassi	Rutegard	Pittman	Sharma	Avery	Le Grande	Nguyen ^b	Viklund	Delaney	Kalliomaki	Hawn	Anthony	Chang	Douma	Kement	Targarona	Peric	El Baz	Deaton	Ferguson	Tully	Gjeilo	Jideus	Kinney	Polese	Rea	Bitzer	Jarvinen	Moller
	Physical- Component	✓			~					✓					~			✓	~			_	~									~	
	Mental Component									*					~				\				~										
	Physical functioning													✓												✓	✓	✓				✓	✓
	Bodily pain													✓					✓							✓		✓	✓	✓	✓		
Short Form scales (e.g. SF-36, SF-12	Role physical													✓												✓			✓	✓	✓	✓	
RAND-36)	Role emotional													✓															✓				
	General health													✓					✓				_			√	✓		~	✓		✓	✓
	Mental health													✓								√				✓			✓	√			
	Social functioning													>					>							✓	>		✓	>			
	Vitality													✓					✓			>				✓		✓		✓			✓
	Physical Functioning			~		✓			✓	~		✓						✓	_		_			✓									
	Global QOL					✓				✓		✓																					
EORTC QLQ-	Social Functioning								~										_		_												
C30+	Fatigue			✓		✓																											
	Role functioning					~			~																								
	Pain			√																													
	Weight loss			<u> </u>																													

	İ	1 1	i	 i	i	i	i	i	1	i	1	ı		ı	ı	ı	ı i	ı	1 1	ı i	1	i	1 1	ı	ı	1	1	1	 	i	
	Dyspnea				✓																										
	Nausea- Vomiting				✓			✓																							
	Coughing					✓																									
	Defecation																✓														
VascuQOL	Total QOL									✓																					
GIQLI	Total QOL																		✓												
	Total QOL		✓																												
mCOH-QOL	Physical QOL					1			<u> </u>																						
	Social QOL					✓														_											
	Total QOL														✓																
54.0T.0	Physical wellbeing						✓								✓																
FACT-C	Social wellbeing													<u> </u>	✓																
	Cancer concerns	_			_										~							_									
CGQL	Total QOL											✓																			
	Physical domain															✓															
WHOQOL- BREF	Pain & discomfort															~															
	Activities of daily living															✓															
IBDQ	Social functioning																✓)										
	Social isolation																		_	✓											
NHP	Sleep																			✓											
	Pain																			✓											
HADS &	Anxiety						✓						✓											✓							
DASS	Depression						✓						✓																		
PANAS	Negative affect						✓																								
MRS	Negative mood						✓																								





Supplementary materials for manuscript entitled:

Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

Supplementary material 1: Search strategies

Embase

- 1. exp mental stress/
- 2. exp emotion/
- 3. exp depression/
- 4. exp ANXIETY/
- 5. exp posttraumatic stress disorder/
- 6. exp "quality of life"/
- 7. exp wellbeing/
- 8. 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9. exp surgery/
- 10. exp complication/
- 11.9 and 10
- 12. exp surgery/co [Complication]
- 13. exp perioperative complication/
- 14. exp peroperative complication/
- 15. exp postoperative complication/
- 16. exp preoperative complication/
- 17. exp surgical error/
- 18. exp iatrogenic disease/su [surgery]
- 19. exp anesthesia complication/
- 20. exp ANESTHESIA/co [Complication]
- 21. exp anesthesia/
- 22. exp complication/
- 23. 21 and 22
- 24. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 23
- 25. exp patient/
- 26. adult/
- 27. female/
- 28. male/
- 29. 25 or 26 or 27 or 28
- 30. 8 and 24 and 29
- 31. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or awareness or iatrogen* or ((adverse or unfavourable or unfavorable or untoward or undesired) adj (outcome*1 or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 32. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anaesth*).ti,ab.
- 33. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 34. 31 and 32 and 33
- 35. 30 or 34
- 36. limit 35 to (human and English language)

MEDLINE

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Stress, Psychological/
- 9. exp Emotions/
- 10. exp Depression/
- 11. exp Anxiety/
- 12. exp Stress Disorders, Post-Traumatic/
- 13. exp "Quality of Life"/
- 14. 8 or 9 or 10 or 11 or 12 or 13
- 15. exp Medical Errors/
- 16. exp Postoperative Complications/
- 17. exp iatrogenic disease/su [surgery]
- 18. exp Anesthesia/ae, co [Adverse Effects, Complications]
- 19. 15 or 16 or 17 or 18
- 20. 14 and 19
- 21. exp Patients/
- 22. exp adult/
- 23. exp women/
- 24. exp men/
- 25. exp research subjects/
- 26. 21 or 22 or 23 or 24 or 25
- 27. 14 and 19 and 26
- 28. 7 or 27
- 29. limit 28 to (English language and humans)

PsycINFO

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Psychological Stress/
- 9. exp emotions/
- 10. exp "depression (emotion)"/
- 11. exp Anxiety/
- 12. exp posttraumatic stress disorder/
- 13. exp "Quality of Life"/
- 14. exp well being/
- 15. 8 or 9 or 10 or 11 or 12 or 13 or 14
- 16. exp postsurgical complications/
- 17. exp patients/
- 18. exp Human Females/
- 19. exp human males/
- 20. 17 or 18 or 19
- 21. 15 and 16 and 20
- 22. 7 or 21
- 23. limit 22 to (human and English language)

Supplementary material 2:

Detailed report of meta-analyses on the impact of complications on patients' psychosocial wellbeing

Quality of life

Due to the different measurement tools that were used for the assessment of QOL as well as the different domains that each tool assesses, a meta-analysis was conducted only on the studies that used the SF-tools. These were the most commonly used tools for the assessment of QoL, they are not condition-specific and they use the same measurement scale. Moreover, all of them yield the same summary scores (i.e. physical and mental). ¹ A meta-analysis was conducted on each summary score. The effect sizes are expressed as mean differences (MD) on a scale ranging from 0 to 100.

Only three studies provided sufficient data for a meta-analysis on the SF- physical and mental component scores between patients with complications and patients without complications. ²⁻⁴ The pooled mean differences between the two groups indicated significantly lower levels of physical and mental quality of life in patients who suffered complications compared to patients without complications (see eTable1).

The estimates of heterogeneity (I^2) were low (<25%).

Anxiety and Depression

Two studies provided sufficient data for a meta-analysis on anxiety levels. ^{5,6} Each study used a different scale, therefore the effect sizes are expressed as standardised mean differences (SMD). The pooled SMD for anxiety was not significant indicating a lack of population effect in terms of the complications' impact on patients' anxiety levels. The estimate of heterogeneity was high (I²=81%), however a sensitivity analysis by the methodological quality of the included studies did not alter the results. A meta-analysis on depression was not possible as only one study provided sufficient data. ⁶

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Supplementary material 3

eTable1: Results of meta-analyses on the impact of surgical complications on patient psychosocial outcomes

	0.1				_		MD D	050/ 01	l ²
Wellbeing outcome Quality of life	Sub-score Physical	Comparison Complications vs.	<u>k</u> 3	N 244	Z 4.51	<i>P</i> 0.00001	(SMD/ænxiety) -3.28 =	95% CI -4.71, -1.86	20%
(SF-scales)	component	complications vs.	3	277	4.51	0.00001	oade	4.71, 1.00	2070
		No complications		1638			èd fra		
	Mental	Complications vs.	3	244	6.52	0.00001	-3.82	-4.97, -2.67	0%
	component	No complications		1638			http://bm		
Anxiety		Complications vs.	2	148	1.12	0.26	0.27	-0.21, 0.75	81%
		No complications		262			n.bmj.c		

Supplementary material 4:

Forest plots of meta-analyses on the impact of surgical complications on patient psychosocial outcomes

SF Physical summary score (SF PCS)

Study or Subgroup	Co	omplicatio	ins	No i	complicat	ions	Weight	Mean Difference	Mean Difference
ataay or aangroup	Mean	SD	Total	Mean	SD	Total	weight	IV, Random, 95% CI /	IV, Random, 95% CI
20-Hawn	41.2	16.0186	105	45.7	52.9351	1479	11.3%	-4.50 [-8.58, -0.42]	_
28-Kement	53.97	2.22	9	57.91	1.63	19	51.5%	-3.94 [-5.57, -2.31]	
39-Deaton	41	9	130	43	8	140	37.2%	-2.00 [-4.04, 0.04]	■
Total (95% CI)			244			1638	100.0%	-3.28 [-4.71, -1.86]	♦
Heterogeneity: Tau ² = 0.34; Chi ² = 2.49, df = 2 (P = 0.29); I ² = 20%									
Test for overall effect: Z = 4.51 (P < 0.00001)									-20 -10 0 10 20
									Favours No complications Favours Complications

SF Mental summary score (SF MCS)

Study or Subgroup	Ci	omplicatio	ns	No i	complicat	ions	Weight	Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	weight	IV, Random, 95% CI /	IV, Random, 95% CI
39-Deaton	43	11	130	48	10	140	20.9%	-5.00 [-7.51, -2.49]	
28-Kement	47.17	1.96	9	50.79	2.09	19	52.3%	-3.62 [-5.21, -2.03]	-
20-Hawn	47.1	10.3346	105	50.4	19.6056	1479	26.9%	-3.30 [-5.51, -1.09]	_ -
Total (95% CI)			244			1638	100.0%	-3.82 [-4.97, -2.67]	♦
Heterogeneity: Tau# = 0.00; Chi# = 1.12, df = 2 (P = 0.57); I# = 0%									
Test for overall effect: Z = 6.52 (P < 0.00001)									-20 -10 0 10 20 Favours No complications Favours Complications
									ravours no complications Favours Complications

Anxiety

Study or Subgroup	Co	mplicatio	ns	No c	omplicati	ons	Weight	Std. Mean Difference	1		Std. Mear	n Difference			
Study of Subgroup	Mean	SD	Total	Mean	SD	Total	vveignt	IV, Random, 95% CI /	4		IV, Rando	m, 95% CI			
18-Kalliomaki	9.18	8.36	56	8.98	6.46	170	49.7%	0.03 [-0.27, 0.33]				•			
44-Tully	4.08	3.45	92	2.56	2.27	92	50.3%	0.52 [0.22, 0.81]]						
Total (95% CI)			148			262	100.0%	0.27 [-0.21, 0.75]				*			
Heterogeneity: Tau ² = 0.10; Chi ² = 5.19, df = 1 (P = 0.02); I ² = 81%									<u> </u>			[- 1	
Test for overall effect: Z = 1.12 (P = 0.26)									-10		5	0	5	10	
									8	Favours	Complications	Favours N	o complications		

References

- 1. Ware JE, Kosinski M. SF-36 physical & mental health summary scales: a manual for users of version 1: Quality Metric Inc; 2001.
- 2. Deaton C, Thourani V. Patients with type 2 diabetes undergoing coronary artery bypass graft surgery: Predictors of outcomes. *Eur J Cardiovasc Nur* 2009; **8(1)**: 48-56.
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- 4. Kement M, Karabulut M, Gezen FC, Demirbas S, Vural S, Oncel M. Mild and severe anal incontinence after lateral internal sphincterotomy: Risk factors, postoperative anatomical findings and quality of life. *Eur Surg Res* 2011; **47**(1): 26-31.
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- 6. Tully PJ, Bennetts JS, Baker RA, McGavigan AD, Turnbull DA, Winefield HR. Anxiety, depression, and stress as risk factors for atrial fibrillation after cardiac surgery. *Heart Lung* 2011; **40(1)**: 4-11.





PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
2 Structured summary 3 4	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
9 Objectives 0	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not available
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Suppl. Materials
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7-8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Suppl. Materials

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PRISMA 2009 Checklist

Synthesis of results 14 Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.

		Page 1 of 2	
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
FRESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9 & Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1-
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Tables 1-
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Suppl. Materials and Tables 1- 3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Suppl. Materials
5 Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	16
5 Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-18



PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	18

For more inton.. From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and metaanalysis

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Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

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Abstract

Objective: Surgical complications may affect patients psychologically due to challenges such as prolonged recovery or long-lasting disability. Psychological distress could further delay patients' recovery as stress delays wound healing and compromises immunity. This review investigates whether surgical complications adversely affect patients' post-operative wellbeing and the duration of this impact.

Methods: The primary data sources were 'PsychINFO', 'Embase' and 'MEDLINE' through OvidSP (year 2000 to May 2012). The reference lists of eligible articles were also reviewed. Studies were eligible if they measured the association of complications after major surgery from four surgical specialties (i.e. cardiac, thoracic, gastro-intestinal and vascular) with adult patients' post-operative psychosocial outcomes using validated tools or psychological assessment. 13,605 articles were identified. Two researchers independently extracted information from the included articles on study aims, participants' characteristics, study design, surgical procedures, surgical complications, psychosocial outcomes and findings. The studies were synthesised narratively (i.e. using text). Supplementary meta-analyses of the impact of surgical complications on psychosocial outcomes were also conducted.

Results: 50 studies were included in the narrative synthesis. Two thirds of the studies found that patients who suffered surgical complications had significantly worse post-operative psychosocial outcomes even after controlling for pre-operative psychosocial outcomes, clinical and demographic factors. Half of the studies with significant findings reported significant adverse effects of complications on patient psychosocial outcomes at 12 months (or more) post-surgery. Three supplementary meta-analyses were completed, one on anxiety (including two studies) and two on physical and mental quality of life (including three studies). The latter indicated statistically significantly lower physical and mental quality of life (p<0.001) for patients who suffered surgical complications.

Conclusions: Surgical complications appear to be a significant and often long-term predictor of patient post-operative psychosocial outcomes. The results highlight the importance of attending to patients' psychological needs in the aftermath of surgical complications.



Strengths and weaknesses of this study

- This is, to our knowledge, the first systematic review of the literature assessing the impact of surgical complications on patients' psychosocial wellbeing.
- The validity of the findings is increased by the fact that only studies that used validated self-report measures for the assessment of patients' wellbeing were included in the review, as well as by the use of a very comprehensive search strategy for the identification of relevant literature.
- Caution should be taken when interpreting these findings to other specialties as the review was limited in four surgical specialties.
- A limitation of this review was the very small number of studies with sufficient data for the
 quantitative synthesis, which did not also permit certain types of sensitivity analyses such as by
 surgical specialty or type of surgery.

Introduction

Surgical complications pose significant challenges for surgical patients. Complications may vary from very minor events that can be resolved relatively quickly without the need for pharmacological treatment or other intervention, to more serious events which can be life-threatening, require multiple interventions (e.g. return to theatre), delay patient's discharge and may lead to multi-organ failure or even death. ¹ A recent review of the literature found that post-operative complications contribute to increased mortality, length of stay and an increased level of care at discharge. ²

Other than the complications' impact on patients' post-operative recovery, they may also affect patients psychologically. They may contribute to the experience of psychological distress such as depression or anxiety due to the challenges that are inherent to them in terms of prolonged recovery or long-lasting disability (e.g. severe post-operative pain, permanent disfigurement). An early study found that patients who experienced serious adverse events after surgery reported higher levels of distress than people who had experienced serious accidents or bereavements and psychosocial adjustment worse than in patients with serious medical conditions. ³ Moreover, the authors of an interview study on patients' experiences of cardio-thoracic surgery reported that a small number of patients who had a long and complicated post-operative hospital stay expressed intense feelings of hopelessness and depression. ⁴ Psychological distress resulting from the experience of surgical complications could further delay patients' recovery from surgery as increased levels of stress delay wound healing ^{5,6} and compromise immunity. ^{7,9}

This review aims to critically review and synthesize the existing literature on the impact of surgical complications on adult surgical patients' psychosocial wellbeing and to estimate the duration of this impact. For the purpose of this review psychosocial wellbeing was defined quite broadly including psychosocial outcomes of relevance to surgery such as anxiety, depression, quality of life and post-traumatic stress. Quantitative studies which assessed the association of surgical complications with adult patients' psycho-social outcomes post-surgery were therefore reviewed. Our hypothesis was

that the occurrence of surgical complications adversely affects patient psychosocial outcomes.

Therefore, this systematic review aims to examine whether surgical complications impact adversely on patient psychosocial outcomes and the duration of this impact.

Methods

Search strategy

The following databases were searched through OvidSP: 'PsychINFO' (1967 to 25th May 2012), 'Embase' (1947 to 25th May 2012) and 'Medline' (1948 to 25th May 2012). A search strategy was developed specific to each database. The three facets of the search strategy were:

A. Adult surgical patients

Terms such as patients, inpatients, outpatients, men, women were used for this facet.

B. Patient psychosocial outcomes

A broad definition of psychosocial outcomes was considered for the purposes of this systemic review including search terms for anxiety, depression, quality of life and post-traumatic stress. ¹⁰ Two generic terms were also used i.e. wellbeing and emotions. The search did not include specific measures, instead it included terms for the outcomes specified above.

C. Surgical complications

Surgical complications were defined as any adverse event in relation to the surgical procedure including search terms for complications (e.g. adverse events, untoward incidents) and terms about the surgical setting (e.g. surgical, post-operative).

Each of the facets was expanded into a list of search terms truncated and combined with each other using Boolean operators, and also by mapping those to their relevant MeSH headings and sub-

headings in each database (through explosion of each MeSH heading). The search was restricted to titles and abstracts, and the results were limited to studies that used human participants and were written in English. The search strategies are presented in supplementary material 1. Database searching was complemented by reviewing the reference lists of eligible articles.

Eligibility criteria

Studies were included in the review if they met the following criteria:

- Any quantitative study that measured the association of surgical complications with adult patients' psychosocial outcomes after surgery, either as a primary or secondary aim. Studies that measured surgical complications and psychosocial outcomes but not their association were not included as a primary analysis of reported data was beyond the scope of this review. Moreover, specific types of complications were not pre-defined as this review was interested in the impact of any surgical complications on patients' wellbeing.
- Psychosocial outcomes were measured with validated self-report tools or psychological assessment.
- Studies that reported surgical complications after cardiac, thoracic, gastro-intestinal or vascular surgery, where complications are more likely to occur. ¹¹ Studies of neuropsychological complications (e.g. delirium) and studies of transplantation procedures were excluded.

Conference proceedings, non-empirical data and articles that were published before the year 2000 or with the majority of their participants recruited before the year 2000 were excluded. This current approach in the selection of literature was expected to reduce bias resulting from studies of outdated surgical practices.

Study selection

A total of 50% of the abstracts were reviewed independently by two researchers (AP and RD) and disagreements were resolved by consensus. The remaining half of the retrieved abstracts were reviewed by the primary researcher (AP) based on the consensus that was achieved for the first half. After excluding ineligible articles at abstract and title level, the remaining articles were assessed in full text. The eligibility criteria were applied again on each article. Reasons for exclusion were coded. Articles for which there was uncertainty were discussed between the primary researcher (AP), a researcher with background in psychology (RD) and a researcher with background in surgery (AA). Any disagreements were resolved by consensus.

Data extraction and quality assessment

The primary researcher (AP) and a researcher with a background in surgery (AA) independently extracted data from 20 articles, which they reviewed for any disagreements. Disagreements were resolved by consensus or referral to a third senior researcher (OF). Data were extracted from the remaining articles by the primary researcher and were later checked by the second reviewer (AA). A total of 10 authors were contacted by email to provide information that was not included in the manuscripts. Three articles were excluded from the analysis because their authors did not respond to our requests for further information. Information was extracted from each article on study aims, participants' characteristics, study design, surgical procedures, surgical complications (i.e. types, definitions and method of recording, where available), psychosocial outcomes (i.e. scales, and time-points of measurement), and the association of psychosocial outcomes with surgical complications. The latter included any reported findings on the association of surgical complications with the psychosocial outcomes, including both overall scale and sub-scale scores where available.

The quality of the included studies was assessed with the Newcastle Ottawa scales (NOS). ¹² The scales were modified in order to reflect the research questions of the review and to also incorporate the assessment of cross-sectional studies.

Data synthesis

The included studies were first synthesised narratively (i.e. using words and text). In order to quantify the degree of the impact of surgical complications on psychosocial outcomes quantitative procedures were also used. A meta-analysis was conducted on each extracted psychosocial outcome using Review Manager (version 5.2).¹³ I² was used to calculate the heterogeneity present in the meta-analyses. Heterogeneity was considered low when it was below 25% and high above 50%. ¹⁴ A random effects approach was chosen, as a degree of heterogeneity between studies should always be assumed in social sciences. ¹⁵ Where multiple assessments were conducted in one single study, only the one furthest from the participants' surgery was included in the meta-analysis.

Results

18,585 articles were retrieved in total across the three databases. After removing duplicate references, a total of 13,605 papers were reviewed at abstract and title level. 994 articles remained to be assessed in full text. A total of 51 articles (50 studies) were eligible for inclusion in the final stage of the review (see Figure 1).

-Figure 1 -

Study characteristics

 Details of the included studies are presented in Tables 1-3. A total of 28 studies were conducted in Europe, 14 in the US, three in Australia, two in Turkey, one in Egypt, one in Japan, and one in Taiwan. There were 29 studies in gastro-intestinal, ¹⁶⁻⁴⁴ 17 in cardio-thoracic, ⁴⁵⁻⁶² and four in vascular surgery. ⁶³⁻⁶⁶ The majority of the included studies (40 studies) assessed major procedures. The most common indications for surgery were heart conditions, followed by different types of cancer. Twenty-three studies examined the association between surgical complications and patients' wellbeing as a primary research aim. ^{17, 19, 28, 30-38, 43, 47, 48, 50-53, 55, 62, 64, 66} The remaining examined this relationship as part of an exploration of the association of different clinical factors with patients' postoperative wellbeing. The majority of the studies were cohort studies. There were four case-control and 20 cross-sectional studies. The majority of the studies were prospective, including baseline measures of psychosocial outcomes.

Quality of life was the main reported psychosocial outcome. Three studies measured anxiety, ^{30, 40, 62} four studies measured depression, ^{31, 41, 49, 62} and one study measured mood states. ⁴¹ No other psychosocial outcomes were measured. The SF-36 (and its associated versions, i.e. SF-12, SF-20) was the most commonly used scale for the measurement of quality of life. ^{18, 25-31, 36-38, 42, 43, 45, 46, 48, 51-55, 57-59, 61, 63}

The vast majority of the studies used a-priori definitions of complications. For example, Bloemen et al. recorded only severe complications based on a grading system of surgical complications. ¹⁹ Dasgupta et al., also recorded major complications which were defined as "those associated with systemic illness requiring transfer to a higher level of care or requiring relaparotomy, or complications needing interventional radiology". ²³ Others used pre-defined categories of complications such as infections, respiratory complications, chronic postoperative pain or perioperative myocardial infarctions. A total of 14 studies did not define or describe the complications that were recorded. The majority of the studies recorded a range of post-operative

 complications. 18 studies focused on a single category of complications (e.g. anastomotic leaks, perioperative myocardial infarctions, wound complications, atrial fibrillation). Complications were mostly recorded through medical records review, clinical examinations and review of administrative databases.

Study quality varied. The scores of the included studies ranged from 2 to 8, with a mean score of 5.9. Points were deducted for the following reasons: lack of information on how complications were defined or on the methods for their recording, ^{16-18, 21-23, 25, 29, 35, 37, 40-42, 46, 51, 55-57, 61, 63} lack of information on response rates, ^{16, 21, 22, 25-27, 29, 37, 40, 50, 52, 54, 55, 57, 60, 61} baseline psychosocial outcomes were either not measured or controlled for, ^{17, 19, 20, 25, 27, 30-36, 38-40, 43-45, 47, 49, 53, 63} and demographic or clinical factors were not controlled for. ^{20, 25, 27, 31, 32, 34, 40, 43, 45, 51, 56, 61, 63} 7 studies scored exceptionally low (i.e. below 4).

-Tables 1,2,3-

The impact of surgical complications on patients' wellbeing

The majority of studies (n=32) found that patients who suffered surgical complications had significantly worse post-operative psychosocial outcomes than patients with uncomplicated recovery. 16-20, 22, 24, 25, 28, 30, 31, 33, 35-37, 39, 41-48, 50-52, 54, 57, 60, 62, 65 This was the case not only after major surgical procedures but also after relatively minor operations such as hernia repairs. 30, 18, 28, 31, 43 The vast majority (n=25, 78%,) were of high quality (i.e. quality assessment score greater than 6 out of 8). For instance, more than half of the studies with significant findings had measured and controlled for patients' baseline psychosocial outcomes (n=18) 16, 18, 22, 24, 28, 37, 41, 42, 46, 48, 50-52, 54, 57, 60, 62, 65 and used multivariate analyses (n=21), 16, 18, 19, 22, 24, 25, 28, 35, 37, 39, 41, 42, 44, 46, 47, 50, 52, 54, 60, 62, 65 suggesting that complications remained a significant independent predictor of patients' postoperative wellbeing even after controlling for a range of clinical and demographic factors. Psychosocial outcomes that were significantly negatively affected by surgical complications included physical, emotional, and social aspects of patients' quality of life as well as anxiety and depression levels (see Table 4).

Complications that were found to be significantly associated with worse psychosocial outcomes included both major events such as perioperative myocardial infarctions after CABG, ⁵⁰ severe incontinence after internal sphincterectomy ³¹ or graft-related events after vascular surgery, ⁶⁵ and minor complications such as wound infections after hepatic resection, ²⁰ or new cardiac arrhythmias after CABG. ⁵⁴ The complications that were significantly associated with patients' post-operative psychosocial outcomes are presented in Tables 1-3.

Six studies reported a confounding association between surgical complications and patients' wellbeing (i.e. complications were significantly associated with worse psychosocial outcomes only under certain conditions) ^{21, 32, 40} or complications were significantly associated with psychosocial outcomes at univariate but not at multivariate analysis. ^{49, 59, 64} A total of 12 studies did not find a significant association of surgical complications with postoperative psychosocial outcomes. ^{23, 26, 27, 29, 34, 38, 53, 55, 56, 61, 63, 66} The majority of them (n=7) scored below 6 on quality assessment. For example, four studies had very small samples. ^{26, 27, 34, 38}

-Table 4 -

Meta-analyses

 A series of supplementary meta-analyses were attempted on each extracted psychosocial outcome (i.e. quality of life, anxiety, depression). For a meta-analysis on quality of life, a synthesis of data from widely disparate assessment tools with very different composite scores (e.g. social, emotional, and physical) was not considered valid. For that reason only studies that used the SF-scales ⁶⁷ were considered as they were the most commonly used quality of life measures. Only three studies had sufficient data on the SF physical and mental quality of life component scores. ^{28, 31, 45} The pooled mean differences (MD) between the two groups were statistically significant (*p*<0.001), indicating lower levels of physical (MD=-3.28, Cl=-4.71, -1.86) and mental (MD=-3.82, Cl=-4.97, -2.67) quality of life in patients who suffered complications compared to patients without complications. Two studies provided sufficient data for a meta-analysis on anxiety. ^{30, 62} The pooled standardised mean

difference was not significant (p>0.05). A meta-analysis on depression was not possible as there was only one study with available data. ³⁰

For a more detailed report of the meta-analyses see supplementary materials 2-4.

The duration of the impact of surgical complications on patients' wellbeing

Eighteen studies which reported significant associations of complications with post-operative psychosocial outcomes found a significant relationship of the presence of post-operative complications with worse psychosocial outcomes at 12 months post-surgery or later. ^{16, 19-22, 25, 28, 30-33, 36, 37, 47, 48, 50, 51, 65} Twenty studies reported a significant association of complications with worse psychosocial outcomes at less than 12 months post-surgery. ^{17, 18, 24, 35, 39-46, 49, 52, 54, 57, 59, 60, 62, 64}

Discussion

This is, to our knowledge, the first systematic review of the literature investigating the impact of surgical complications on patients' psychosocial wellbeing. In line with our hypothesis, two thirds of the included studies found a significant negative association between the occurrence of surgical complications and patients' postoperative wellbeing. The vast majority of those studies were of high quality. For instance, more than half of the studies with significant findings found that complications were an independent predictor of post-operative psychosocial outcomes after controlling for pre-existing differences on psychosocial outcomes, clinical and demographic variables.

Significant associations were reported in individual studies between surgical complications and lower scores on physical, emotional and social dimensions of the various quality of life measures. A meta-analysis of three studies with sufficient QOL data collected with the SF-scales suggests significant adverse effects of complications both on the physical and the mental health components.

 These findings are in agreement with earlier preliminary findings on the psychological burden that surgical adverse events often impose on patients. ^{3, 4} Surgical complications were also significantly associated with higher post-operative anxiety and depression in individual studies, even though a population effect could not be shown due to the very small number of studies that measured the impact of surgical complications on anxiety and depression. Despite the fact that quality of life is a useful screening outcome offering a general picture of a person's physical health and psychological state, ⁶⁸ future studies on the psychosocial impact of surgical complications should also consider outcomes such as anxiety and depression as they offer a more accurate picture of a person's psychological wellbeing. Other relevant psychological outcomes such as post-traumatic stress, which was not measured in any of the included studies, would also be of relevance for future research in this area. It is also worth noting that strong conclusions cannot not been drawn on the basis of the meta-analyses results due to the small number of studies included in them.

Complications that were found to significantly contribute to patients' low post-operative wellbeing ranged from severe adverse events such as anastomotic leaks after gastro-intestinal surgery or perioperative myocardial infarctions after cardiac surgery to relatively minor complications such as wound infections or atrial fibrillation. It appears therefore that other than severe post-operative events, minor complications could also cause psychological distress during patients' recovery. For instance, wound complications could affect patients' satisfaction with their body image which could further compromise their quality of life and psychological wellbeing. ⁶⁹ This finding potentially implies that the severity of complications as judged by healthcare professionals does not always correspond with patients' experience of complications. Moreover, complications were negatively associated with post-operative psychosocial outcomes not only after major surgical procedures but also after relatively minor operations, ^{30, 18, 28, 31, 43} which suggests a potential independence of the magnitude of initial surgery with the effect of complications on patients' wellbeing. Further research on how complications affect patients' wellbeing after different types of surgery could help clarify this finding.

A number of studies also found a significant negative contribution of surgical complications to psychosocial outcomes more than one year post-operatively, suggesting that patients may suffer psychologically due to the experience of surgical complications for an extensive period of time after surgery. The above findings hold important implications for patients' recovery as there is growing evidence on the role of psychological stress in compromising the function of the immune system and slowing down wound healing. ⁷⁻⁹ Surgical complications are likely to further prolong patients' recovery in almost a reciprocal cycle of distress and decreased immune function. The exact relationships between surgical complications, psychological distress and speed of recovery warrant further investigation.

It is noteworthy that a smaller number of studies did not find a significant association between complications and patients' postoperative psychosocial outcomes or found significant univariate associations which were not replicated in multivariate analyses. Even in studies showing a significant impact there will be many patients who largely maintain their psychological health and quality of life in the aftermath of complications. Other than clinical factors, patients' ways of coping with stress, their appraisals of surgery and their health, as well as their perceptions of support from their loved ones and healthcare professionals could explain the conditions under which complications affect patients' wellbeing, as suggested by wider literature on patients' adjustment after surgical treatment. 70-72 The role of psychological factors as potential moderators of the psychological impact of surgical complications needs to be further explored.

Overall the quality of the included studies was good as indicated by their relatively high quality assessment scores and the small number of studies that scored exceptionally low. A substantial number of studies with significant findings controlled not only for patients' pre-operative psychosocial outcomes but also for a variety of clinical and demographic factors confirming that surgical complications were an independent predictor of postoperative psychosocial outcomes above and beyond any pre-existing differences. The fact that the included studies used validated

self-report measures for the measurement of psychosocial outcomes and the use of a very comprehensive search strategy also increase the validity of the findings.

Limitations

A few caveats should be borne in mind when interpreting the above findings. Firstly, one third of the studies did not define complications or did not describe the methods they used to record complications. Moreover, almost one third of the studies did not provide information on response rates, which does not allow inferences about the representativeness of their samples.

Regarding the methodology of the systematic review, studies that were published before the year 2000 or with the majority of patients recruited before the year 2000 were excluded, albeit limiting this review to literature that was published in the last decade is expected to be more reflective of current surgical practice. It should also be noted that studies that were published past the final run of the search strategy (i.e. May 2012) have not been considered. Caution should also be taken when interpreting these findings to other specialties as the clinical setting in which complications occur may affect their impact on patients' wellbeing. Another limitation was the very small number of studies with sufficient data for quantitative synthesis and the difficulty of synthesising data from different quality of life measures, which resulted in restricting the meta-analyses on data collected only with the SF scales. The small number of studies with available data did not permit certain types of sensitivity analyses such as by surgical specialty, type of surgery (i.e. minor versus major surgery) or underlying disease (e.g. cancer versus other conditions), which could be significant determinants of the impact of complications on patients' wellbeing. Lastly, there is always the potential for publication bias where studies with significant results and big effect sizes are more easily published. It is worth adding that none of the included studies were randomised controlled trials due to the non-appropriateness of this design for the research questions that this review aims to answer.

Implications of findings

The results highlight the importance of considering patients' psychological needs in the aftermath of surgical complications. Surgical and nursing staff need to be aware of the challenges of surgical complications for patients' wellbeing and ensure that their psychological needs are not neglected. Screening patients who suffer post-operative complications for symptoms of psychological distress could help identify those patients who need psychological support. Facilitating patients' access to psychological support during and after their hospital stay could also be of great value for patients' post-operative wellbeing. For example, early referral to psychological services could prevent long-term psychological distress and may also mitigate the negative effects of stress on patients' recovery. Primary care practitioners and carers need to be aware of the psychological burden that surgical complications impose on patients in order to recognise their distress in time and to provide the support that patients need.

Conclusions

This is the first systematic review of the literature on the impact of surgical complications on patients' psychosocial wellbeing. The findings of this review suggest that surgical complications are potentially a significant independent predictor of patients' impaired post-operative psychosocial wellbeing often for a very long time post-surgery. It also appears that other than major complications relatively minor adverse events may also compromise patients' psychosocial wellbeing, which implies that the clinical severity of complications may not always indicate how seriously patients will be affected by them. Patients who experience surgical complications report worse levels of different aspects of quality of life than patients with uncomplicated recovery, often more than a year after their operation. The ways in which complications are managed (e.g.

reoperation versus conservative management), the type of surgery (e.g. minor versus major), the underlying disease (e.g. cancer versus other conditions), psychological factors (e.g. patients' perceptions of support, illness perceptions, coping strategies) or cultural influences may be key moderators of the impact of surgical complications on patients' psychosocial wellbeing. Future research is needed on the contribution of the above factors on the impact of surgical complications on psychological outcomes such as anxiety, depression and post-traumatic stress, as well as on how to support patients who experience a complicated post-operative recovery.

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Data sharing: No additional unpublished data

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0	First author's name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of surgical complications with patients' wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
2										Quality of life			
- 1					Nt1=71/?	Colorectal cancer,			Morbidity was defined as any event that resulted	(QOL)/at time of			
3					Nt2=63	male patients who	Observational,	Open surgical	in the need for additional therapy or readmission	diagnosis and 12			
4						underwent open	cohort,	therapy for colorectal	to the hospital within 30 days of initial	months after		Any complications/12	
۔ ا	Anthony	2003	US	Secondary	Nc=16	surgical therapy	prospective	cancer	discharge/Method not specified	surgery/FACT-C ¹	YES*	months post- surgery	6
5						Patients with			A major complication was defined as reoperation,				
6						esophageal or		Upper gastro-	readmission to the high-dependency or intensive				
7					_	gastric cancer who		intestinal surgical	care unit, readmission to the hospital within 30	QOL/39.6days after			
′					N=139/162	underwent upper		treatment for	days of operation, or death within 30 days of	treatment (range,6-		Any complications/39.6	
8						gastro-intestinal	Observational,	esophageal or gastric	operation or later if the patient did not leave the	105)/EORTC QLQ-C30		days after treatment	
9	Avery	2006	UK	Primary	Nc=37	surgical treatment	cross-sectional	cancer	hospital/Method not specified	•	YES	(range: 6–105)	5
0 1 2 3	8 1	2008	Germany	Secondary	Nt1=151/205 Nt2=130 (86.1%) Nc(complaints)=49 Nc(wound infection)=5 Nc(seroma)=13 Nc(pneumonia)=1 Nc(other)=28	Patients undergoing cholecystectomy	Observational, cohort, prospective	Cholecystectomy	Retrospective list: Any complaint, Wound infection, Seroma, Pneumonia, other complaints/Patient reports	QOL/14 days pre-op, 14 days post-op, and 6 months post-op/SF- 36	YES*	Any complications/6 months post-surgery	_
4	Bitzer	2008	Germany	Secondary	NC(Other)=28	cholecystectomy	prospective	Cholecystectomy	Only severe complications were considered: Grade	30	11.5	months post-surgery	/
5 6 7	_				N=121/170	Rectal cancer	Observational,	Surgical treatment for adenocarcinoma of	III or IV complications (according to Dindo's model) were defined as severe, whereas absence of complications or Grade I and II complications were defined as absent or mild	QOL/36 (16–51) months post-op /EORTC QLQ-C30 & CR38 ³		Severe post-operative complications/Median of 36 (range, 16–51)	
8	Bloemen	2009	Netherlands	Primary	Nc=33	patients Patients who	cross-sectional	the rectum	complications/patient records	CR38	YES	months post-surgery	6
9						underwent curative hepatic resection for malignant or non			Surgical (e.g. bile leak or biloma, pneumothorax, wound infection, liver abscess, bleeding, and				
2	Prune	2010	Cormany	Secondary	N=96/188 Nc(any morbidity)=30 Nc(wound infections)=10	malignant diseases, disease free at time of	Observational,	Hanatastamu	surgical dehiscence) and medical (e.g. pleural effusion, renal failure, hepatic failure, pneumonia, cardiac insufficiency, and cholangitis)/patient records	QOL/ 3-36 months post-op /SF-12	YES	Wound infections/3-36 months post-surgery	5
3L	Bruns	2010	Germany	secondary	ive(wound infections)=10	assessment	cross-sectional	Hepatectomy	records	post-0p / Sr-12	TES	months post-surgery	5

¹ Functional assessment of cancer therapy questionnaire with the colorectal module

 $^{^2}$ European Organisation for Research and Treatment of Cancer core 3 European Organisation for Research and Treatment of colorectal cancer

Retrospective list: pulmonary atelectasis or

7	El-Awady	2009	Egypt	Secondary	N=40/? Nc=14	Patients with inguinal hernia	Observational, prospective, cohort	Anterior open Lichtenstein tension free hernioplasty	Postoperative complications: seroma, haematoma, 2ry infection, neuralgia and anaesthesia/patient observations	QOL/pre-op, 3, 6 &12 months post-op/SF- 36	NO	N/A	4
	Dubernard	2006	France	Secondary	Nc=9	resection	prospective	endometriosis	drainage/Patient observations	op/SF-36	NO*	N/A	6
34					50	colorectal	cohort,	resection for	anastomosis requiring a laparoscopic	QOL/pre & post-			
33					Nt1=58/? Nt2=58	who underwent a segmental	Observational,	Laparoscopic segmentalcolorectal	uroperitoneum requiring a ureteral stent for 6 weeks and an abscess behind colorectal				
2						endometriosis			treated by laparoscopic coagulation,	7 7			
						colorectal			fistulae, vessel injury of the protective colostomy				
1	Douma	2011	rectification	Secondary	140-1	Women with	G 033-3ECUOIIAI	poryposis (i Ar j	Retrospectively listed complications: rectovaginal	or ibbq	123	> 10 years post-surgery	2
80	Douma	2011	Netherlands	Secondary	Nc=?	FAP who had been surgically treated	Observational, cross-sectional	adenomatous polyposis (FAP)	Surgery-related complications/Self-reports + medical records	of the Dutch version of IBDQ ⁷	YES	Any complications/0 to >10 years post-surgery	
9					N=296/?	296 patients with		Surgery for familial		Functioning subscale			
8										C38,Social			
27										post-op/SF-36, EORTC-QLQ-			
										QOL/0 to >10 years			
6	Delaney	2003	US	Secondary	Nc(major)=9	Crohn's Disease	prospective	loop or end stoma)	obstruction and wound infection/Database review	days post-op/CGQL ^b	YES*	days post-op	7
25					Nc(any)=19	Patients with	cohort,	(abdominal perineal,	dehydration, intraabdominal abscess, small bowel	QOL/pre-op & 30		Any complications/30	
4					32/103		Observational,	Surgery for CD	thrombosis, renal failure, and pneumonia,				
23					Nt1=109/109 Nt2=82/109				Retrospectively listed complications: anastomotic leak, intraabdominal abscess, bleeding, venous				
4	Dasgupta	2008	UK	Secondary	Nc=44 N±1=100/100	cancer	cohort	hepatic malignancies	radiology/Method not specified	op/EORTC QLQ-C30	NO*	N/A	6
				C d	No. 44	surgery for liver	prospective,	Liver resection for	complications needing interventional	36-48 months post-	110*	21/2	
1					Nt4=33	undergoing liver	Observational,		intensive care unit) or requiring relaparotomy, or	QOL/pre-op, 6, 12,			
20					Nt3=80	patients			to a higher level of care (high-dependency or				
9					Nt2=87	Consecutive,			associated with systemic illness requiring transfer				
8					Nt1=102/122				Major complications were defined as those				
<u>,</u>	Chang	2010	Taiwan	Secondary	N(GORD)=2	bariatric surgery.	longitudinal	Roux-en-Y bypass	bleeding and GORD/Method not specified	op/WHOQOL-BREF ⁵	YES*	surgery	5
7					bleeding) =1	undergoing	case-control,		anastomotic ulcer, upper gastro-intestinal	and 12 months post-		6, 12 months post-	
6					Nc(upper gastro-intestinal	Patients	Observational,		gastrojejunal anastomotic stricture, gastrojejunal	QOL/pre-op, 1, 3, 6		Any complications/1, 3,	
5					anastomotic ulcer) =9				Operation related complications, including				
4					stricture)=12 Nc(gastrojejunal								
					Nc(anastomotic								
3													
2					N=102/218								
1	Champault	2006	France	Secondary	Nc=(unclear)	obesity.	prospective	of a gastric band	break/Method not specified	post-op/GIQLI ⁴	CONFOUNDING*	surgery	6
0					Nt(4)-159	patients operated on for morbid	cohort,	Laparoscopic placement	immediate intolerance, and recurrent tubing	months & 2 years		erosion, slippage, intolerance/2 year post-	
ا ٍ`					Nt1=152/? Nt(4)=139	Consecutive	Observational,	Lanaroscopic	hematoma, leak, disconnection), bands explanted, associated with erosion, obstruction,	QOL/pre-op, 1, 3		complications such as	
					AU4 452/2				stomach. Access port problems (infection,			Band removal for	
3									year. Band erosion with penetration into the				
<i>'</i>									peak incidence during the second postoperative				
5									problems and urinary retention. Slippage with a				
									pneumonia, prolonged ileus, minor wounds				

⁴ Gastrointestinal Quality of Life index

⁵World Health Organization Quality of Life – Brief

⁶ Cleveland Global Quality of Life

⁷Inflammatory Bowel Disease Questionnaire

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				Nt1=1983/3518								
				Nt2=1526 (77%)				Complications were summarized by 4 categories:				
				Nt3=1603 (81%)				(1) hematoma/seroma, (2) orchitis, (3) neuralgia				
								of the leg or groin, and (4) other. Complications				
				Nc(neuralgia t1)=94				classified as "other" included: (1) early				
				Nc(hematoma t1)=51				postoperative complications (urinary tract				
				Nc(orchitis t1)=13				infection, urinary retention, and hematuria); (2)				
				Nc(recurrence t1)=76								
)								life-threatening complications (respiratory				
				Nc(other t1)=124				insufficiency, myocardial ischemia, cardiac				
								arrhythmia, intraoperative hypotension, and				
21				Nc(neuralgia t2)=105				stroke); and (3) long-term complications (4 weeks				
				Nc(hematoma t2)=55		Observational,		or more postoperative)/Patient reports for				
)				Nc(orchitis t2)=18	Men who received	cohort,	Inguinal	neuralgia & orchitis + Expert consensus for life-	QOL/pre-op, 1 &2		Neuralgia, orchitis/2	
Hawn	2006	US	Primary	Nc(other t2)=150	a hernia repair.	prospective	herniorrhaphy	threatening complications	years post-op/SF-36	YES*	years post-surgery	8
				_	Patients who							
					underwent							
					colorectal							
				Nt1=?/568	resection for							
				Nt2=166	benign and	Observational,						
,					malignant	cohort,	Laparoscopic		QOL/pre-op, 4weeks			
'l	2011	US	Secondary	Nc=?	diseases.	retrospective	colorectal resection	No reference	post-op/SF-36	NO*	N/A	3
Ince	2011	03	Secondary	140-1	Patients who had	retrospective	colorectarresection	No reference	post op/51 50	140	14/5	3
\ l												
,					been operated on							
					for groin hernia.							
					Controls matched							
<u>'</u>					for age, gender							
el .					and method of							
<u> </u>					surgical repair							
ļ.					were allotted from			Persistent postoperative pain (patients with pain	QOL, anxiety,			
:				N(total)=184/423	the group of			of Grade 3, i.e. pain that could not be ignored but	depression/(on			
)					persons without	Observational,		did not interfere with everyday activities, or	average 4.9 years		Persistent post-	
5				N1=92 (cases)	persisting pain	case-control,		higher on IPQ)/Patient reports (Inguinal Pain	post-op, range > 7		op/Mean of 4.9 years	
Kalliomaki	2009	Sweden	Primary	N2=92 (controls)	(Grade 1 in IPQ)	cross-sectional	Hernia repair	Questionnaire) & clinical examination	years)/SF-36, HADS ⁸	YES	post-surgery	5
Kumomaki	2003		.,	(, , , , , , , , , , , , , , , , , , ,	Consecutive				7		,	
31				N=253/351	patients with							
		1		14-233/331	chronic anal						Severe	
		1		N(incontinence)=28	fissure who			Anal incontinence/Patient reports: Wexner	QOL/23.3 +/- 7.1		incontinence/23.3 (SD ±	
		1				Observational	On on lateral internal					
		Turkey	Deimon	N(severe incont)=9	underwent open LIS.	Observational,	Open lateral internal	Incontinence Score system (WIS) + Clinical	months post-op/SF-	YES	7.1) months post-	_
Kement	2011	Turkey	Primary	N(mild incont)=19		cross-sectional	sphincterotomy	examination	36	YES	surgery	5
		1			Consecutive							
		1			patients under the							
3		1			care of three							
		1		N=92/112	consultant							
		1			surgeons who							
		1		Nc(leaks)=23	underwent							
		1		Nc(clinical leaks)=13	procedures with	Observational,	Low rectal	Anastomotic leaks (clinical & subclinical)/Patient	QOL/10-18 months		Anastomotic leaks/10-	
Lim	2006	UK	Primary	Nc(sub-clinical leaks)=10	LRA	cross-sectional	anastomosis (LRA)	observations, CT scans, WCE	post-op/EORTC QOL	CONFOUNDING	18 months post-op	5
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8 Hospital Anxiety and Depression Scale

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					11 073/1300								
'					Nc(early comps/anast)=54								
'					Nc(late comps/anast)=126 Nc(early				-Digestive, skin, genitourinary, surgical, medical,				
					comps/anast/rectal cancer				immediate indirect complications			Enterocutaneous fistula	
'					only)=42				-Early complications: those that were first			for all patients & any	
					Nc(late	Long-term			recorded within 30 days of the surgery. Late	QOL/ 5-15 years		late complications for	
0					comps/ostom/rectal	Colorectal Cancer	Observational,	Colorectal cancer	complications: occurring 31 days after	post-op/mCOH-QOL-		ostomy patients>5 years	
٠.	Liu	2010	US	Primary	cancer only)=105	patients	cross-sectional	surgery	surgery/Patient computerised data	Ostomy ⁹	YES	post-surgery	6
1					Nt1=253/302	Patients who							
2					Nt2=244	underwent Lateral							
						internal		Lateral internal		QOL/pre-op	UNCLEAR (due to		
3					Nc(anal fistula/abscess)=3	sphincterotomy	Observational,	sphincterotomy (LIS)		(admission) & 12	small number of		
4					Nc(FISI>0)=7	(LIS) for chronic	cohort,	for chronic anal		months post-	patients with		
5	Mentes	2006	Turkey	Primary	Nc(FISI, 0->4, 21, 7)=3	anal fissure (CAF)	prospective	fissure (CAF)	Anal Incontinence/Patient examination+ FISI score	op/GIQLI & FIQL ¹⁰	complications)	N/A	6
						Veterans with an			Ostomy complications: skin problems, leakage,				
6						ostomy after			and difficulty with adjustment (i.e. leakage,			0.1	
7					N=239/322	major gastro-	Observational,	Gastro-intestinal	peristomal irritant dermitis, pain, bleeding, stomal	QOL/6months post-		Ostomy complications (skin problems,	
'					N=239/322	intestinal surgery requiring an	case-control,	surgery requiring an	necrosis, prolapse, stenosis, herniation, retraction, infection, mucotaneous separation, difficulty	op/mCOH-QOL-		leakage)/ 6 months	
8	D '11	2008	US	Primary	Nc=56	intestinal stoma	cross-sectional	intestinal stoma	adjusting)/Patient reports	Ostomy	YES	·	
9	Pittman	2008	03	rilliary	NC-36	Patients who	CIOSS-SECTIONAL	intestinai stoma	adjusting// Patient reports	Ostoniy	11.3	post-surgery	6
-						underwent							
0						elective left							
1						colonic or rectal							
2						resection and							
						colorectal							
3					N=147/211	anastomosis for		Left colonic or rectal					
4						neoplastic or		resection and		QOL/mean 58		Anastomotic stenosis/58	
-					Nc(anastomotic	inflammatory	Observational,	colorectal		(SD ± 31) months		(SD ± 31) months post-	
5	Polese	2012	Italy	Primary	stenoses)=22	disease.	cross-sectional	anastomosis	Anastomotic stenosis/Clinical examination	post-op/SF-36	YES	surgery	6
6					Nt1=505/?								
7					Nt2=237								
•					Nt3=106	Patients who		LRYGB for morbid					
8						underwent LRYGB	Observational,	obesity without				Complications requiring	
9					Nc(t2)=41	by one surgeon	cohort,	conversion to an	Postoperative complications requiring	QOL/baseline, 1 & 2		intervention/1 & 2 years	
_	Rea	2007	US	Primary	Nc(t3)=23	for morbid obesity	prospective	open procedure.	intervention/Method not specified	years post-op/SF-36	YES*	post-surgery	6
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N=679/1308

⁹ City of Hope Quality of Life for Ostomates questionnaire 10 Fecal Incontinence Quality of Life Instrument

Rectal resection for

overall pelvic organ

malignancies on

Oesophageal

Bowel resection

through midline laparotomy or with

laparoscopic

ileostomy,

assistance, end

stricturoplasty

Elective resection

Resection of the

colon or rectum

sigmoid

for colorectal cancer

Anastomotic leakage: Defined as grade A (no

(requires active therapeutic intervention but is

institutional colorectal database and individual

requiring a reoperation, anastomotic insufficiency,

recurrent nerve, thoracic duct damage or gastric

perforation/Prospective scrutiny of medical and

Medical and surgical complications and need of

obstructions, 2 intestinal bleeding, and a wound

Wound, urinary tract and chest infections, cardiac

and respiratory complications, deep venous

Postoperative complications (anastomotic leak,

wound infection, delayed food intake, fever, and

bladder dysfunction)/Method not specified

thrombosis, pulmonary embolism and

complications related to anastomotic

breakdown/Method not specified

reoperation (2 anastomotic leaks, 3 intestinal

infection were recorded and two re-

laparotomies)/Method not specified

QOL/106.8 months

QOL/6months post-

QLQ-OES1812 11

op/EORT QLQ-C30, &

QOL/3 months post-

depression, positive

affectivity, mood

states/pre-op (5-12

days pre-op) & 6-8

weeks post-op/FACT-

C, EuroQOL (EQ-5D),

QOL/pre-op, 3 & 12

months post-op/SF-

36 & GLQI¹⁴

HADS, PANAS12,

MRS¹³

op/CGQLI QOL, anxiety,

vs. negative

NO

CONFOUNDING

N/A

Technical

post-surgery

complications/6 months

Any complications/3

months post-surgery

Complications within 30

days of operation/6-8

weeks post-surgery

Any complications/3

months post-surgery

post-op (32.4-170.4)/SF-12

managed without relaparotomy) and grade C

change in patient's management), grade B

(requires relaparotomy)/Review of the

Technical surgical complications, including

postoperative bleed exceeding 2000 ml or

necrosis of the substitute, damage to the

histopathological records, operation charts,

extensive study protocol with predefined

exposure alternatives

Cases: patients

Controls: Patients

period and had an uneventful

postoperative

course matched

by sex, age (±5

years), type of

resection, and

diagnosed with an

cardia cancer who

macroscopically

microscopically

radical resection

Patients admitted

for intestinal

Crohn's Disease

surgery for

Consecutive

patients with

colorectal

newly diagnosed

cancer scheduled

for elective open

resection in one

colorectal surgery

for benign and

hospital trust

undergoing

malignant

Patients

oesophageal or

underwent

neoadjuvant

therapy.

N1=16/36 (cases)

N2=16/? (controls)

N=355/446 (79·6 %)

N=47/?

Nt1=104 /110

Nt1=93/113

Nt2,t3=79

Nt2=92

Observational.

cross-sectional

Observational

cross-sectional

cross-sectional

Observational,

prospective

Observational,

prospective,

case-control,

operated for rectal cancer at the same time

developed anastomotic leak

Rutegard

Scarpa

Sharma

42

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48

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¹¹ Oesophageal cancer-specific questionnaire
12 Desitive and acceptive offers seeded via

¹³ Mood rating scale

Austria

2011

2008

2009

2007

2009

Primary

Secondary

Secondary

¹⁴ Gastrointestinal Quality of Life Index

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15 Glasgow Dyspepsia Severity Score ¹⁶ Symptoms specific to oesophageal cancer

1						Patients							
						diagnosed with							
'						paraesophageal or							
						mixed hiatal			Hernia recurrence (any migration of the cardia to				
						hernia (types II, III,			chest level or evidence of a new paraesophageal	QOL/>=6 months			
					N=37/46	and IV) with >50%		Laparoscopic repair	sac)/A barium swallow was given to all patients to	post-op (median, 24;		Clinically recurrent	
						of the stomach in	Observational,	of paraesophageal	rule out an anatomic recurrence. An independent	range, 6–50)/SF-36,		hernias/>=6 months	
0	Targarona	2004	Spain	Primary	Nc(recurrent hernias)=3	the chest.	cross-sectional	hiatal hernia	radiologist evaluated all the explorations.	GDSS ¹⁵ and GIQLI	YES	post-surgery	5
1						Patients newly							
1						diagnosed with a							
2						histologically verified							
3						adenocarcinoma							
						or squamous-cell							
4						carcinoma of the							
5						esophagus or							
6						adenocarcinoma							
						of the gastric							
7						cardia that			Anastomotic leakage , infections, respiratory			Any complications,	
8						underwent			insufficiency, cardiac complications, technical			anastomotic leakage,	
						macroscopically			complications, anastomotic strictures, and others			infection, respiratory	
						and			(intervention needed to treat embolus, deep			insufficiency, cardiac	
9					N=100/146	microscopically			venous thrombosis, rupture of the wound,	QOL/6 months post-		complications, technical	
					14-100/140								
0					N-100/140	radical tumor	Observational,	Esophageal resection		discharge/QLQ-C30 &		complications/6 months	
0	Viklund	2005	Sweden	Secondary	Nc=44		Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES	complications/6 months post-discharge	7
0 1 2				Secondary	Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5 6 7 8					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5 6 7 8 9					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0 1 2 3 4 5 6 7					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
012345678901					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
0123456789012					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
01234567890123					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
012345678901234					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer		discharge/QLQ-C30 & OES-24 ¹⁶	YES		7
01234567890123					Nc=44	radical tumor	Observational, cross-sectional	Esophageal resection surgery for cancer	intestinal obstruction, stroke, renal failure, or liver	discharge/QLQ-C30 & OES-24 ¹⁶	YES		7

^{*}Study controlled for patients' preoperative wellbeing

Table 2: Key characteristics of cardio-thoracic surgery studies (n=17)

First author name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome/time- points/measuremen t tool	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
Deaton	2009	US	Secondary	Nt1= 317/442 Nt2=270 Nc=44% (130)	Patients with documented T2DM undergoing CABG	Observational, cohort, prospective	CABG	Infection of the leg, thorax, sternum, bloodstream or urinary tract; central neurological deficit (stroke or transient ischemia, coma); pneumonia, pulmonary insufficiency with prolonged ventilation or reintubation, pulmonary embolism; renal failure; arrhythmias requiring treatment; prolonged inotropic support or use of intra-aortic balloon pump; or reoperation for bleeding or tamponade/Patient records	QOL/ 3 months post- op/SF-36	YES	Any complications/3 months post-surgery	6
El Baz	2008	Netherlands	Secondary	Nt1=198/256 Nt2=168 Nc=?	Consecutive patients who were scheduled for CABG following a coronary angiography	Observational, cohort, prospective	CABG	Postoperative events such as use of inotropes, atrial arrhythmias, or ventricular arrhythmias, sternal resuturing, re-exploration for bleeding, and time spent on mechanical ventilation/Registry database, medical notes, outpatient notes and intensive therapy unit charts	QOL/pre-op & 6 months post-op/SF- 36	YES*	Re-exploration for bleeding and sternal resuturing/6 months post-surgery	8
Ferguson	2009	US	Primary	N=124/221 Nc=22	Prospective patients who underwent major lung resection for early stage lung cancer.	Observational, cross-sectional	Major lung resection for early stage lung cancer (lobectomy, bilobectomy, pneumonectomy)	Complications were categorized as pulmonary (pneumonia, prolonged intubation, reintubation, air leak more than 7 days, lobar collapse requiring intervention), cardiovascular (pulmonary embolism, myocardial infarction, new postoperative arrhythmia, need for intravenous inotropic agents), other, and any complication/Administrative database, hospital medical records, office shadow files	QOL/average of 2.6 years post-op (3 months to 6.4 years)/EORTC QLQ- C30, EORTC QLQLC13 ¹⁷ and DASS- 21 ¹⁸	YES	Pulmonary complications/2.6 years post-surgery (Range: 3 months-6.4 years)	6
Gjeilo	2010	Norway	Primary	Nt1=534/631 Nt2=462 Nt3=465 Nc(t2)=52	Patients undergoing cardiac surgery	Observational, cohort, prospective	Midline sternotomy	Chronic pain (pain arising after surgery and persisting either continuously or intermittently for 3 months or more/BPI (Brief Pain Inventory)	QOL/pre-op, 6 & 12 months post-op/SF- 36	YES*	Chronic post-surgical pain/12 months post-surgery	6
Hata	2006	Japan	Secondary	N=452/452 Nc=?	Consecutive adult patients who underwent open heart surgery	Observational, cross-sectional	CABG	Postoperative morbidity (minor stroke, infection, pneumonia, haemodialysis, paraplesis)/Patient records	Depression/5-7 days post-op/Interviewed by a psychiatrist and CES-D ¹⁹	CONFOUNDING	Post-operative minor stroke and pneumonia/5-7 days post-surgery	6

¹⁷ EORTC Lung Cancer Questionnaire

¹⁸ Short version of the Depression Anxiety Stress Scales

¹⁹ Center for Epidemiological Studies Depression Scale

					1		CARC (DOOK :-		I			
							CABG [89% via					
							sternotomy incision with					
							cardiopulmonary					
				Nt1=501/1128			bypass (CPB; on-					
				Nt2=485		Observational,	pump) and 11%	Perioperative myocardial infarctions/Clinical	QOL/pre-op & 12		Perioperative myocardial	
				N(2-483	Patients who	cohort,	without CPB (off-	examination + clinical tests (ECGs, echocardiography,	months post-		infarctions /12 months	
rvinen	2004	Finland	Primary	Nc=80	underwent CABG	prospective	pump)]	laboratory tests)	op/RAND-36	YES*	post-surgery	7
	2001	Timunu		110 00	-Cases: patients who	prospective	pampy	ideoratory testsy	00/10/11/0	120	post surgery	+ -
					developed sternal							
					wound infection (SWI)							
					after cardiopulmonary							
					bypass.							
					-Controls: patients prior							
					to CABG and evaluated							
					1 year postoperative							
					and matched for time of	Observational,		Serious wound infections (SWIs: deep infection	QOL/20 months post-		Serious wound infections	
				N1=73/84 (cases)	the operation, age and	case-control,	Cardiopulmonary	involving retrosternal tissue and/or the sternal	op (range 7-40)/SF-		/20 (Range: 7-40) months	
deus	2009	Sweden	Primary	N2=42/? (controls)	sex	cross-sectional	bypass	bone)/Clinical examination	36	YES*	post-surgery	4
				N=99								
							Serratus-sparing					
				Nt1=120/?			posterolateral					
				Nt2=99	Patients aged 45 to 75	Observational,	thoracotomy or				1	
				33	years undergoing	cohort,	limited	Chronic post-thoracotomy pain/Leeds Assessment of	QOL/pre-op, 3 moths		Chronic post-thoracotomy	
	2012	US	Primary	Nc=75	elective thoracotomy	prospective	thoracotomy	Neuropathic Symptoms and Signs + self-reports	post-op/SF-36	VEC*	pain/ 3 months post-	1 -
nney	2012	US	rilliary	NC-/3		prospective	unoracotomy	recuropatine symptoms and signs + sen-reports	ρυσε-υμ/σε-συ	YES*	surgery	
					-Cases: patients who							
					underwent cardiac							
					surgery and developed ARF requiring RRT and							
					left the hospital alive.							
]	-Controls: matched							
					controls who did not	Observational,	Cardiac surgery	ARF (acute renal failure) requiring RRT (renal				
				N1=22/42 (cases)	develop ARF and did not	case-control,	(procedures not	replacement therapy)/Administrative database,	QOL/23-42 months			
	2006							registry	post-op/SF-36	NO	N/A	
andoni		Italy	Primary	N2=40/42 (controls)	receive RRT.	cross-sectional	specified)				N/A	`6
andoni	2000	Italy	Primary	N2=40/42 (controls)	receive RRT.	cross-sectional	specified)	registry			N/A	6
andoni	2000	Italy	Primary	N2=40/42 (controls)	receive RRT.	cross-sectional	specified)	registry			N/A	6
andoni	2000	Italy	Primary	Nt1=182/444	receive RRT.	cross-sectional	specified)	Tegrati y			,	6
andoni	2000	Italy	Primary	Nt1=182/444 Nt2=128	receive RRT.		specified)	regiony			New cardiac arrhythmia	6
andoni	2000	Italy	Primary	Nt1=182/444		Observational,	specified)	" h	QOL/pre-op, 2 & 6		New cardiac arrhythmia post-surgery, atrial	6
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,		Post-surgical complications such as cardiac	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
	2006	Italy Australia	Primary Secondary	Nt1=182/444 Nt2=128		Observational,	CABG	" h	QOL/pre-op, 2 & 6	YES*	New cardiac arrhythmia post-surgery, atrial	7
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart	Post-surgical complications such as cardiac	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve	Post-surgical complications such as cardiac	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis,	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma,	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114 Nc=?	Adults on the waiting	Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114 Nc=?	Adults on the waiting list for CABG	Observational, cohort, prospective	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure;	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation,	QOL/pre-op, 2 & 6 months post-op/SF-		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
		·	.,	Nt1=182/444 Nt2=128 Nt3=114 Nc=?	Adults on the waiting list for CABG	Observational, cohort, prospective	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure	QOL/pre-op, 2 & 6 months post-op/SF- 36		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	
Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt1=836/2,007	Adults on the waiting list for CABG Patients undergoing elective open heart	Observational, cohort, prospective Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method	QOL/pre-op, 2 & 6 months post-op/SF- 36	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	
e Grande		·	.,	Nt1=182/444 Nt2=128 Nt3=114 Nc=?	Adults on the waiting list for CABG	Observational, cohort, prospective	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified	QOL/pre-op, 2 & 6 months post-op/SF- 36		New cardiac arrhythmia post-surgery, atrial fibrillation/ 6 months post-	7
e Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt1=836/2,007	Adults on the waiting list for CABG Patients undergoing elective open heart surgery	Observational, cohort, prospective Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified Retrospective list of complications: Atrial fibrillation,	QOL/pre-op, 2 & 6 months post-op/SF- 36	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	7
e Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt2=2.007 Nc=189	Adults on the waiting list for CABG Patients undergoing elective open heart surgery All patients over 65	Observational, cohort, prospective Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified Retrospective list of complications: Atrial fibrillation, re-exploration for bleeding, low cardiac output	QOL/pre-op, 2 & 6 months post-op/SF- 36 QOL/pre-op, 1 year post-op/SF-20	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	7
e Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt2=2.007 Nc=189 Nt1=63/63	Adults on the waiting list for CABG Patients undergoing elective open heart surgery All patients over 65 presenting a 1, 2 or 3	Observational, cohort, prospective Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified Retrospective list of complications: Atrial fibrillation, re-exploration for bleeding, low cardiac output syndrome, acute respiratory failure, sternal wound	QOL/pre-op, 2 & 6 months post-op/SF- 36 QOL/pre-op, 1 year post-op/SF-20 QOL/pre-op, 4 & 12	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	7
e Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt2=2.007 Nc=189	Adults on the waiting list for CABG Patients undergoing elective open heart surgery All patients over 65	Observational, cohort, prospective Observational, cohort,	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified Retrospective list of complications: Atrial fibrillation, re-exploration for bleeding, low cardiac output syndrome, acute respiratory failure, sternal wound infection, neurological dysfunction, mild problems	QOL/pre-op, 2 & 6 months post-op/SF- 36 QOL/pre-op, 1 year post-op/SF-20 QOL/pre-op, 4 & 12 months post-	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	7
e Grande	2006	Australia	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=? Nt1=836/2,007 Nt2=2.007 Nc=189 Nt1=63/63 Nt2=59	Adults on the waiting list for CABG Patients undergoing elective open heart surgery All patients over 65 presenting a 1, 2 or 3 vessel disease treated	Observational, cohort, prospective Observational, cohort, prospective	CABG Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal	Post-surgical complications such as cardiac arrhythmias, stroke and infections/Medical records Perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay/Method not specified Retrospective list of complications: Atrial fibrillation, re-exploration for bleeding, low cardiac output syndrome, acute respiratory failure, sternal wound	QOL/pre-op, 2 & 6 months post-op/SF- 36 QOL/pre-op, 1 year post-op/SF-20 QOL/pre-op, 4 & 12	YES*	New cardiac arrhythmia post-surgery, atrial fibrillation/6 months post- surgery	7

Tully	2011	Australia	Primary	Nc=56	first-time CABG surgery	prospective	CABG	scores	days)/ DASS ²⁰	YES*	(SD=2 days) post-surgery	7
					Patients undergoing	cohort,		reviewers blinded to patients' psychological distress	(mean=6 days, SD=2		Atrial fibrillation/6 days	
				Nt2=222		Observational,		echocardiographs reviewed by technicians and	days) & post-op			
				Nt1=226/238				during the index hospitalization/ECGs, transthoracic	(mean=2 days, SD=2			
				_				and the median day of discharge (day 5) after CABG	Stress/pre-op			
								patient's day of admission to the intensive care unit	Anxiety, Depression,			
								New-onset atrial fibrillation (AF) between the				
Rodriguez	2008	US	Secondary	Nc=23	treated with TS.	prospective	hyperhidrosis	-Method not specified	36	NO*	N/A	3
					upper extremity HH	cohort,	axillary	requiring hydration	months post-op/SF-			
				Nt4=?	Patients diagnosed with	Observational,	for palmar and	-Excessive dryness: Dryness affecting the hands and	discharge, 6 & 12			
				Nt3=?			sympathectomy	foods	QOL/pre-op,			
				Nt2=?			Thoracoscopic	-Gustatory sweating: Facial sweating after eating				
				Nt1=397/?				TS.				
								considered abnormal in other parts of the body after				
								-Compensatory sweating (CS): Excessive sweating				
Peric	2008	Montenegro	Secondary	Nc=60	CABG	prospective	CABG	ECGs, echocardiography, laboratory tests	Questionnaire (NHP)	YES*	months post-surgery	7
		Serbia &			who underwent elective	cohort,		abdominal complications, and other/Observations,	Health Profile		Any complications/6	
				Nt2=192	Consecutive patients	Observational,		ventricular tachycardia, ventricular fibrillation),	op/Nottingham			
				Nt1=208/?				effusion, arrhythmic complications (atrial fibrillation,	months post-			
								reoperation for bleeding, sternal wound infection, perioperative myocardial infarction, pericardial	QOL/pre-op, 6			ļ.
								mechanical ventilation longer than 24 hours,				
								output (cardiac index lower than 2 L/min/m2),				
								Retrospective list of complications: low cardiac				
Myles	2006	Australia	Secondary	Nc=69	patients	prospective	specified)	radiologic data, electrocardiograms etc.)	op/SF-36	CONFOUNDING*	months post-surgery	8
	&				Adult cardiac surgical	cohort,	procedures not	-Clinical and laboratory tests (microbial cultures,	months, 3 years post-		Any complications/3	
	2001					Observational,	(specific	(other than pneumonia)	QOL/pre-op, 1 & 3			
				Nt4=94			Cardiac surgery	 Sepsis: wound infection requiring excision of tissue or antibiotic therapy, or positive microbial culture 				
				Nt3=108 Nt4=94				neurologic deficit;				
				Nt2=120 (days 1,2,3)				Neurologic: stroke, defined as a new central				
				Nt1=120/125				creatinine concentration greater than 200 M;				
								3. Renal: acute renal failure, defined by serum				
								concentration greater than twice normal;				
								electrocardiogram or creatine kinase-MB isoenzyme				
								or myocardial infarction, defined by new Q waves on				
								antiarrhythmic medication or electrical cardioversion reversion; radiologic evidence of pulmonary edema;				
								Cardiac: arrhythmia requiring treatment with				
								pulmonary infiltrate with positive microbial cultures;				
								for more than 24 h or pneumonia, defined as				
								Respiratory: postoperative mechanical ventilation			F 0 /	-
Moller	2012	Sweden	Secondary	Nc=?	surgery for lung cancer	prospective	Lung surgery	more/Method not specified	36	YES*	months post-surgery	6
					scheduled for lung	cohort,		reoperation, or hospital stay of 8 days or	months post-op/SF-		Any complications/6	
				Nt2=213	Prospective patients	Observational,		for more than 5 days), pneumonia, re-intubation,	QOL/pre-op, 6			
				Nt1=249/?				fibrillation, prolonged air leak (chest tubes in place				
								postoperative complications: new onset atrial				
								Complication was defined as any of the following				

^{*}Study controlled for patients' preoperative wellbeing

²⁰ Depression Anxiety Stress Scales

Table 3: Key characteristics of studies in vascular surgery (n=4)

3	First author name	Year	Country	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Surgical complications/method of recording	Psychosocial outcome & timepoints	Significant association of complications with wellbeing (Yes/No/Confoun ding)	Types of complications and time-points of significant effects	Quality assessment score (out of 8)
7									Retrospective list: Postoperative				
ч									bleeding, Myocardial infarction,				
2						Consecutive patients			Stroke, Pneumonia, Respiratory	QOL/36.4 ± 15.5			
3					N=110/124	who received a			insufficiency, Acute renal dysfunction,	months post-op			
3						replacement of the	Observational,	Ascending aorta	Sepsis, Lung fistula/Method not	(11–58			
4	Lohse	2009	Germany	Secondary	Nc=?	dilated ascending aorta.	cross-sectional	replacement	specified	months)/SF-36	NO	N/A	4
5					•				Wound complications (WC): patients				
6						Patients who			having infection, necrosis, hematoma- haemorrhage, or seroma-lymphocele				
_						underwent IB for			at the surgical incision or harvest site				
7					Nt1=1296/1404	Critical Limb Ischaemia			within 30 days of the bypass				
8					Nt2=862	(CLI) in community and		Lower extremity vein	surgery/Adverse events clinical trial				
					Nt3=732	university hospitals	Observational,	bypass for limb salvage	documentation with reference to	QOL/baseline, 3 &			
9						across the US and	cohort,	in critical limb ischemia	source documentation (hospital notes	12 months post-		Wound complications/3	
n	Nguyen ^a	2007	US & Canada	Primary	Nc=543	Canada	prospective	(CLI) patients	etc.)	op/VascuQol ²¹	CONFOUNDING*	months post-surgery	8
34	11647211	2007	os a canada	,				, ,,	Graft-related events (GREs):			, ,	
۱۱ ک									development of a >70% graft stenosis				
22						Patients who			or having undergone a percutaneous				
23						underwent IB for			or surgical revision or a major				
					N1=1296/1404 (92.3%)	Critical Limb Ischaemia			amputation/Clinical tests				
24					N2=862 (61.4%)	(CLI) in community and		Infrainguinal vein	(angiography, ultrasonography etc.),				
25					N3=732 (52.1%)	university hospitals	Observational,	grafting for limb salvage	source documentation (hospital notes,	QOL/pre-op, 3 &			
20						across the US and	cohort,	in critical limb ischemia	discharge notes, operative and	12 months post-		Graft-related events/12	
20	Nguyen ^b	2006	US & Canada	Secondary	Nc=?	Canada	prospective	(CLI) patients	procedural notes etc.)	op/VascuQol	YES*	months post-surgery	8
27						Patients with varicose							
28						veins, either							
						symptomatic or with							
29						skin changes, resulting							
30						from incompetence of							
1					Nt1=70/70	the LSV as confirmed by handheld Doppler							
) I					Nt2=59	examination or duplex				QOL/pre-op,			
32					Nt3=62	ultrasonography or			-Bruising/Tracing method	discharge & 6			
33					1413-02	both and requiring			-Sensory abnormalities, both	weeks post-			
					Nc(sensory abnormalities)=25	surgical intervention	Observational,		subjective (paresthesia and	op/Aberdeen			
34					Nc(bruising at t1)=58	(both day cases and	cohort,	Conventional LSV	dysesthesia) and objective/Patient	Varicose Vein			
35	Subramonia	2005	UK	Primary	Nc(bruising at t2)=16	inpatients).	prospective	stripping	reports, sensory testing	Questionnaire 2	NO*	N/A	7
- 4				reonerative wellhei		•			·				

^{*}Study controlled for patients' preoperative wellbeing

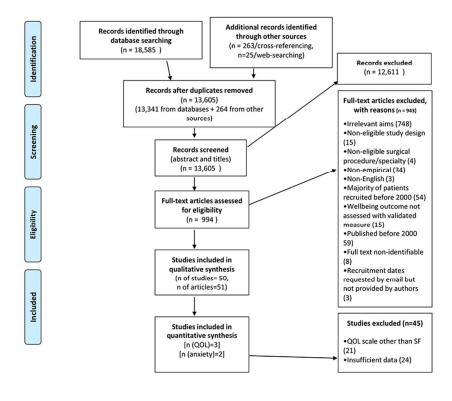
²¹ A validated instrument assessing pain, symptoms, activities, social life and emotional state in patients with vascular disease

Table 4: Domains of patients' wellbeing that were significantly affected by surgical complications

		Studies																															
Mea	asures	Bruns	Liu	Bloemen	Siassi	Rutegard	Pittman	Sharma	Avery	Le Grande	Nguyen ^b	Viklund	Delaney	Kalliomaki	Hawn	Anthony	Chang	Douma	Kement	Targarona	Peric	El Baz	Deaton	Ferguson	Tully	Gjeilo	Jideus	Kinney	Polese	Rea	Bitzer	Jarvinen	Moller
	Physical- Component	✓			>					~					~	_		>	>				✓									✓	
	Mental Component									×					✓				~				~										
	Physical functioning													√												√	✓	✓				✓	✓
	Bodily pain													✓					✓							✓		✓	✓	✓	✓		
Short Form scales (e.g. SF-36, SF-12	Role physical													✓												✓			✓	✓	✓	✓	
RAND-36)	Role emotional													~															✓				
	General health													√					✓				_			√	✓		✓	>		✓	~
	Mental health													√								✓				✓			✓	✓			
	Social functioning													√		_			√							√	✓		✓	~			
	Vitality													~					✓			✓				~		✓		✓			✓
	Physical Functioning			✓		✓			~	~		✓						✓						✓									
	Global QOL					✓				✓		√																					
EORTC QLQ-	Social Functioning								~							_																	
C30+	Fatigue			✓		✓																											
	Role functioning					~			~																								
	Pain			~																													
	Weight loss			<u> </u>																													

Ī	ı			1	1	l .	I	İ	ı	I	1	ı	l	ı	I	I	ı	l	I			İ	ı	I	1	ı	ı	ı	ı		. 1	
	Dyspnea					✓																										
	Nausea- Vomiting					✓			✓																							
	Coughing						✓																									
	Defecation																	✓														
VascuQOL	Total QOL										✓																					
GIQLI	Total QOL				•															✓												
	Total QOL		✓																													
mCOH-QOL	Physical QOL						✓																									
	Social QOL						✓																									
	Total QOL															✓																
FACT-C	Physical wellbeing							✓								✓																
PACI-C	Social wellbeing														<u> </u>	✓																
	Cancer concerns	_														✓																
CGQL	Total QOL												✓																			
	Physical domain																✓															
WHOQOL- BREF	Pain & discomfort																✓														1	
	Activities of daily living										_						✓				_											
IBDQ	Social functioning																	√														
	Social isolation	_				_							_					_			✓											
NHP	Sleep																				✓			J								
	Pain																				✓											
HADS &	Anxiety							✓						✓											✓							
DASS	Depression							✓						✓																		
PANAS	Negative affect							✓																								
MRS	Negative mood							✓																								





Supplementary materials for manuscript entitled:

Surgical complications and their impact on patients' psychosocial wellbeing: A systematic review and meta-analysis

Supplementary material 1: Search strategies

Embase

- 1. exp mental stress/
- 2. exp emotion/
- 3. exp depression/
- 4. exp ANXIETY/
- 5. exp posttraumatic stress disorder/
- 6. exp "quality of life"/
- 7. exp wellbeing/
- 8. 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9. exp surgery/
- 10. exp complication/
- 11.9 and 10
- 12. exp surgery/co [Complication]
- 13. exp perioperative complication/
- 14. exp peroperative complication/
- 15. exp postoperative complication/
- 16. exp preoperative complication/
- 17. exp surgical error/
- 18. exp iatrogenic disease/su [surgery]
- 19. exp anesthesia complication/
- 20. exp ANESTHESIA/co [Complication]
- 21. exp anesthesia/
- 22. exp complication/
- 23. 21 and 22
- 24. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 23
- 25. exp patient/
- 26. adult/
- 27. female/
- 28. male/
- 29. 25 or 26 or 27 or 28
- 30. 8 and 24 and 29
- 31. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or awareness or iatrogen* or ((adverse or unfavourable or unfavorable or untoward or undesired) adj (outcome*1 or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 32. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anaesth*).ti,ab.
- 33. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 34. 31 and 32 and 33
- 35. 30 or 34
- 36. limit 35 to (human and English language)

MEDLINE

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Stress, Psychological/
- 9. exp Emotions/
- 10. exp Depression/
- 11. exp Anxiety/
- 12. exp Stress Disorders, Post-Traumatic/
- 13. exp "Quality of Life"/
- 14. 8 or 9 or 10 or 11 or 12 or 13
- 15. exp Medical Errors/
- 16. exp Postoperative Complications/
- 17. exp iatrogenic disease/su [surgery]
- 18. exp Anesthesia/ae, co [Adverse Effects, Complications]
- 19. 15 or 16 or 17 or 18
- 20. 14 and 19
- 21. exp Patients/
- 22. exp adult/
- 23. exp women/
- 24. exp men/
- 25. exp research subjects/
- 26. 21 or 22 or 23 or 24 or 25
- 27. 14 and 19 and 26
- 28.7 or 27
- 29. limit 28 to (English language and humans)

PsycINFO

- 1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
- 2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or perioperative or perioperative or intra-operative or intra-operative or intra-operative or intra-operative or intra-operative or anaesth* or anesth*).ti,ab.
- 3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
- 4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
- 5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1)))).ti,ab.
- 6. 2 and 5
- 7. 2 and 3 and 5
- 8. exp Psychological Stress/
- 9. exp emotions/
- 10. exp "depression (emotion)"/
- 11. exp Anxiety/
- 12. exp posttraumatic stress disorder/
- 13. exp "Quality of Life"/
- 14. exp well being/
- 15. 8 or 9 or 10 or 11 or 12 or 13 or 14
- 16. exp postsurgical complications/
- 17. exp patients/
- 18. exp Human Females/
- 19. exp human males/
- 20. 17 or 18 or 19
- 21. 15 and 16 and 20
- 22. 7 or 21
- 23. limit 22 to (human and English language)

Supplementary material 2:

Detailed report of meta-analyses on the impact of complications on patients' psychosocial wellbeing

Quality of life

Due to the different measurement tools that were used for the assessment of QOL as well as the different domains that each tool assesses, a meta-analysis was conducted only on the studies that used the SF-tools. These were the most commonly used tools for the assessment of QoL, they are not condition-specific and they use the same measurement scale. Moreover, all of them yield the same summary scores (i.e. physical and mental). ¹ A meta-analysis was conducted on each summary score. The effect sizes are expressed as mean differences (MD) on a scale ranging from 0 to 100.

Only three studies provided sufficient data for a meta-analysis on the SF- physical and mental component scores between patients with complications and patients without complications. ²⁻⁴ The pooled mean differences between the two groups indicated significantly lower levels of physical and mental quality of life in patients who suffered complications compared to patients without complications (see eTable1).

The estimates of heterogeneity (I^2) were low (<25%).

Anxiety and Depression

Two studies provided sufficient data for a meta-analysis on anxiety levels. ^{5, 6} Each study used a different scale, therefore the effect sizes are expressed as standardised mean differences (SMD). The pooled SMD for anxiety was not significant indicating a lack of population effect in terms of the complications' impact on patients' anxiety levels. The estimate of heterogeneity was high (I²=81%), however a sensitivity analysis by the methodological quality of the included studies did not alter the results. A meta-analysis on depression was not possible as only one study provided sufficient data. ⁶

50 BMJ Open

Supplementary material 3

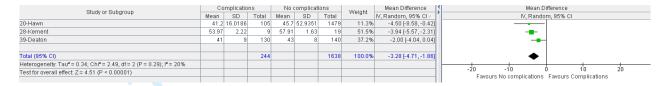
eTable1: Results of meta-analyses on the impact of surgical complications on patient psychosocial outcomes.

									
Wellbeing outcome	Sub-score	Comparison	k	N	Z	P	MD □ (SMD/ænxiety)	95% CI	l ²
Quality of life (SF-scales)	Physical component	Complications vs.	3	244	4.51	0.00001	-3.28 oad	-4.71, -1.86	20%
(6) 553.55)		No complications		1638			ed fro		
	Mental component	Complications vs.	3	244	6.52	0.00001	-3.82 3	-4.97, -2.67	0%
	P. P.	No complications		1638			o://bm		
Anxiety		Complications vs.	2	148	1.12	0.26	0.27	-0.21, 0.75	81%
		No complications		262			.bmj.o		

Supplementary material 4:

Forest plots of meta-analyses on the impact of surgical complications on patient psychosocial outcomes

SF Physical summary score (SF PCS)



SF Mental summary score (SF MCS)

Study or Subgroup	Co	omplicatio	ns	No i	complicat	ions	Weight	Mean Difference	Mean Difference				
Study of Subgroup	Mean	SD	Total	Mean	SD	Total	weight	IV, Random, 95% CI /	IV, Random, 95% CI				
39-Deaton	43	11	130	48	10	140	20.9%	-5.00 [-7.51, -2.49]					
28-Kement	47.17	1.96	9	50.79	2.09	19	52.3%	-3.62 [-5.21, -2.03]	-				
20-Hawn	47.1	10.3346	105	50.4	19.6056	1479	26.9%	-3.30 [-5.51, -1.09]	_ -				
Total (95% CI)			244			1638	100.0%	-3.82 [-4.97, -2.67]	♦				
Heterogeneity: Tau# = 0.00; Chi# = 1.12, df = 2 (P = 0.57); I# = 0%													
Test for overall effect: Z = 6.52 (P < 0.00001)									-20 -10 0 10 20 Favours No complications Favours Complications				
									ravours No complications ravours complications				

Anxiety

Study or Subgroup	Co	mplication	ons	No complications			Weight	Std. Mean Difference	Std. Mean Difference					
atuay or aungroup	Mean	SD	Total	Mean	SD	Total	vveigni	IV, Random, 95% CI /	IV, Random, 95% CI					
18-Kalliomaki	9.18	8.36	56	8.98	6.46	170	49.7%	0.03 [-0.27, 0.33]				•		
44-Tully	4.08	3.45	92	2.56	2.27	92	50.3%	0.52 [0.22, 0.81]				-		
Total (95% CI)			148			262	100.0%	0.27 [-0.21, 0.75]				*		
Heterogeneity: Tau#= 0.10; Chi#= 5.19, df= 1 (P = 0.02); I#= 81%									1			1	1	
Test for overall effect: Z = 1.12 (P = 0.26)									-10		b	U	5	10
										Favours	Complications	: Favours N	lo complications	

References

- 1. Ware JE, Kosinski M. SF-36 physical & mental health summary scales: a manual for users of version 1: Quality Metric Inc; 2001.
- 2. Deaton C, Thourani V. Patients with type 2 diabetes undergoing coronary artery bypass graft surgery: Predictors of outcomes. *Eur J Cardiovasc Nur* 2009; **8(1)**: 48-56.
- 3. Hawn MT, Itani KM, Giobbie-Hurder A, McCarthy Jr M, Jonasson O, Neumayer LA. Patient-reported outcomes after inguinal herniorrhaphy. *Surgery* 2006; **140(2)**: 198-205.
- 4. Kement M, Karabulut M, Gezen FC, Demirbas S, Vural S, Oncel M. Mild and severe anal incontinence after lateral internal sphincterotomy: Risk factors, postoperative anatomical findings and quality of life. *Eur Surg Res* 2011; **47**(1): 26-31.
- 5. Kalliomaki ML, Sandblom G, Gunnarsson U, Gordh T. Persistent pain after groin hernia surgery: A qualitative analysis of pain and its consequences for quality of life. *Acta Anaesth Scand* 2009; **53(2)**: 236-46.
- 6. Tully PJ, Bennetts JS, Baker RA, McGavigan AD, Turnbull DA, Winefield HR. Anxiety, depression, and stress as risk factors for atrial fibrillation after cardiac surgery. *Heart Lung* 2011; **40(1)**: 4-11.





PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
2 Structured summary 3 4	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
9 Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6
METHODS			
3 Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not available
6 Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search 2	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Suppl. Materials
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7-8
6 Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual 2 studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means). For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Suppl. Materials

For peer review only - http://binjopen.binj.com/site/about/guidelines.xhtml



PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8-9
,		Page 1 of 2	
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
8 Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9 & Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1-
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Tables 1-
26 Results of individual studies 27 28 9 9	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Suppl. Materials and Tables 1- 3
SP Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Suppl. Materials
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION	•		
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	16
5 Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research. For peer review only http://bmjopen.bmj.com/site/about/guidelines.xhtml	17-18



PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	18

ISMA Group (a.)
For more infon..

Pau From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

