

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Determining Surgical Complications in the Overweight (DISCOVER): A Multicentre Observational Cohort Study to Evaluate the Role of Obesity as a Risk Factor for Post-operative Complications in General Surgery
AUTHORS	Nepogodiev, Dmitri; Chapman, Stephen; Glasbey, James; Kelly, Michael; Khatri, Chetan; Drake, Tom; Kong, Chia Yew; Mitchell, Harriet; Harrison, Ewen; Fitzgerald, James; Bhangu, Aneel

VERSION 1 - REVIEW

REVIEWER	Rhiannon Harries University Hospital of Wales, Cardiff
REVIEW RETURNED	30-Nov-2014

GENERAL COMMENTS	The anticipated number of recruited patients varies between the abstract (at least 8,880 patients) and the manuscript (at least 5,920 patients). Please address
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REVIEWER	Vimal J Gokani University of Leicester, UK
REVIEW RETURNED	05-Dec-2014

GENERAL COMMENTS	An interesting manuscript and study - the authors should be praised for developing this. I only have one query, however: why were open/laparoscopic abdominal aortic aneurysm repairs excluded?
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REVIEWER	Paula Berstad Cancer Registry of Norway, Norway
REVIEW RETURNED	26-Jan-2015

GENERAL COMMENTS	<p>The manuscript describes the protocol for a large multicentre study, which aims to evaluate the effect of obesity on post-operative complications in general surgery. Data will be collected using a novel medical student network. The study will greatly add to the knowledge in this field.</p> <p>My first concern is the equality of the exposed (obese) and unexposed (normal weight) patient groups included in the study. Obesity increases some conditions leading to general surgery, therefore differential selection into the groups obese/normal weight cannot be avoided. The authors should pursue to include as similar groups of obese and normal weight patients as possible, in order to be able to handle confounding. I suggest excluding patients</p>
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	<p>undergoing bariatric surgery. There will probably not be any normal weight patients undergoing bariatric surgery, so stratification into this subgroup will not be possible. Although the authors may not have planned to stratify in subgroups according to types of surgery, they may find it necessary later.</p> <p>Second, the manuscript would profit from more detailed information on the data collection. A high number of variables will be collected from each participant. These will be anthropometric measurements, self-reported data and possibly also blood samples and variables from medical journals or death registry. Collecting patient data at hospital surgical units is demanding. The authors might like to describe in the manuscript some of information that will available in the detailed protocol for the collaborators. Information of interest is when and how the data will be collected (pre- or post-operative), whether the self-reported data will be collected in an interview or by a questionnaire to be filled in by the patient him/herself, how the anthropometric measurements will be carried out (and what if the patient is unable to complete the examination?), and in the case blood samples will be collected and analyzed, so will this be done pre- or post-operative, and in fasting or non-fasting condition? If the data will be collected pre-operative, how will the data be collected in the emergency patients?</p> <p>Possible limitations of the study, eg. those relating to difficulties in the data collection should be discussed.</p> <p>Minor comment: -Write out the DISCOVER in the text, not only in the title, please.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1	
<p>The anticipated number of recruited patients varies between the abstract (at least 8,880 patients) and the manuscript (at least 5,920 patients). Please address</p>	<p>Thank you for identifying this typographical error. This has been corrected.</p>

Reviewer #2	
<p>An interesting manuscript and study - the authors should be praised for developing this. I only have one query, however: why were open/laparoscopic abdominal aortic aneurysm repairs excluded?</p>	<p>This predominantly UK-based student-led project will be registered as clinical audit at individual centres by students on their general surgical placements. It was felt that it would be impractical to ask students to approach consultants across the full range of specialties that perform abdominal surgery (e.g. vascular surgery, urology and gynaecology) to register the audit with each individual specialty, hence</p>

	<p>this exclusion.</p> <p>Moreover, the difficulty in collecting data across such a broad range of specialties would potentially result in lower case ascertainment and lower data accuracy. Therefore we chose to focus on one specialty with the aim of collecting the highest quality data possible.</p>
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Reviewer #3	
<p>The manuscript describes the protocol for a large multicentre study, which aims to evaluate the effect of obesity on post-operative complications in general surgery. Data will be collected using a novel medical student network. The study will greatly add to the knowledge in this field.</p> <p>My first concern is the equality of the exposed (obese) and unexposed (normal weight) patient groups included in the study. Obesity increases some conditions leading to general surgery, therefore differential selection into the groups obese/normal weight cannot be avoided. The authors should pursue to include as similar groups of obese and normal weight patients as possible, in order to be able to handle confounding. I suggest excluding patients undergoing bariatric surgery. There will probably not be any normal weight patients undergoing bariatric surgery, so stratification into this subgroup will not be possible. Although the authors may not have planned to stratify in subgroups according to types of surgery, they may find it necessary later.</p> <p>Second, the manuscript would profit from more detailed information on the data collection. A high number of variables will be collected from each participant. These will be anthropometric measurements, self-reported data and possibly also blood samples and variables from medical journals or death registry.</p> <p>Collecting patient data at hospital surgical units is demanding. The authors might like to describe in the manuscript some of information that will be available in the detailed protocol for the collaborators. Information of interest is when and how the data will be collected (pre- or post-operative), whether the self-reported data will be collected in an interview or by a questionnaire to be filled in by the patient him/herself, how the</p>	<p>We thank the reviewer for their positive comments.</p> <p>Thank you for your thoughtful comment. Bariatric surgery was included as it represents a high-volume, high-risk set of procedures that obese patients undergo. We recognise that the distribution of pathologies and procedures may not be even across the full range of BMIs. We propose to address this through propensity score matching in our analysis. As you indicate, one variable we shall include is the classification of the complexity of the procedure. We will use the British United Provident Association (BUPA) Schedule of Procedures which categorises procedures into minor, intermediate, major and major+ complexity procedures. This has been clarified in the manuscript.</p> <p>DISCOVER will be a purely observational study. It will entirely rely upon the casenote and computer records produced by healthcare providers (medical and nursing staff). There are no patient reported outcome measures and patients will not be approached to complete questionnaires. Anthropometric data will include patient height and weight. This data will be extracted from the admission medical and nursing notes. Inevitably there are several reasons why this data may be unavailable for some patients; a key limitation of this observational study. No additional blood samples will be required. The only biochemical value we will be collecting is admission serum albumin; this will be a pre-operative baseline value. In the detailed guidance to collaborators it has been clarified that this albumin may be derived from</p>

anthropometric measurements will be carried out (and what if the patient is unable to complete the examination?), and in the case blood samples will be collected and analyzed, so will this be done pre- or post-operative, and in fasting or non-fasting condition? If the data will be collected pre-operative, how will the data be collected in the emergency patients?

blood tests taken in pre-operative assessment clinic (elective patients) or admission (pre-operative) blood tests (emergency patients). Although this is likely to generate data from a mix of fasting and non-fasting patients, we do not believe the small differences in fasting and non-fasting albumin levels justify the significant cost and inconvenience of subjecting patients to additional blood tests unrequired for their routine clinical care. Whilst some of the complications included in our data collection tool are based on blood tests, we will not be collecting raw biochemical values, but rather whether a clinical diagnosis of this complication (e.g. hyperkalaemia) was documented.

A short new section entitled 'patient identification and data collection' has been included in the revised manuscript to address these comments raised. This details how and when data should be collected. The contents of the protocol for collaborators have been described in greater detail in the manuscript, under the heading 'quality assurance.'

Possible limitations of the study, eg. those relating to difficulties in the data collection should be discussed.

The discussion of DISCOVER's limitations has been expanded in the discussion in the manuscript.

Minor comment:

Thank you, we have now spelt this out in full in the text.

-Write out the DISCOVER in the text, not only in the title, please.