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Reporting quality of abstracts in pain trials: a protocol for a systematic survey of the literature

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Title: Reporting quality of abstracts in pain trials: a protocol for a systematic survey of the literature

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Abstract:

Introduction: Abstracts of randomized control trials (RCTs) are often the first and only source read in a journal by busy healthcare providers or those who cannot access full trial reports. This necessitates good reporting of abstracts. The quality of reporting of abstracts, though gradually improving over time is still not uniform across medical journals. The improvement in quality or completeness of reporting of abstracts after publication of consolidated standards of reporting trials (CONSORT) extension for abstracts in 2008 has been documented in systematic reviews of trial reports published in general medical journals. Currently, this aspect has not been assessed with regards to pain journals where RCTs are increasingly being published. This study aims to compare the quality or completeness of reporting of abstracts before and after the publication of CONSORT statement for abstracts in five pain journals.

Methods and analyses: The abstracts of RCTs published from 01-01-2005 to 31-12-2007 (pre-CONSORT) and from 01-01-2013 to 31-12-2015 (post-CONSORT) will be assessed for the quality of reporting. A study without abstract, non-English abstracts, abstracts not reporting on RCTs or on humans and abstracts of conference proceedings will be excluded. A thorough search of Ovid-Medline database will be carried out in April-2016 using key terms. All identified studies will be screened for inclusion based on titles and abstracts. Data will be extracted by four independent reviewers in duplicate regarding compliance with CONSORT statement for abstracts. Full-text review will be performed to obtain additional characteristics which are likely to affect reporting quality.

Ethics and dissemination: This is the first review to evaluate reporting quality of abstracts of five exclusive pain journals based on CONSORT extension to abstracts. The findings of this

review will be disseminated by a presentation at conference and through publication in peer-reviewed journal. Ethics committee approval was not sought for this review.

Strengths and limitations:

- This is the first review on quality of reporting of abstracts of randomized controlled trials in pain journals
- Review of abstract quality independently and in duplicate and evaluating the possible factors contributing to quality of reporting
- Comparison of reporting before and after the publication of CONSORT extension for abstracts to assess possible improvement
- Restriction of abstracts published in English and on humans is the limitation

Introduction:

Evidence originating from randomized controlled trials (RCTs) is considered superior to other sources of evidence in clinical research. [1] Abstracts of RCTs are often the initial source on which decision about full-text reading is made. Many busy clinicians make healthcare decisions based on the information available in the abstracts. [2] This could be due to limitations posed by time, non-availability of the full-text due to absence of journal subscription or non-English language of the relevant article. Researchers, especially those doing systematic reviews rely on the content of the abstract to perform initial screen to include potential studies for meta-analysis. [3] Incomplete reporting of the essential details of the study in the abstract can therefore lead to inaccurate interpretation of the findings and possibly, wrong application in clinical practice. Hence, complete and structured reporting of the abstracts is necessary for meaningful and quick understanding of the study details. The consolidated standards of reporting trials (CONSORT) statement was first developed by the CONSORT group in 1996 to provide a minimum set of recommendations for reporting of RCTs. [4] The most recent statement published in 2010 consists of a 25-item checklist for reporting of RCTs. [5] The CONSORT extension for abstracts published in 2008 provides the list of 17 minimum items to be reported by the authors in the abstract that are considered necessary for good interpretation of the RCTs. [6] Previous studies have documented poor quality of reporting of abstracts in major medical journals before the publication of CONSORT statement [7] and subsequent improvement in the reporting details following publication of the CONSORT statement for abstracts. [8] However, non-adherence to CONSORT for abstracts guidelines was observed in four high impact general medical journals even after two years of publication of these guidelines. [9] Similarly, a mere 2.4% points improvement in proportion of items complying with CONSORT statement for abstracts was seen

from pre-CONSORT period in major anesthesia journals. [10] Despite an increase in the number of RCTs in pain and palliative care domains published over the years, [11] the assessment of quality of reporting has been limited and even these papers report mixed findings with respect to improvement over the years. [12,13] Moreover, the quality of reporting of abstracts related to RCTs in pain journals has not been evaluated till now, necessitating this review.

Objectives:

The purpose of this review is to inform pain researchers on the current quality of reporting of abstracts and how reporting of abstracts of RCTs actually need to be done. The specific objectives to fulfill this purpose are 1] to assess the number of items complied from the CONSORT abstract statement in five pain journals before and after the publication of CONSORT extension for abstracts and 2] to explore the factors associated with the quality of reporting of abstracts.

Methods:

Study design: This study will be a methodological review. A thorough search of the database of Ovid Medline will be conducted in April 2016 for the RCTs published in the year 2005-2007 and 2013-2015 in top five exclusive pain journals (based on impact factor) as per the Journal Citation Report 2014 published by Thomson Reuters; [14] Pain (5.213), Pain Physician (3.542), European journal of pain (2.942), Clinical journal of pain (2.527) and Pain practice (2.361). The search strategy will include terms for RCTs (*randomized control**, *clinical trial**), journal names (as above), exclusions for other type of articles (study protocol, review, cohort, case control, case series, guideline and editorial) and limits set for the specific time periods of interest (01/01/2005 to 31/12/2007 and 01/01/2013 to 31/12/2015). The search strategy that we adopted for searching of the relevant abstracts is described in Appendix 1. All the RCTs published in these five

journals during these years will be included based on pre-specified criteria: the abstract should be a report of an RCT, published in English language, and involving human subjects. Studies will be excluded if the abstract is not available, they are published only as abstracts (for example, conference proceedings), still recruiting or are duplicate publications. Figure 1 demonstrates the flow diagram showing the study selection procedure. A summary of our objectives, outcomes, hypotheses and methods of analysis are depicted in Table 1.

Sample size calculation:

The primary objective of this systematic review is to compare the mean number of reported items in pre- vs post-publication of the CONSORT extension to abstracts based on the corresponding checklist. [6] We hypothesize that there will be significant improvement in the mean number of reported items post-CONSORT extension to abstracts. An earlier review assessed the quality of abstracts in general medical journals before and after the publication of CONSORT statement for abstracts and observed an 18% improvement in reporting quality of abstracts. [8] The mean difference in the number of items reported in this study was 3.05; 95% confidence interval (CI 2.44-3.65); $p < 0.001$. Based on this study, we estimated that the sample size required in each study period (pre- vs post-CONSORT) with a significance of 0.05 and a power of 0.8 is 111 to observe a similar difference. Considering further 3% improvement/year in reporting over the last two years since this publication and eight years from CONSORT statement for abstracts, a sample size of 122 was determined. This basic calculation assumes that the comparison of means would be based on a t-test. To account for possible clustering of articles published in the same journal, we inflated the sample size by a factor of 1.796 (variable inflation factor; VIF) to n = 220—assuming an intra-class correlation coefficient of 0.034 and an average number of articles of 24.4 per journal. The primary analysis will also be adjusted for potential confounding

using the following six variables: endorsement of CONSORT statement by the journal, number of centers involved in the RCT, type of intervention, sample size, results of the trial and funding status. Therefore, we adjusted the sample size upward by adding five articles for each variable for a total sample size of n= 250. If excess articles are obtained for the search period than the required sample size, the articles will be randomly selected.

Data extraction and synthesis:

Data will be extracted regarding the compliance of the abstract to the CONSORT statement for abstracts. [6] Additional details will also be obtained with regards to endorsement of the CONSORT statement for RCTs and for abstracts of RCTs by the journals, whether the study is done at a single center or multiple centers, total number of patients recruited in the study, whether the study involved pharmacological intervention, whether the study was industry sponsored and whether the study reported positive or negative results. General information regarding journal name, author, year of publication and free availability of the full text of the article will also be extracted. Full text review will be done to obtain the additional information for analysis. Screening and data abstraction will be done independently and in duplicate by four reviewers (for both pre- and post-CONSORT period) using a customized data extraction form in Microsoft Excel® format and between reviewer agreements will be measured using the Kappa statistic. [15] Each of the four reviewers (SK, SB, MW and LPFA) will review half of the abstracts each for both the study periods. An initial trial run involving 10% of the eligible articles will be undertaken to improve the clarity regarding inclusions and exclusions and to increase accuracy and consistency among the reviewers. A simple customized instruction manual, examples contained in the CONSORT checklist [16] and CONSORT elaboration and explanation guidance document [17] will be used by all the reviewers to assess the articles for data extraction.

Disagreements will be resolved through consensus between the reviewers and if it persists, by arbitration by the senior author (LT).

Statistical analyses:

The characteristics of the included articles will be analyzed using descriptive statistics reported as mean (standard deviation) or median (first quartile, third quartile) for continuous variables depending on the distribution and count (percent) for categorical variables. We will describe the count (percent) of articles reporting each item by period of publication (pre- vs post-CONSORT). We will also report the mean number of reported items by period of publication. The mean number of items reported (0–17) for each period (pre- and post publication of CONSORT extension for abstracts) will be calculated and the unadjusted and adjusted differences will be estimated using a two-sample t-test and generalized estimation equations (GEEs) respectively. [18] The means will be reported along with their standard deviations (SDs). The mean differences and adjusted means will be also reported with 95% CIs and p-values. Next, the compliance with the 17 items of the CONSORT statement for abstracts for years 2005-2007 versus 2013-2015 will be compared using individual Chi-squared tests. This will be followed by an adjusted analysis using GEE. For binary outcomes (item reported yes or no), we will assume binomial distributions and unstructured correlation matrices. The adjusted odds ratios, 95% CI and p-values will be reported. Lastly, the incidence rate ratios (IRRs) for reporting items for the period 2013-2015 compared to the period 2005-2007 will be estimated using GEE, assuming a Poisson distribution and an unstructured correlation matrix. Adjusted IRRs, 95% CIs and p-values will be reported. The criterion for statistical significance will be set at alpha = 0.05.

For the GEE, adjustments will be made for 1) whether or not the journal endorses the CONSORT statement, 2) number of centers [multiple centers versus single center], 3) type of

intervention [pharmaceutical versus all others], 4) sample size [≤ 100 versus > 100], 5) results of trial [negative versus positive result] and 6) funding status [industry funded versus non-funded] with journal as a grouping factor – to adjust for potential clustering or similarity in articles published in the same journal. Descriptive data will be presented as counts and percentages. Data will be analyzed using Statistical Package for Social Sciences (SPSS) Version 16.0 (SPSS, Inc., 2009, Chicago, Illinois, USA).

Discussion and dissemination:

Ethics approval was not sought for this review. Pain journals are increasingly publishing RCTs to disseminate high quality evidence to their readers in clinical practice similar to the journals belonging to other medical sub-specialties. However, a general reading of the abstracts of RCTs in pain journals suggests that the quality of reporting across various journals is variable with some journal abstracts communicating adequate information and some grossly insufficient for accurate interpretation. Uniform and complete reporting of various aspects of the study design, methods and results help the reader to interpret the abstract accurately and to make well-informed decisions for better patient care. Patients or their families, who seek authentic information regarding problems relating to their pain and who possibly wish to enroll for trials that might benefit them, are likely to make inaccurate judgments if reporting is incomplete. [19] Similarly, a structured and detailed reporting of RCTs helps guideline developers and policy makers as they rely heavily on RCTs. Incomplete information makes it difficult to trust the findings resulting in suboptimal use of these RCTs. [20] Evidence-based pain management based on accurate reporting of trials and their correct interpretation has shown to improve patients' outcomes and satisfaction. [21] Hence, it is imperative for authors to report complete details of their research and for journals to ensure good reporting is adhered to by authors.

It is in this context, we chose five top pain journals as per their impact factors to assess their quality of reporting of abstracts of RCTs for this methodological review. This assessment becomes important in view of the increasing quantity of publications in the recent years on the subject of pain. In addition to the compliance with 17 components of CONSORT checklist, we will assess in this review certain other characteristics of the article that might affect the reporting quality of RCTs. We hypothesize that the reporting quality in these journals will vary depending on the journal's endorsement of the CONSORT, number of sites the study is conducted, sample size, type of intervention, significance of the result of primary outcome and funding of the study.

We expect RCTs from journals that endorse CONSORT, [22,23] multi-centric studies, [23,24] studies with larger sample size, [23,25] studies involving pharmacological intervention, [23,26] studies reporting positive results for their primary outcome [27] and industry sponsored studies [27] to be more compliant with the CONSORT extension for abstracts. Since substantial years (eight) have passed from the time of publication of CONSORT statement for abstracts in 2008, we hypothesize that the overall quality of study abstracts will be better for the post-CONSORT statement for abstracts time period than for the pre-CONSORT period.

Upon completion, this review will be submitted to a peer-reviewed biomedical journal for publication and the findings will also be presented at an upcoming conference.

To conclude, the results of this review are likely to clarify the current standards of reporting of abstracts in pain journals and improvement if any, over time compared to the period before CONSORT statement for abstracts were published. In case the current reporting quality is found to be inadequate, this comparative analysis will emphasize the need for journals to consider incorporating the CONSORT statement for abstracts in the guidelines for authors.

References:

1. Concato J, Shah N, Horwitz RI: Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000; 342:1887–92

2. Barry HC, Ebell MH, Shaughnessy AF, Slawson DC, Nietzke F: Family physicians' use of medical abstracts to guide decision making: style or substance? J Am Board Fam Pract 2001; 14:437–42

3. Assessing the Quality and Applicability of Systematic Reviews 2012 at <http://ktdrr.org/ktlibrary/articles_pubs/ncddrwork/aqasr/>(Accessed on 05-04-2016)

4. Begg C, Cho M, Eastwood S, Els D, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF: of Randomized Controlled Trials The CONSORT Statement 1996; 8:637–9

5. Schulz KF, Altman DG, Moher D: CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c332

6. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomised trials in journal and conference abstracts. Lancet 2008; 371:281–3

7. Berwanger O, Ribeiro RA, Finkelsztejn A, Watanabe M, Suzumura EA, Duncan BB, Devereaux PJ, Cook D: The quality of reporting of trial abstracts is suboptimal: Survey of major general medical journals. J Clin Epidemiol 2009; 62:387–92

8. Mbuagbaw L, Thabane M, Vanniyasingam T, Debono VB, Kosa S, Zhang S, Ye C, Parpia S, Dennis BB, Thabane L: Improvement in the quality of abstracts in major clinical

journals since CONSORT extension for abstracts: A systematic review. Contemp Clin Trials 2014; 38:245–50

9. Ghimire S, Kyung E, Kang W, Kim E: Assessment of adherence to the CONSORT statement for quality of reports on randomized controlled trial abstracts from four high-impact general medical journals. Trials 2012; 13:77

10. Can OS, Yilmaz A a, Hasdogan M, Alkaya F, Turhan SC, Can MF, Alanoglu Z: Has the quality of abstracts for randomised controlled trials improved since the release of Consolidated Standards of Reporting Trial guideline for abstract reporting? A survey of four high-profile anaesthesia journals. Eur J Anaesthesiol 2011; 28:485–92

11. Henschke N, Kuijpers T, Rubinstein SM, Middelkoop M Van, Ostelo R, Verhagen A, Koes BW, Tulder MW Van: Trends over time in the size and quality of randomised controlled Trials of interventions for chronic low-back pain. Eur Spine J 2012; 21:375–81

12. Piggott M, McGee H, Feuer D: Has CONSORT improved the reporting of randomized controlled trials in the palliative care literature? A systematic review. Palliat Med 2004; 18:32–8

13. Sauzet O, Williams JE, Ross J, Branford R, Farquhar-Smith P, Griffith GL, Fox-Rushby J a., Peacock JL: The Characteristics and Quality of Randomized Controlled Trials in Neuropathic Pain. Clin J Pain 2012; 29:1

14. JCR-Web 4.5 Marked List at <http://admin-apps.webofknowledge.com/JCR/JCR?RQ=LIST_MARKED>(Accessed on 13-03-2016)

15. Viera AJ, Garrett JM: Understanding interobserver agreement: the kappa statistic. Fam

Med 2005; 37:360–3

16. http://www.consort-statement.org/Media/Default/Downloads/Extensions/CONSORT%20Extension%20for%20Abstracts%20Checklist.pdf (Accessed on 01-04-2016)

17. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med 2008; 5:e20

18. Hanley JA, Negassa A, Edwardes MD deB, Forrester JE: Statistical analysis of correlated data using generalized estimating equations: An orientation. Am J Epidemiol 2003; 157:364–75

19. Clarke M: Can you believe what you read in the papers? Trials 2009; 10:55

20. Mayo-Wilson E, Montgomery P, Hopewell S, Macdonald G, Moher D, Grant S: Developing a reporting guideline for social and psychological intervention trials. Br J Psychiatry 2013; 203:250–4

21. Glowacki D: Effective pain management and improvements in patients' outcomes and satisfaction. Crit Care Nurse 2015; 35:33–41; quiz 43

22. Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D: Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane database Syst Rev 2012; 11:MR000030

23. Samaan Z, Mbuagbaw L, Kosa D, Borg Debono V, Dillenburg R, Zhang S, Fruci V,

Dennis B, Bawor M, Thabane L: A systematic scoping review of adherence to reporting guidelines in health care literature. J Multidiscip Healthc 2013; 6:169–88

24. Balasubramanian SP, Wiener M, Alshameeri Z, Tiruvoipati R, Elbourne D, Reed MW: Standards of reporting of randomized controlled trials in general surgery: can we do better? Ann Surg 2006; 244:663–7

25. Borg Debono V, Zhang S, Ye C, Paul J, Arya A, Hurlburt L, Murthy Y, Thabane L: The quality of reporting of RCTs used within a postoperative pain management meta-analysis, using the CONSORT statement. BMC Anesthesiol 2012; 12:13

26. Thabane L, Chu R, Cuddy K, Douketis J: What is the quality of reporting in weight loss intervention studies? A systematic review of randomized controlled trials. Int J Obes 2007; 31:1554–9

27. Lai R: Quality of Randomized Controlled Trials Reporting in the Primary Treatment of Brain Tumors. J Clin Oncol 2006; 24:1136–44

Authors' contributions:

All authors contributed to the protocol and approved the final manuscript. LT was responsible for the conception of the review. RC was involved in the search strategy. SK and LT were involved in the designing of the review. SK, SB, LPFA and MW were involved in designing and testing of the data extraction form. SK was involved in writing the initial draft, SB, MW and LPFA contributed to improvements in the manuscript and LM and LT critically revised the final draft.

Funding statement: No funding was obtained for this study.

Competing interests' statement: The authors do not have any competing interests to report.

Data Sharing: No additional data available.

Appendix 1: Search strategy adopted for RCTs published in five pain journals in the years 2005-2007 and 2013-2015 in the Ovid Medline database

1 pain.jn. (9225)

2 pain physician.jn. (1516)

3 "european journal of pain".jn. (1992)

4 "clinical journal of pain".jn. (2353)

5 pain practice.jn. (976)

6 or/1-5 (16062)

7 RCT.mp. (11818)

8 randomized control*.mp. (546495)

9 clinical trial*.mp. (845245)

10 or/7-9 (1108405)

11 6 and 10 (3257)

12 (protocol or systematic review or metaanalysis or editorial* or narrative review or case report or cohort stud* or case control or case series or guideline*).ti. (394735)

13 11 not 12 (3067)

14 limit 13 to yr="2005 - 2007" (430)

15 limit 13 to yr="2013 - 2015" (523)

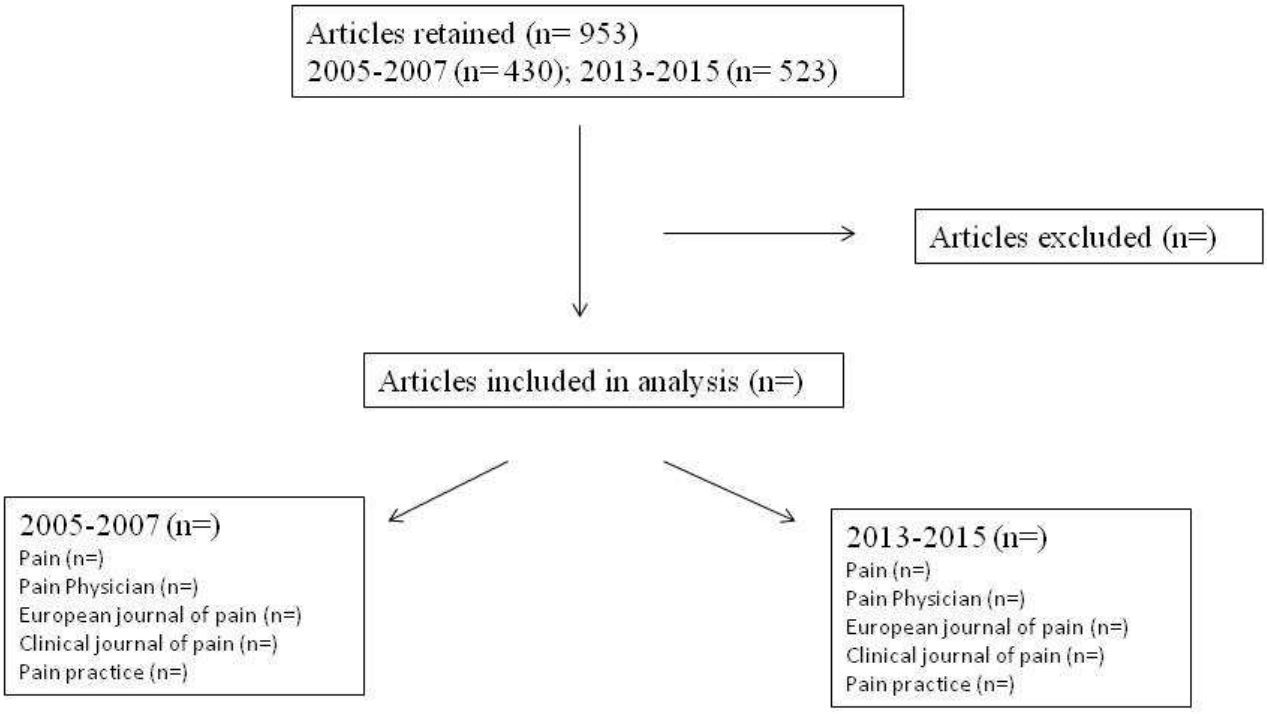
16 14 or 15 (953)

Objectives	Outcomes	Explanatory variables	Hypothesis	Methods of analyses

Table 1: Summary of objectives, outcomes, hypotheses and methods of analysis

Primary: To assess the quality of reporting of abstracts of RCTs in top pain journals before and after publication of CONSORT extension for abstracts	1. Overall quality of the reporting of abstracts 2. Quality of reporting of the individual items	Timing of publication (pre vs post CONSORT publication)	The quality of reporting of abstracts is better for period after publication of CONSORT statement for abstracts than before	Unadjusted and adjusted* regression using generalized estimating equations (GEE)
Secondary: To explore the factors associated with quality of reporting of abstracts		1. CONSORT endorsement by the journal 2. Number of centres (single vs multi-centric) 3. Sample size (≤ 100 vs >100) 4. Type of intervention (pharmacological vs non-pharmacological) 5. Significance of results for primary outcome (significant vs non-significant) 6. Source of funding (industry funded vs non-industry funded)		GEE
*This analysis will be adjusted for the number of centres, sample size, type of intervention, significance of results for primary outcome and source of funding				

Figure 1: Flow diagram showing study selection procedure



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Abstract:

Introduction: Abstracts of randomized control trials (RCTs) are often the first and only source read in a journal by busy healthcare providers. This necessitates good reporting of abstracts. The quality of reporting of abstracts, though gradually improving over time, is still not uniform across medical journals. Improvement in completeness of reporting of abstracts has been documented in general medical journals after publication of the consolidated standards of reporting trials (CONSORT) extension for abstracts in 2008. Currently, this aspect has not been assessed with regards to pain journals. This study aims to compare the completeness of reporting of abstracts before and after the publication of CONSORT statement for abstracts in five pain journals.

Methods and analyses: The abstracts of RCTs published from 01-01-2005 to 31-12-2007 (pre-CONSORT) and from 01-01-2013 to 31-12-2015 (post-CONSORT) will be assessed for the quality of reporting. Studies without abstracts, non-English abstracts, abstracts not reporting on RCTs or on humans and conference abstracts will be excluded. A thorough search of MEDLINE will be carried out in April-2016. All identified studies will be screened for inclusion based on titles and abstracts. Data will be extracted by two-sets of independent reviewers for each abstract in duplicate regarding compliance with CONSORT statement for abstracts. Full-text review will be performed to obtain additional characteristics which are likely to affect reporting quality. The unadjusted and adjusted differences in the mean number of items reported will be analyzed using a two-sample t-test and generalized estimation equation in SPSS.

Ethics and dissemination: As far as we know, this is the first study to evaluate reporting quality of abstracts of pain journals based on CONSORT extension for abstracts. The findings of this

study will be disseminated by a presentation at conference and through publication in peer-reviewed journal. Ethics committee approval was not sought for this survey.

Strengths and limitations:

- This is the first review on quality of reporting of abstracts of randomized controlled trials in pain journals
- Review of abstract quality independently and in duplicate and evaluating the possible factors contributing to quality of reporting
- Comparison of reporting before and after the publication of CONSORT extension for abstracts to assess possible improvement
- Only MEDLINE search will be carried out for a pre-specified time period and only abstracts of pain trials published in five pain journals will be considered
- Restriction to abstracts published in English and on humans are additional limitations

Introduction:

Evidence originating from randomized controlled trials (RCTs) is considered superior to other sources of evidence in clinical research. [1] Abstracts of RCTs are often the initial source on which decision about full-text reading is made. Many busy clinicians make healthcare decisions based on the information available in the abstracts. [2] This could be due to limitations posed by time, non-availability of the full-text due to absence of journal subscription or non-English language of the relevant article. Researchers, especially those doing systematic reviews rely on the content of the abstract to perform initial screen to include potential studies for meta-analysis. [3] Incomplete reporting of the essential details of the study in the abstract can therefore lead to inaccurate interpretation of the findings and possibly, wrong application in clinical practice. Hence, complete and structured reporting of the abstracts is necessary for meaningful and quick understanding of the study details. The consolidated standards of reporting trials (CONSORT) statement was first developed by the CONSORT group in 1996 to provide a minimum set of recommendations for reporting of RCTs. [4] The most recent statement published in 2010 consists of a 25-item checklist for reporting of RCTs. [5] The CONSORT extension for abstracts published in 2008 provides the list of 17 minimum items to be reported by the authors in the abstract that are considered necessary for good interpretation of the RCTs. [6] Previous studies have documented poor quality of reporting of abstracts in major medical journals before the publication of CONSORT statement [7] and subsequent improvement in the reporting details following publication of the CONSORT statement for abstracts. [8] However, non-adherence to the CONSORT statement for abstracts was observed in four high impact general medical journals even after two years of publication of these guidelines. [9] Similarly, a mere 2.4% points improvement in proportion of items complying with CONSORT statement for abstracts was seen

from pre-CONSORT period in major anesthesia journals. [10] Despite an increase in the number of RCTs in pain and palliative care domains published over the years, [11] the assessment of quality of reporting of RCTs has been limited and even these papers report mixed findings with respect to improvement over the years. [12,13] Moreover, the quality of reporting of abstracts related to RCTs in pain journals has not been evaluated till now, necessitating this study. Given the complex and multidimensional nature of pain, non-uniform methods and different outcome domains are used in trials published in pain journals. In the absence of compete reporting of abstracts, this can lead to misleading interpretations with implications on clinical decisions.

Objectives:

The purpose of this study is to inform pain practitioners and researchers on the current quality of reporting of abstracts and how reporting of abstracts of RCTs actually need to be done. The specific objectives to fulfill this purpose are 1] to assess the number of items reported from the CONSORT abstract statement in five pain journals before and after the publication of CONSORT extension for abstracts and 2] to explore the factors associated with the quality of reporting of abstracts.

Methods:

Study design: This study will be a methodological review. A thorough search of MEDLINE will be conducted in April 2016 for the RCTs published in the year 2005-2007 and 2013-2015 in top five exclusive pain journals (based on impact factor) as per the Journal Citation Report 2014 published by Thomson Reuters; [14] Pain (5.213), Pain Physician (3.542), European journal of pain (2.942), Clinical journal of pain (2.527) and Pain practice (2.361). The search strategy will include terms for RCTs (*randomized control**, *clinical trial**), journal names (as above), exclusions for other type of articles (study protocol, review, cohort, case control, case series,

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Sample size calculation:

The primary objective of this study is to compare the mean number of reported items in pre- vs post-publication of the CONSORT extension to abstracts based on the corresponding checklist. [6] We hypothesize that there will be significant improvement in the mean number of reported items post-CONSORT extension to abstracts. An earlier review assessed the quality of abstracts in general medical journals before and after the publication of CONSORT statement for abstracts and observed an 18% improvement in reporting quality of abstracts. [8] The mean difference in the number of items reported in this study was 3.05; 95% confidence interval (CI 2.44-3.65); $p < 0.001$. Based on this study, we estimated that the sample size required in each study period (pre- vs post-CONSORT) with a significance of 0.05 and a power of 0.8 is 111 to observe a similar difference. Considering further 3% improvement/year in reporting over the last two years since this publication and eight years from CONSORT statement for abstracts, a sample size of 122 was determined. This basic calculation assumes that the comparison of means would be based on a t-test. To account for possible clustering of articles published in the same journal, we inflated the sample size by a factor of 1.796 (variable inflation factor; VIF) to n

= 220—assuming an intra-class correlation coefficient of 0.034 and an average number of articles of 24.4 per journal. The primary analysis will also be adjusted for potential confounding using the following six variables: endorsement of CONSORT statement by the journal, number of centers involved in the RCT, type of intervention (pharmaceutical vs other), sample size, significance of the results of the trial and funding status (industry vs non-industry). Therefore, we adjusted the sample size upward by adding five articles for each variable for a total sample size of n= 250. If more than 250 eligible articles are found, 250 will be randomly selected for inclusion.

Data extraction and synthesis:

Data will be extracted regarding the compliance of the abstract to the CONSORT statement for abstracts. [6] Additional details will also be obtained with regards to endorsement of the CONSORT statement for RCTs and for abstracts of RCTs by the journals, whether the study is done at a single center or multiple centers, total number of patients recruited in the study, whether the study involved pharmacological intervention, whether the study was industry sponsored and whether the study reported statistically significant results. General information regarding journal name, author, year of publication and free availability of the full text of the article will also be extracted. Full text review will be done to obtain the additional information for analysis. Screening and data abstraction will be done independently and in duplicate (each abstract will be reviewed by two reviewers for pre- and post-CONSORT period) using a customized data extraction form in Microsoft Excel® and between reviewer agreements will be measured using the Kappa statistic. [15] Each of the four reviewers (SK, SB, MW and LPFA) will review half of the abstracts for both the study periods. An initial trial run involving 10% of the eligible articles will be undertaken to improve the clarity regarding inclusions and exclusions and

to increase accuracy and consistency among the reviewers. A simple customized instruction manual, examples contained in the CONSORT checklist [16] and CONSORT elaboration and explanation guidance document [17] will be used by all the reviewers to assess the articles for data extraction. Disagreements will be resolved through consensus between the reviewers and if it persists, by arbitration by the senior author (LT).

Statistical analyses:

The characteristics of the included articles will be analyzed using descriptive statistics reported as mean (standard deviation) or median (first quartile, third quartile) for continuous variables depending on the distribution and count (percent) for categorical variables. We will describe the count (percent) of articles reporting each item by period of publication (pre- vs post-CONSORT). We will also report the mean or median number of reported items by period of publication. The mean (median) number of items reported (0–17) for each period (pre- and post publication of CONSORT extension for abstracts) will be calculated and the unadjusted and adjusted differences will be estimated using a two-sample t-test and generalized estimation equations (GEEs) respectively. [18] The means or medians will be reported along with their standard deviations (SDs) or inter-quartile ranges. The mean (median) differences and adjusted means (medians) will be also reported with 95% CIs and p-values. Next, the compliance with the 17 items of the CONSORT statement for abstracts for years 2005-2007 versus 2013-2015 will be compared using individual Chi-squared tests. This will be followed by an adjusted analysis using GEE. For binary outcomes (item reported yes or no), we will assume the binomial distribution and unstructured correlation matrices. The adjusted odds ratios, 95% CI and p-values will be reported. Lastly, the incidence rate ratios (IRRs) for reporting items for the period 2013-2015 compared to the period 2005-2007 will be estimated using GEE, assuming a Poisson distribution

and an unstructured correlation matrix. Adjusted IRRs, 95% CIs and p-values will be reported. The criterion for statistical significance will be set at alpha = 0.05.

For the GEE, adjustments will be made for 1) whether or not the journal endorses the CONSORT statement, 2) number of centers [multiple centers versus single center], 3) type of intervention [pharmaceutical versus all others], 4) sample size [≤ 100 versus > 100], 5) results of trial [statistically significant versus not significant] and 6) funding status [industry funded versus non-funded] with journal as a grouping factor – to adjust for potential clustering or similarity in articles published in the same journal. Descriptive data will be presented as counts and percentages. Data will be analyzed using Statistical Package for Social Sciences (SPSS) Version 16.0 (SPSS, Inc., 2009, Chicago, Illinois, USA).

Discussion and dissemination:

Ethics approval was not sought for this survey as it only involved assessment of previously published information. Pain journals are increasingly publishing RCTs to disseminate high quality evidence to their readers in clinical practice similar to the journals belonging to other medical sub-specialties. However, a general reading of the abstracts of RCTs in pain journals suggests that the quality of reporting across various journals is variable with some journal abstracts communicating adequate information and some grossly insufficient for accurate interpretation. Uniform and complete reporting of various aspects of the study design, methods and results help the reader to interpret the abstract accurately and to make well-informed decisions for better patient care. Patients or their families, who seek authentic information regarding problems relating to their pain and who possibly wish to enroll for trials that might benefit them, are likely to make inaccurate judgments if reporting is incomplete. [19] Similarly, a structured and detailed reporting of RCTs helps guideline developers and policy makers as they

rely heavily on RCTs. Incomplete information makes it difficult to trust the findings resulting in suboptimal use of these RCTs. [20] Evidence-based pain management based on accurate reporting of trials and their correct interpretation has shown to improve patients' outcomes and satisfaction. [21] Hence, it is imperative for authors to report complete details of their research and for journals to ensure good reporting is adhered to by authors.

It is in this context, we chose five top pain journals as per their impact factors to assess their quality of reporting of abstracts of RCTs for this methodological review. This assessment becomes important in view of the increasing quantity of publications in the recent years on the subject of pain. In addition to the compliance with 17 components of CONSORT checklist, we will assess in this review certain other characteristics of the article that might affect the reporting quality of RCTs. We hypothesize that the reporting quality in these journals will vary depending on the journal's endorsement of the CONSORT, number of sites the study is conducted, sample size, type of intervention, significance of the result of primary outcome and funding of the study.

We expect RCTs from journals that endorse CONSORT, [22,23] multi-centric studies, [23,24] studies with larger sample size, [23,25] studies involving pharmacological intervention, [23,26] studies reporting significant results for their primary outcome [27] and industry sponsored studies [27] to be more compliant with the CONSORT extension for abstracts. Since substantial years (eight) have passed from the time of publication of CONSORT statement for abstracts in 2008, we hypothesize that the overall quality of study abstracts will be better for the post-CONSORT statement for abstracts time period than for the pre-CONSORT period.

Upon completion, this study will be submitted to a peer-reviewed biomedical journal for publication and the findings will also be presented at an upcoming conference.

To conclude, the results of this study are likely to clarify the current standards of reporting of abstracts in pain journals and improvement if any, over time compared to the period before CONSORT statement for abstracts were published. In case the current reporting quality is found to be inadequate, this comparative analysis will emphasize the need for journals to consider incorporating the CONSORT statement for abstracts in the guidelines for authors.

References:

1. Concato J, Shah N, Horwitz RI: Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000; 342:1887–92

2. Barry HC, Ebell MH, Shaughnessy AF, Slawson DC, Nietzke F: Family physicians' use of medical abstracts to guide decision making: style or substance? J Am Board Fam Pract 2001; 14:437–42

3. Assessing the Quality and Applicability of Systematic Reviews 2012 at <http://ktdrr.org/ktlibrary/articles_pubs/ncddrwork/aqasr/>(Accessed on 05-04-2016)

4. Begg C, Cho M, Eastwood S, Els D, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF: of Randomized Controlled Trials The CONSORT Statement 1996; 8:637–9

5. Schulz KF, Altman DG, Moher D: CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c332

6. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomised trials in journal and conference abstracts. Lancet 2008; 371:281–3

7. Berwanger O, Ribeiro RA, Finkelsztejn A, Watanabe M, Suzumura EA, Duncan BB, Devereaux PJ, Cook D: The quality of reporting of trial abstracts is suboptimal: Survey of major general medical journals. J Clin Epidemiol 2009; 62:387–92

8. Mbuagbaw L, Thabane M, Vanniyasingam T, Debono VB, Kosa S, Zhang S, Ye C, Parpia S, Dennis BB, Thabane L: Improvement in the quality of abstracts in major clinical journals since CONSORT extension for abstracts: A systematic review. Contemp Clin Trials 2014; 38:245–50

9. Ghimire S, Kyung E, Kang W, Kim E: Assessment of adherence to the CONSORT statement for quality of reports on randomized controlled trial abstracts from four high-impact general medical journals. Trials 2012; 13:77

10. Can OS, Yilmaz A a, Hasdogan M, Alkaya F, Turhan SC, Can MF, Alanoglu Z: Has the quality of abstracts for randomised controlled trials improved since the release of Consolidated Standards of Reporting Trial guideline for abstract reporting? A survey of four high-profile anaesthesia journals. Eur J Anaesthesiol 2011; 28:485–92

11. Henschke N, Kuijpers T, Rubinstein SM, Middelkoop M Van, Ostelo R, Verhagen A, Koes BW, Tulder MW Van: Trends over time in the size and quality of randomised controlled Trials of interventions for chronic low-back pain. Eur Spine J 2012; 21:375–81

12. Piggott M, McGee H, Feuer D: Has CONSORT improved the reporting of randomized controlled trials in the palliative care literature? A systematic review. Palliat Med 2004; 18:32–8

13. Sauzet O, Williams JE, Ross J, Branford R, Farquhar-Smith P, Griffith GL, Fox-Rushby J

a., Peacock JL: The Characteristics and Quality of Randomized Controlled Trials in Neuropathic Pain. Clin J Pain 2012; 29:1

14. JCR-Web 4.5 Marked List at <http://admin-apps.webofknowledge.com/JCR/JCR?RQ=LIST_MARKED>(Accessed on 13-03-2016)

15. Viera AJ, Garrett JM: Understanding interobserver agreement: the kappa statistic. Fam Med 2005; 37:360–3

16. http://www.consort-statement.org/Media/Default/Downloads/Extensions/CONSORT%20Extension%20for%20Abstracts%20Checklist.pdf (Accessed on 01-04-2016)

17. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med 2008; 5:e20

18. Hanley JA, Negassa A, Edwardes MD deB, Forrester JE: Statistical analysis of correlated data using generalized estimating equations: An orientation. Am J Epidemiol 2003; 157:364–75

19. Clarke M: Can you believe what you read in the papers? Trials 2009; 10:55

20. Mayo-Wilson E, Montgomery P, Hopewell S, Macdonald G, Moher D, Grant S: Developing a reporting guideline for social and psychological intervention trials. Br J Psychiatry 2013; 203:250–4

21. Glowacki D: Effective pain management and improvements in patients' outcomes and satisfaction. Crit Care Nurse 2015; 35:33–41; quiz 43

22. Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D: Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane database Syst Rev 2012; 11:MR000030

23. Samaan Z, Mbuagbaw L, Kosa D, Borg Debono V, Dillenburg R, Zhang S, Fruci V, Dennis B, Bawor M, Thabane L: A systematic scoping review of adherence to reporting guidelines in health care literature. J Multidiscip Healthc 2013; 6:169–88

24. Balasubramanian SP, Wiener M, Alshameeri Z, Tiruvoipati R, Elbourne D, Reed MW: Standards of reporting of randomized controlled trials in general surgery: can we do better? Ann Surg 2006; 244:663–7

25. Borg Debono V, Zhang S, Ye C, Paul J, Arya A, Hurlburt L, Murthy Y, Thabane L: The quality of reporting of RCTs used within a postoperative pain management meta-analysis, using the CONSORT statement. BMC Anesthesiol 2012; 12:13

26. Thabane L, Chu R, Cuddy K, Douketis J: What is the quality of reporting in weight loss intervention studies? A systematic review of randomized controlled trials. Int J Obes 2007; 31:1554–9

27. Lai R: Quality of Randomized Controlled Trials Reporting in the Primary Treatment of Brain Tumors. J Clin Oncol 2006; 24:1136–44

Authors' contributions:

All authors contributed to the protocol and approved the final manuscript. LT was responsible for the conception of the review. RC was involved in the search strategy. SK and LT were involved in the designing of the review. SK, SB, LPFA and MW were involved in designing and testing of the data extraction form. SK was involved in writing the initial draft, SB, MW and LPFA contributed to improvements in the manuscript and LM and LT critically revised the final draft.

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Competing interests' statement: The authors do not have any competing interests to report.

Table 1: Summary of objectives, outcomes, hypotheses and methods of analysis

Objectives	Outcomes	Explanatory variables	Hypothesis	Methods of analyses
Primary: To assess the quality of reporting of abstracts of RCTs in top pain journals before and after publication of CONSORT extension for abstracts	1. Overall quality of the reporting of abstracts 2. Quality of reporting of the individual items	Timing of publication (pre vs post CONSORT publication)	The quality of reporting of abstracts is better for period after publication of CONSORT statement for abstracts than before	Unadjusted and adjusted* regression using generalized estimating equations (GEE)
Secondary: To explore the factors associated with quality of reporting of abstracts		1. CONSORT endorsement by the journal 2. Number of centres (single vs multi-centric) 3. Sample size (≤ 100 vs >100) 4. Type of intervention (pharmacological vs non-pharmacological) 5. Significance of results for primary outcome (significant vs non-significant) 6. Source of funding (industry funded vs non-industry funded)		GEE
*This analysis will be adjusted for the number of centres, sample size, type of intervention, significance of results for primary outcome and source of funding				

Appendix 1: Search strategy adopted for RCTs published in five pain journals in the years 2005-2007 and 2013-2015 in the Ovid Medline database

1 pain.jn. (9225)

2 pain physician.jn. (1516)

3 "european journal of pain".jn. (1992)

4 "clinical journal of pain".jn. (2353)

5 pain practice.jn. (976)

6 or/1-5 (16062)

7 RCT.mp. (11818)

8 randomized control*.mp. (546495)

9 clinical trial*.mp. (845245)

10 or/7-9 (1108405)

11 6 and 10 (3257)

12 (protocol or systematic review or metaanalysis or editorial* or narrative review or case report or cohort stud* or case control or case series or guideline*).ti. (394735)

13 11 not 12 (3067)

14 limit 13 to yr="2005 - 2007" (430)

15 limit 13 to yr="2013 - 2015" (523)

16 14 or 15 (953)

BMJ Open

Reporting quality of abstracts of trials published in top five pain journals: a protocol for a systematic survey

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Keywords:	PAIN MANAGEMENT, QUALITATIVE RESEARCH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Authors:

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Abstract:

Introduction: Abstracts of randomized control trials (RCTs) are often the first and only source read in a journal by busy healthcare providers. This necessitates good reporting of abstracts. The quality of reporting of abstracts, though gradually improving over time, is still not uniform across medical journals. Improvement in completeness of reporting of abstracts has been documented in general medical journals after publication of the consolidated standards of reporting trials (CONSORT) extension for abstracts in 2008. Currently, this aspect has not been assessed with regards to pain journals. This study aims to compare the completeness of reporting of abstracts before and after the publication of CONSORT statement for abstracts in five pain journals.

Methods and analyses: The abstracts of RCTs published from 01-01-2005 to 31-12-2007 (pre-CONSORT) and from 01-01-2013 to 31-12-2015 (post-CONSORT) will be assessed for the quality of reporting. Studies without abstracts, non-English abstracts, abstracts not reporting on RCTs or on humans and conference abstracts will be excluded. A thorough search of MEDLINE will be carried out in April-2016. All identified studies will be screened for inclusion based on titles and abstracts. Data will be extracted by two-sets of independent reviewers for each abstract in duplicate regarding compliance with CONSORT statement for abstracts. Full-text review will be performed to obtain additional characteristics which are likely to affect reporting quality. The unadjusted and adjusted differences in the mean number of items reported will be analyzed using a two-sample t-test and generalized estimation equation in SPSS.

Ethics and dissemination: As far as we know, this is the first study to evaluate reporting quality of abstracts of pain journals based on CONSORT extension for abstracts. The findings of this

study will be disseminated by a presentation at conference and through publication in peer-reviewed journal. Ethics committee approval was not sought for this survey.

Strengths and limitations:

- This is the first review on quality of reporting of abstracts of randomized controlled trials in pain journals
- Review of abstract quality independently and in duplicate and evaluating the possible factors contributing to quality of reporting
- Comparison of reporting before and after the publication of CONSORT extension for abstracts to assess possible improvement
- Only MEDLINE search will be carried out for a pre-specified time period and only abstracts of pain trials published in five pain journals will be considered
- Restriction to abstracts published in English and on humans are additional limitations

Introduction:

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= 220—assuming an intra-class correlation coefficient of 0.034 and an average number of articles of 24.4 per journal. The primary analysis will also be adjusted for potential confounding using the following six variables: endorsement of CONSORT statement by the journal, number of centers involved in the RCT, type of intervention (pharmaceutical vs other), sample size, significance of the results of the trial and funding status (industry vs non-industry). Therefore, we adjusted the sample size upward by adding five articles for each variable for a total sample size of n= 250. If more than 250 eligible articles are found, 250 will be randomly selected for inclusion.

Data extraction and synthesis:

Data will be extracted regarding the compliance of the abstract to the CONSORT statement for abstracts. [6] Additional details will also be obtained with regards to endorsement of the CONSORT statement for RCTs and for abstracts of RCTs by the journals, whether the study is done at a single center or multiple centers, total number of patients recruited in the study, whether the study involved pharmacological intervention, whether the study was industry sponsored and whether the study reported statistically significant results. General information regarding journal name, author, year of publication and free availability of the full text of the article will also be extracted. Full text review will be done to obtain the additional information for analysis. Screening and data abstraction will be done independently and in duplicate (each abstract will be reviewed by two reviewers for pre- and post-CONSORT period) using a customized data extraction form in Microsoft Excel® and between reviewer agreements will be measured using the Kappa statistic. [15] Each of the four reviewers (SK, SB, MW and LPFA) will review half of the abstracts for both the study periods. An initial trial run involving 10% of the eligible articles will be undertaken to improve the clarity regarding inclusions and exclusions and

to increase accuracy and consistency among the reviewers. A simple customized instruction manual, examples contained in the CONSORT checklist [16] and CONSORT elaboration and explanation guidance document [17] will be used by all the reviewers to assess the articles for data extraction. Disagreements will be resolved through consensus between the reviewers and if it persists, by arbitration by the senior author (LT).

Statistical analyses:

The characteristics of the included articles will be analyzed using descriptive statistics reported as mean (standard deviation) or median (first quartile, third quartile) for continuous variables depending on the distribution and count (percent) for categorical variables. We will describe the count (percent) of articles reporting each item by period of publication (pre- vs post-CONSORT). We will also report the mean or median number of reported items by period of publication. The mean (median) number of items reported (0–17) for each period (pre- and post publication of CONSORT extension for abstracts) will be calculated and the unadjusted and adjusted differences will be estimated using a two-sample t-test and generalized estimation equations (GEEs) respectively. [18] The means or medians will be reported along with their standard deviations (SDs) or inter-quartile ranges. The mean (median) differences and adjusted means (medians) will be also reported with 95% CIs and p-values. Next, the compliance with the 17 items of the CONSORT statement for abstracts for years 2005-2007 versus 2013-2015 will be compared using individual Chi-squared tests. This will be followed by an adjusted analysis using GEE. For binary outcomes (item reported yes or no), we will assume the binomial distribution and unstructured correlation matrices. The adjusted odds ratios, 95% CI and p-values will be reported. Lastly, the incidence rate ratios (IRRs) for reporting items for the period 2013-2015 compared to the period 2005-2007 will be estimated using GEE, assuming a Poisson distribution

and an unstructured correlation matrix. Adjusted IRRs, 95% CIs and p-values will be reported. The criterion for statistical significance will be set at alpha = 0.05.

For the GEE, adjustments will be made for 1) whether or not the journal endorses the CONSORT statement, 2) number of centers [multiple centers versus single center], 3) type of intervention [pharmaceutical versus all others], 4) sample size [≤ 100 versus > 100], 5) results of trial [statistically significant versus not significant] and 6) funding status [industry funded versus non-funded] with journal as a grouping factor – to adjust for potential clustering or similarity in articles published in the same journal. Descriptive data will be presented as counts and percentages. Data will be analyzed using Statistical Package for Social Sciences (SPSS) Version 16.0 (SPSS, Inc., 2009, Chicago, Illinois, USA).

Discussion and dissemination:

Ethics approval was not sought for this survey as it only involved assessment of previously published information. Pain journals are increasingly publishing RCTs to disseminate high quality evidence to their readers in clinical practice similar to the journals belonging to other medical sub-specialties. However, a general reading of the abstracts of RCTs in pain journals suggests that the quality of reporting across various journals is variable with some journal abstracts communicating adequate information and some grossly insufficient for accurate interpretation. Uniform and complete reporting of various aspects of the study design, methods and results help the reader to interpret the abstract accurately and to make well-informed decisions for better patient care. Patients or their families, who seek authentic information regarding problems relating to their pain and who possibly wish to enroll for trials that might benefit them, are likely to make inaccurate judgments if reporting is incomplete. [19] Similarly, a structured and detailed reporting of RCTs helps guideline developers and policy makers as they

rely heavily on RCTs. Incomplete information makes it difficult to trust the findings resulting in suboptimal use of these RCTs. [20] Evidence-based pain management based on accurate reporting of trials and their correct interpretation has shown to improve patients' outcomes and satisfaction. [21] Hence, it is imperative for authors to report complete details of their research and for journals to ensure good reporting is adhered to by authors.

It is in this context, we chose five top pain journals as per their impact factors to assess their quality of reporting of abstracts of RCTs for this methodological review. This assessment becomes important in view of the increasing quantity of publications in the recent years on the subject of pain. In addition to the compliance with 17 components of CONSORT checklist, we will assess in this review certain other characteristics of the article that might affect the reporting quality of RCTs. We hypothesize that the reporting quality in these journals will vary depending on the journal's endorsement of the CONSORT, number of sites the study is conducted, sample size, type of intervention, significance of the result of primary outcome and funding of the study.

We expect RCTs from journals that endorse CONSORT, [22,23] multi-centric studies, [23,24] studies with larger sample size, [23,25] studies involving pharmacological intervention, [23,26] studies reporting significant results for their primary outcome [27] and industry sponsored studies [27] to be more compliant with the CONSORT extension for abstracts. Since substantial years (eight) have passed from the time of publication of CONSORT statement for abstracts in 2008, we hypothesize that the overall quality of study abstracts will be better for the post-CONSORT statement for abstracts time period than for the pre-CONSORT period.

Upon completion, this study will be submitted to a peer-reviewed biomedical journal for publication and the findings will also be presented at an upcoming conference.

To conclude, the results of this study are likely to clarify the current standards of reporting of abstracts in pain journals and improvement if any, over time compared to the period before CONSORT statement for abstracts were published. In case the current reporting quality is found to be inadequate, this comparative analysis will emphasize the need for journals to consider incorporating the CONSORT statement for abstracts in the guidelines for authors.

References:

1. Concato J, Shah N, Horwitz RI: Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000; 342:1887–92

2. Barry HC, Ebell MH, Shaughnessy AF, Slawson DC, Nietzke F: Family physicians' use of medical abstracts to guide decision making: style or substance? J Am Board Fam Pract 2001; 14:437–42

3. Assessing the Quality and Applicability of Systematic Reviews 2012 at <http://ktdrr.org/ktlibrary/articles_pubs/ncddrwork/aqasr/>(Accessed on 05-04-2016)

4. Begg C, Cho M, Eastwood S, Els D, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF: of Randomized Controlled Trials The CONSORT Statement 1996; 8:637–9

5. Schulz KF, Altman DG, Moher D: CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c332

6. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomised trials in journal and conference abstracts. Lancet 2008; 371:281–3

7. Berwanger O, Ribeiro RA, Finkelsztejn A, Watanabe M, Suzumura EA, Duncan BB, Devereaux PJ, Cook D: The quality of reporting of trial abstracts is suboptimal: Survey of major general medical journals. J Clin Epidemiol 2009; 62:387–92

8. Mbuagbaw L, Thabane M, Vanniyasingam T, Debono VB, Kosa S, Zhang S, Ye C, Parpia S, Dennis BB, Thabane L: Improvement in the quality of abstracts in major clinical journals since CONSORT extension for abstracts: A systematic review. Contemp Clin Trials 2014; 38:245–50

9. Ghimire S, Kyung E, Kang W, Kim E: Assessment of adherence to the CONSORT statement for quality of reports on randomized controlled trial abstracts from four high-impact general medical journals. Trials 2012; 13:77

10. Can OS, Yilmaz A a, Hasdogan M, Alkaya F, Turhan SC, Can MF, Alanoglu Z: Has the quality of abstracts for randomised controlled trials improved since the release of Consolidated Standards of Reporting Trial guideline for abstract reporting? A survey of four high-profile anaesthesia journals. Eur J Anaesthesiol 2011; 28:485–92

11. Henschke N, Kuijpers T, Rubinstein SM, Middelkoop M Van, Ostelo R, Verhagen A, Koes BW, Tulder MW Van: Trends over time in the size and quality of randomised controlled Trials of interventions for chronic low-back pain. Eur Spine J 2012; 21:375–81

12. Piggott M, McGee H, Feuer D: Has CONSORT improved the reporting of randomized controlled trials in the palliative care literature? A systematic review. Palliat Med 2004; 18:32–8

13. Sauzet O, Williams JE, Ross J, Branford R, Farquhar-Smith P, Griffith GL, Fox-Rushby J

a., Peacock JL: The Characteristics and Quality of Randomized Controlled Trials in Neuropathic Pain. Clin J Pain 2012; 29:1

14. JCR-Web 4.5 Marked List at <http://admin-apps.webofknowledge.com/JCR/JCR?RQ=LIST_MARKED>(Accessed on 13-03-2016)

15. Viera AJ, Garrett JM: Understanding interobserver agreement: the kappa statistic. Fam Med 2005; 37:360–3

16. http://www.consort-statement.org/Media/Default/Downloads/Extensions/CONSORT%20Extension%20for%20Abstracts%20Checklist.pdf (Accessed on 01-04-2016)

17. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF: CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med 2008; 5:e20

18. Hanley JA, Negassa A, Edwardes MD deB, Forrester JE: Statistical analysis of correlated data using generalized estimating equations: An orientation. Am J Epidemiol 2003; 157:364–75

19. Clarke M: Can you believe what you read in the papers? Trials 2009; 10:55

20. Mayo-Wilson E, Montgomery P, Hopewell S, Macdonald G, Moher D, Grant S: Developing a reporting guideline for social and psychological intervention trials. Br J Psychiatry 2013; 203:250–4

21. Glowacki D: Effective pain management and improvements in patients' outcomes and satisfaction. Crit Care Nurse 2015; 35:33–41; quiz 43

22. Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D: Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane database Syst Rev 2012; 11:MR000030

23. Samaan Z, Mbuagbaw L, Kosa D, Borg Debono V, Dillenburg R, Zhang S, Fruci V, Dennis B, Bawor M, Thabane L: A systematic scoping review of adherence to reporting guidelines in health care literature. J Multidiscip Healthc 2013; 6:169–88

24. Balasubramanian SP, Wiener M, Alshameeri Z, Tiruvoipati R, Elbourne D, Reed MW: Standards of reporting of randomized controlled trials in general surgery: can we do better? Ann Surg 2006; 244:663–7

25. Borg Debono V, Zhang S, Ye C, Paul J, Arya A, Hurlburt L, Murthy Y, Thabane L: The quality of reporting of RCTs used within a postoperative pain management meta-analysis, using the CONSORT statement. BMC Anesthesiol 2012; 12:13

26. Thabane L, Chu R, Cuddy K, Douketis J: What is the quality of reporting in weight loss intervention studies? A systematic review of randomized controlled trials. Int J Obes 2007; 31:1554–9

27. Lai R: Quality of Randomized Controlled Trials Reporting in the Primary Treatment of Brain Tumors. J Clin Oncol 2006; 24:1136–44

Authors' contributions:

All authors contributed to the protocol and approved the final manuscript. LT was responsible for the conception of the review. RC was involved in the search strategy. SK and LT were involved in the designing of the review. SK, SB, LPFA and MW were involved in designing and testing of the data extraction form. SK was involved in writing the initial draft, SB, MW and LPFA contributed to improvements in the manuscript and LM and LT critically revised the final draft.

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Table 1: Summary of objectives, outcomes, hypotheses and methods of analysis

Objectives	Outcomes	Explanatory variables	Hypothesis	Methods of analyses
Primary: To assess the quality of reporting of abstracts of RCTs in top pain journals before and after publication of CONSORT extension for abstracts	1. Overall quality of the reporting of abstracts 2. Quality of reporting of the individual items	Timing of publication (pre vs post CONSORT publication)	The quality of reporting of abstracts is better for period after publication of CONSORT statement for abstracts than before	Unadjusted and adjusted* regression using generalized estimating equations (GEE)
Secondary: To explore the factors associated with quality of reporting of abstracts		1. CONSORT endorsement by the journal 2. Number of centres (single vs multi-centric) 3. Sample size (≤ 100 vs >100) 4. Type of intervention (pharmacological vs non-pharmacological) 5. Significance of results for primary outcome (significant vs non-significant) 6. Source of funding (industry funded vs non-industry funded)		GEE
*This analysis will be adjusted for the number of centres, sample size, type of intervention, significance of results for primary outcome and source of funding				

Appendix 1: Search strategy adopted for RCTs published in five pain journals in the years 2005-2007 and 2013-2015 in the Ovid Medline database

1 pain.jn. (9225)

2 pain physician.jn. (1516)

3 "european journal of pain".jn. (1992)

4 "clinical journal of pain".jn. (2353)

5 pain practice.jn. (976)

6 or/1-5 (16062)

7 RCT.mp. (11818)

8 randomized control*.mp. (546495)

9 clinical trial*.mp. (845245)

10 or/7-9 (1108405)

11 6 and 10 (3257)

12 (protocol or systematic review or metaanalysis or editorial* or narrative review or case report or cohort stud* or case control or case series or guideline*).ti. (394735)

13 11 not 12 (3067)

14 limit 13 to yr="2005 - 2007" (430)

15 limit 13 to yr="2013 - 2015" (523)

16 14 or 15 (953)