Quality of abstracts of randomized control trials in five top pain journals: A systematic survey

Kamath Sriganesh[a,b], Suparna Bharadwaj[a], Mei Wang[c], Luciana P.F. Abbade[d], Yanling Jin[c], Mariamma Philip[e], Rachel Couban[f], Lawrence Mbuagbaw[c,g], Lehana Thabane[c,g,h,i,j,*]

[a] Department of Neuroanaesthesia, National Institute of Mental Health and Neurosciences, Bangalore, India
[b] Department of Anaesthesia, McMaster University, Hamilton, ON, Canada
[c] Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON, Canada
[d] Department of Dermatology and Radiotherapy, Botucatu Medical School, Universidade Estadual Paulista, UNESP, São Paulo, Brazil
[e] Department of Biostatistics, National Institute of Mental Health and Neurosciences, Bangalore, India
[f] Michael G. DeGroote Institute for Pain Research and Care, McMaster University, Hamilton, ON, Canada
[g] Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare-Hamilton, ON, Canada
[h] Departments of Paediatrics and Anaesthesia, McMaster University, Hamilton, ON, Canada
[i] Centre for Evaluation of Medicine, St Joseph's Healthcare-Hamilton, ON, Canada
[j] Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada

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ABSTRACT

Background: The reporting quality of abstracts of randomized control trials (RCTs) is inadequate despite the publication of consolidated standards of reporting trials extension for abstracts (CONSORT-A). We compared the reporting quality of abstracts in pain journals before and after the publication of CONSORT-A.

Methods: We searched MEDLINE in April-2016 for RCTs published in five pain journals: Pain, Pain Physician, European Journal of Pain, Clinical Journal of Pain and Pain Practice for pre- and post-CONSORT-A period (2005–2007 and 2013–2015). Data were extracted in duplicate from 250 abstracts for compliance with CONSORT-A, and for items known to affect reporting quality: journal endorsement of CONSORT, number of trial centers, sample-size, type of intervention, industry-sponsorship and significance of results. The primary outcome was mean number of items reported and the secondary outcome was the reporting of each item. We used logistic regression and Poisson regression for analyses.

Results: Most trials were single centric (76%), had sample size < 100 (63%), involved pharmacological intervention (59%) and were non-industry funded (70%). The mean number of items reported was better for 2013–2015 (mean difference 0.94; 95% confidence-interval [CI]: 0.50–1.38, p < 0.001). Post-CONSORT-A, trials were more likely to report as randomized in the title (odds ratio (OR) 2.69; 95% CI 1.61–4.49), describe eligibility criteria and settings (OR 2.47; 95% CI 1.35–4.54), provide effect size and precision for primary outcome (OR 2.47; 95% CI 1.19–5.16), inform harms (OR 1.80; 95% CI 1.05–3.07) and report trial registration (OR 5.13; 95% CI 1.44–18.32). Post-CONSORT-A period (incident rate ratio (IRR) 1.15; 95% CI 1.07–1.24), endorsement of CONSORT statement by the journal (IRR 1.08; 95% CI 1.02–1.14), multi-centric studies (IRR 1.14; 95% CI 1.08–1.20), and studies with pharmacological interventions (IRR 1.07; 95% CI 1.02–1.13) were significantly associated with reporting of more items.

Conclusions: Abstract reporting for trials in pain literature was better in the post-CONSORT-A period, but there is room for improvement.

1. Introduction

Pain journals are increasingly publishing RCTs over the last few years. Abstracts of randomized controlled trials (RCTs) are often the first and the only source read by busy physicians [1]. This could be due to non-availability of full-text from lack of paid subscription, non-English language of articles or most commonly, time constraint. Therefore, it is necessary that important details about the trial are transparently and completely provided to the readers to make accurate judgment regarding suitability of applying the trial findings to their

patients. Previous studies have demonstrated that reporting quality is poor among general medical journals [2] and adherence to the consolidated standards of reporting trials extension for abstracts (CONSORT-A) has resulted in some improvements in reporting [5,10]. The CONSORT-A is a 17-item checklist that the authors are expected to adhere to while reporting the abstracts of trials [6]. The quality of reporting of abstracts of RCTs in pain journals and the impact of CONSORT-A on the reporting quality is currently not known. The purpose of this study is to inform pain practitioners and researchers on the current quality of reporting of abstracts in pain journals and how reporting of abstracts of RCTs actually need to be done. To achieve this purpose, we compared the completeness of reporting of abstracts before and after the publication of CONSORT-A in five top pain journals and secondarily, explored the factors that might possibly influence the quality of reporting.

2. Methods

We conducted a thorough search of Medline in April 2016 for abstracts of RCTs published in top five pain journals as determined by the journal citation index report of the Thomson Reuters 2014 [7] for the period 01-01-2005 to 31-12-2007 (pre-CONSORT-A) and 01-01-2013 to 31-12-2015 (post-CONSORT-A). The journals included in the study were Pain, Pain Physician, European Journal of Pain, Clinical Journal of Pain and Pain Practice. Our search strategy and other aspects about the methods are reported in detail in our protocol [12]. Briefly, we included abstracts of RCTs if they were reports of RCTs, published in English language and involved human subjects. We excluded articles if the abstract was not available, if the abstract was published as a conference proceeding, if the trial was still recruiting patients and if it was a duplicate publication. Ethical approval was not obtained as this study was only a systematic survey of the published literature. The sample size for this study was determined based on our hypothesis that there will be significant improvement in the mean number of items reported after the publication of CONSORT-A. The details regarding sample size estimation is described in our protocol [12].

We extracted data regarding adherence to each of the 17 items of the CONSORT-A for both the study periods. Additionally, we obtained information regarding journal endorsement of CONSORT statement, number of centers included in the trial, sample size of the study, type of therapeutic intervention, industry sponsorship and significance of results for the primary outcome from the article full-text to explore and explain the quality of reporting. Both screening of titles and abstracts and full-text review were done independently and in pairs by four reviewers. The agreement between reviewers for inclusion of abstracts was assessed using kappa statistic. Any disagreement was resolved through consensus and if consensus could not be reached, through arbitration by a third author. A pilot exercise was performed before formal data extraction with 10% of the abstracts to improve clarity regarding eligibility criteria and to increase consistency among reviewers.

2.1. Statistical analyses

The characteristics of the included trials were analyzed using descriptive statistics and reported as mean (standard deviation [SD]) or median (first quartile, third quartile) for continuous variables depending on the data distribution and count (percent) for categorical variables. We describe the count (percent) of articles reporting each item by period of publication (2005–2007 vs. 2013–2015). The mean (median) number of items (0–17) reported for each study period and the unadjusted and adjusted mean (median) differences were compared using a two-sample t-test and generalized estimation equations (GEE), respectively and reported with 95% confidence intervals (CIs) and p values. Similarly, the compliance with each of the 17 items of the CONSORT-A for 2005–2007 period were compared with 2013–2015

period using Chi-squared tests and GEE test was used to analyze the data adjusting for confounders. The unadjusted ORs, and 95% CI are reported. Finally, the incidence rate ratios (IRRs) for reporting items for 2013–2015 period was compared with 2005–2007 period using GEE assuming a Poisson distribution and an unstructured correlation matrix. Adjusted IRRs, 95% CIs and p-values are reported. The threshold for statistical significance was set at alpha = 0.05.

For the multivariable analysis using GEE, adjustments were made for 1) journal endorsement of the CONSORT statement, 2) number of trial centers [multiple centers versus single center], 3) type of intervention [pharmacological versus non-pharmacological], 4) sample size [≤ 100 versus > 100], 5) statistical significance for primary outcome of the trial [statistically significant versus not significant] and 6) funding status [industry funded versus others] with journal as a grouping factor. Data was analyzed using Statistical Package for Social Sciences (SPSS) Version 24.0 (SPSS, Inc., 2009, Chicago, Illinois, USA).

3. Results

We retrieved 953 abstracts from our search, 430 in the pre-CONSORT-A period and 523 in the post-CONSORT-A period. We excluded 536 ineligible abstracts; retaining 417 (146 in pre-CONSORT-A and 271 in post-CONSORT-A period) for inclusion. Based on our sample size estimation as described in our protocol [12], we needed 125 abstracts for each period. Hence, we randomly selected 125 abstracts from each period for analysis. The flow diagram demonstrating details of the study process is shown in PRISMA Flow diagram (Fig. 1). We achieved a very high agreement for inclusion of articles between the reviewers; kappa = 0.94 (95% CI = 0.91, 0.96), p < 0.001. Table 1 provides information on the pre-defined study characteristics and description of articles by study period. The mean number of items reported were 6.12 (1.59) and 7.06 (1.93) for pre- and post-CONSORT-A periods respectively. The unadjusted difference by a two-sample t-test was 0.94 (95% CI: 0.50–1.38, p < 0.001) and the adjusted difference by GEE was 0.89 (95% CI: 0.47–1.31, p < 0.001).

We observed statistically significant improvements in completeness of reporting during the post-CONSORT-A period for five of the seventeen items, compared to the pre-CONSORT-A period. More abstracts in the 2013–2015 periods identified the trial as randomized in their titles (OR 2.69; 95% CI 1.61–4.49), reported eligibility for participants and details regarding settings better (OR 2.47; 95% CI 1.35–4.54), provided effect size for primary outcome and it's precision (OR 2.47; 95% CI 1.19–5.16), reported adverse events (OR 1.80; 95% CI 1.05–3.07) and informed about trial registration number and name of the registry (OR 5.13; 95% CI 1.44–18.32) (Table 2). The rest of the items were similarly reported during both the study periods.

After GEE, post-CONSORT-A period (IRR 1.15; 95% CI 1.07–1.24; p < 0.001), endorsement of CONSORT statement by the journal (IRR 1.08; 95% CI 1.02–1.14; p = 0.005), multi-centric studies (IRR 1.14; 95% CI 1.08–1.20; p < 0.001), and studies with pharmacological interventions (IRR 1.07; 95% CI 1.02–1.13; p = 0.014) were significantly associated with reporting of more items. Sample size, statistical significance of the primary outcome and funding status were not associated with number of items reported (Table 3).

4. Discussion

In this study, we observed that the overall reporting quality of abstracts in pain journals was poor and the improvement in the number of items of the CONSORT-A reported was also marginal (6.12 ± 1.59 and 7.06 ± 1.93 for pre- and post-CONSORT-A periods, respectively). We observed improvement for only five of the seventeen items of CONSORT-A for the period 2013–2015 compared to 2005–2007 in our study, while for other items there was no difference between the two time periods studied. In a study evaluating the reporting quality in four high impact factor medical journals two years after the publication of