

# Evaluation of quality of abstracts of randomized controlled trials on procedural sedation in children after publication of CONSORT guidelines for abstracts: A systematic review

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## Abstract

The extension of the Consolidated Standards of Reporting Trials (CONSORT) statement provides guidelines for abstracts of randomized controlled trials (RCTs). This study was done to assess the reporting quality of abstracts of RCTs, on procedural sedation in children and identify factors associated with better quality. A PubMed search was conducted from inception of database till July 2017 to identify RCTs on procedural sedation in children. Search terms used were (procedural [All Fields] AND sedation [All Fields]) AND (“child” [MeSH Terms] OR “child” [All Fields] OR “children” [All Fields]) were included in the analysis, while primary RCTs, published in the English language unstructured abstracts, secondary analysis of primary RCTs and studies not exclusively on children we excluded. Our search strategy initially yielded 582 abstracts. Out of these, 535 abstracts were excluded. 47 articles were included in the final analysis. We extracted basic information and data on CONSORT items from abstracts. Each abstract was assessed using a 16-item composite abstract score (CAS) based on the CONSORT guidelines. This abstract quality was further explored by Method Score and by Result Score. Regression analysis was conducted to analyze factors associated with reporting quality. In majority of the abstracts, only objectives and conclusion were adequately reported. Inadequately reported items in >90% of abstracts included randomization, trial status, registration & funding. There was no significant difference in the CAS of abstracts (mean  $\pm$  SD) published in & before 2008 (12.63  $\pm$  4.0), to those published after 2009 (12.48  $\pm$  4.23). Similarly, there was no significant difference in Result Score and Method Score of the abstracts. After the publication of ‘CONSORT for abstracts’ guideline, the quality of abstracts of RCTs on procedural sedation has shown suboptimal improvement. We suggest stricter adherence to guidelines by editors and reviewers. A checklist for adherence to CONSORT guidelines could be introduced during submission for the same.

**Keywords:** CONSORT guidelines, children, procedural sedation, quality of abstracts

## Introduction


Evidence obtained from high-quality Randomized Controlled Trials (RCTs) is considered the highest level of evidence in medical research, as it eliminates bias and confounding factors. Initial appraisal of quality, utility, internal and external validity

of a clinical trial is often made by clinicians on the basis of its abstract. Browsing through only the abstracts of relevant articles is popular, especially, due to limitations of time, non-availability of the full-text of the articles easily or articles being published in a language, that the reader is non-conversant with. So a structured, well written, transparent, fairly detailed abstract is imperative.

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Literature on procedural sedation in children has witnessed an explosion in recent times, probably due to widespread availability, convenience and perceived safety. More than 500 publications, ranging from those in emergency medicine journals to pediatrics journals to pediatric anesthesia journals are available, on this subject, till date. Needless to say, there is a lot of heterogeneity in the published literature and specialists from numerous specialties have published on this topic. We hypothesized that this study, on a specific topic without any journal restriction will give an insight into broad publication trends.

The consolidated standards of reporting trials (CONSORT) statement, first developed by the CONSORT group in 1996, aimed to provide a minimum framework for standardized reporting of RCTs.<sup>[1]</sup> CONSORT guidelines for reporting RCTs have undergone periodic revisions and the latest guidelines were published in 2011.<sup>[2]</sup> The CONSORT extension for reporting of abstracts, henceforth referred to as “CONSORT (abstract)” was published in 2008. It provides a checklist of 16 items to be reported in an RCT abstract that are necessary for good interpretation of its validity and relevance by readers and hence considered essential for reporting.<sup>[3]</sup>

Previous studies have documented certain factors associated with better quality of reporting of RCT abstracts. These include endorsement of CONSORT (abstract) guidelines by journals,<sup>[4,5]</sup> multi-authorship,<sup>[6]</sup> larger sample size,<sup>[6]</sup> positive outcome,<sup>[6]</sup> multi-centric nature<sup>[7]</sup> and word count of the study.<sup>[8]</sup>

This study was planned with a primary objective of evaluating the reporting quality of abstracts of all published RCTs on procedural sedation in children, as per the CONSORT (abstract) checklist, using a score we created, called Composite Abstract Score (CAS). Our secondary objectives were: (a) to compare the quality of abstracts of RCTs (on procedural sedation in children), in and before the year 2008 (pre-CONSORT), to those published after 2008 when the CONSORT (abstract) guidelines were published (post-CONSORT) and (b) to explore factors associated with better reporting quality of these RCTs.

## Material and Methods

Ethics approval was not sought for this survey as it only involved assessment of previously published information. This systematic review is reported following the “Preferred Reporting Items for Systematic Reviews and Meta-Analyses” (PRISMA) guideline.

## Search strategy

A PubMed/Medline search was conducted from inception of database to 23-07-17, to identify all RCTs, published in English and conducted on human subjects related to procedural sedation in pediatric patients. Search terms used were (procedural [All Fields] AND sedation [All Fields]) AND (“child” [MeSH Terms] OR “child” [All Fields] OR “children” [All Fields]). A study was defined as a RCT if the allocation of participants to interventions was described as random, randomly allocated, randomized, or if the word randomization was mentioned in this reference and if a control group was included. The control group could receive a placebo, usual care, or a comparator. Inclusion criteria was defined as - Primary RCTs, published in the English language. Exclusion criteria were unstructured abstracts, secondary analysis of primary RCTs and studies not exclusively on children. Study eligibility was identified by screening titles and abstracts by two of the three reviewers independently. In case of ambiguity the full text was also screened to determine the eligibility of the study. When there were differences, consensus was reached through discussion and was confirmed by the third researcher.

## Extraction of data

The CONSORT checklist for abstracts, the CONSORT elaboration and explanation guidance document and the examples quoted therein, were used by all the reviewers to assess articles for data extraction.<sup>[9]</sup> All authors underwent training in evaluating RCTs using the CONSORT (abstract) checklist, and the definition of each checklist item was discussed prior to data extraction. An initial trial run involving 10% of the eligible articles was undertaken to improve the clarity regarding inclusions and exclusions and to increase accuracy and inter-observer agreement among the reviewers. Two out of the three authors reviewed each abstract independently. In case of any discrepancy between the two, a common consensus was achieved after discussion with the third author and further evaluation of the full text if required. Data on each of the 16 essential items, as prescribed by the CONSORT (abstract) checklist, was extracted. Extracted data also included descriptive information such as the name and impact factor of the journal, the year of publication, number of authors and their affiliation, region of publication, abstract format (structured or unstructured), sample size, availability of free full text and abstract word count. The region of publication was determined from the address of the first authors’ institution.

## Development of Composite abstract score (CAS), method score and result score

Abstract of each study was scored on the 16 Item “CONSORT (abstract) checklist”, to determine the

Composite Abstract Score (CAS). Because all the items could not be scored in a binary fashion i.e either yes or no, a score of 0,1 or 2 was assigned to each item depending on whether it was not reported, reported inadequately or reported adequately, respectively. Each item was given equal weight and a maximum score of 2. Score of each item on the CONSORT (abstract) checklist was tabulated to obtain the CAS. So, for the 16 item checklist, the maximum CAS was 32, while minimum was 0.

Further, out of these 16 checklist items, 6 items describing the methodology of RCTs (participants and setting, interventions, details of the trial's objectives, primary outcome, methods of randomization, blinding) were tabulated separately as Method Score (Minimum score 0, maximum score 12). Similarly, 5 checklist items describing the results of RCTs (number of participants randomized, trial status, number of participants analyzed in each group, effect of interventions on primary outcomes and adverse outcome) were tabulated as Result Score (Minimum score 0, maximum score 10).

### Analysis

All the data was entered in data extraction forms, followed by Microsoft excel worksheets. For the purpose of this study we created two groups; pre-CONSORT (in or before 2008) and post-CONSORT (2009 onwards) as referred to earlier. The characteristics of the included abstracts were analyzed using descriptive statistics and reported as mean ( $\pm$ SD) for continuous variables and number (percent) for categorical variables. Proportions of reported items in two groups were compared using independent sample Student's *t*-test. Correlation coefficient was calculated for CAS and impact factor, word count and sample size. We also carried out a univariate analysis with CAS, Method Score and Result Score as dependent variables and number of authors, sample size and region of origin as independent variables. Data analysis for descriptive statistics was performed using Microsoft Excel 2007 and SPSS (version 13.0; SPSS, Inc., Chicago, IL, USA). Level of significance was set at  $P < 0.05$ .

### Results

Our search strategy initially yielded 582 abstracts. Out of these, 535 abstracts were excluded as depicted in the PRISMA diagram [Figure 1]. We finally included 47 RCTs on 'Procedural sedation for children' in the analysis.

Characteristics of the included RCT abstracts have been mentioned in Table 1. 46.8% of the eligible abstracts were published in 2008 or earlier (pre-CONSORT) and most of the studies were from USA (48.9%). This was followed by

India (12.77%). Majority of these abstracts were published in Pediatric journals (40.43%) followed by Emergency medicine journals (14.89%). Majority of the articles were published by 4-6 authors (72.34%) in journals with impact factor between 1- 4 (57.45%). Free full text was available for < 15% of the studies. All eligible abstracts were published in English.

### Fulfillment of items on CONSORT (abstract) checklist by the included abstracts

Analysis of fulfillment of the CONSORT (abstract) checklist, as shown in Table 2, revealed that about 46.8% of articles identified their study as 'randomized' in the title, the first point on the checklist. Also, of all the items, 'objectives' (97.9%) and 'conclusions' (100%) were reported clearly almost universally. More than half articles also clearly reported 'interventions' (55.3%), 'blinding' (61.7%) and 'adverse effects' (55.3%). In contrast, less than 20% articles adequately reported the following items: 'trial design' (14.9%), 'randomization' (4.3%), 'trial status' (4.3%), 'number analysed' (17%). Results specific to the 'primary outcome' were reported by only 27.7% of articles. Another observation was that, though 87.2% articles reported 'participants and settings', only 31.9% articles reported them adequately, as mandated by the guidelines. Significantly, only one article reported 'trial registration' and none of them reported 'funding' in the abstracts.

### Comparison of pre-CONSORT and post-CONSORT fulfillment of checklist

On comparing each individual item on the CONSORT (abstract) checklist between pre-CONSORT ( $\leq 2008$ ) and post-CONSORT ( $\geq 2009$ ) groups [Table 2], no statistically significant change was found between the two groups. There were statistically insignificant improvements in reporting of 'title', 'trial

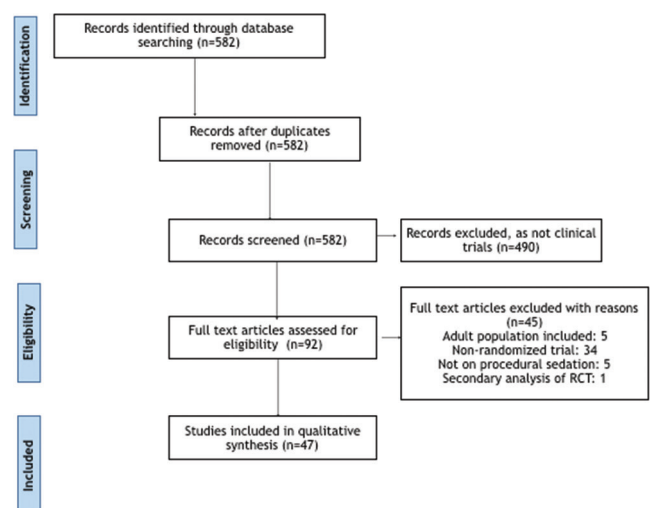


Figure 1: PRISMA diagram showing the results of literature search

design', 'primary outcome', 'randomization' in the Checklist items of Method Score and 'primary outcome' of Result Score, in the post-CONSORT group. However, there was a decline in reporting of 'participants and settings', 'interventions', and 'numbers of patients randomized' and 'analysed' and 'adverse outcome'. Moreover, no significant change was found in the Method Score ( $p$  value 0.47), Result Score ( $p$  value 0.38) and CAS ( $p$  value 0.70) in between the pre-CONSORT and post-CONSORT groups. The characteristics of CAS with Specialty of journal are depicted in Figure 2.

### Exploration of factors influencing the Quality of abstract

There were no identifiable factors influencing the quality of RCT abstracts [Table 3]. Both the groups (Pre-CONSORT and Post-CONSORT) were similar on comparing sample size, no. of authors, full text availability and proportion of studies that were multicentric. However, the number of studies published in high impact factor journals decreased significantly in the post-CONSORT group. Also articles originating in Asia, significantly increased in the latter period. There was no significant correlation between the CAS on one hand and word count ( $p$  value 0.18), sample size ( $P$  value 0.61) or impact factor of the journal in which it was published ( $P$  value 0.76). Further, there was also no correlation between Method Score ( $p$  value 0.57) and Result Score ( $P$  value 0.54) with Impact factor. [Table 4]

### Univariate analysis

We fitted univariate linear models with CAS, Result Score and Method Score as dependent variables and number of study authors, sample size and region of origin, as the independent variables.

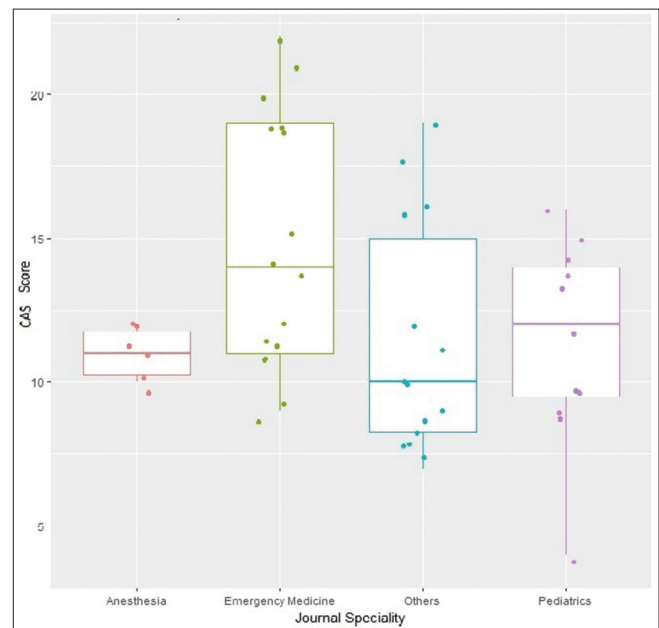
The results obtained on regression analysis have been depicted in Table 5. As we did not find significant results on the univariate analysis, we did not carry out a multivariate analysis.

### Discussion

Uniform and complete reporting of various aspects of the study design, methods and results help the reader to interpret the abstract of an RCT accurately and to make well-informed decisions for better patient care. Poor quality of RCT abstracts can undermine the impact of even a well-planned clinical trial and may be a cause of its exclusion from meta-analyses thus influencing secondary literature as well.<sup>[10]</sup> Poor reporting can result in overestimation of treatment effect and erroneous conclusions.<sup>[11]</sup>

**Table 1: Characteristics of abstracts of RCTs included in the systematic review**

Characteristics	Sub-categories	Number of Studies n, (%)
Year of Publication	2008 & earlier	22 (46.81%)
	2009 onwards	25 (53.19%)
	Total	47 (100%)
Country of origin	USA	23 (48.94%)
	India	6 (12.77%)
	Turkey	3 (6.38%)
	Others	15 (31.9%)
	Total	47 (100%)
Number of authors	3 or less	4 (8.51%)
	4 to 6	34 (72.34%)
	More than 6	9 (19.15%)
	Total	47 (100%)
Specialty of Journal	Paediatrics	19 (40.43%)
	Emergency medicine	7 (14.89%)
	Anaesthesiology	6 (12.77%)
	Others	12 (25.53%)
	Not mentioned	3 (6.38%)
	Total	47 (100%)
Full text availability	Freely available	7 (14.89%)
	Not available	40 (85.11%)
	Total	47 (100%)
Impact factor	< 1	5 (10.64%)
	1 to 4	27 (57.45%)
	4 to 6	12 (25.53%)
	> 6	3 (6.38%)
	Total	47 (100%)



**Figure 2:** Comparison of CAS with journal specialty

The aim of this study was to assess improvement in quality of reporting of abstracts of RCTs on procedural sedation in children after publication of CONSORT guidelines for abstracts in the year 2008.<sup>[3]</sup>

**Table 2: Fulfillment of items on CONSORT (abstract) checklist by the included abstracts in the pre-CONSORT group (n=22) and post-CONSORT group (n=25)**

Checklist item	(n=47) Adequately reported RCTs, (%)	Pre - CONSORT RCTs (n=22) Adequately reported, (%)	Post- CONSORT RCTs (n=25) Adequately reported, (%)	Odds ratio	P
Title	22, (46.8%)	9, (40.9%)	13, (52.0%)	1.55	0.56
Trial design	7, (14.9%)	2, (9.1%)	5, (20.0%)	2.45	0.42
Checklist items included in Method Score					
Participants & settings	15, (31.9%)	9, (40.9%)	6, (24.0%)	0.46	0.35
Interventions	26, (55.3%)	14, (63.6%)	12, (48.0%)	0.53	0.38
Objective	46, (97.9%)	21, (95.5%)	25, (100.0%)	Inf	0.47
Primary Outcome	13, (27.7%)	4, (18.2%)	9, (36.0%)	2.48	0.21
Randomization	2, (4.3%)	0, (0%)	2, (8.0%)	Inf	0.49
Blinding	29, (61.7%)	14, (63.6%)	15, (60.0%)	0.86	1
Checklist items included in Result Score					
Numbers randomised	17, (36.2%)	10, (45.5%)	7, (28.0%)	0.47	0.24
Trial Status	2, (4.3%)	1, (4.5%)	1, (4.0%)	0.87	1
Numbers analysed	8, (17%)	5, (22.7%)	3, (12.0%)	0.47	0.45
Primary outcome	13, (27.7%)	4, (18.2%)	9, (36.0%)	2.48	0.21
Adverse outcomes	26, (55.3%)	13, (59.1%)	13, (52.0%)	0.75	0.77
Conclusions	47, (100%)	22, (100%)	25, (100%)	0	0.47
Trial registration	1, (2.1%)	1, (4.5%)	0, (0.0%)	0	0.47
Funding	0, (0%)	0, (0%)	0, (0.0%)	0	N. A.
Method Score (Mean±SD)	-	5.31±3.15	6.4±2.53	-	0.4782
Result Score (Mean±SD)	-	3.09±1.99	2.64±2.11	-	0.388
CAS (Mean±SD)	-	12.63±4.0	12.48±4.23	-	0.7077

Inf=Infinity

**Table 3: Evaluation of abstracts of RCTs in Pre and Post- CONSORT group**

Factor	Groups	pre-CONSORT RCTs (n=22) Number (%)	Post -CONSORT RCTs (n=25) Number (%)	Total RCTs	P
Sample size	<100	13 (59.09%)	17 (68%)	30	Reference
	>100	9 (40.9%)	8 (32%)	17	0.558
Impact factor	<5	10 (45.45%)	22 (88%)	32	Reference
	5-10	11 (50%)	3 (12%)	14	0.004*
	>10	1 (4.54%)	0 (0%)	1	0.333
Number of authors	<4	3 (13.63%)	1 (4%)	4	Reference
	4-6	16 (72.72%)	18 (72%)	34	0.604
	>6	3 (13.63%)	6 (24%)	9	0.266
Full text availability	Yes	4 (18.18%)	3 (12%)	7	Reference
	No	18 (81.81%)	22 (88%)	30	0.690
Multicentric	Yes	0 (0%)	2 (8%)	2	Reference
	No	22 (100%)	23 (92%)	45	0.491
Region	North America	14 (63.63%)	12 (48%)	26	Reference
	Europe	4 (18.18%)	5 (20%)	9	0.711
	Asia	1 (4.54%)	7 (28%)	8	0.053*
	others	3 (13.63%)	1 (4%)	4	0.613

\*p&lt;0.05

There has been an exponential increase in volume of research activity on this topic [Table 1]. 47% of eligible RCTs were published since inception of database to 2008 while 53% were published in a shorter period of time from 2009-2017. Maximum eligible RCTs originated in the USA in line with global publication trends. Full text of RCTs were not freely available for 85.1% of the eligible

studies underscoring the importance of complete and detailed abstracts [Table 1].

On the basis of the study data, the quality of reporting of RCT abstracts on procedural sedation in children is overall poor and has not improved after publication of CONSORT guidelines [Table 2].

**Table 4: A Correlation of Word count, Sample size and Impact factor with CAS and with other Scores (Results Score and Method Scores)**

Items correlated	Correlation coefficient	P
Word count and CAS	0.2	0.1873
Sample size and CAS	0.076	0.6109
Impact factor and CAS	-0.045	0.7617
Impact factor and Results Scores	0.091	0.5412
Impact factor and Method Score	-0.083	0.5789

**Table 5: Univariate analysis**

	Method Score		Result Score		CAS	
	RC*	P	RC*	P	RC*	P
Number of authors	0.428	0.134	-0.239	0.245	0.053	0.898
Sample size	0.001	0.715	0.0003	0.763	0.001	0.611
Word count	0.006	0.274	0.003	0.5353	0.011	0.187
Impact factor	0.043	0.713	0.0982	0.242	0.217	0.191
Year of publication	-1.082	0.199	0.004	0.943	0.137	0.160

\*RC=Regression Coefficient

The CAS was similar,  $12.63 \pm 4.0$  (mean  $\pm$  SD) and  $12.48 \pm 4.23$  (mean  $\pm$  SD) in the pre and post-CONSORT period respectively [Table 2]. Similarly, there was no improvement in Result Score which was  $3.09 \pm 1.99$  and  $2.64 \pm 2.11$  in the pre and post-CONSORT period respectively. There was however, a small improvement in the Method Score from  $5.31 \pm 3.15$  in the pre-CONSORT period to  $6.4 \pm 2.53$  in the post-CONSORT period.

On analysis of compliance to CONSORT (abstract) checklist it was found that percentage of articles referring to their study as 'randomized' in their title increased from 40.9% to 52% in the post-CONSORT period. This increase was, however, not statistically significant. Similarly, description of the 'trial design' improved from 9.1% to 20% but this improvement was also not significant statistically. Such poor improvement of the first two points on the CONSORT (abstract) checklist, which are the easiest points to include, indicates poor awareness of the guidelines among researchers and poor compliance by journals and editors.

On evaluating the CONSORT (abstract) checklist points, related to study methodology (Method Score), we found that 'objectives' of the study were clearly defined in both the pre and post-CONSORT period. However, there was a major lacuna in describing the items 'outcomes' and 'randomization'. [Table 2].

Similarly, the CONSORT (abstract) checklist points, related to results (Result Score), almost all components were poorly described including number of 'patients randomized' and 'analysed' as well as 'outcomes' [Table 2].

None of the abstracts reported 'funding' in any of the study periods or reported 'trial status' in the post-CONSORT group. A clear conclusion was, however, almost universally indicated in all RCTs.

Analysis of published literature reveals heterogeneous results. Few studies have reported small improvement of quality of reporting after publication of guidelines.<sup>[12]</sup> However, majority of studies have reported marginal improvement or no improvement of quality of reporting after publication of guidelines.<sup>[13-16]</sup>

Can *et al.* in a study involving 527 RCT abstracts found that reporting of only two items improved significantly (blinding and harmful effects). Overall they reported a mere 2.4% point improvement in items complying with the guidelines and they concluded that the adherence to the guidelines remained poor.<sup>[13]</sup> Our findings were similar to theirs. Similarly, Ghimire *et al.* in a study of 271 RCT abstracts from four high-impact general medical journals (*NEJM*, *Lancet*, *JAMA* and *BMJ*) reported marginal improvement in the reporting quality of RCT abstracts after publication of the CONSORT abstract guidelines.<sup>[14]</sup> This has been the case despite structured efforts like the establishment of the Enhancing the Quality and Transparency of health research (Equator) network.<sup>[17]</sup>

Cause of lack of tangible results despite structured efforts appears to be multifactorial. Authors have cited non endorsement of guidelines by editors and journals, lack of awareness of publication ethics, to name a few. It has been seen that endorsement of CONSORT guidelines leads to better quality of reporting of RCT abstracts.<sup>[18-20]</sup>

Though it is recommended that abstracts be structured,<sup>[21]</sup> it has not been incorporated in the CONSORT checklist. We recommend that the use of structuring be added to the CONSORT (abstract) checklist. Also journal editors should ensure that their 'Instructions to Authors' includes a reference to the appropriate guidelines. They could also ensure that authors fill and submit an appropriate checklist along with the manuscript so as to enforce adherence to the prescribed guidelines.

### Limitations of this study

Though we tried to ensure a high degree of inter-reviewer agreement while scoring the abstracts, we did not quantify it objectively. Low quality of abstract does not necessarily mean study is methodologically weak. Therefore we cannot draw conclusions regarding quality of RCTs as a whole by only analyzing the abstracts. Journals were represented by a few articles and hence limit the ability to assess the quality of

abstracts of the journals as a whole. Also we have compared the RCTs published upto 2008 to those after 2008. However, as the CONSORT abstract guidelines were published in the year 2008, it would have taken a few months for them to be disseminated widely which is likely to take some time to be reflected in the published literature.

### Strengths of this study

This study provides a snapshot of publication trends on this topic across a spectrum of journals belonging to different specialities thus highlighting the endemic nature of the problem of incomplete reporting of RCT abstracts.

### Conclusion

To conclude, our study reinforces the fact that the publication of the CONSORT guidelines for abstracts has not translated into better abstract reporting. Sustained efforts are required to ameliorate this problem.

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### Conflicts of interest

There are no conflicts of interest.

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