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Are randomised controlled trials involving adenotonsillectomy well reported?

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ABSTRACT

Introduction: Evidence-based medicine guides clinical practice. Currently, the evidence base on adenotonsillectomy is under scrutiny to establish clinical guidelines. It is therefore important that reports of clinical trials are of high quality. Guidance on reporting of randomised controlled trials (RCTs) are available in the Consolidated Standards for Reporting Trials (CONSORT) statement first published in 1996 and revised in 2001 and 2010.

Methods: A review of randomised controlled trials on adenotonsillectomy published after 2001 was undertaken. Each report was systematically assessed using the checklist of items from the CONSORT statement.

Results: Twenty-five trials were identified. All trials, except one, were identified as a randomised controlled trial by title or abstract. Twenty percent of trials reported a sample size calculation. A third of trials reported their method of generating a random allocation sequence. Similarly, a third stated the method of implementing the random allocation. A fifth of trials reported a clear flow of trial participants, with only a single trial reporting this with the aid of a diagram.

Conclusion: This review shows the quality of reporting needs to be improved. Critical appraisal of poorly reported trials may result in erroneous conclusions, even though these trials may have been carried out with rigorous adherence to a protocol of high standard. Authors of clinical trial reports should be encouraged to consult the CONSORT statement.

1. Introduction

Evidence based medicine was introduced over a decade ago and its premise is the integration of the best available evidence, clinical judgment and patient values in making clinical decisions [1]. The findings from randomised controlled trials are one of the best sources of evidence to support clinical management plans [2]. It is therefore imperative that reports of randomised controlled trials provide comprehensive and detailed information on such trials. This ensures the readership of these reports can accurately critique the trial methodology and results and assess its quality before accepting or refuting the conclusions drawn from the trial.

The quality of reporting of randomised controlled trials can be assessed using various tools [3,4]. One of these is the CONSORT statement [2]. It is a document that was first drawn up in Ottawa, Canada by an expert panel and published in 1996. It comprised a checklist of items that if omitted from a trial report could lead to biased estimates of the effects of the intervention under investigation. The CONSORT statement underwent further revisions in 2001 and 2010 and is currently a 25-item checklist and flow diagram stating the minimum set of recommendations of reporting of trials.

Adenotonsillectomy is one of the commonest operative procedures undertaken by ENT Surgeons [5]. It is a procedure undertaken for various indications that continues to accrue evidence on the best technique as well as the prevention and management of the associated complications. These trials provide the basis for guiding clinical practice and establishing guidelines.

The aim of this study is to assess the quality of reports of randomised controlled trials published involving adenotonsillectomy.

2. Method

A database search of Pubmed was undertaken to identify randomised controlled trials published from 2001. To maximise the number of papers included in our study we chose 2001 as the earliest date of publication in line with the date of introduction of the revised CONSORT statement. Using 2010 as the cut-off date in line with the 2010 revised CONSORT statement would have resulted in the identification of only a small number of trial reports. The terms used were: adeontonsillectomy and tonsillectomy in conjunction with the Pubmed filter for randomised controlled trials. The search was limited to English language articles.

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Table 1
Adherence of trials to the CONSORT checklists' individual items.

Section/topic	Item No	Checklist item	Score (%)
Title and Abstract	1a	Identification as a randomised trial in the title	10 (40%)
	1b	Structured summary of trial design, methods, results, and conclusions	25 (100%)
Introduction			
	2a	Scientific background and explanation of rationale	25 (100%)
	2b	Specific objectives or hypotheses	25 (100%)
Methods			
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3 (12%)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	1 (4%)
	4a	Eligibility criteria for participants	25 (100%)
	4b	Settings and locations where the data were collected	25 (100%)
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	25 (100%)
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	17 (68%)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	1 (0.04%)
	7a	How sample size was determined	5 (20%)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
	8a	Method used to generate the random allocation sequence	8 (32%)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5 (20%)
	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8 (32%)
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4 (16%)
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6 (24%)
	11b	If relevant, description of the similarity of interventions	0
	12a	Statistical methods used to compare groups for primary and secondary outcomes	22 (88%)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	1 (4%)
Results			
	13a	For each of group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	24 (96%)
	13b	For each group, losses and exclusions after randomisation, together with reasons	0
	14a	Dates defining the periods of recruitment and follow-up	22 (88%)
	14b	Why the trial ended or was stopped	1 (4%)
	15	A table showing baseline demographic and clinical characteristics for each group	15 (60%)
	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17 (68%)
	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17 (68%)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	0
	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	2 (8%)
	19	All important harms or unintended effects in each group	19 (76%)
Discussion			
	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11 (44%)
	21	Generalisability (external validity, applicability) of the trial findings	25 (100%)
	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	25 (100%)
Other Information			
	23	Registration number and name of trial registry	0
	24	Where the full trial protocol can be accessed, if available	0
	25	Sources of funding and other support (such as supply of drugs), role of funders	7 (28%)

The checklist of items from the CONSORT statement 2010 was used as the gold standard against which the quality of reporting of these trials was assessed.

3. Results

3.1. Search results

118 papers were identified. The abstracts were screened and 93 trials were excluded. 25 papers were included in this study [6–30].

A summary of the reporting from each trial for each item of the CONSORT checklist is presented in Table 1.

Chart 1 shows the percentage adherence of individual trial reports to the CONSORT statement, this ranges from 35 to 80%. This score was obtained after excluding those items from the checklist that were irrelevant to each trial report.

4. Discussion

Good reporting of RCTs is essential for validity assessment [31]. One is able to replicate the structure of the trial in order to establish what has and has not been done. Inadequate reporting may be at fault rather than poor trial design, conduct or analysis, but this can only be rectified by raising the standards of trial reporting.

In our study, we found that no single trial fulfilled all the CONSORT criteria. Very few sections of the CONSORT checklist were completed well, these included some of the items in all sections of the checklist. Chart 1 shows that the 'best CONSORT score' for any trial report was 80%. Just under half of trials obtained