A cross-sectional study of the reporting quality of pilot or feasibility trials in high-impact anesthesia journals

Étude transversale sur les rapports d'études pilotes et d'études de faisabilité dans les journaux d'anesthésie à facteur d'impact élevé

Harsha Shanthanna, MD, MSc · Alka Kaushal, MBBS · Lawrence Mbuagbaw, PhD · Rachel Couban, MSc · Jason Busse, PhD · Lehana Thabane, PhD

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Abstract

Purpose Pilot trials inform the design and conduct of larger scale trials. Using the Consolidated Standards of Reporting Trials (CONSORT) pilot extension guidelines, we assessed reporting quality in five high-impact anesthesia journals and explored factors associated with reporting quality.

Methods The five highest-impact anesthesia journals were screened for randomized-controlled trials published as pilot or feasibility trials between 2006 and 2016. A pair of reviewers independently screened citations, extracted data, and assessed reporting quality using the CONSORT pilot trial extension checklists for abstracts and full texts. We reported the percentage adherence for each item, along with the median [interquartile range (IQR)] or mean (standard deviation [SD]) for all items. The factors considered to influence reporting were: 1) trial registration, 2) industry funding, 3) trial identification as

a pilot or feasibility in the title or abstract, 4) primary objective as “feasibility”, and 5) the specific journal. The association was estimated using generalized estimating equations and reported as incidence rate ratios with 99% confidence intervals.

Results Of 364 citations, 58 articles were eligible. The median [IQR] number of CONSORT abstract items reported was 5 [4–7], and the mean (SD) number of full text items reported was 13 (5). Significantly poor reporting was associated with “not registering the trial” (both abstracts and full texts), “trial not identified as a pilot” (abstracts), and “using clinical hypothesis as the primary objective” (full texts).

Conclusion The reporting quality of pilot trials published in leading anesthesia journals is poor. Journal editorial boards can encourage improved reporting by supporting adherence to the CONSORT extension for pilot trials.

Résumé

Objectif Les études pilotes renseignent sur la conception et la réalisation d'essais à plus grande échelle. Nous avons utilisé les lignes directrices sur l'extension aux études pilotes du regroupement des normes relatives aux rapports d'étude (CONSORT) pour évaluer la qualité des rapports dans cinq journaux d'anesthésie à fort impact et explorer les facteurs associés à la qualité des rapports.

Méthodes Nous avons recherché les publications d'essais contrôlés randomisés d'études pilotes ou de faisabilité dans les cinq journaux d'anesthésie ayant les facteurs d'impact les plus élevés entre 2006 et 2016. Deux réviseurs indépendants ont examiné les citations et les données extraites; ils ont évalué la qualité des rapports (résumés et textes complets) en utilisant les listes de vérification CONSORT pour l'extension aux études pilotes. Nous

H. Shanthanna, MD, MSc (✉) · L. Thabane, PhD
Department of Anesthesia, St. Joseph's Healthcare Hamilton,
McMaster University, 50 Charlton Avenue East, Hamilton, ON
L8N 4A6, Canada
e-mail: shanthhh@mcmaster.ca

H. Shanthanna, MD, MSc · A. Kaushal, MBBS · L. Mbuagbaw,
PhD · J. Busse, PhD · L. Thabane, PhD
Department of Health Research Methods, Evidence, and Impact,
McMaster University, Hamilton, ON, Canada

A. Kaushal, MBBS · R. Couban, MSc · J. Busse, PhD
The Michael G. DeGroote Institute for Pain Research and Care,
McMaster University, Hamilton, ON, Canada

L. Mbuagbaw, PhD · L. Thabane, PhD
Biostatistics Unit, St Joseph's Healthcare, Hamilton, ON,
Canada

avons fourni le pourcentage d'adhésion à chaque critère avec les valeurs médianes (écart interquartile [EIQ]) ou moyennes (écart-type [ET]) pour tous les critères. Les facteurs qui ont été considérés comme influençant les rapports étaient les suivants : 1) l'enregistrement de l'étude, 2) le financement par l'industrie, 3) l'identification de l'essai en tant qu'étude pilote ou de faisabilité dans son titre, 4) l'objectif principal indiquant « faisabilité », et 5) le journal dans lequel paraît la publication. L'association a été estimée au moyen d'équations d'estimation généralisée et décrite sous forme d'incidences avec des intervalles de confiance à 99 %.

Résultats Sur 364 références, 58 articles ont été retenus. Le nombre médian (EIQ) de critères dans les résumés CONSORT rapportés était de 5 (4 à 7) et le nombre moyen (ET) de critères rapportés dans les textes complets était de 13 (5). Un rapport de qualité significativement médiocre était associé au « non-enregistrement de l'essai » (pour les résumés comme pour les textes complets), à la « non-identification de l'essai en tant qu'étude pilote » (résumés) et à « l'utilisation d'une hypothèse clinique comme objectif principal » (textes complets).

Conclusion La qualité des rapports des études pilotes publiés dans les principaux journaux d'anesthésie est médiocre. Les Comités éditoriaux des journaux peuvent encourager l'amélioration des rapports en soutenant l'adhésion aux critères CONSORT d'extension aux études pilotes.

Pilot trials are considered preliminary studies performed to inform methodologic considerations to design a subsequent study that is larger and confirmatory.^{1,2} Most consider a pilot study to be a feasibility test of the methods and procedures¹⁻³ and as such do not address clinical efficacy.⁴ Accurate, transparent, and consistent reporting indicates scientific integrity and minimizes the potential for bias and distortion of effect estimates associated with incomplete reporting. The Consolidated Standards of Reporting Trials (CONSORT) framework was introduced to improve reporting of randomized-control trials (RCTs).⁵ Nevertheless, an assessment of reporting in anesthesia literature, comparing before and after CONSORT implementation, did not show much improvement.⁶ It is essential that pilot studies are reported to avoid redundancy to make appropriate use of resources and funds and to allow the possibility of including the results in an appropriate meta-analysis.^{7,8} Despite the relative increase in their publication,⁹ their reporting quality is often poor.⁷ In response, a framework for reporting pilot studies based

on the CONSORT statement was developed and published in 2016.¹⁰ This includes separate guidance statements and checklists for the abstract (16 items) and full text of the manuscript (26 items). As suggested, for the purposes of this study, “pilot” and “feasibility” will be used interchangeably and the included studies will be referred to as pilot trials. To assess standards of reporting, previous studies have looked at adherence to CONSORT RCT guidelines,¹¹ and some have explored predictive factors.¹²⁻¹⁴ Since no studies have evaluated the reporting standards of pilot trials in the anesthesia literature, we decided to look at studies published between 2006 and 2016 (prior to the CONSORT pilot trial extension) and evaluate their reporting in reference to the CONSORT pilot trial extension checklists for abstracts and full texts. Our objectives were to assess the reporting quality of 1) abstracts and 2) full texts in five leading anesthesia journals and explore potential factors associated with reporting quality.

Methods

This is a cross-sectional study of pilot trials published in leading anesthesia journals. This manuscript adheres to the STROBE statement and checklist for cross-sectional studies.

Study screening and selection

We identified the top five highest impact journals in the field of anesthesiology and pain according to the 2015 journal citation reports.¹⁵ The impact factor (IF) refers to an index number assigned and calculated by Thomson Reuters as the number of citations received in a specific year for articles published in that journal during the two preceding years divided by the total number of articles published in that journal during the two preceding years.¹⁶ Our search strategy was designed by an experienced librarian (R.C.) using the OVID platform and was guided by the terms “pilot”, “feasibility”, or “preliminary” studies (Appendix 1). The initial search was performed on 6 October 2016 to look for studies published from 2012 to 2016 (last five years). Since our first search potentially led to only 38 full-text articles, we expanded our search on 26 October 2016 to expand the search to include articles from the last ten years. We included all pilot trials that were designed to assess the feasibility, safety, or acceptability of an intervention and that included a randomization procedure. We excluded trials on animals and pharmacokinetic studies. No language exclusion criterion was applied. For our review, study selection based on the term “feasibility” was challenging. In

general, the term “feasibility” reflects the “ease” or “possibility” of either an intervention or method. For example, we had to separate studies that were aimed at looking at the ease of ultrasound use for injection or visualization or time taken with a fiberoptic bronchoscope compared with other methods of intubation. Such studies were excluded as they were not expected to lead to a subsequent larger trial. The study selection process was carried out in duplicate by two independent reviewers (A.K. and H.S.), both trained in health research methods. The title and abstract screening was conducted using a free online software, “rayyan” (<https://rayyan.qcri.org/>). The full-text screening was done independently and in duplicate. The agreement on full-text screening was reported using a kappa (k) statistic and interpreted as poor if $k \leq 0.2$, fair if $0.21 \leq k \leq 0.4$, moderate if $0.41 \leq k \leq 0.6$, substantial if $0.61 \leq k \leq 0.8$, and good if $k > 0.8$.¹⁷ Disagreement was resolved by consensus or arbitration by a third reviewer (L.M.).

Data abstraction

Data abstraction was carried out by two independent reviewers (A.K. and H.S.) using extraction forms created in Microsoft Excel, 2016 (Microsoft, Redmond, WA, USA). Extracted items included the study characteristics; reason for identifying a study as a pilot trial; study conclusion as feasible, not feasible, or unclear; and CONSORT reporting items separately for the abstract and full text, as guided by the recently published CONSORT pilot trial extension statement.¹⁰ Reviewers were provided with clear and explicit rules to judge each CONSORT item as either “reported” or “not reported” (Appendix 3). All items with sub-items were collapsed into a single item allowing for a single decision to be made as “reported” or “not reported” for each item. The extraction forms were piloted to ensure consistency until an agreement score of $k > 0.8$ was achieved for at least three consecutive studies. The total number of items assessed for abstracts was 15; the item “recruitment” was not considered as it was relevant only to conference abstracts.¹⁰ The total number of items assessed for full texts was 24; the items “ancillary analyses (results of any other analyses performed that could be used to inform the future definitive trial)” and “trial protocol (where the pilot trial protocol can be accessed, if available)” were omitted from the total items as they were optional and difficult to judge.

Study outcomes

Our primary outcomes were to assess the reporting quality of 1) abstracts and 2) full texts using the CONSORT

extension for pilot trials and secondarily as explored factors associated with reporting quality.

Predictor variables

Apart from including the following four variables as either present or absent in all studies—1) industry funding; 2) clinical trial registration as a pilot trial; 3) primary outcome or objective as a feasibility outcome or objective; 4) trial identified as either “pilot” or “feasibility” in either its title and/or abstract—we considered the journal name as a grouping factor. We hypothesized that not registering the trial as a pilot trial, not reporting the feasibility target as a primary objective or outcome, and not identifying the trial as a pilot trial in its title and/or abstract would be associated with poor reporting quality. Information on industry funding was considered when it was identified with any part of study reporting. For registration, we checked whether each trial was registered within ClinicalTrials.gov or the International Clinical Trials Registry Platform (ICTRP)-World Health Organization registry. Further, whenever registered we also checked whether they were in fact registered as a pilot or feasibility trial and if there were any amendments to that effect. We hypothesized that a higher journal impact factor and industry funding would be associated with better reporting quality.

Statistical analysis

Important study characteristics were tabulated along with their reported frequencies and percentages. For continuous outcomes, mean (SD) or median [interquartile range (IQR)], was reported. Categorical data, such as the number of studies reporting a particular item, were reported as counts and percentages. All included trials were assessed for completeness of CONSORT items reporting (abstract = 15 and full text = 24). Normality of the distribution was tested using the Kolmogorov-Smirnov (KS) test (at a significance of $P < 0.05$) and visual inspection of Q-Q plots.

Individual abstract and full-text items, and their percentage reporting across studies, were represented with bar diagrams. We explored the association of predictive factors with the total number of CONSORT-recommended abstract and full-text items reported using a generalized estimating equations model. Our exploratory variables included four categorical variables and the specific journal (grouping factor). The articles from each journal can be clustered and correlated because of the journal policy, word limitations, and other publication considerations. Nevertheless, since we do not know the structure of this correlation, we assumed the working

correlation matrix as unstructured, with the covariance matrix for the robust estimator and not the model-based estimator. With a generalized linear modelling (genlin), we used the Poisson log-linear function after checking for Poisson distribution, by KS test (at a significance of $P \leq 0.05$) for Poisson distribution, and also comparing the mean and variance of the dependent variables. Under the model, we considered the above-specified covariates and looked for main effects. Under parameter estimation, we used a hybrid method with Fisher (1): scale = 1, maximum iterations = 100 and maximum step-halving = 5, and parameter convergence = 1E-006 (absolute). Under statistics, we looked for analysis type III for Wald Chi-square statistics with a confidence interval (CI) specified at 99% and full log quasi-likelihood function. Although we had more than five counts (dependent variable) per covariate, there is potential for a false discovery rate, so we considered significance at alpha (α) ≤ 0.01 and estimated the incidence rate ratios (IRR), along with their 99% CI. We explored variance inflation factors (VIFs), with a threshold of 10, to assess collinearity between predictors.¹⁸ Microsoft Excel 2016 and IBM SPSS 24.0.0.0 (2016; IBM Corporation, Armonk, NY, USA) were used to perform the statistical analysis.

Sample size

We did not estimate the actual sample size required. To get a fairly unbiased estimate we decided to obtain at least 50 studies as a convenience sample.

Results

The five highest-impact anesthesia journals identified as per the 2015 journal citation reports (ranked from higher to lower) were British Journal of Anaesthesia (BJA), Pain, Anesthesiology, Anesthesia & Analgesia (AA), and Anaesthesia; IFs ranged from 5.61 to 3.79. Our search identified a total of 364 potential citations, of which 83 were selected for full-text review and 58 were eligible for data extraction (Fig. 1). The reviewers agreed on 79 of the 83 articles leading to a kappa of 0.91 (95% CI, 0.81% to 1.00). Of 58 articles, three were published as letters to editors¹⁹⁻²¹ and the rest as original articles. Important study characteristics are highlighted in Table 1. Two of the five journals (BJA and AA) contributed 62% of the included articles. The median [IQR] sample size was 43 (30-76). In 42 studies (72%) the rationale for reporting the study as pilot or feasibility was unclear or not provided (Table 1).

Primary outcomes

CONSORT ABSTRACT REPORTING

We considered a total of 55 articles for the reporting quality of abstracts (by excluding the three trials reported as letters). Tests for normality indicated that they were not normally distributed. The median [IQR] number of items reported was 5 [4-7]. All CONSORT recommended items except four (trial design, participants, intervention, and randomization) were reported in less than 40% of studies (Fig. 2). “Trial funding” was observed to be the least commonly reported item. For CONSORT full-text reporting, we included all 58 articles for assessment. The reporting of CONSORT items was normally distributed (KS test significance 0.200) with a mean (SD) of 13 (5). Among CONSORT items, we observed that “ethical approval” was the most commonly reported item, while “title and abstract” was the least commonly reported (Fig. 3). Reporting of individual studies is provided in Appendix 2.

Secondary outcomes (Table 2)

None of the VIFs were > 10 in our regression models, suggesting no major collinearity among independent factors. The IRR is interpreted similarly to the odds ratio.²² For example, an IRR of 1.0 for “trial registration” would mean there is no difference in reporting, whereas > 1 would mean there is increased odds of better reporting with trial registration. For CONSORT abstract reporting, our regression analysis showed that “not registering the trial as a pilot trial” (IRR, 0.68; 99% CI, 0.54 to 0.87; $P < 0.001$) and “not identifying it as a pilot trial in the title or abstract” (IRR, 0.69; 99% CI, 0.54 to 0.89; $P < 0.001$) were significantly associated with poor reporting quality. For CONSORT full-text reporting, “not registering the trial as a pilot trial” (IRR, 0.67; 99% CI, 0.54 to 0.82; $P < 0.001$) and “using clinical hypothesis testing as the primary objective and/or outcome” (IRR, 0.77; 99% CI, 0.63 to 0.93; $P = 0.001$) were significantly associated with poor reporting quality (Table 2).

Discussion

Summary of findings

We found that the reporting quality of pilot trials is poor for both the abstract and full text or reports published in leading anesthesia journals. For abstracts, the median [IQR] items reported was 5 [4-7], and for full texts the mean (SD) items reported was 13 (5). A significant association of poor reporting was observed with “not

Fig. 1 Study flow chart

registering as a pilot trial” and “not identifying as a pilot trial in their title or abstract” and with “not registering as a pilot trial” and “reporting clinical hypothesis testing as the primary outcome/objective” for abstracts and full texts, respectively.

To measure the quality of reporting of published RCTs, the CONSORT RCT statement and its checklist have been widely used.²³ All journals included in this study do endorse CONSORT guidelines as per the CONSORT website.²⁴ A recent study looking at the top 11 anesthesia journals and their CONSORT adherence of all items among 319 RCTs reported a median [IQR] compliance rate of 60% [22.9–88.9%]. They also observed a weak correlation between adherence to CONSORT items and the number of citations.²⁵ Similar observations have been made in other studies in general medical journals²⁶ and specialty journals.²⁷ While previous studies have evaluated specific elements of reporting, the present study uses the entire CONSORT pilot extension statement and checklists

to assess the reporting quality of pilot trials. Outside of anesthesia, other published studies on pilot trials have only looked at specific items of pilot study reporting. Arian *et al.* studied pilot trial reporting in seven major medical journals published between 2007–2008.⁴ Out of 54 studies, 26 were studies of interventions, of which 86% incorporated hypothesis testing and 62% included randomization. Shanyinde *et al.* looked at a sample of 50 pilot trials among 3,652 publications of pilot RCTs identified within the MEDLINE and EMBASE databases between 2000–2009. Only 56% articles discussed adequate methodologic issues and only 18% discussed future trials.⁹

In our study, items such as “title and abstract”, “background and objectives”, “outcomes”, and “statistical methods” were observed to be appropriately reported in < 20% of studies, as the majority focused on hypothesis testing as their primary outcome (Fig. 3). Duffett *et al.* studied pilot RCTs published in pediatric critical care literature and found only 32 trials up to July 2014. They

Table 1 Characteristics of included studies ($n = 58$)

Years published	2007-2016
Number of articles in each journal [IF] ($n = 58$)	British Journal of Anaesthesia [IF: 5.61], $n = 20$ (34.5%) Pain [IF: 5.55], $n = 10$ (17.2%) Anesthesiology [IF: 5.55], $n = 7$ (12.1%) Anesthesia and Analgesia [IF: 3.82], $n = 16$ (27.6%) Anaesthesia [IF: 3.79], $n = 5$ (8.6%)
Main topic addressed among studies ($n = 58$)	Anesthesia = 36 (62%) Chronic pain = 13 (22%) Others = 9 (16%)
Sample size among the included trials ($n = 58$)	Median [IQR] = 43 [30-76]
Studies categorized based on their study design ($n = 58$)	Parallel arm RCT = 49 (84%) Crossover RCT = 8 (14%) Cluster RCT = 1 (2%)
Studies providing appropriate rationale for pilot study (as feasibility, proof concept, or phase 2) ($n = 58$)	Provided = 14 (24%)
Studies categorized based on number of centres ($n = 58$)	Single centre = 51 (88%) Multiple centres = 7 (12%)
Industry funding among studies reporting funding ($n = 49$)	Yes = 10 (17.2%)
Studies with pilot or feasibility indicated in title or abstract ($n = 58$)	Yes = 49 (84.5%)
Studies with primary objective or primary outcome as clinical hypothesis testing ($n = 58$)	Yes = 48 (82.8%)
Studies with trial registration as pilot or feasibility study ($n = 58$)	Yes = 20 (34.5%)
Did the results suggest feasibility for a full trial? ($n = 58$)	Unclear = 40 (69%) Feasible = 17 (29%) Modification to methods required = 1 (2%)

IF = impact factor; IQR = interquartile range; RCT = randomized-controlled trial

also observed that the majority of those trials focused on clinical outcomes and uncommonly reported explicit feasibility outcomes.²⁸ This finding is similar to our study, wherein we also observed a significant association of poor reporting when a clinical hypothesis was tested as their primary outcome. Possibly as a consequence of misdirected objectives, we also observed that 40/58 trials were rated as “unclear” for their conclusions on the feasibility of a larger study (Table 1).

In our study, poor reporting was associated with “not registering the trial as a pilot”. Registration improves the quality of reporting and makes the trial information publicly available, thereby making the authors accountable, and helps to reduce publication bias and selective reporting.^{29,30} It has been observed that registered trials tend to have a low risk of bias for random sequence generation, allocation concealment, and selective reporting, but not blinding or incomplete outcome data.³¹ Nine trials did not identify their study as a pilot in either their title or abstract. As the title and abstract are the items freely accessible to readers, it is important to be as explicit as possible. For example, Bakri *et al.* noted their trial to be pilot only in their discussion section.³² A clear rationale to identify as a pilot trial was unavailable in 76% of the trials

(Table 2). We also think it is possible that many were identified so because of the small sample size. It is important that one distinguishes between a small-sized trial, whose estimate of effect can have a large boundary of CI and hence uncertainty, from a pilot study (large or small is relative) that should be powered or conducted to test the study methods and not the clinical hypothesis. Our study is not without limitations. Selection of studies only from the five journals with the highest IF may not reflect the true picture in anesthesia. Moreover, there are inherent limitations in considering IF as a metric of a journal’s quality. It has been observed that citations can be increased by promoting more editorial letters, proportionately more review articles compared original research articles, and by self citations.¹⁶ Nevertheless, our pre-study preparatory search revealed relatively fewer pilot trials in low-impact anesthesia journals. Although we did not approach the individual journal editors to enquire about their policy on publication of pilot trials, it could be important as observed by Arain *et al.*⁴ They note that, while some journal editors did not encourage them, others considered them less rigorous, and some considered them when trials did not include a sample size calculation.⁴ The item of “sample size” was difficult to judge. Although sample size

Fig. 2 Consolidated Standards of Reporting Trials pilot extension abstract items reported in percentages

Fig. 3 Consolidated Standards of Reporting Trials pilot extension full-text items reported in percentages

Table 2 Multivariable regression analysis of predictive factors and CONSORT-pilot extension reporting adherence for abstracts and full texts

Factor and its effect	Adjusted incidence rate ratio 99% confidence interval		Significance	Adjusted incidence rate ratio 99% confidence interval		Significance
	ABSTRACT			FULL TEXT		
Industry funding						
No	1.21	0.94 to 1.54	0.0	1.16	0.94 to 1.44	0.07
Yes	1			1		
Registered as pilot/feasibility study*						
No	0.68	0.54 to 0.87	< 0.001*	0.67	0.54 to 0.82	< 0.001*
Yes	1			1		
Identified as pilot/feasibility in title or abstract*						
No	0.69	0.54 to 0.89	< 0.001*	0.92	0.72 to 1.17	0.37
Yes	1			1		
Primary objective/outcome as feasibility and not hypothesis testing						
No	0.98	0.78 to 1.22	0.82	0.77	0.63 to 0.93	0.001*
Yes	1			1		
Journal						
BJA	1.78	1.04 to 3.07	0.06	0.87	0.61 to 1.25	0.33
Pain	1.40	0.79 to 2.48	0.13	1.08	0.75 to 1.56	0.57
Anesthesiology	1.46	0.82 to 2.60	0.09	1.17	0.83 to 1.64	0.24
Anesth Analg	1.59	0.94 to 2.70	0.02	0.94	0.68 to 1.29	0.59
Anaesthesia	1			1		

Anesth Analg = Anesthesia and Analgesia; BJA = British Journal of Anesthesia. *Significance shown at $P < 0.01$ level for abstracts and full texts

estimation for a clinical hypothesis has clear elements, the same may not apply for a pilot trial. We based our judgement as “appropriately reported” if the authors provided any clarification about their sample size based on feasibility objectives and not on hypothesis testing.² Finally, although it is possible that reporting quality could be greater when separately published study protocols are assessed along with their resulting manuscripts,^{18,33} we have to note that adherence to the CONSORT statement and its checklist is for each individual manuscript and not to be considered as a whole for the protocol plus resulting manuscript.

In conclusion, the reporting of pilot trials in leading anesthesia journals is poor for both abstracts and full texts. By being consistent in their policy towards adherence to the CONSORT extension statement on pilot trials and possibly enforcing it as a mandatory requirement, journal editorial boards can encourage and improve reporting standards. Investigators and authors should be aware of the differences in the conduct and reporting of pilot studies.

Conflicts of interest None declared.

Editorial responsibility This submission was handled by Dr. Gregory L. Bryson, Deputy Editor-in-Chief, *Canadian Journal of Anesthesia*.

Author contributions Harsha Shanthanna was the primary investigator involved in the study design, conduct of the literature search, data extraction and analysis, and manuscript writing. Alka Kaushal was co-investigator involved in the study design, conduct of the literature search, data extraction, and manuscript writing. Lawrence Mbuagbaw was co-investigator involved in the study methodology, supervision of data extraction and analysis, interpretation of the trial, and manuscript writing. Rachel Couban was co-investigator and senior librarian involved with the literature search, data management, and manuscript writing. Jason Busse and Lehana Thabane were co-investigators involved in the study methodology, supervision and interpretation of the trial, and manuscript writing.

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Appendix 1 Search strategy

Search (((((((“Anesthesiology”[Journal]) OR “Br J Anaesth”[Journal]) OR “Anaesthesia”[Journal]) OR “Pain”[Journal]) OR “Anesth Analg”[Journal])) AND (((pilot or preliminary or feasibility)) AND (study or trial)))) Filters: published in the last ten years.

Appendix 2 CONSORT item reporting scores in individual studies

Number	Author	Year	Journal	CONSORT abstract score {0-15} [%]	CONSORT full text score {0-24} [%]
1.	Cohen	2007	Anesthesiology	5 [35.71]	13 [54.17]
2.	Kok	2014	Anaesthesia	5 [35.71]	15 [62.50]
3.	Berger	2009	BJA	5 [35.71]	5 [20.83]
4.	Jaura	2014	BJA	6 [42.86]	10 [41.67]
5.	Stopee	2013	BJA	10 [71.43]	14 [58.33]
6.	Goon	2013	BJA	4 [28.57]	7 [29.17]
7.	Singla	2015	Pain	4 [28.57]	12 [50.00]
8.	Chang	2010	Anesthesiology	2 [14.29]	8 [33.33]
9.	Ahola Kohut	2016	Pain	4 [28.57]	19 [79.17]
10.	Bakri	2008	Anesth Analg	4 [28.57]	11 [45.83]
11.	Candiotti	2011	Anesth Analg	4 [28.57]	10 [41.67]
12.	Carson	2010	Pain	5 [35.71]	12 [50.00]
13.	Sondergaard	2010	BJA	4 [28.57]	13 [54.17]
14.	Schulz	2016	Anesth Analg	7 [50.00]	8 [33.33]
15.	Martinez	2015	BJA	5 [35.71]	13 [54.17]
16.	Al tmimi	2014	BJA	9 [64.29]	18 [75.00]
17.	Buckley	2009	BJA	5 [35.71]	8 [33.33]
18.	Weingarten	2015	Anesth Analg	3 [21.43]	8 [33.33]
19.	Smith	2007	Anesthesiology	5 [35.71]	12 [50.00]
20.	Benger	2016	BJA	8 [57.14]	20 [83.33]
21.	Goldberg	2011	Pain	6 [42.86]	13 [54.17]
22.	Beringer	2015	BJA	Not applicable	14 [58.33]
23.	Short	2014	Anesth Analg	12 [85.71]	21 [87.50]
24.	Palermo	2015	Pain	9 [64.29]	23 [95.83]
25.	Hong	2008	Anesth Analg	7 [50.00]	12 [50.00]
26.	Candiotti	2007	Anesth Analg	4 [28.57]	10 [41.67]
27.	Parke	2016	BJA	10 [71.43]	19 [79.17]
28.	Warner	2015	Anesthesiology	3 [21.43]	15 [62.50]
29.	Olson	2009	Anesth Analg	6 [42.86]	13 [54.17]
30.	Chung	2009	Anesth Analg	7 [50.00]	16 [66.67]
31.	Blum	2013	Anesthesiology	5 [35.71]	18 [75.00]
32.	Zhang	2012	Anesth Analg	5 [35.71]	9 [37.50]
33.	Feldheiser	2102	BJA	5 [35.71]	15 [62.50]
34.	Manjunath	2008	Anesth Analg	5 [35.71]	8 [33.33]
35.	Kanai	2009	Anesth Analg	5 [35.71]	11 [45.83]
36.	Morelli	2008	BJA	6 [42.86]	14 [58.33]
37.	Curry	2015	BJA	13 [92.86]	23 [95.83]
38.	Dingley	2015	Anesth Analg	3 [21.43]	8 [33.33]
29.	Morone	2007	Pain	6 [42.86]	15 [62.50]
40.	Thorn	2011	Pain	6 [42.86]	17 [70.83]
41.	Grunewald	2014	BJA	7 [50.00]	14 [58.33]
42.	Chen	2010	Anesthesiology	4 [28.57]	10 [41.67]
43.	McCohan	2011	Anaesthesia	4 [28.57]	13 [54.17]
44.	Grossherr	2009	BJA	4 [28.57]	8 [33.33]
45.	Duan	2012	Anesth Analg	5 [35.71]	8 [33.33]
46.	Wu	2016	Anesthesiology	8 [57.14]	16 [66.67]

Number	Author	Year	Journal	CONSORT abstract score {0-15} [%]	CONSORT full text score {0-24} [%]
47.	Sen	2013	BJA	Not applicable	3 [12.50]
48.	Skelton	2016	Anesth Analg	4 [28.57]	12 [50.00]
49.	McElwain	2008	Anesth Analg	7 [50.00]	9 [37.50]
50.	Paauwe	2008	Anaesthesia	4 [28.57]	9 [37.50]
51.	Karkouti	2012	Anesthesiology	6 [42.86]	19 [79.17]
52.	Papagallo	2013	Pain	4 [28.57]	15 [62.50]
53.	Cattano	2012	BJA	Not applicable	4 [16.67]
54.	Kothman	2009	BJA	6 [42.86]	12 [50.00]
55.	Rini	2015	Pain	6 [42.86]	22 [91.67]
56.	Meierhenrich	2010	Anaesthesia	1 [7.14]	10 [41.67]
57.	Short	2011	Pain	7 [50.00]	14 [58.33]
58.	Deschamps	2016	Anesthesiology	10 [71.43]	23 [95.83]

An59.esth Analg = Anesthesia and Analgesia; BJA= British Journal of Anesthesia; CONSORT = Conso60.litated Standards of Reporting Trials

Appendix 3 CONSORT Pilot extension items adapted for decision making

Abstract items

Item	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
1. Title	Identification of study as randomized	Identification of study as randomized pilot trial	Must Have the terms Pilot/feasibility and randomized-controlled trial
2. Trial design	Description of the trial design (e.g., parallel, cluster, non-inferiority)	Description of pilot trial design (e.g., parallel, cluster)	Design: usually the 2-arm parallel trial is assumed if they say 2 groups; if it is not obvious—such as cluster, parallel, non-inferiority—they must report it
METHODS			
3. Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for participants and the settings where the pilot trial was conducted	Must have Study patient population description [e.g., which surgical population and the settings of the trial such as chronic pain clinic, OR, etc.]
4. Interventions	Interventions intended for each group	Same	Must—Clear descriptions for both groups
5. Objective	Specific objective or hypothesis	Specific objectives of the pilot trial	They must have a FEASIBILITY OBJECTIVE as either primary or secondary If they report hypothesis testing as their main objective, it is noted separately
6. Outcome	Clearly defined primary outcome for this report	Pre-specified assessment or measurement to address the pilot trial objective(s) ¹	Must be described at least for (one) the FEASIBILITY OBJECTIVE If they report hypothesis testing as their main objective, it is noted separately
7. Randomization	How participants were allocated to interventions	Same	Reported as randomized
8. Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Same	Must: describe who were blinded, and who were not blinded. Single blinded or double blinded or triple blinded is acceptable Normally assumed as (if they do not report any specific blinding): single (patient), double (patient and physician)

Item	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
RESULTS			
9. Numbers randomized	Number of participants randomized to each group	Number of participants screened and randomized to each group for the pilot trial objective(s) ¹	Clear numbers for participants screened and randomized to each group (2 items)
10. Recruitment	Trial status (for conference abstracts)	Same	NOT APPLICABLE
11. Numbers analyzed	Number of participants analyzed in each group	Number of participants analyzed in each group for the pilot objective(s) ¹	Numbers analyzed for each group compared with numbers randomized
12. Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results for the pilot objective(s); including any expressions of uncertainty ¹	Must: Clear reporting of outcomes with their effect size and uncertainty (both important) If they report hypothesis testing as their main outcome, it is noted separately
13. Harms	Important adverse events or side-effects	Same	They must report the adverse events that were considered in Methods, or at least mention no adverse effects such as —
14. Conclusions	General interpretation of the results	General interpretation of the results of pilot trial and their implications for the future definitive trial	2 requirements must be met. On the feasibility success/failure and future trial implications
15. Trial registration	Registration number and name of trial register	Registration number for pilot trial and name of trial register	If it is not registered, they do not fulfil it. They must mention both the number and the trial registry name
16. Funding	Source of funding	Source of funding for pilot trial	They must declare it as: funded or unfunded, and if funded-details of funding Industry funding is noted separately for either complete trial or part of the trial

Full text items

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
Title and abstract			
1a	Identification as a randomized trial in the title	Identification as a pilot or feasibility randomized trial in the title	Must have both fulfilled.
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1. Title: Pilot/feasibility and randomized-controlled trial 2. Abstract: Design, Methods, Results, and Conclusions. To facilitate a decision: we require at least one feasibility objective and outcome, and Conclusion must be based on pilot (feasibility) trial not subsequent (clinical) trial

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
Introduction			
Background and objectives:			Must have all the following:
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomized pilot trial	1. Background 2. Rationale for pilot/feasibility 3. Rationale for RCT 4. Objective as at least one feasibility objective clearly outlined
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	If they report hypothesis testing as their main objective, it is noted separately
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Must have the description of design Design description-parallel, factorial, cluster, crossover; for parallel group it is implied if the description informs of 2 groups
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Important changes—if any
Participants:			
4a	Eligibility criteria for participants		Must have all three
4b	Settings and locations where the data were collected		1. Eligibility criteria 2. Specific settings such as preop clinic, OR, chronic pain clinic
4c		How participants were identified and consented	3. How was the screening and consent done
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		Must have Description of intervention (how and when) enough to allow for replicability
Outcomes:			
6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Must have both the following items fulfilled 1. At least one feasibility objective 2. How and when they were measured If they report hypothesis testing as their main outcome, it is noted separately
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Any changes if any (not necessary otherwise)
6c		If applicable, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial	Only if applicable

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	Must describe
7b	When applicable, explanation of any interim analyses and stopping guidelines		An explanation of the sample estimate and its basis, even if no statistical calculation If sample size estimate was based on hypothesis testing of clinical parameters, it is noted separately
Randomization			
Sequence generation:			
8a	Method used to generate the random allocation sequence	Type of randomization(s); details of any restriction (such as blocking and block size)	Must describe the method used to randomize; just saying randomized is not sufficient
8b	Type of randomization; details of any restriction (such as blocking and block size)		Whether it was appropriately performed or not, this judgement is considered separately as a measure of study methods and noted separately
Allocation concealment mechanism:			
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		Allocation concealment: must report how? Whether it was appropriately performed or not, this judgment, is considered separately as a measure of study methods, and noted separately
Implementation:			
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		Must have all three 1. Who generated the random sequence 2. Who enrolled the patients 3. Who allocated the patients and how Description of allocation concealment in a way that can be implemented and replicated in the future definitive RCT
Blinding:			
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Must: describe who were blinded and who were not Single or double or triple blinded is acceptable.
11b	If relevant, description of the similarity of interventions		Normally assumed as (if they do not report any specific blinding): single (patient), double (patient and physician) Whether it was appropriately performed or not, this judgment, is considered separately as a measure of study methods and noted separately

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
Analytical methods:			
12a	Statistical methods used to compare group for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	Must describe the analysis used for the feasibility objective/outcome stated Should describe analysis of feasibility outcomes and clinical outcomes (efficacy) If hypothesis testing was done as the primary objective and reported as primary outcome, it is noted separately
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	Not applicable
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Must have the following three patient numbers Eligible, randomized and assessed Patients approached—assessed for eligibility—randomly assigned—received treatment—and assessed for each objective
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			
14a	Dates defining the periods of recruitment and follow up		Must have at least the following Report the start of recruitment and end of recruitment
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	Whether the trial was stopped as planned and if not why?
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Must report a table with baseline features Baseline data
Numbers analyzed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these analyses should be by randomized group	Must describe the following The number of participants analyzed for each objective/outcome reported, randomized by group
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomized group	Must have the following Reported outcomes should include expressions of uncertainty Note: for this item, it is not specific to feasibility objective
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	This may not be reported, as effect sizes are not informative for pilot trials

Section/topic and item no.	Standard checklist item	Extension for pilot trials	Decision-making rules for items. CHECK Whether the ITEM WAS REPORTED OR NOT
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	NOT CONSIDERED
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		Must describe the following Relevant harms/obvious harms must be reported as either did not occur or if occurred compared for each group
19a		If relevant, other important unintended consequences	
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Must describe the limitations in the form of both or either: Sources of bias; uncertainty about feasibility
Generalizability:			
21	Generalizability (external validity, applicability) of the trial findings	Generalizability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Must describe whether the methods and results are applicable for the full trial or other studies If they describe or generalize based on hypothesis testing result/clinical result, then it is scored as unsatisfactory
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Must have both the following 1. Interpretation mostly on feasibility objectives and not hypothesis testing 2. Implications for progression from pilot to future definitive trial
22a		Implications for progression from pilot to future definitive trial including any proposed amendments	
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	Registration number and name of registry Need to check to see if it was registered as pilot/feasibility and noted separately
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	NOT CONSIDERED
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		Must report the following Funding as not funded, industry funded, or any other sources of funding If industry funded, noted separately
26		Ethical approval/research review committee approval confirmed with reference number	Must report Ethics approval

CONSORT = Consolidated Standards of Reporting Trials; OR = operating room; RCT = randomized-controlled trial

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