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ORIGINAL ARTICLE

Meta-meta-analysis: A paradigm in the case of surgical publications

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Summary

Purpose: *Meta-analyses are considered to provide level I-II evidence. Based on this premise, several statements have been developed to standardize guidelines and optimize results. The purpose of this study was to investigate the quality of the information delivered by meta-analyses.*

Methods: *Meta-analyses published in Annals of Surgery during an 11-year period were reviewed whereas individual publications of each meta-analysis were assessed. An Excel database encompassing 29 parameters was constructed based on the Quality of Reporting of Meta-analyses (QUOROM) statement.*

Results: *The present study included 31 consecutive meta-analyses. The number of meta-analyses conforming with each of the parameters considered was as follows: information obtained from more than 2 databases 23/31; language of publication exclusively English 25/31; defined population, intervention, and principal outcomes 31/31; study design encompassing review of randomised controlled trials (RCTs) 10/31; quality assessment of contributing publications 10/31; handling of missing data 10/31; assessment of statistical heterogeneity 30/31; subgroup analysis 23/31; assessment of publication bias 26/31; agreement on selection and validity assessment 22/31; simple summary results 28/31; data available to calculate effect size and confidence interval 27/31; key findings summarized 30/31; clinical inferences based on internal and external validity 24/31; description of potential biases in the review process 23/31; future research agenda suggested 18/31.*

Conclusions: *Evidence derived from meta-analyses must be interpreted with caution. Although QUOROM guidelines were observed, quality assessments showed considerable variability.*

Key words: *meta-analysis, publication bias, quality assessment, PRISMA statement, randomised controlled trials, systematic review*

Introduction

Meta-analyses represent integrated reviews in which results of relevant studies on a specific topic are evaluated according to a predetermined and explicit statistical method [1]. They constitute not only an important educational tool for physicians, patients, reviewers, editors, and researchers, but also a source of evidence-based practice guidelines, financial evaluations, and future research agendas [2,3].

Although bias is minimised by the use of explicit statistical methods, the suboptimal quality of some meta-analyses often limits the accuracy and reliability of the conclusions. There is extensive evidence that key information is regularly ill-addressed, and that data reporting does not allow for an accurate assessment of the strengths and weaknesses of the investigation [4-7]. Such results led to the creation of the QUOROM and the PRISMA

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(Preferred Reporting Items for Systematic reviews and Meta-Analyses) [2] statements on standards for meta-analyses of clinical randomized controlled trials.

In this study we performed a meta-meta-analysis, i.e. a meta-analysis of all meta-analyses published in Annals of Surgery (the highest ranked surgical journal) intending to evaluate the quality of published information using the QUOROM statement.

Methods

All consecutive meta-analyses published in Annals of Surgery during the period 03/2000-03/2011 were reviewed for the purpose of this study. The quality of information of each study was evaluated using specific parameters described in the QUOROM statement.

The QUOROM statement

The QUOROM conference was convened in 1996 in an effort to address quality standards for meta-analyses of clinical randomised controlled trials (RCTs). The QUOROM group consisted of 30 scientists of different specialties (including clinical epidemiologists, clinicians, statisticians, editors, and researchers) who identified a checklist of potential standards based on research evidence in order to avoid biased results. All candidate items for inclusion in the final proposed checklist were assessed using a modified Delphi technique [9]. This process resulted in the QUOROM statement published in 1999 [8]. The final checklist includes various items describing the preferred way to present the Abstract, Introduction, Methods, Results, and Discussion sections in meta-analyses. The list is organised into 21 headings and subheadings (Table 1). Information on the number of RCTs identified, included, exclud-

Table 1. QUOROM-statement checklist. A total of 21 headings and subheadings describe the preferred reporting for the Abstract, Introduction, Methods, Results, and Discussion sections of meta-analyses (edited from Lancet 1999;354:1896-900)

Heading	*Subheading*	*Descriptor*
Title		Identify the report as a meta-analysis or systematic review of RCTs
Abstract		Use a structured format
	Objectives	The clinical question explicitly
	Data sources	The databases and other information sources
	Review methods	The selection criteria; methods for validity assessment, data abstraction, and study characteristics, and quantitative data synthesis in sufficient detail to permit replication
	Results	Characteristics of the RCTs included and excluded; qualitative and quantitative findings; and subgroup analyses
	Conclusion	The main results
Introduction		The explicit clinical problem, biological rationale for the intervention, and rationale for review
Methods	Searching	The information sources in detail, and any restrictions
	Selection	The inclusion and exclusion criteria, principal outcomes and study design
	Validity assessment	The criteria and process used (masked conditions, quality assessments)
	Data abstraction	The process or processes used (completed independently, in duplicate)
	Study characteristics	The type of study design, participants' characteristics, details of intervention, outcome definitions, and how clinical heterogeneity was assessed
	Quantitative data synthesis	The principal measures of effect, methods of combining results, handling of missing, data, how statistical heterogeneity was assessed, a rationale for any a-priori sensitivity and subgroup analyses, assessment of publication bias
Results	Trial flow	Provide a meta-analysis profile summarizing trial flow
	Study characteristics	Present descriptive data for each trial
	Quantitative data synthesis	Report agreement on the selection and validity assessment, present simple summary results, and present data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses
Discussion		Summarize key findings, discuss clinical inferences based on internal and external validity, interpret the results in light of the totality of available evidence, describe potential biases in the review process, and suggest a future research agenda

ed, and reasons for exclusion should be provided in a flow diagram.

Data extraction and classification

In concordance with the checklist proposed by the QUOROM statement, we formulated an Excel-database, which included 29 parameters. Independent investigation of individual publications of each meta-analysis was performed when needed in order to extract required data for each section of the manuscript. Parameters evaluated included:

Methods section

Search methodology was evaluated by examining specific parameters such as source of information (e.g. databases, registers, personal files, expert informants, agencies, hand-searching), years included in the study period, and language of publication. Selection was evaluated by considering inclusion and exclusion criteria (defining population, intervention, principal outcomes, and study design [systematic literature review, retrospective review, review of RCTs, review of prospective studies, review of comparative non-randomized studies, etc]) [10]. Validity was determined based on criteria and processes, including scores/scales for quality assessment and randomized trials [11-13]. Data abstraction was also evaluated by examining whether the process was completed independently or not [13]. Study characteristics were appraised by assessing the type of study design (systematic review of the literature, retrospective review, review of RCTs, etc), participants' characteristics, details of interventions, and outcome definitions. Principal measures of effect (eg, relative risk), handling of missing data, assessment of statistical heterogeneity, performance of subgroup analysis, and methods for assessing publication bias were examined in order to evaluate quantitative data synthesis [14,15].

Results section

When evaluating Results, we looked for a profile summarizing trial flow. Study characteristics were examined based on the presentation of descriptive data/table (eg, age, sample size, intervention, dose, duration, follow-up period) for each trial. Quantitative data synthesis was evaluated based on: report of agreement on the selection and validity assessment, presentation of simple summary results, presentation of data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses.

Discussion section

Discussion sections were evaluated by verifying whether key findings were summarized, clinical inferences discussed based on internal and external validity, results interpreted in light of all available evidence, potential biases in the review process clearly described, and suggestions for future research agendas outlined.

Results

The present study included a total of 31 successive meta-analyses [16-46] (Table 2). Information was obtained from more than 2 databases in 23/31 (74.2%) and from only one in 2/31(6.5%) (Medline search). Thirty of 31 studies (96.8%) reported the years considered in their meta-analyses, ranging from 1950- December 2009. Language of publications considered included English in 25/31(80.1%), all languages in 4/31(12.9%), English, French, German, Italian, Spanish, Danish, and Dutch in 1/31 (3.3%), and was undefined in the remaining study (3.3%). With regard to inclusion and exclusion criteria, all studies defined the

Table 2. First author, publication year, and number of contributing publications for each of the studies reviewed

First author	*Publication year*	*Included studies*
Hodgson	2000	13
EU Hernia Triallist Collaboration	2002	58
Sewnath	2002	23
Vincent	2003	90
Hall	2004	8
Mulier	2005	95
Aziz	2006	23
Lovegrove	2006	21
Andersson	2007	61
Diener	2007	6
Sanabria	2007	6
Abulkhir	2008	37
Diener	2008	4
Ferreyra	2008	9
Hsia	2008	22
Hüser	2008	27
Karanikolas	2008	17
Nanidis	2008	73
Petrov	2008	3
Treadwell	2008	19
Campos	2009	105
Slim	2009	14
Zhao	2009	10
Diener	2010	19
Lanitis	2010	9
Lansdale	2010	3
Maeso	2010	31
Mingtai	2010	10
Ahmad	2011	11
Jay	2011	11
Pontiroli	2011	8

selected population and provided information on the type of intervention as well as on its principal outcomes. Study design encompassing a review of RCTs was observed in 10/31(32.3%). A systematic literature review was performed in 6/31 (19.4%). The quality of contributing publications was assessed in 10/31(32%). Jadad Quality Scale [47] and Newcastle-Ottawa Scale [48] were the most common used systems. Only one study (3.2%) assessed the quality of its publications according to the QUOROM statement. Data abstraction was completed independently in 24/31(77.4%). Two or 3 reviewers were involved in 19/31(61.3%). Seven of 31 (22.5%) studies did not provide information on data abstraction.

Twenty-nine of 31 studies (93.5%) reported details with regard to participant characteristics. One did not provide relevant information, and the remaining one lacked information on patient selection. Twenty-nine (93.5%) provided information on the principal measures of effect (e.g. odds ratio, weighted averages, etc.) and the methods of combining results (statistical testing e.g. Mantel Haenszel method and confidence intervals). Ten (32.3%) described the handling of missing data. Statistical heterogeneity was calculated in 30/31(96.8%) studies, most commonly using the Forest plot test. Chi square and Fisher's exact tests were applied less frequently. Subgroup analysis was performed in 23/31(74.2%) cases. Six did not provide any relevant information. Publication bias was assessed in 26/31(83.9%), most commonly applying the Funnel or Forest plot.

In the Results section, 30/31 (96.8%) provided a meta-analysis profile summarising trial flow. Twenty-nine of 31 (93.5%) presented a Table with descriptive data for each trial. Twenty-two (71%) provided information regarding agreement on selection and validity assessment. Simple summary results were present in 28/31(90.3%). Data required to calculate effect size and confidence intervals were available in 27/31 (87.1%).

Key findings were summarized in the Discussion section in 30 of 31 (96.8%) studies. Clinical inferences based on internal and external validity were discussed in 24 (77.4%). Potential biases in the review process (including small number of patients, lack of long-term follow-up, historical control groups, and lack of randomization) were reported in detail in 23/31(74.2%). Only 18 (58.1%) suggested a future research agenda (Table 3).

Discussion

In 1999, an international group consisting of 30 clinical epidemiologists, clinicians, statisticians, editors, and researchers published the QUOROM Statement in an attempt to address the suboptimal quality of meta-analyses [2]. This statement provided a checklist with the preferred ways of reporting methods, results, and discussion-interpretations. The authors aimed to trigger interested reviewers, authors, researchers, and editors to use the QUOROM as a guide for meta-analyses [49]. The purpose of our study was to evaluate the quality of all meta-analyses published in Annals of Surgery in the 11-year period (2000-2011) following the publication of the QUOROM guidelines. Our results have been published in an abridged electronically version in the above mentioned Journal [50].

Individual QUOROM guidelines towards which a greater compliance was noted included: years considered, inclusion and exclusion criteria, definition of the selected population, information on the studied type of intervention, and principal outcomes. Acceptable concurrence with QUOROM guidelines was also demonstrated with information on principal measures of effect (e.g. odds ratio, weighted averages etc.) and statistical methods of combining results. Moreover, statistical heterogeneity was widely calculated and reported. In the Results section, 96.8% of the reviewed studies provided a meta-analysis profile summarising trial flow according to QUOROM guidelines. Such diagrams enable the readers to follow a transparent process of study selection from the initially identified citations [51]. Descriptive data for each included trial were also reported in the vast majority (93.5%) of the reviewed meta-analyses. Key findings were summarised in almost all studies (96.8%).

Nevertheless, despite the above-observed good compliance with particular QUOROM guidelines, noticeable variability was recorded in QUOROM quality assessment measures (Table 3). Remarkably, only 10 out of the 31 meta-analyses reviewed RCTs, which represent studies with the highest level of evidence. Moreover, quality assessment of the contributing publications was performed in only 10 (32%) reviewed studies, while QUOROM guidelines were followed in only one case. Inclusion of studies with disputable quality may significantly alter the validity of reported observations. The possibility that the summary measures of a particular intervention approach the truth depends on the quality, methodological characteristics, and risk of bias of the contributing publications [3,4,52,53]. Trials with inadequate reporting of allocation concealment may augment the intervention effect by up to 30% when compared to those

Table 3. Compliance with the QUOROM statement guidelines of each study included, concerning some quality parameters: Review of only RCTs, quality assessment, information on data abstraction, handling of missing data, agreement on selection/validity assessment, and future research agenda

First author and publication year	*Review of only RCTs*	*Quality assessment*	*Information on data abstraction*	*Handling of missing data*	*Agreement on selection/ validity assessment*	*Future research agenda*
Hodgson 2000	Yes	Yes	Yes	No	Yes	Yes
EU Hernia Triallist Collaboration 2002	No	No	No	No	No	No
Sewnath 2002	No	Yes	Yes	No	Yes	Yes
Vincent 2003	No	No	Yes	No	Yes	No
Hall 2004	No	No	No	No	No	Yes
Mulier 2005	No	No	No	No	No	No
Aziz 2006	No	No	Yes	No	Yes	Yes
Lovegrove 2006	No	Yes	Yes	Yes	Yes	Yes
Andersson 2007	No	No	No	No	No	No
Diener 2007	Yes	No	Yes	Yes	Yes	Yes
Sanabria 2007	Yes	Yes	Yes	No	No	No
Abulkhir 2008	No	No	No	No	No	Yes
Diener 2008	Yes	No	Yes	No	Yes	Yes
Ferreyra 2008	Yes	No	Yes	No	Yes	Yes
Hsia 2008	Yes	No	Yes	No	Yes	Yes
Hüser 2008	No	No	Yes	No	Yes	No
Karanikolas 2008	Yes	No	Yes	No	Yes	No
Nanidis 2008	No	Yes	Yes	Yes	Yes	Yes
Petrov 2008	No	Yes	Yes	Yes	Yes	Yes
Treadwell 2008	No	Yes	Yes	No	No	Yes
Campos 2009	No	No	No	No	No	No
Slim 2009	Yes	No	Yes	Yes	Yes	No
Zhao 2009	Yes	No	Yes	Yes	Yes	Yes
Diener 2010	No	No	Yes	Yes	Yes	Yes
Lanitis 2010	No	Yes	Yes	No	Yes	No
Lansdale 2010	No	No	Yes	Yes	Yes	Yes
Maeso 2010	No	No	No	No	Yes	Yes
Mingtai 2010	Yes	Yes	Yes	Yes	No	Yes
Ahmad 2011	No	Yes	Yes	No	Yes	No
Jay 2011	No	No	Yes	Yes	Yes	No
Pontiroli 2011	No	No	Yes	No	Yes	No
Compliance with QUOROM Guidelines	10/31	10/31	24/31	10/31	22/31	18/31

with acceptable concealment [8,11]. Evaluation of the quality and risk of bias of each single publication as well as clear description of the methods used for this purpose are of critical importance.

Almost 20% of the studies did not provide information on data abstraction. This represents a remarkable limitation given the shortcomings that may originate from duplicated data or disagreements between researchers who extract the data [2]. Restriction to English language was noticed in approximately 80% of meta-analyses. Although reports in English show little or no difference in important methodological features when compared to those in other languages [8], there is evidence that language restrictions may contribute to summary biases [8,54-56]. For example, it has been shown that studies with statistically positive results are more likely to be written in English [54], and that certain countries/languages exhibit a trend to report positive outcomes [57].

Missing data suggests another critical issue that requires close attention as validity and gravity of reported results may potentially be compromised in the light of the absence of information from particular studies. Barely only one third of the reviewed studies forehand noted their handling of missing data. A tendency to publish more promptly and more often studies with statistical-

ly important results than those with no observed differences is noted [58,59] - generating "missing studies" [2]. Moreover, not all eligible studies may report results on the particular outcome being considered - leading to "missing outcomes." Both "missing studies" and "missing outcomes" can lead to selection bias [2], a condition that further underlines the need for clear reporting on the handling of missing data.

Subgroup analyses were performed in three quarters of the herein reviewed studies. Subgroup analyses aim to assess whether the summary effects vary in relation to specific group characteristics of study participants, and should be reported whenever performed [2,8]. In addition, 1 of every 6 studies evaluated did not assess publication bias, a fact that as previously mentioned can contribute to exaggerated assessment of particular intervention effects in systematic reviews and meta-analyses [8,60]. Moreover, one third of studies did not provide any information regarding agreement on selection and validity assessment. Since the use of two or more reviewers has been shown to contribute to a more objective selection of relevant reports [61], authors should ideally provide information with regard to the level of inter-reviewer agreement [2].

Limitations such as potential biases in the review process were not reported in 25% of the studies considered despite the fact that such discussion is clearly recommended in the QUOROM statement.

Finally, almost half of the studies did not discuss any implications for future research agendas. Published evidence suggests that clinical research should be planned and conducted based on a comprehensive knowledge of already existing research [62]. The information provided by systematic reviews and meta-analyses can have a great impact on this planning [2].

The present review proves that despite the fact that meta-analyses and systematic reviews published in Annals of Surgery during the period 2000-2011 attempted to follow the QUOROM guidelines, there was considerable variance in terms of compliance. Despite observation of very good compliance for specific QUOROM guidelines, a noteworthy percentage of studies failed to pursue critical QUOROM guidelines. Further evaluation and reformation of these guidelines by reviewers is essential in order to enhance reproducibility and validity of future manuscripts considered eligible for publication. To conclude, our study underlines that despite the QUOROM publication, results of currently published meta-analyses as well as systematic reviews should be interpreted with caution considering they still present with validity problems. Many of these reported weaknesses are not unique to surgical meta-analyses and have actually leaded to the development of a new reporting standard that is replacing QUOROM: the PRISMA statement [2]. Hopefully, wider application of and compliance to the PRISMA statement both from authors and reviewers may reduce the risk of biases in the reporting of evidence generated from meta-analyses [63].

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Conflict of interests

The authors declare no confict of interests.

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