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Compliance with QUOROM and quality of reporting of overlapping meta-analyses on the role of acetylcysteine in the prevention of contrast associated nephropathy: case study

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Abstract

Objective To appraise multiple systematic reviews on the same clinical topic, focusing on predictors and correlates of quality of reporting of meta-analysis (QUOROM) scores.

Design Case study.

Setting Reviews providing at least individual quantitative estimates on role of acetylcysteine in the prevention of contrast associated nephropathy.

Data sources PubMed, the database of abstracts of reviews of effects, and the Cochrane database of systematic reviews (updated March 2005).

Main outcome measures Funding, compliance with the QUOROM checklist, scores on the Oxman and Guyatt quality index, and authors’ recommendations.

Results 10 systematic reviews, published August 2003 to March 2005, were included. Nine pooled events despite heterogeneity and five recommended routine use of acetylcysteine, whereas the remaining studies called for further research. Compliance with the 18 items on the QUOROM checklist was relatively high (median 16, range 11 to 17), although shorter manuscripts had significantly lower scores ($R = 0.73$; $P = 0.016$). Reviewers who reported previous not for profit funding were more likely to score higher on the Oxman and Guyatt quality index. No association was found between QUOROM and Oxman and Guyatt scores ($R = -0.06$; $P = 0.86$), mainly because of greater emphasis of the Oxman and Guyatt scores on the appraisal of bias in selection and validity assessment (inadequate in five reviews).

Conclusions Multiple systematic reviews on the same clinical topic varied in quality of reporting and recommendations. Longer manuscripts and previous

not for profit funding were associated with higher quality.


Introduction


Since the mid-70s a large number of systematic reviews have been published, varying widely in quality and standards.¹⁻⁵ Anecdotal reports of multiple reviews focusing on the same clinical topic have differed in quality and methods used, leading to conflicting conclusions.^{4 6 7}

The quality of reporting of meta-analysis (QUOROM) statement was developed to improve and standardise the reporting of systematic reviews,⁸ not to avoid duplication of research. Yet the effect of the QUOROM guidelines on the design, conduct, and reporting of systematic reviews is unclear.

Several randomised controlled trials have investigated the role of acetylcysteine in the prevention of contrast associated nephropathy, but with conflicting results. A systematic review was therefore carried out to provide more comprehensive and robust conclusions.^{w1} Subsequent systematic reviews on the same topic were published, with different findings.

We appraised this cluster of duplicate systematic reviews, focusing on predictors and correlates of QUOROM quality scores. We explored the association between compliance with the QUOROM statement and characteristics of the manuscripts.

 Description of Oxman and Guyatt index and references w1-w10 are on bmj.com

 This is the abridged version of an article that was posted on bmj.com on 16 January 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38693.516782.7C>

Methods

We searched PubMed,⁹ The Cochrane database of systematic reviews, and the database of abstracts of reviews of effects. We included systematic reviews of randomised controlled trials that compared acetylcysteine with control for the prevention of contrast associated nephropathy, reviews published as complete reports, and reviews that reported quantitative estimates at least for individual studies. (See bmj.com for exclusion criteria.) We applied no language restrictions.

Study abstraction and appraisal

We abstracted data on several characteristics, including article length (pages), abstract length (words), study design, number of trials and patients, and whether estimates were pooled (see bmj.com). We also checked for use of funnel plots, whether heterogeneity was explored and discussed, methods used, and whether formal metaregression had been carried out and the control event rate had been used as covariate.^{10 11} We contacted the corresponding authors for details of funding.

We considered that the study had complied with any of the 18 specific items on the QUOROM checklist if it met over 50% of the requirements for each item. We also used the Oxman and Guyatt index for quality of systematic reviews.^{10 12} Finally, we assessed the main findings and conclusions. Two unblinded reviewers (GGLB-Z, PA) independently appraised the studies. Discrepancies were resolved by consensus.

Statistical analysis

We used Fisher's exact test to compare the proportions of categorical variables and Mann-Whitney U or Kruskal-Wallis tests to compare the means (ranges) for continuous variables. Pearson and Spearman tests were used to assess correlations. We used the means of

Cohen κ and ϕ to determine the agreement between QUOROM scores, funding source, and authors' recommendations before consensus.¹³

Results

After exclusions, 10 articles were included (table 1 and bmj.com).^{w1-w10} Details of the randomised controlled trials that were pooled for each included review are on bmj.com. In three cases the publishing journal was a general medicine one, in three cases a cardiology journal, and in four cases a nephrology journal. The median impact factor was 3.9 (range 18.3 to 0).

Funding was from for profit sources in five cases, not for profit sources in seven cases, and specific for the review in one case (table 1).

Search strategies varied from using five databases to only one. Summary estimates used for pooling were odds ratios (three reviews), relative risks (six), and risk differences (one), by means of random effects (eight) or fixed effects (one) methods (see bmj.com). Quantitative results were reported using both P values and confidence intervals in all cases. Exploratory meta-regression was carried out because of statistical heterogeneity in six studies. Although most metaregressions included covariates likely to accommodate variability in underlying risk, none formally tested the role of control group event rates as covariate.

Five reviews recommended routine, or almost routine, use of acetylcysteine in the prevention of contrast nephropathy. The other five were more cautious (see bmj.com). These discrepancies occurred despite similar pooled effect estimates.

Compliance with the QUOROM statement

Agreement before consensus between reviewers was high for compliance with the QUOROM items (174/180 (91.2%), $\kappa=0.89$, 95% confidence interval

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Table 1 Included systematic reviews comparing acetylcysteine with controls for the prevention of contrast associated nephropathy

Database (selection criteria)	Trial and reference	Journal	Article details							Funding		
			Date published	Date first submitted	No of pages	Impact factor, 2003	No of authors	No of trials (patients)	For profit*	Not for profit*	Specific for review	
Biosis+/RRM, Cochrane Library, Current Contents, Medline, Web of Science (RCT)	Birck et al ^{w1}	<i>Lancet</i>	Aug 2003	NA	6	18.3	6	7 (805)	Yes	Yes	No	
Biosis, Embase, PubMed, other online databases (RCT)	Isenbarger et al ^{w2†}	<i>American Journal of Cardiology</i>	Dec 2003	May 2003	5	3.1	3	7 (805)	Yes	Yes	Yes‡	
Central, CARE, HealthSTAR, Medline (RCT)	Alonso et al ^{w3}	<i>American Journal of Kidney Disease</i>	Jan 2004	Jun 2003	9	3.9	5	12 (1312)	Yes	Yes	No	
Central, Embase, Medline (RCT, non-RCT)	Kshirsagar et al ^{w4}	<i>Journal of the American Society of Nephrology</i>	Mar 2004	Sep 2003	9	7.5	10	16 (1539)§	Yes	Yes	No	
Central, Embase, Medline, Science Citation Index (RCT)	Pannu et al ^{w5}	<i>Kidney International</i>	Apr 2004	Jul 2003	9	5.3	4	15 (1776)	Yes	Yes	No	
Medline (RCT)	Guru and Frenes ^{w6†}	<i>Clinical Nephrology</i>	Aug 2004	Dec 2003	7	1.3	2	11 (1207)	No	No	No	
Central, Embase, Medline (RCT)	Bagshaw and Ghali ^{w7}	<i>BMC Medicine</i>	Oct 2004	Apr 2004	12	NA	2	14 (1261)	No	Yes	No	
Medline (RCT)	Misra et al ^{w8†}	<i>Clinical Cardiology</i>	Nov 2004	Jul 2004	4	1.2	5	5 (643)	No	No	No	
Central, Current Contents, Medline (RCT)	Nallamothu et al ^{w9}	<i>American Journal of Medicine</i>	Dec 2004	Jan 2004	10	4.4	7	20 (2195)	No	Yes	No	
Central, Medline (RCT, non-RCT)	Duong et al ^{w10}	<i>Catheterization and Cardiovascular Interventions</i>	Mar 2005	Jun 2004	9¶	1.5	3	21 (2420)	No	No	No	

Contrast nephropathy defined as >44.2 $\mu\text{mol/l}$ or >25% increase in serum creatinine concentration from baseline to 48 hours, or both.

RCT=randomised controlled trial; NA=not available.

*Any previous funding.

†Restricted to English language.

‡Indirect support from a not for profit source.

§15 randomised controlled trials.

¶Includes appendix.

Table 2 Compliance of included studies with quality of reporting of meta-analyses (QUOROM) checklist and Oxman and Guyatt index*

Characteristic	Birck et al ¹¹	Isenbarger et al ¹²	Alonso et al ¹³	Kshirsagar et al ¹⁴	Pannu et al ¹⁵	Guru et al ¹⁶	Bagshaw et al ¹⁷	Misra et al ¹⁸	Nallamothu et al ¹⁹	Duong et al ¹⁰
Identifying title†	-	+	+	+	-	-	-	-	-	-
Abstract:										
Structured	+	-	+	-	+	+	+	+	+	-
Objectives	+	+	+	+	+	+	+	+	+	+
Data sources	+	-	+	+	+	+	+	-	-	-
Review methods	-	-	+	+	+	+	-	+	+	+
Results	+	-	+	-	+	+	+	-	+	+
Conclusion	+	-	+	+	+	+	+	+	+	+
Introduction	+	+	+	+	+	+	+	+	+	+
Methods:										
Searches	+	+	+	+	+	+	+	+	+	+
Selection	+	+	+	+	+	+	+	+	+	+
Validity assessment	+	+	-	+	+	-	+	-	+	+
Data abstraction	+	+	+	+	+	-	+	-	+	+
Study characteristics	+	+	+	+	+	+	+	-	+	+
Quantitative data synthesis	+	+	+	+	+	+	+	+	+	+
Results:										
Trial flow	-	-	+	+	-	-	+	-	-	+
Study characteristics	+	+	+	+	+	+	+	+	+	+
Quantitative data synthesis	+	+	+	+	+	+	+	+	+	+
Discussion	+	-	+	+	+	+	+	+	+	+
Total QUOROM score	15	11	17	16	16	16	16	12	15	14
Explicit quotation of QUOROM statement by authors	+	-	-	-	-	-	+	-	+	‡
Guidelines for meta-analysis endorsed by journal	+‡	-	-	-	-	-	-	+‡§	-	-
Oxman and Guyatt score¶	7	6	3	4	6	1	7	2	6	6

+More than 50% of requirements accomplished; -non-compliance.
 *Compliance with QUOROM items assessed by two independent reviewers.
 †Title includes study design.
 ‡Explicit reference to *Cochrane Collaboration Reviewers' Handbook*.¹⁷
 §Explicit reference to the QUOROM statement.
 ¶Ranging from 1 for extensive flaws to 7 for minimal flaws.¹⁰

0.80 to 0.97; $\phi=0.89$), and 100% (10 reviews) for authors' recommendations. The median compliance with the QUOROM checklist was 16 (range 11 to 17; table 2).

In only three cases could the report be identified from the title as a meta-analysis or systematic review. A structured abstract was available in seven reviews, and objectives and conclusions were explicitly stated in 10 and nine, respectively. In the abstract sections, data sources, review methods, and results complied with the QUOROM statement in only six cases.

All the studies fulfilled the QUOROM requirements for the introduction and discussion sections. Most of the studies complied with the recommendations for reporting of the assessment of the methodological quality of the primary studies (seven reviews), data abstraction (eight), and study characteristics (nine).

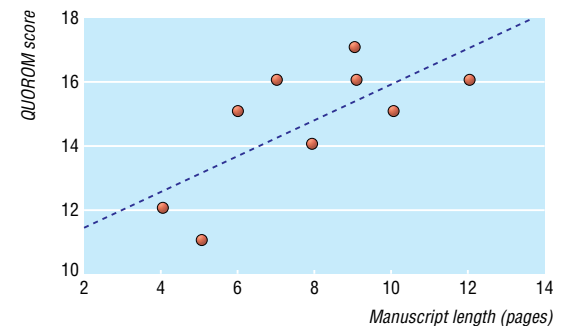
No review quantified the agreement between reviewers on selection and appraisal of the methodological quality of the primary studies. A diagram showing the flow of the trial was provided in only three cases. Study characteristics and quantitative data synthesis in the results section were provided in enough detail in all the reviews.

Quantitative analyses and predictors of QUOROM score

A significant association was found between number of published pages and overall QUOROM score (Pearson $R=0.73$, Spearman $\rho=0.64$), suggesting that the longer the manuscript, the greater the likelihood of complying with the QUOROM statement (figure).

Language restrictions were associated with fewer trials analysed (7, range 5-11 *v* 15, range 7-21, $P=0.040$) and fewer patients analysed (805, range 643-1207 patients *v* 1539, 805-2420; $P=0.033$) (table 1 and [bmj.com](#)).

Studies from reviewers reporting previous not for profit funding were more likely to score higher on the Oxman and Guyatt index (6, range 3-7 *v* 2, range 1-4; $P=0.037$), to search more databases (4, 3-5 *v* 1.3, 1-2; $P=0.014$), and to be published in a journal with a greater impact factor (4.9, 3.1-18.3 *v* 1.3, 1.2-1.5; $P=0.020$). Conversely, funding was not significantly associated with authors' recommendations supporting the routine use of acetylcysteine (43% (three of seven) for studies reporting previous not for profit funding



Scatter plot showing relation between manuscript length and quality of reporting of meta-analyses (QUOROM) score. Thorough and complete reports achieved higher scores

compared with 66% (two of three) for the others; $P=0.42$) or QUOROM score (16, range 11-17 for studies with previous not for profit funding compared with 14, range 12-16 for the others; $P=0.38$).

Journal type was significantly associated with quality of reporting, with a significant trend towards increasing QUOROM scores from reviews published in cardiology journals. Moreover, QUOROM scores and Oxman and Guyatt scores were not associated (Pearson $R = -0.06$, $P=0.86$, Spearman $\rho = -0.11$, $P=0.76$).

Limits of the included studies

Heterogeneity was appraised in most of the included meta-analyses (nine reviews). In all cases evidence for statistical heterogeneity was present (P values ranging from 0.05 to <0.001), and in all studies except one^{w4} reviewers computed pooled effect size on the basis of random effects methods (seven reviews), fixed effects (one), and both methods (one).

Bias due to small study size was acknowledged and explicitly tested in most (eight) reviews, using Begg, Egger, or Rosenthal tests. Such tests provided significant results, suggesting potential bias in five cases, prompting reporting and discussion of funnel plots in four of the five, plus another review that had none the less reported a non-significant test (table 1). Despite checking for small study bias among the same pool of seven studies, two reached disparate conclusions, one in favour and one against the likely presence of bias. All meta-analyses went forward with the pooled estimates, thus providing potentially biased results. Another study carried out two separate analyses, the first limited to trials published as complete reports and the second including trials available only as abstracts.^{w10} The authors showed that bias due to small study size was likely when selecting studies published only as complete reports ($P=0.02$), but that it was no longer evident when including studies reported only as abstracts ($P=0.22$).^{w9}

Discussion

Overall compliance with the QUOROM checklist was relatively good by the investigators of 10 overlapping systematic reviews on the role of acetylcysteine in the prevention of contrast associated nephropathy. Shorter manuscripts were of significantly lower quality and previous not for profit funding was associated with higher quality.

Less rigorous reviews have reported positive conclusions more often than more robust reviews focusing on the same topic.⁷ Systematic reviews have the drawback that several independent meta-analysts may conceive, carry out, and submit a review on the same topic simultaneously. This phenomenon has already occurred.^{14 15} This may be welcomed as a means of highlighting the subjective choices and different perspectives of carrying out research synthesis. The risk of wasting resources and providing contradictory conclusions should not be dismissed. In the present series, 49 investigators analysed the same clinical topic, highlighting the waste of time and duplication of efforts in such research.

Constraints on space reflected by manuscript and abstract length are important hurdles. We found that

What is already known on this topic

Multiple systematic reviews on the same clinical topic may produce conflicting results

The quality of reporting of meta-analysis (QUOROM) statement was developed to improve the quality of reviews, yet its effect is uncertain

What this study adds

Ten overlapping systematic reviews on acetylcysteine to prevent contrast nephropathy varied in quality of reporting and recommendations

Longer manuscripts and previous not for profit funding were associated with higher quality

no meta-analysis can achieve optimal quality scores unless sufficient space is provided for all its sections.

Funding might influence outcomes and quality of research.¹⁶ Reviewers who reported previous not for profit funding were more likely to carry out higher quality systematic reviews.

Although the QUOROM statement concerns the reporting of quality, the Oxman and Guyatt index focuses on methodological quality.¹² The relative disagreement between the scores in our study stems from the different purposes of the checklists. Indeed, lack of reporting on the assessment of the internal validity of single randomised controlled trials may restrict Oxman and Guyatt scores to the low 1-3 range, even for well reported meta-analyses.¹⁰

One major difference between the systematic reviews we appraised was the number of primary studies included, with some reviews analysing as few as five.⁸ Potential explanations might be the extent of database searches, language restrictions, selection restricted to randomised controlled trials or included non-randomised studies, and timing of review.

Finally, almost all reviewers carried out and reported formal meta-analyses in the presence of heterogeneity and small study size. Although meta-regression and sensitivity analyses were employed to tackle these issues, the conflicting recommendations may in part be a consequence of such discrepancies and biased publication of primary studies.

Prospective registration of titles and protocols may avoid multiple overlapping reviews.¹⁷ Another option might be online registration of meta-analyses already accepted for publication. These measures are none the less likely to impose logistical and financial hurdles potentially proving counterproductive.

Limitations of our study include its design, its scope for generating the hypothesis, and the risk of α and β errors.¹⁸ Moreover, most of this study involved the appraisal of published meta-analyses using the QUOROM checklist. Although scientific evidence supports only a subset of the items on the checklist, we believe that it should be used as a standard in the preparation, reporting, and appraisal of meta-analyses of randomised controlled trials on the basis of its wide dissemination and endorsement and the relative ease with which compliance can be achieved.

This study is part of a senior training project from the Center for Overview, Meta-analysis, and Evidence-based medicine Training (COMET) (http://it.geocities.com/comet_milano/Home.htm). We thank the authors of the systematic reviews for their help.

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Receiving a summary of the results of a trial: qualitative study of participants' views

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Abstract

Objective To explore trial participants' responses to receiving a summary of the results of a trial in pregnancy.

Design Qualitative study with semistructured interviews.

Participants 20 women who had when pregnant participated in the ORACLE trial of antibiotics for preterm labour and preterm rupture of the membranes and requested a copy of the trial results.

Results Less than a fifth of women who participated in the ORACLE trial indicated that they wished to receive the trial results. Reactions to the leaflet summarising the trial results were generally positive or neutral, although some women had difficulty in understanding the leaflet, and there was evidence of possible negative implications for women who had adverse outcomes. Women requested the results because they were interested in being able to complete their own personal narrative. They wished to know to which arm of the trial they had been allocated and the implications for their own pregnancy, and they were disappointed with receiving a generic summary. Women's accounts indicated some confusion about the trial findings.

Conclusions Recommendations that research participants be routinely provided with the results of studies have been made without the benefit of research to show the consequences of doing this or how it should best be managed. Caution is needed, as

is more evaluation of how feedback of results should be handled, and assessment of the risks, benefits, and costs.

Introduction

The idea that research participants should be given the results of studies in which they have participated is one that has gained ground. It has been promoted as an element of responsible ethical research practice,¹ and as a participant's right.²⁻⁵ Despite these positions on the desirability of feeding back results to study participants, little research has been done into the outcomes and implications of providing such feedback or into how it should best be managed.⁶ We explored the views of women who received a leaflet summarising the findings of the trial in pregnancy in which they had participated.

Methods

We conducted a qualitative study based on in-depth interviews with women who had participated in the United Kingdom in ORACLE, a large randomised trial, and who had requested the results of the trial. All participants provided informed consent.

ORACLE was a double blind randomised controlled trial of antibiotics in pregnancy, designed to test the



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