



Quality of reporting of the literature on gastrointestinal reflux after repair of esophageal atresia–tracheoesophageal fistula^{☆,☆☆}



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ABSTRACT

Objectives: There is variation in the management of postoperative gastroesophageal reflux (GER) in esophageal atresia–tracheoesophageal fistula (EA-TEF). Well-reported literature is important for clinical decision-making. We assessed the quality of reporting (QOR) of postoperative GER management in EA-TEF.

Methods: A comprehensive search of MEDLINE, EMBASE, CINHAL, CENTRAL databases and gray literature was conducted. Included articles reported a primary diagnosis of EA-TEF, a secondary diagnosis of postoperative GER, and primary treatment of GER with antireflux medications. The QOR was assessed using the STrengthening the Reporting of OBServational studies in Epidemiology (STROBE) checklist.

Results: Retrieval of 2910 articles resulted in 48 relevant articles ($N = 2592$ patients) with an overall quality percentage score of 48%–95% (median = 65%). The best reported items were “participants” and “outcome data” (93.8% each), “generalisability” (91.7%) and “background/rationale” (89.6%). Less than 20% of studies provided detailed “main results”; less than 5% of studies reported adequately on “bias” or “funding.” Sample size calculation and study limitations were included in 17 (35.4%) and 16 (33.3%) studies respectively. Follow-up time was inconsistently reported.

Conclusions: Although the overall QOR is moderate using STROBE, important areas are underreported. Inadequate methodological reporting may lead to inappropriate clinical decisions. Awareness of STROBE, emphasizing proper reporting is needed.

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Evidence-based health care requires physicians to keep up to date with the available literature to be able to integrate best research evidence with clinical expertise and patient values [1]. However, with so many articles published weekly, it is impossible to read all articles relevant to one's field. Thus, systematic reviews and meta-analyses are key in summarizing published data into one paper for application to surgical practice. Although widely accepted as a “gold standard,” systematic reviews fail to assess the quality of the reporting of the included literature [2].

Quality appraisal is gaining popularity and there are multiple checklists to ensure quality of reporting in different study designs [3–6]. Pediatric surgery studies are mostly observational in nature and thus comprised of a heterogeneous group of study designs. In addition to checklists provided by journals for manuscript submission (eg, “Guidelines for the reporting of clinical research data in the *Journal of Pediatric Surgery*” [3]), the STROBE statement (STrengthening the Reporting of OBServational studies in Epidemiology) provides researchers with a checklist of items to include in the reporting of observational studies, to strengthen the ability of reviewers to critically appraise the data presented [5]. The benefits of quality appraisal

tools include ranking, weighting, or scoring of studies; however, subjective assessment is still required, as most checklists use terms such as “adequate” and “appropriate” to describe criteria [7,8].

The medical management of postoperative gastroesophageal reflux (GER) in esophageal atresia (EA) with or without tracheoesophageal fistula (TEF) is one area of pediatric surgery where there is wide practice variation; many agents are available to manage GER yet there is no consensus on how to utilize these medications. Postoperative GER has an incidence of 27%–75%, thus it is important for studies to be appraised so that surgeons can make appropriate clinical decisions [9–12]. The aim of this study was to assess the overall quality of reporting (QOR) of published observational studies in the postoperative medical treatment of GER in the EA-TEF literature. We hypothesized that despite widespread availability of guidelines and methodological recommendations, varying levels of quality of reporting (QOR) will be encountered [5,13]. Additionally, we hypothesized that there would be a positive correlation between QOR and level of evidence (LOE) [14].

1. Methods

1.1. Study selection

We examined the published observational literature regarding the postoperative care of GER of infants with EA-TEF. A comprehensive

[☆] Level of evidence: n/a (quality appraisal).

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search of MEDLINE, EMBASE, CINAHL, CENTRAL, and Cochrane Systematic Review Database online databases, as well as gray literature including PapersFirst and ProceedingsFirst, was carried out. We searched based on MeSH headings and their permutations for “esophageal atresia” with or without “tracheoesophageal fistula” and “gastroesophageal reflux” in combination with terminology for medication therapy (antireflux medication, proton pump inhibitor, histamine-2 antagonist, thickened feeds, positioning), from all databases’ inception until November 2012. Keyword searching was used when database capabilities were limited. A priori eligibility included studies reporting on postoperative outcomes of patients with GER treated medically after surgical repair of their EA-TEF and an observational study design. We included all observational designs (ie, case series, cross-sectional, case-control, and retrospective and prospective cohort), with the exception of case reports ($n = 1$). Two reviewers (A.S., J.D.) independently assessed the title, abstract, and keywords of all eligible articles to determine whether they met the inclusion criteria. If there was any doubt, the full text of the article was retrieved and read by both reviewers. Disagreements were discussed and resolved by consensus.

1.2. Quality of reporting assessment

The literature retrieved was examined for threats to the internal and external validity specific to longitudinal research and epidemiologic methods in general. Two independent reviewers (A.A., D.K.) assessed the quality of reporting using the STROBE checklist. The checklist contains a list of 22 items, with 4 items having specific criteria depending on the study design. For example, “Participants,” which includes specific criteria for the eligibility/handling of patients based on if the study is a cohort, case-control or cross-sectional study. The other items with specific criteria were “Statistical methods,” “Descriptive data,” and “Outcome data.” Reviewers independently determined whether each item of the checklist was described adequately in the text to assess the quality of reporting in the included articles. (Note: Not the likelihood of bias but only the quality of reporting.) Disagreements were resolved by consensus. Once a final score out of 22 was established, an overall quality percentage (OQP) score based on included items from the STROBE statement was calculated for each study. Studies were rated as high (OQP >70%), moderate (OQP 40%–70%) or low reporting quality (OQP ≤40%). We adapted the categorization of the Assessment of Multiple

Systematic Reviews (AMSTAR) checklist (which characterizes 3 quality levels) to our OQP scores to permit comparison to LOE [15,16].

1.3. Statistical analysis

Descriptive statistics including counts, percentages, means, and standard deviations were calculated and data were explored graphically for trends and to assess normality. Agreement between reviewers was calculated using Cronbach’s α and the intraclass correlation coefficient (ICC) for reliability. Fisher’s exact test was performed to delineate the relationship between LOE and OQP. All statistical analyses were conducted in SPS (V20.0) [17].

2. Results

A total of 2910 articles were retrieved resulting in 48 relevant articles ($N = 2592$ patients) [18–65]. There was excellent agreement between reviewers (Cronbach α 0.935) (ICC 0.088, 95% CI 0.793–0.931). Most were single center studies (90.0%). The majority were retrospective studies (39/48), 5 were cross-sectional studies (surveys), and four were prospective observational studies; there were no randomized control trials. Included studies were from North America (14), Europe (25), Middle East (3), and Asia (6).

The median OQP across all included studies was 65% (minimum 48%, maximum 95%) (Fig. 1). The best reported individual items were “participants” and “outcome data” (45/48 each, 93.8%), “generalisability” (44/48, 1.7%), and “background/rationale” (43/48, 89.6%). “Main results” were reported adequately in less than 17% of studies (8/48); “bias” or “funding” in less than 5% (1/48 and 2/48 respectively). Descriptions of sample size calculation and study limitations were included in 17 (35.4%) and 16 (33.3%) studies respectively.

Thirty-nine papers were published during or before 2007, and 9 after 2007. There was no significant difference in OQP between studies published before and after the publication of STROBE in 2007 (χ^2 (1, $N = 48$) = 0.14, $p = 0.71$) (Fig. 2).

Papers with sample sizes greater than 50 were of high OQP (12/20) whereas 12/28 of those with sample size less than 50; however, this was not significantly different because of the small proportion of studies (χ^2 (1, $N = 48$) = 1.37, $p = 0.24$) (Fig. 3).

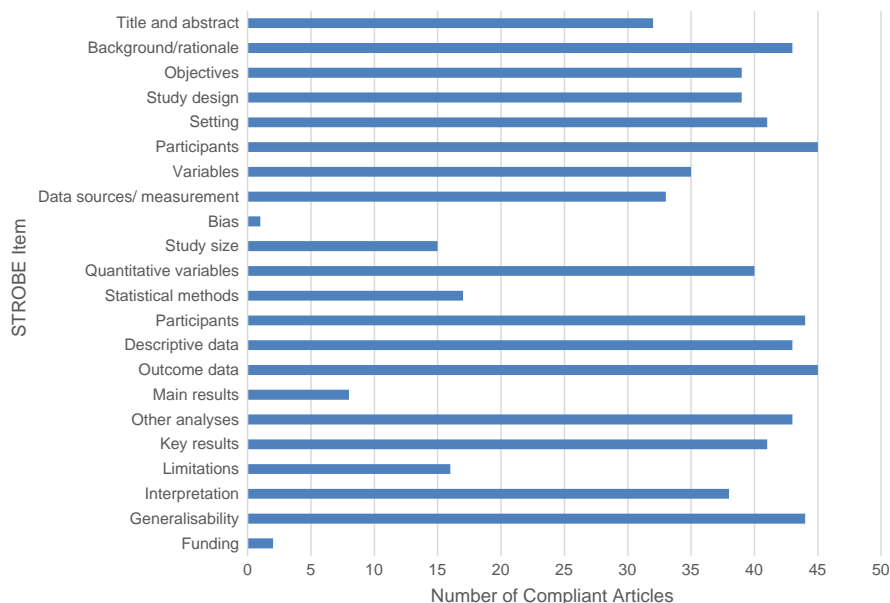


Fig. 1. Number of articles reporting items on the STROBE checklist.

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