Pyloric drainage (pyloroplasty) or no drainage in gastric reconstruction after esophagectomy: a meta-analysis of randomized controlled trials

Urschel J D, Blewett C J, Young J E, Miller J D, Bennett W F

Authors' objectives
To compare pyloric drainage with no pyloric drainage in patients undergoing oesophagectomy and gastric reconstruction for cancer.

Searching
MEDLINE was searched to July 2001 and details of the search strategy were presented. The bibliographies of identified studies and the first author's index file were manually searched. Foreign language studies were translated into English.

Study selection
Published randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Comparisons of pyloric drainage with no pyloric drainage were eligible for inclusion. Only studies with a no drainage control were included. The studies included in the review used pyloroplasty or pyloromyotomy to provide drainage.

Participants included in the review
The authors did not explicitly state any inclusion criteria for the participants. However, the searches attempted to identify studies of patients undergoing oesophagectomy and gastric reconstruction for cancer. Around 10% of the included patients did not have malignant disease. The included studies used various surgical techniques: oesophagectomy was carried out using transthoracic or transhiatal methods; surgery was curative, palliative or bypass; the route of reconstruction was posterior or anterior; and gastric conduit, where reported, was achieved using whole stomach or gastric tube.

Outcomes assessed in the review
The outcomes that had to be reported for the studies to be eligible were not explicitly stated. The review assessed early and late (several months) outcomes. The early outcomes were operative mortality, oesophagogastric anastomotic leaks (diagnosed clinically or radiologically), pulmonary morbidity (including pneumonia, atelectasis and respiratory failure), pyloric drainage complications (including leakage and structuring), fatal pulmonary aspiration, and gastric outlet obstruction. Gastric outlet obstruction, as defined by the author or by the impairment of gastric emptying on 1-week post-operatively contrast examination, was defined differently in the individual studies. The late outcomes were gastric emptying (including scintographic assessment), bile reflux, food intake and nutritional status, and obstructive foregut symptoms.

How were decisions on the relevance of primary studies made?
The searches were conducted independently and in duplicate.

Assessment of study quality
Study quality was assessed using the 5-point scale of Jadad et al. (see Other Publications of Related Interest), which assesses the adequacy of randomisation, blinding and the handling of withdrawals. Inter-rater agreement was assessed. Study quality was assessed independently and in duplicate.

Data extraction
The data were extracted independently and in duplicate, and any disagreements were resolved by consensus. The
information tabulated for studies reporting early post-operative outcomes included: author and year of publication, route of reconstruction, location of anastomosis, type of gastric conduit and type of drainage procedure, and early post-operative outcomes. Thirty-day in-hospital mortality outcomes were extracted where possible. In the individual studies, the late outcomes were scored as follows: zero where there were similar outcomes between interventions; -1 or +1 where there was a non statistically-significant trend; and -2 or +2 where there was a statistically-significant difference between the interventions. Negative values indicated 'less than' and positive values indicated 'greater than'. The ratio of pyloric drainage versus no pyloric drainage for scintographic gastric emptying data was calculated for each study. Erect emptying times were used where possible.

Methods of synthesis
How were the studies combined?
The pooled relative risk (RR) and 95% confidence intervals (CIs) were calculated for the early outcomes using a random-effects model. A semi-quantitative synthesis was undertaken with the data for the late outcomes. The data for scintographic gastric emptying were also combined, with weighting by sample size.

How were differences between studies investigated?
Differences between the studies were not formally investigated, although the authors discussed differences between the studies.

Results of the review
Nine RCTs (533 patients) were included.

Inter-rater agreement on study quality was 100%. The trials differed in the inclusion criteria for the patients, outcome assessments, surgical method used, extent of surgery, pathology, route of reconstruction, type of gastric conduit and method used for pyloric drainage.

Early post-operative outcomes (3 RCTs, 347 patients).

There was no statistically-significant difference between pyloric drainage and no drainage for post-operative mortality, oesophagogastric anastomotic leaks, pulmonary morbidity, pyloric drainage complications or fatal pulmonary aspiration. The RR was 0.92 (95% CI: 0.34, 2.44, P=0.86) for post-operative mortality, 0.90 (95% CI: 0.47, 1.76, P=0.77) for oesophagogastric anastomotic leaks (2 RCTs, 307 patients), 0.69 (95% CI: 0.42, 1.14, P=0.15) for pulmonary morbidity, 2.55 (95% CI: 0.34, 18.98, P=0.36) for pyloric drainage complications, and 0.25 (95% CI: 0.04, 1.60, P=0.14) for fatal pulmonary aspiration. For gastric outlet obstruction, the RR was 0.18 (95% CI: 0.03, 0.97, P=0.046) for pyloric drainage.

Late outcomes.

There was no statistically-significant difference between pyloric drainage and no drainage for gastric emptying (-0.97), food intake and nutritional status (+1.02), obstructive foregut symptoms (-0.84) and bile reflux (+1.0). Gastric emptying was shorter with pyloric drainage (the ratio of pyloric drainage to no drainage was 0.53). The CI and P value were not presented in the review.

Authors’ conclusions
Pyloric drainage reduced early post-operative gastric outlet obstruction after oesophagectomy with gastric reconstruction, compared with no pyloric drainage, but there was no difference between pyloric drainage and no drainage for the other outcomes.

CRD commentary
The review question was clear in terms of the intervention, outcomes and study design. Restricting the search to published studies identified in one database may have resulted in the omission of other relevant studies, and it also raises the possibility of publication bias. The study selection, data extraction and quality assessment processes were
carried out in duplicate, which helps to reduce errors and any bias. Study quality was assessed, but the results were not reported and study quality was not mentioned in the text of the review. There was only limited information on the studies reporting early post-operative outcomes, and there was no information (not even the number of participants) on the studies reporting late outcomes. Statistical heterogeneity was not assessed for studies providing data for the meta-analysis. Consequently, it is not possible to assess the appropriateness of combining these studies in a meta-analysis. The late outcomes were combined using a semi-quantitative method that gave numerical values that were not easy to interpret. A narrative synthesis may have provided more accessible and useful information for late outcomes.

The authors' conclusions appear to follow from the evidence presented, although it must be taken into account that the evidence was based on a small number of clinically heterogeneous studies.

**Implications of the review for practice and research**
Practice: The authors did not state any implications for practice.

Research: The authors state that further larger trials are required.

**Bibliographic details**

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12119515

**Other publications of related interest**

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