A meta-analysis on the efficacy of preoperative biliary drainage for tumors causing obstructive jaundice

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Authors' objectives
To compare pre-operative biliary drainage (PBD) with no pre-operative draining in patients with obstructive jaundice caused by tumours.

Searching
MEDLINE, EMBASE, Current Contents and the Cochrane Database of Systematic Reviews were searched from 1966 to September 2001 for studies published in the English language in peer-reviewed journals. The search terms were stated. The bibliographies of the identified studies were also examined.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and non-randomised controlled studies that used a concurrent control were eligible for inclusion. The non-randomised studies included in the review were prospective cohort studies and retrospective cohort studies.

Specific interventions included in the review
Comparisons of PBD and no preoperative draining were eligible for inclusion. The included studies used solely internal PBD, solely external PBD or both methods. In addition, the patients underwent definitive surgery to deal with the obstruction, such as resection, bypass, exploratory laparotomy and others (hepatic lobectomy, choledochotomy and bile duct resection).

Participants included in the review
Studies of patients with obstructive jaundice due to tumours were eligible for inclusion. The patients in the included studies were obstructed at different levels of the biliary tract (from proximal to distal) and had either benign or malignant tumours. These included pancreatic cancer, ampullary cancer and distal or proximal cholangiocarcinoma. The mean age of the patients was approximately 63 years.

Outcomes assessed in the review
Studies that reported post-operative death and complications due to PBD, and the length of hospital stay due to the PBD and after surgery, were eligible for inclusion. Studies were included even if the analysis of the outcomes was based on data collected retrospectively.

How were decisions on the relevance of primary studies made?
Two authors independently assessed the eligibility of the identified studies with respect to study design.

Assessment of study quality
Study quality was reported as being assessed and scored using the following criteria (see Other Publications of Related Interest): adequacy of methods of randomisation; blinded assessment of outcome; estimation of sample size; treatment of withdrawals; description of patient characteristics; evaluation of patient enrolment; and assessment of interventions. Two authors independently assessed study quality and resolved any disagreements by discussion. Inter-rater agreement was measured using the intraclass correlation.

Data extraction
Two reviewers extracted data on the study design, number of patients per treatment group, type of drainage, outcomes
and validity criteria using a standardised form. The reviewers were masked to the authors names and institutions, study location, reference lists and other possible identifiers. Inter-rater agreement was measured.

**Methods of synthesis**

*How were the studies combined?*

The studies were classified into 2 groups: RCTs (level 1 studies); and non-randomised studies with a concurrent control group plus studies that analysed outcomes post hoc (level 2 studies). Within each of these groups, the studies were combined in a meta-analysis. For mortality and morbidity outcomes, the pooled odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using the fixed-effect (Peto) method. The pooled mean length of hospital stay and its standard error were calculated for the PBD and the no PBD group. A p-value was then calculated for the difference in the means.

*How were differences between studies investigated?*

Statistical heterogeneity was tested using the chi-squared statistic, and presented graphically using forest plots for mortality and morbidity ORs only.

**Results of the review**

Five RCTs (312 patients) and 18 non-randomised studies (2,853 patients) were included. The non-randomised studies included 11 prospective cohort studies (2,115 patients) and 5 retrospective cohort studies (738 patients).

The inter-rater agreement on the data extraction was 100%. In 4 of the 5 RCTs adequate allocation concealment was reported and the outcome assessor was blinded.

**Level 1 studies (RCTs).**

There was no significant difference between PBD and no PBD in the overall death rate: 15.9% with PBD versus 13.5% with no PBD. The OR was 1.90 (95% CI: 0.63, 2.23). No significant statistical heterogeneity was found (p=0.78). The pre-operative death rate was 5.1% with PBD versus 1.3% with no PBD. The post-operative death rate was 10.8% with PBD versus 13.5% with no PBD. Neither difference was statistically significant.

The overall complication rate was significantly higher with PBD than with no PBD: 57.3% with PBD versus 41.9% with no PBD. The OR was 1.99 (95% CI: 1.25, 3.16). No significant statistical heterogeneity was found (p=0.40). The drainage-related complication rate was 27.4% with PBD. These complications included perforation of the duodenal wall, bleeding and pancreatitis. The post-operative complication rate was significantly lower with PBD (29.9%) than with no PBD (41.9%). The OR was 0.59 (95% CI: 0.37, 0.94). No significant statistical heterogeneity was found (p=0.28).

The mean total length of hospital stay was significantly increased with PBD compared with no PBD: 42 days versus 24 days (p<0.01). The mean number of pre-operative days was 14.6 days with PBD. There was no significant difference in the length of post-operative hospital stay between PBD (27 days) and no PBD (24 days).

**Level 2 studies.**

There was no significant difference between PBD and no PBD in the overall death rate: 3.2% with PBD versus 4.9% with no PBD. The OR was 0.91 (95% CI: 0.61, 1.36). No significant statistical heterogeneity was found (p=0.25).

The overall complication rate was significantly higher with PBD (58.8%) than with no PBD (42.1%). The OR was 1.64 (95% CI: 1.20, 2.26). The studies were very heterogeneous.

The mean length of hospital stay was significantly increased with PBD compared with no PBD: 33 days versus 18 days (p<0.01).

**Authors’ conclusions**
PBD cannot be routinely recommended for unselected patients with obstructive jaundice due to tumours.

**CRD commentary**
The review question was clear in terms of the study design, participants, intervention and outcome. A number of electronic databases were searched, but restricting the search to studies published in the English language in peer-reviewed journals might have resulted in the omission of other relevant studies. The study selection, assessment of validity and data extraction processes were carried out in duplicate, which helps to reduce bias and errors. However, the criteria used to assess validity were not applicable to cohort studies, and it does not appear that the quality of the cohort studies was adequately assessed. In addition, there was insufficient information on the included studies.

The studies were appropriately grouped according to study design, and the RCTs were appropriately combined in a meta-analysis. However, in reviews of observational studies, meta-analysis should not be a major component. Statistical heterogeneity was assessed for some outcomes, but no comment was made on significant heterogeneity where this was detected. The considerable clinical heterogeneity among studies and the implications of this diversity were, however, discussed. The authors’ conclusions appear to follow from the evidence presented from the RCTs.

**Implications of the review for practice and research**
**Practice:** The authors state that PBD cannot be recommended as a routine procedure.

**Research:** The authors state that further well-designed RCTs are required to identify any subgroups of patients who may benefit from PBD. The authors also state that a cost-benefit analysis should be part of any future trials.

**Bibliographic details**

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12131081

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.