Biliary stenting versus bypass surgery for the palliation of malignant distal bile duct obstruction: a meta-analysis
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Authors' objectives
To compare endoscopic stenting with surgical bypass in patients with unresectable, malignant, distal common bile duct obstruction.

Searching
MEDLINE was searched from 1986 to May 1999 using the MeSH terms: 'extrahepatic bile duct obstruction', 'pancreatic neoplasms' and 'clinical trials'. References were scanned and academic clinicians (hepatobiliary surgeons, hepatologists and interventional radiologists) contacted for details of either ongoing trials or trials reported in abstract form. Only studies published after 1986 in the English language were eligible.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) with at least twenty patients per treatment group, which followed-up patients until death and reported follow-up and complications similarly in each treatment arm were eligible.

Specific interventions included in the review
Inclusion criteria were not defined in terms of interventions. Included studies compared plastic endoscopic stenting (stent size 10 F used in 85 to 100% of cases) with surgical bypass operations (choledochojjunostomy, cholecystojjunostomy and choledochoduodenostomy). Additional treatments, required when the first treatment was initially successful but symptoms persisted, were stent replacement, percutaneous transhepatic drainage and surgery.

Participants included in the review
The inclusion criteria for the review were not defined in terms of the participants. A large number of patients in the review did not have a pathologically-confirmed diagnosis of malignancy (range from 24 to 59%) though clinical characteristics were consistent with malignant disease. Inclusion criteria in specific studies were: primary malignancy, obstructive jaundice, resection not possible and endoscopic retrograde cholangiopancreatography (ERCP) technically possible; age greater than 60 years, distal lesion on ERCP, probable malignancy, bypass technically possible and fit for general anaesthesia; and distal obstruction caused by primary malignancy, serum bilirubin level greater than 100 mmol/L and surgical resection not possible. Mean age ranged from 70 to 77 years across treatment arms and the proportion of men ranged from 32 to 68%.

Outcomes assessed in the review
The inclusion criteria were not defined in terms of the outcomes. The specific outcomes assessed were the number of treatment failures, serious complications, patients requiring additional treatment, and deaths in first 30 days after treatment. Treatment failure was defined as failure to achieve effective palliation or the failure of the patient to receive the assigned treatment. The definition of serious complication varied across studies and the investigators' definition was accepted.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
Validity was assessed using a 10-point scoring system for RCTs (see Other Publications of Related Interest no.1). The authors do not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.
Data extraction

Tables presented in the review include the following data: patient inclusion and exclusion criteria; time of randomisation; method of randomisation; advance sample size calculation; number of patients per treatment arm; mean age; number of men; percentage in whom cancer was confirmed pathologically; and surgical procedure. Data were extracted by two of the authors, one of whom was blinded to the identity and institutional affiliations of the investigators. Investigators were contacted for additional data and for data not presented in the initial report (only one investigator from one study responded).

For each study the relative odds (OR) and 95% confidence interval (CI) of outcome (number of treatment failures, serious complications, patients requiring additional treatment, and deaths in first 30 days after treatment) were calculated for stent relative to surgery.

Methods of synthesis

How were the studies combined?
Where there was no evidence of statistical heterogeneity across studies, the Mantel-Haenszel method was used to estimate a pooled OR. Where statistical heterogeneity was detected, the studies were combined in a narrative review. All results were presented as forest plots.

How were differences between studies investigated?
The Breslow-Day test was used to assess statistical heterogeneity.

Results of the review

Three RCTs were included in the review (303 patients).

All 3 studies scored 7 or more for validity and were judged to be of adequate quality. Methodological problems included small sample size, poorly defined outcomes and inadequate blinding. No studies that used metallic expandable stents were identified.

Evidence of statistical heterogeneity was found across studies for rates of treatment failure and serious complications; summary ORs were, therefore, not calculated.

Significantly more treatment sessions were required after stent replacement than after surgery. There was no statistically-significant difference in 30-day mortality between patients receiving stents or surgical bypass.

Treatment failure: 2 RCTs showed no significant difference between treatment groups and 1 RCT showed lower odds for the stent group. Heterogeneity was significant (p=0.041).

Serious complications: in 2 RCTs, serious complications were less common in the surgery group, whereas in the other study, complications were less common in the stent group. Heterogeneity was significant (p=0.021).

Number of additional treatment sessions: significantly more treatment sessions were required after stent replacement than after surgery. All 3 studies found that the stent group required significantly more treatment sessions compared to the surgery group. OR favouring stents was 7.23 (95% CI: 3.73, 13.98; heterogeneity, p=0.98). Thirty-day mortality: there was no statistically-significant difference in 30-day mortality between patients receiving stents or surgical bypass (OR 0.522, 95% CI: 0.263, 1.036).

Authors' conclusions

Whilst surgical bypass required fewer additional treatment sessions, existing data do not allow a definitive conclusion on which treatment is preferable. A larger RCT using newer metallic stents and proper quality-of-life instruments is required.
The aims were stated and the inclusion criteria were defined in terms of study design and outcome. English language publications were sought from only one database, although experts in the field were contacted for additional ongoing studies or those published in abstract format. Other relevant studies may have been identified by including articles published in other languages. Only RCTs were included and validity was assessed using an index; however, no details were given of criteria included in the index or methods used to assess and score validity. Comprehensive details of the included studies were presented in tabular format and data were extracted by two researchers, but it was not reported how discrepancies were handled. Pooling of data was performed appropriately but only in the absence of statistical heterogeneity; when heterogeneity was detected, potential causes were not discussed.

The evidence as presented supports the authors' conclusions.

**Implications of the review for practice and research**

Practice: The authors state that for patients who could be candidates for either stent or bypass surgery, currently, the choice may be based on patient preference and local availability.

Research: The authors state that a larger RCT using newer metallic stents and validated quality-of-life instruments is required. Widespread use of a classification system for surgical complications would be useful in improving the similarity of reports from various centres (see Other Publications of Related Interest nos.2-4).

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**Other publications of related interest**


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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.