Endoscopic palliation of malignant obstructive jaundice: an evidence-based review

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CRD summary
This review concluded that endoscopic palliation of malignant obstructive jaundice might be more effective than surgery for distal biliary obstructions, while for hilar tumours it should be used when the tumour is unresectable, cholangitis is present and in clinically ambiguous situations. The conclusions should be interpreted cautiously given that they are based on small numbers of diverse studies with often small numbers of participants.

Authors’ objectives
To compare the clinical effectiveness, safety and cost-effectiveness of endoscopic versus surgical palliation of malignant obstructive jaundice.

Searching
MEDLINE, EMBASE, Excerpta Medica, Current Contents and the Cochrane CENTRAL Register were searched to July 2006; the search terms were reported. Only studies published in the English language were eligible for inclusion. The bibliographies of relevant studies and the authors’ personal databases were also checked for additional studies.

Study selection
Study designs of evaluations included in the review
Inclusion criteria for the study design were not explicitly stated.

Specific interventions included in the review
Studies evaluating the efficacy of endoscopic palliation in patients with malignant biliary obstruction, as well as studies comparing endoscopic palliation versus any other form of palliation (radiological or surgical), were eligible for inclusion. Endoscopic palliation used plastic, covered or uncovered self-expandable metal stents (SEMS).

Participants included in the review
Studies including patients with malignant jaundice from distal or proximal biliary obstruction were eligible for inclusion in the review.

Outcomes assessed in the review
The primary outcomes included technical success, survival, relief of jaundice, quality of life, length of hospital stay, overall costs, rate of re-intervention and procedure-related morbidity. Overall mortality; 30-day mortality or inhospital mortality were also assessed.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected studies for inclusion.

Assessment of study quality
Validity was assessed, but the authors did not state how many reviewers performed the validity assessment. The assessment of study quality was based on the CONSORT (Consolidated Standards of Reporting Trials) statement. Blinding was not considered since the authors stated that all evaluated trials were not blinded. The final quality score ranged from 0 to 21: poor-quality studies scored 0 to 7, medium quality 8 to 14, and high quality 15 to 21.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Incidences or percentage values were extracted for each outcome.
Methods of synthesis
How were the studies combined?
The studies were described narratively and the data were tabulated.

How were differences between studies investigated?
Differences in study design and outcomes were discussed in the text and presented in the tables.

Results of the review
Forty-four studies (4,994 participants) were included in the review.

Distal biliary obstruction.

There were 5 studies of endoscopic palliation versus surgical bypass. Compared with surgery, endoscopic palliation carried a comparable overall survival, peri-operative mortality and morbidity, jaundice relief and improvement in the patient's quality of life. Overall hospitalisation was also comparable (3 studies) although 2 studies suggested a statistically significant shorter initial hospitalisation with endoscopic palliation. Three studies reported a higher readmission rate with endoscopic palliation. The endoscopic palliation group was associated with significantly fewer major complication in comparison with the surgery group.

There were 5 studies of plastic versus metal stents. A similar median survival and rate of jaundice relief were found for metal and plastic stents (4 studies). SEMS were associated with a longer patency rate, which resulted in a decreased need for hospital readmission and endoscopic reintervention. No significant differences in peri-operative mortality or in complications were reported (4 studies). The patency rate seemed higher for covered SEMS than for uncovered stents (2 studies).

There were 12 studies of pre-operative biliary drainage. No differences in peri-operative mortality (10 studies) or in post-operative complications or death (5 studies) were reported between stented and non-stented groups. Discordant data were found for the length of hospitalisation.

Hilar biliary obstruction.

Endoscopic palliation of hilar malignant strictures achieved successful drainage rates of 15 to 100%, with no need for biliary re-intervention in most cases (4 studies). In a small randomised trial comparing metal with plastic stents, patients treated with plastic stents were more likely to experience a stent failure (50% versus 18.2%), an episode of cholangitis (33% versus 9%), to undergo re-interventions for stent-related problems (2.4 +/- 2.6 versus 0.4 +/- 0.5, p=0.05), or be hospitalised for stent complications (9.4 versus 1.1, p=0.03).

Left or right hepatic duct stenting appeared to have similar efficacy (1 study). Compared with bilateral stent placement, unilateral hepatic duct drainage was associated with a higher rate of successful drainage (81% versus 73%, p=0.049) and a lower rate of cholangitis (8.8% versus 16.6%, p=0.013), while 30-day mortality, late complications and median survival were similar for the two groups.

Cost information
Compared with plastic stents, SEMS seemed less expensive (3 studies). Among SEMS, covered stents were associated with lower costs than uncovered stents ($3,901 versus $5,129; 1 study).

Authors' conclusions
In the endoscopic palliation of distal biliary obstruction, stent insertion seems to provide effective palliation with comparable morbidity and mortality, and possibly shorter hospital stay, than surgery. Endoscopic palliation could be considered in older patients and those with advanced cancer, with metal stents preferred over plastic ones if expected survival is more than 6 months. In the case of hilar tumours, endoscopic palliation with SEMS might be indicated when the tumour is unresectable or cholangitis is present. Unilateral endoscopic stents appear safe and effective in most
cases.

CRD commentary
This review addressed a well-defined question in terms of the participants, interventions and outcomes, while a broad definition of study design was used. The authors carried out a reasonable search for published studies, but it is unclear whether unpublished studies were specifically sought; since the potential for publication bias was not assessed, this might be a problem. In addition, only studies published in English were included, which might have introduced language bias. The authors attempted to minimise bias and errors by carrying out the study selection in duplicate, but it is unclear whether the data extraction and study quality assessment were also performed in duplicate, therefore reviewer error and bias might have been introduced at these stages. The assessment of study quality was based on the CONSORT statement, which is concerned with the standards of reporting trials and is not designed to assess study validity.

The authors’ decision not to pool the data in a meta-analysis appears appropriate given the level of clinical heterogeneity in the identified studies. Overall, the small number of apparently heterogeneous and often small trials may limit the reliability and generalisability of the authors' conclusions, which remain at least partially based on findings from subgroup analysis.

Implications of the review for practice and research
Practice: The authors stated that routine biliary drainage should be avoided pre-operatively and it should be reserved for those cases with acute cholangitis, coagulation abnormalities or malnutrition, or if surgery is delayed for several weeks.

Research: The authors stated that additional higher quality studies are needed to confirm the role of endoscopy in the palliation of malignant hilar biliary obstruction, as well as to compare modern surgical approaches with the latest stent technology.

Bibliographic details

PubMedID
17317347

DOI

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
AccessionNumber
12007001311

Date bibliographic record published
30/04/2008

Date abstract record published
16/05/2008

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.