Systematic review and meta-analysis of outcomes after intraoperative pancreatic duct stent placement during pancreaticoduodenectomy


CRD summary
The authors concluded that pancreatic duct stenting, compared with no stenting, did not reduce the incidence of pancreatic fistula and other complications, in pancreaticoduodenectomy. External stents seemed to reduce the incidence of pancreatic fistula, compared with no stent. They appropriately advised caution in interpreting their results and recommended further randomised controlled trials.

Authors' objectives
To analyse the evidence on the outcome of pancreaticoduodenectomy with or without stenting, and compare internal versus external stent placement.

Searching
PubMed, EMBASE, The Cochrane Library, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched, for studies published in English, in peer-reviewed medical journals, from January 1973 to September 2011. Search terms were reported. Relevant studies were sought in the bibliographies of papers found by the searches. Investigators of and experts on pancreaticoduodenectomy were contacted to find further studies.

Study selection
Randomised controlled trials or observational studies that compared either pancreatic duct stent with no stent, or internal with external stent placement, in patients undergoing pancreaticoduodenectomy, were eligible for inclusion. Studies had to report at least one of the following: the incidence of pancreatic fistula, as defined by the Johns Hopkins Hospital and the International Study Group on Pancreatic Fistula (ISGPF); delayed gastric emptying; postoperative intra-abdominal collection; overall morbidity; or mortality. Studies with duodenum-preserving pancreatic head resection or total pancreatectomy, and those that did not have a control group, were excluded.

The included studies were conducted in Japan, Germany, the USA, Hong Kong, South Korea, Thailand, Greece, or France. The surgical anastomosis technique and the definition of pancreatic fistula varied across studies. Half of them used the ISGPF definition of a pancreatic fistula. Where reported, a third of studies included octreotide or somatostatin injection after pancreaticoduodenectomy.

Two reviewers independently selected studies for the review; disagreements were resolved by consensus or by discussion with a third reviewer.

Assessment of study quality
The quality of the randomised controlled trials was assessed for randomisation, blinding, and withdrawals and dropouts, using the Jadad scale, producing scores from 0 to 5.

The quality of the observational studies was assessed using criteria described by McKay and colleagues, covering data collection (prospective versus retrospective), assignment to stent or no-stent group other than by surgeon’s preference, and explicit definition of pancreatic fistula or leak. Studies were given a point for each of these items; producing scores from 1 to 4.

It appears that more than one reviewer assessed quality.

Data extraction
The data were extracted to calculated odds ratios and their 95% confidence intervals. Two reviewers independently extracted the data; disagreements were resolved by consensus or by discussion with a third reviewer.

Methods of synthesis
The odds ratios and their 95% confidence intervals were pooled using a fixed-effect model, where there was no evidence of heterogeneity; otherwise a random-effects (DerSimonian and Laird) model was used. Heterogeneity was assessed using $\chi^2$ and $I^2$, with $I^2$ values of 50% or higher considered to be evidence of heterogeneity. Publication bias was assessed in a funnel plot.

**Results of the review**

Sixteen studies were included in the review, with 1,726 patients (range 43 to 234). Five were randomised controlled trials (RCTs) and 11 were observational studies. All RCTs scored 3 points on the Jadad scale, except one, which scored 2 points. Eight observational studies scored 1 point and three scored 3 points, in quality assessment. The funnel plot for the observational studies showed no evidence of publication bias.

**Stent versus no stent**: There were three RCTs and 10 observational studies. The meta-analysis of the three randomised controlled trials showed no significant difference in pancreatic fistula rate between the two groups, using the ISGPF definition (OR 0.73, 95% CI 0.49 to 1.10; $I^2=73\%$). The meta-analysis of the observational studies differed, showing that patients who had a stent were less likely to develop pancreatic fistula than those with no stent (OR 0.47, 95% CI 0.31 to 0.72; $I^2=39\%$; nine studies). There was no statistically significance difference between the two groups in overall mortality, postoperative morbidity, delayed gastric emptying, and intra-abdominal fluid collection, for both study designs.

**External versus internal stent**: The pooled results of the two RCTs showed no statistically significance difference between external and internal stent groups, in developing pancreatic fistula, delayed gastric emptying, and overall mortality. The pooled results of the two observational studies found no difference between the two groups, in developing pancreatic fistula.

**External versus no stent**: There were two RCTs and seven observational studies. An external stent was associated with a statistically significant reduction in the incidence of pancreatic fistula (OR 0.42, 95% CI 0.24 to 0.76; $I^2=0$; two RCTs; and OR 0.43, 95% CI 0.27 to 0.68; $I^2=48\%$; seven observational studies), postoperative morbidity (two RCTs) and delayed gastric emptying (two RCTs). No statistically significant difference was found for the other outcomes.

**Internal versus no stent**: The meta-analysis of the three observational studies showed no statistically significant differences between the two groups for all included outcomes.

**Authors' conclusions**

Pancreatic duct stenting, compared with no stenting, did not reduce the incidence of pancreatic fistula and other complications. There was no difference in efficacy between external and internal stents, but external stents did seem to reduce the incidence of pancreatic fistula, compared with no stent.

**CRD commentary**

The review addressed a clear question and was supported by appropriate inclusion criteria. Relevant sources were searched, but unpublished studies and studies in languages other than English were not sought, so relevant studies may have been missed. Appropriate methods to reduce reviewer error and bias were used. The quality of the included trials was assessed, but only the scores and not the full results were reported, which makes it difficult to interpret the reliability of the review findings. Appropriate methods were used to pool the data and to assess heterogeneity, but the possible sources of any heterogeneity could not be explored due to the small number of included studies.

The authors appropriately advised caution in interpreting their results, due to the small number of RCTs included in the review, and the potential for bias in the observational studies. They acknowledged some limitations, such as the small samples and the presence of significant statistical and clinical variation, and they rightly recommended further research.

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

**Practice**: The authors stated that the evidence was not sufficiently reliable to conclude that stents might reduce the incidence of pancreatic fistula.

**Research**: The authors stated that further appropriately powered multicentre RCTs were needed.

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