Prophylactic octreotide administration does not prevent post-endoscopic retrograde cholangiopancreatography pancreatitis: a meta-analysis of randomized controlled trials

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CRD summary
This review assessed prophylactic efficacy of octreotide on post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis and concluded that octreotide did not prevent post-ERCP pancreatitis. The authors’ conclusions appeared to reflect the evidence, but interpretation should take into consideration the poor quality of most included trials and uncertainty over pooling of data.

Authors' objectives
To assess the prophylactic efficacy of octreotide on post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis.

Searching
MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Library and Science Citation Index were search to January 2007 for articles in any language. Search terms were not explicitly stated. Reference lists of identified articles were searched and proceedings of major international meetings (no further details given) were handsearched.

Study selection
Randomised controlled trials (RCTs) that compared prophylactic administration of octreotide with placebo in patients who received ERCP and that reported post-ERCP pancreatitis were eligible for inclusion.

Included trials administered between 0.1mg and 0.5mg octreotide before and (in some trials) after ERCP. No other details were reported.

The authors did not state how many reviewers screened studies for inclusion.

Assessment of study quality
Two reviewers independently assessed the methodological quality of trials with criteria that included randomisation, allocation concealment and blinding. Trials that adequately fulfilled all three criteria were deemed to be at low risk of bias; trials that provided inadequate or unclear data on one or more criteria were considered at high risk of bias. Disagreements were resolved by consensus.

Data extraction
Two reviewers independently extracted quantitative data to calculate differences in outcomes between treatment groups and ultimately to calculate odds ratios (ORs) and their 95% confidence intervals (CIs).

Methods of synthesis
Odds ratios and 95% CIs were pooled using a fixed-effect model in the absence of heterogeneity or a random-effects model where statistical heterogeneity was present. The number needed to treat to prevent one outcome event was calculated. Subgroup analyses were undertaken by administration method (only before ERCP versus before and after ERCP, by sample size (more versus fewer than 200 patients) and pre-ERCP risk (high versus average risk). Sensitivity analyses were performed by exclusion of trials published as an abstract only and trials with high risk of bias.

Statistical heterogeneity was assessed using the Cochran X² test and I² statistic. Publication bias was assessed through visual inspection of a funnel plot.

Results of the review
Fifteen RCTs (n=2,621) were included in the review. Two RCTs were reported as abstracts only. Sample sizes ranged from 40 to 832 patients. Four RCTs were at low risk of bias and 11 were at high risk of bias.

There were no statistically significant differences in occurrence of post-ERCP pancreatitis between patients in intervention and control groups (OR 0.78, 95% CI 0.57 to 1.08; 15 RCTs). There was no evidence of statistical heterogeneity ($I^2=28.7\%$). Sensitivity analyses did not significantly alter the results. Subgroup analyses showed that RCTs with 200 patients or more indicated that octreotide was statistically significantly more effective than control on post-ERCP pancreatitis (OR 0.50, 95% CI 0.32 to 0.79, $I^2=0\%$; five RCTs). The number needed to treat with octreotide to prevent one outcome event was 31 patients.

There was evidence of potential publication bias.

**Authors' conclusions**
Octreotide did not prevent post-ERCP pancreatitis.

**CRD commentary**
The review question and inclusion criteria were clearly defined. A comprehensive literature search was undertaken, but the start date was unclear. Articles in any language and articles published only as abstracts were included in the review, which reduced potential for language and publication biases. However, there was evidence of publication bias on inspection of the funnel plot. Trials were assessed on methodological quality with three appropriate criteria. Most trials were found to be at high risk of bias. Validity assessment and data extraction were performed in duplicate; it was unclear whether this was true for study selection, so reviewer error and bias could not be ruled out completely. No data were provided on patient characteristics and trial details were limited and so it was unclear whether pooling of results was appropriate. The authors went some way to identify potential sources of heterogeneity. Subgroup analyses indicated that larger trials showed beneficial results with octreotide and smaller studies did not. The authors’ conclusions appeared to reflect the evidence, but interpretation should take into consideration the limitations mentioned above.

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

**Research:** The authors stated that future research should focus on participants at high risk of post-ERCP pancreatitis. Trials should be large, look at the administration of octreotide at the end of the ERCP procedure and for a short time thereafter, and include all endoscopic-related and patient-related risk factors of post-ERCP pancreatitis.

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