Incidence rates of post-ERCP complications: a systematic survey of prospective studies

CRD summary
The authors concluded that the rate of post-endoscopic retrograde cholangiopancreatography complications is approximately seven per cent, of which about one in four complications is severe. Given limitations in the review methods, particularly the limited search and failure to adequately address variability between the studies, these conclusions may not be reliable.

Authors' objectives
To assess the rates of morbidity and mortality associated with endoscopic retrograde cholangiopancreatography (ERCP).

Searching
MEDLINE was searched from January 1977 to May 2006; the search terms were reported. The reference lists of retrieved articles were checked. The search was restricted to articles published in full in English.

Study selection
Prospective surveys of post-ERCP complications in adults were eligible for inclusion, provided they reported ERCP-specific morbidity and mortality (e.g. post-procedural pancreatitis, bleeding, infection, perforation and related mortality). Other types of complications, such as cardiovascular events and 30-day mortality, were also of interest. Studies solely reporting one type of complication (e.g. post-ERCP pancreatitis) were excluded, as were studies that did not report each type of outcome separately and studies that focused on selected participant groups. Interventional studies (e.g. comparing prophylaxis with placebo, or one endoscopic treatment with another) were also excluded.

In the included studies, most participants received not only ERCP but also an additional therapeutic intervention (e.g. standard biliary sphincterotomy, precut papillotomy or pancreatic sphincterotomy). The intervention setting varied; some studies involved more than one institution and/or different endoscopists (classified in the review as multicentre/operator), while others involved a single endoscopist or did not report this information (classified as single-centre/operator). The techniques used to access the common bile duct differed, with studies using varying rates of incisional sphincterotomy (precut) as opposed to cannulation. Most of the studies included whole populations of patients undergoing ERCP, but some were restricted to patients with gallbladder problems, cholelithiasis or a previous failed examination. Sphincter of Oddi dysfunction was a minor indication in all studies. The mean age of the participants in the included studies ranged from 53 to 73 years, and 45 to 72% were female. The review reported total post-ERCP morbidity and mortality, as well as reporting these events as separate outcomes.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Incidence rates were extracted as percentages of participants experiencing the event in each study, with associated 95% confidence intervals (CIs). Data were analysed comparing mild-to-moderate versus severe complications. For this purpose, complications were graded (where study reporting allowed) using the international consensus definition (Cotton 1991) or according to the criteria used in the primary study. Perforations were graded as severe in all cases.

Two reviewers extracted the data for the review, which a third reviewer checked.

Methods of synthesis
The data were pooled to obtain an overall incidence rate, with associated 95% CIs. Clinical heterogeneity between the
studies was investigated by subgroup analyses, which investigated the effect of study enrolment period (before or after 1996), setting (multicentre/operator versus single-centre/operator), precut rate (in more or less than 10% of patients), whether the procedure involved a therapeutic intervention (in more or less than 90% of patients), and whether there was sphincter of Oddi dysfunction (in more or less than 10% of patients). These analyses used χ² or Fisher’s tests with Bonferroni’s correction (corrected p) for multiple testing.

### Results of the review

Twenty-one studies (n=16,855) were included.

There was wide variation between the studies in the reported rates of ERCP complications.

Total ERCP-attributable morbidity and mortality: a total of 1,154 patients experienced post-ERCP pancreatitis, bleeding, perforation and/or infection (6.85%, 95% CI: 6.46, 7.24). Of these, 75.6% were graded mild to moderate and 24.4% were severe; 5.17% (95% CI: 4.83, 5.51) and 1.67% (95% CI: 1.47, 1.87) of the total population, respectively. ERCP-specific mortality occurred in 55 patients (0.33%, 95% CI: 0.24, 0.42) of the total population. Complication rates varied widely across the individual studies (range: 2.5 to 14%).

Pancreatitis (21 studies, n=16,855): a total of 585 patients experienced post-ERCP pancreatitis (3.47%, 95% CI: 3.19, 3.75). Of these, 44.8% were graded mild, 43.8% were moderate and 11.4% were severe. Severe cases comprised 0.40% of the total population. Mortality among patients with pancreatitis was 3.08% (95% CI: 1.65, 4.51).

Infections (21 studies, n=16,855): a total of 242 patients experienced post-ERCP colecystitis or cholangitis (1.44%, 95% CI: 1.26, 1.62). Of these, 19.8% were graded severe. Mortality among patients with infection was 7.85% (95% CI: 4.39, 11.4).

Bleeding (21 studies, n=16,855): a total of 226 patients experienced post-ERCP gastrointestinal bleeding (1.34%, 95% CI: 1.16, 1.52). Of these, 70.8% were graded moderate and 66 cases were severe. Mortality among patients with bleeding was 3.54% (95% CI: 1.08, 6.00).

Perforation (21 studies, n=16,855): a total of 101 patients experienced duodenal or biliary perforation during endoscopy (0.60%, 95% CI: 0.48, 0.72). Mortality among patients with perforation was 9.90% (95% CI: 3.96, 15.84).

Other complications (14 studies, n=12,973): a total of 173 patients experienced other post-ERCP complications (1.33%, 95% CI: 1.13, 1.53). Mortality among patients with other complications was 0.07% (95% CI: 0.02, 0.12).

### Subgroup analyses.

Rates of bleeding were significantly lower in multicentre/operator studies than in single-centre/operator studies (1.2% versus 2.3%, corrected p<0.001; 21 studies). Infections were significantly lower in studies that enrolled patients from 1977 to 1996 than in later (1997 to 2005) studies, whereas bleeding was significantly higher (1.1% versus 1.7%, corrected p=0.0162 and 1.6% versus 1.1%, corrected p=0.0126, respectively; 21 studies). Complication rates were significantly higher in studies that used therapeutic interventions in over 90% of patients than in studies with lower rates (8.4% versus 5.8%, p<0.01; 20 studies). Complication rates were also significantly higher in studies with a precut sphincterotomy rate of over 10% than in studies with a lower rate (5.9% versus 8.4%, p<0.01; 18 studies). There was no statistically significant difference between the groups for any other subgroup analyses.

### Authors' conclusions

The rate of post-ERCP complications such as pancreatitis, bleeding, infection or perforation is 6.85% (95% CI: 6.46, 7.24%). About one in four complications is severe. The overall complication rate appears relatively consistent across time.

### CRD commentary

The review question was focused and inclusion criteria were defined in terms of the study design, interventions and outcomes, but were not entirely clear with respect to which participant groups were eligible. Only one database was searched, which means that some studies might have been missed, and the search was limited to studies published in Database of Abstracts of Reviews of Effects (DARE)

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English, which means that language and publication biases may have occurred. Although steps were taken to minimise the risk of error and bias at the data extraction stage by having more than one author independently make decisions, this approach does not appear to have been used when selecting the studies. There is no indication that study validity was assessed, and the resulting lack of information on factors such as follow-up rates makes it difficult to assess the reliability of the data reported. It is unclear whether it was appropriate to pool the study data, given the wide variation in incidence rates between the included studies (which is evident by visually scanning the graph) and the statistically significant differences between studies with differing clinical features that were found in the subgroup analyses. There was little information on the statistical methods used to pool the studies, but it appears that incidence rates were simply totalled with no weighting for study variance and without assessing statistical heterogeneity. Given these limitations in the review methods, particularly the limited search and the failure to adequately address heterogeneity between the studies, the authors’ conclusions may not be reliable.

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

**Practice:** The authors stated that ERCP remains the most risky endoscopic procedure, necessitating careful patient selection and attention to informed consent. However, severe complications are rare.

**Research:** The authors did not state any implications for further research.

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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.