# Impact of Optimal Timing of Early Precut Sphincterotomy on the Risk of Endoscopic Retrograde Cholangiopancreatography Related Adverse Events: A Meta-Analysis

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**Abstract**

*Background/Aims:* ERCP is an invaluable procedure in the management of pancreaticobiliary disorders. Cannulation fails in 5-20% of cases using standard techniques even in the hands of experienced endoscopists. Needle-knife precutting is the most widely used method reported to improve selective biliary cannulation success rates. However, studies have demonstrated higher complications with this technique. Two meta-analyses found that early precut sphincterotomy is associated with lower risk of post-ERCP pancreatitis (PEP) compared with persistent cannulation. The purpose of this meta-analysis is to investigate whether early precut sphincterotomy is associated with increased risk of procedure-related adverse events (PRAE), including post-ERCP pancreatitis, in comparison with persistent cannulation. Likewise, we aim to determine the optimal timing of precut sphincterotomy to prevent the development of PEP.

*Methods:* A systematic search on four online databases (Pubmed, Embase, Cochrane Controlled Trial Registry and Cochrane Library) for articles on the incidence of PRAE between early precut sphincterotomy group (EPG) and persistent cannulation group (PCG) up to May 2020. The studies were validated using the Cochrane risk-of-bias assessment tool and Newcastle Ottawa scale. Results were analyzed using Cochrane RevMan v5.3 (random-effects model). The primary endpoints were the overall incidence of PRAE and optimal time for precut sphincterotomy.

*Results*: Nine RCTs and 1 retrospective cohort (1,571/14,017) were included. Pooled incidence showed lower rates of PEP in EPG than in PCG (4.3% vs. 7.5%) [RR 0.60; 95% CI 0.39-0.92; I2= 0%; Chi2= 5.97]. Subgroup analysis showed that precut sphincterotomy performed between 5-10 minutes from initial cannulation had lower rates of PEP, 32 vs. 63 (RR 0.50; 95% CI 0.26-0.94). Although, the cumulative risk ratio of PRAE favored the EPG, it was not statistically significant [RR 0.75 (95% CI 0.53-1.02); I2=0%].

*Conclusion*: This meta-analysis showed that overall rate of PRAE was not statistically different between early pre-cut sphincterotomy after failed cannulation and persistent cannulation. However, early precut sphincterotomy was associated with decreased risk of PEP. Performing precut sphincterotomy after 5 minutes, but not exceeding 10 minutes of failed biliary cannulation had less risk of post-ERCP pancreatitis.

## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has become an invaluable procedure in the diagnosis and management of a variety of pancreaticobiliary disorders since 1968.(1) Selective cannulation of the common bile duct (CBD) is a prerequisite for successful therapeutic ERCP. Cannulation can be difficult and may fail in 5% to 20% of cases using standard cannulation techniques even when performed by experienced endoscopists.(2) Precut sphincterotomy is a technique used to gain access to the CBD when standard methods using catheters or guidewires are not possible or have failed. Needle-knife precutting is the most widely used method and has been reported to improve selective biliary cannulation success rates. (3) However, some studies have demonstrated high rates of complications such as pancreatitis, bleeding and perforation associated with this technique.(4,5)

Post-ERCP pancreatitis is the most common complication of ERCP. PEP occurs in 5% of diagnostic ERCPs, 7% of therapeutic ERCPs, and up to 25% in those with suspected SOD or in those with a history of PEP.(6–8) Several meta-analyses of randomized control trials (RCT) compared the incidence of PEP between early precut sphincterotomy (EPS) and persistent biliary cannulation in patient with difficult biliary cannulation but with inconsistent results.(9–15) In the latest meta-analysis by Tang and colleagues, they did not include the studies by de Weerth et al and Khatibian et al since their participants were not classified to have a difficult biliary access and instead underwent immediate precut sphincterotomy.(16,17) The latest RCTs showed that EPS can significantly reduce the risk of PEP with no significant difference in the success rates of primary biliary cannulation.(18) However, there is still no consensus regarding the optimal time to perform precut sphincterotomy. In the study by Takano et al, successful biliary cannulation was higher in the early precut group when sphincterotomy was performed within 20 minutes with 90% success rates and 2 PEP complications compared with 70% and 4 PEP after 20 minutes. (19) However, in a database review by Lee and colleagues, PEP occurred in 3.9%, 11.8%, and 16.2% of patients with biliary cannulation duration lasting 3 to 5 minutes, >5 minutes, and >5 minutes with inadvertent PD manipulation, respectively.(20)

We conducted this meta-analysis to investigate whether early precut sphincterotomy was associated with increased risk of PEP and other procedure-related adverse events (PRAE) in comparison to persistent cannulation. In addition, we aimed to determine the optimal timing of precut sphincterotomy to prevent the development of post-ERCP pancreatitis (PEP).

## Methodology

### Study Selection

This meta-analysis followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) protocol guideline. Pubmed, Embase, Cochrane Controlled Trial Registry and Cochrane Library were searched up to May 2020 to identify all relevant articles on the association of precut sphincterotomy and the risk of procedure-related adverse events (PRAE). No language restrictions were imposed. Electronic databases were searched using the following search terms: (“endoscopic retrograde cholangiopancreatography”[All Fields] OR (“cholangiopancreatography, endoscopic retrograde”[MeSH Terms] OR (“cholangiopancreatography”[All Fields] AND “endoscopic”[All Fields] AND “retrograde”[All Fields]) OR “endoscopic retrograde cholangiopancreatography”[All Fields] OR “ercp”[All Fields])) AND (“early precut sphincterotomy”[All Fields] OR “precut sphincterotomy”[All Fields] OR “optimal timing”[All Fields]) AND “post-ERCP pancreatitis”[All Fields]. Studies from previous meta-analysis were also retrieved and assessed for inclusion.

Two reviewers independently assessed the titles and abstracts of the included studies that have met the inclusion criteria. We included 7 RCTs and 1 retrospective cohort where early precut sphincterotomy was compared with persistent standard cannulation in adults with difficult biliary access. The term difficult biliary access is poorly defined, so we included all RCTs where patients were randomized after a period of initial failed cannulation. We also included 2 RCTs in which immediate precut was done in contrast to persistent cannulation. Both papillotomy and fistulotomy techniques of precut were allowed in the intervention arm. No language restrictions were placed. Abstract papers and articles which do not have the complete results were excluded from this study.

### Data Abstraction

Two reviewers extracted the data from each included studies independently. The following data were collected: year of publication, study design, intervention and control group, randomization technique, blinding, follow-up rate and outcome. Any differences between the two reviewers were settled with a third reviewer and agreement was reached by consensus.

### Outcome Assessment

The primary outcome of interest was the association of precut sphincterotomy and the risk of PEP in comparison with persistent cannulation. Subgroup analysis was performed based on the differences in the timing of sphincterotomy.

### Quality of Evidence

The Grading of Recommendation Assessment, Development and Evaluation (GRADE) was used to evaluate the quality of evidence of randomized control trials. The following factors were considered in judging the quality of evidence of each study: risk of bias, directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias.

The Newcastle-Ottawa Scale (NOS) was used to evaluate cohort studies. The factors included for determining the quality of evidence were grouped into three categories: selection, comparability and outcome. Possible total points were 4 points for selection, 2 points for comparability and 3 points for outcomes. We set a score of 7 in the NOS as having low risk of bias.

### Statistical Analysis

Analysis was performed using Review Manager (Revman) version 5.3 software. Meta-analysis summary estimates (RR) and 95% CI were obtained by pooling effect estimates (RRs) from all the eligible studies. Random effects model was used due to the differences in the study designs and timing of performing early precut sphincterotomy in the included studies. Statistical heterogeneity was ascertained using Chi-square (X2) of $p<0.10$. An I2 statistic >50% was defined as significant heterogeneity. Assessment of publication bias was used using the funnel plot for analysis (Figure 6).

## Results

### Literature Search

A total of 50 references were retrieved in the literature search and 13 studies from previous meta-analysis papers. Fifty-three studies were excluded based on the titles and abstracts due to irrelevance and redundancies. Ten studies comprising of 1,571 patients were included in the meta-analysis (9 RCTs and 1 cohort study).

### Characteristics of Included Studies

Ten studies (1,571 participants) were included in our systematic review and meta-analysis. Study characteristics of each study were summarized in (Table1).(16,18,19,21–26) Included studies were 9 randomized controlled trials and 1 retrospective cohort. All studies included at the minimum, the incidence of PEP as one of their endpoints. All studies used published consensus criteria by Cotton et al, which defined PEP as a 3-fold increase in amylase with abdominal pain <24 hours after ERCP.(27) (Cotton 1991) However, 1 study did not specify how pancreatitis was defined.(22)

Some differences in the methodology were noted between the included studies. The indication for ERCP in majority of the trials was for therapeutic intervention for suspected or definite common bile duct stones. However, definition of difficult biliary access or cannulation was not uniform across the included studies. In addition, the timing of early precut was varied. Two studies performed immediate precut without cannulation attempts, while the other 8 studies did precut after failed cannulation attempts.(16,17) (de Weerth, Khatibian) Seven studies utilized needle-knife papillotomy as precut technique, while the other 2 studies used needle-knife fistulotomy. One study allowed either techniques. An endoscopic fellow was involved in 2 of the studies before randomization.(21,25) All studies except 1 excluded patients who had previous sphincterotomy, a recent episode of acute pancreatitis, and patients with altered biliary anatomy.(26) (Zagalsky)

Table 2 summarizes the baseline characteristics of the participants included in the 10 studies. Data on overall PRAE, which include the rate of PEP, bleeding, perforation and cholangitis, were also enumerated in this table.

### Risk of Bias in Studies

Quality assessment is summarized in (Figure 5).

**Overall Rate of Procedure-related Adverse Events**

The ten studies described the overall rate of adverse events related to pre-cut sphincterotomy and persistent cannulation. These reports included a total of 730 cases under the pre-cut sphincterotomy group and 841 under the persistent cannulation. Total rates of adverse events by pre-cut sphincterotomy and persistent cannulation were 7.75% and 9.87%, respectively. The cumulative risk ratio of procedure-related adverse events was 0.75 (95% CI 0.53-1.02). The between-study heterogeneity of the ten studies were low (I2 = 0%)(Figure 2). This result indicates that the rate of adverse events did not statistically differ between pre-cut sphincterotomy and persistent cannulation.

**Incidence of Bleeding**

The ten studies also assessed the incidence of bleeding that may occur due to pre-cut sphincterotomy and persistent cannulation. The incidence of bleeding by pre-cut sphincterotomy and persistent cannulation were 2.05% and 1.55%, respectively. Having a risk ratio of 1.24 (95% CI 0.60-2.58), the incidence of bleeding did not significantly differ between pre-cut sphincterotomy and persistent cannulation. The between-study heterogeneity of the ten studies were low (I2 = 0%)(Figure 2).

**Incidence of Perforation**

Perforation was also reported in the ten studies. The incidence of perforation by pre-cut sphincterotomy and persistent cannulation were 0.82% and 0.59%, respectively. Having a risk ratio of 1.28 (95% CI 0.43-3.79), the incidence of perforation did not differ between pre-cut sphincterotomy and persistent cannulation. The between-study heterogeneity of the ten studies were low (I2 = 0%)(Figure 2).

**Overall Post-ERCP Pancreatitis Rates**

This meta-analysis included a total of 1,571 of 14,017 screened patients from all the studies based on the inclusion criteria. Among the 730 participants who underwent early precut, 32 (4.3%) developed PEP, while 63 (7.5%) participants out of 841 developed PEP among those who had persistent cannulation. The pooled RR of developing PEP was 0.60; 95% CI (0.39-0.92). Using a random effects model, the test for heterogeneity showed an I2 = 0% and Ch2 = 5.97 (Figure 3).

**Optimal Timing of Precut Sphincterotomy**

The studies of de Weerth et al. and Khatibian et al. performed immediate precut, while Cennamo et al., Mariani et al and Zagalsky et. al performed precut sphincterotomy within 5 to 10 minutes after failed cannulation. Remaining studies performed precut sphincterotomy more than 10 minutes from initial cannulation. Using a random effects model, the test for heterogeneity was low (I2 = 0% - 17%). Although there was no significant heterogeneity, subgroup analysis was performed due to possible effects of different timing in precut sphincterotomy. Subgroup analysis stratified based on the timing of precut sphincterotomy showed that studies performing precut sphincterotomy at 5-10 minutes from initial cannulation had significantly lower rates of PEP (RR 0.50; 95% CI 0.26-0.94); while the other subgroups showed no statistically significant difference between the EPG and persistent cannulation group. (Figure 3 and 4).

**Discussion**

Our meta-analysis showed that compared with persistent biliary cannulation attempts, performing early precut sphincterotomy was associated with a significantly lower risk of developing PEP. Subgroup analysis on the timing of precut showed that performing sphincterotomy after 5 minutes, but not exceeding 10 minutes after failed biliary cannulation, conferred 50% less risk of developing PEP.

Difficult biliary cannulation associated with repeated and prolonged attempts increases the risks of ERCP PRAE, particularly the risk of PEP.(28) PEP is the most common PRAE of ERCP and is potentially fatal.(14) The mechanisms that lead to PEP are complex and not fully understood. Rather than a single pathogenesis, PEP is believed to be multifactorial, involving a combination of chemical, hydrostatic, enzymatic, mechanical, and thermal factors.(29) Several factors have been associated with increased risk of PEP, including patient characteristics, procedure-related factors and operator techniques.(30) (Testoni) A retrospective study by Slot et al reported that precut sphincterotomy is a safe and highly effective method for gaining biliary access in patients with difficult biliary access, and compared with persistent standard cannulation, it reduces the overall PEP rate.(31)

Compared with the last meta-analysis, this study included the 2 RCTs which performed immediate precut and 1 retrospective cohort comparing early precut and persistent cannulation. Including the studies by de Weerth et al and Khatibian et

al, our study showed that performing immediate precut sphincterotomy did not have any significant effect on the rate of PRAE; however, future large RCTs may be more conclusive.

Strengths of this meta-analysis include having a larger sample size with majority of the studies included were randomized controlled trials from high-volume centers. Furthermore, this study also included good quality trials conducted in different parts of the world, with no significant heterogeneity in any of the analyzed outcomes noted. However, our study was limited by several factors. Different types of precut techniques were utilized. Although there was no significant heterogeneity using I2 statistic, sensitivity analysis was done to explore possible effect of the differences in the timing of performing the precut sphincterotomy. One study did not exclude patients who had previous sphincterotomy, a recent episode of acute pancreatitis, and patients with altered biliary anatomy, which could either positively or negatively affect the rate of PRAE.(26) All these factors may introduce significant bias that should not be overlooked.

## Conclusion

In conclusion, early precut sphincterotomy by an experienced endoscopist can reduce the risk of PEP occurrence in patients with difficult biliary cannulation during ERCP. Immediate precut sphincterotomy does not completely eliminate the risk of PEP. Performing precut after 5 to 10minutes after failed cannulation may further decrease the risk of PEP. However, future prospective randomized controlled trials is recommended to further validate the optimal timing and determine the best technique of precut sphincterotomy.

## Tables

| | Type of Trial (Country) | Study Design | Precut Technique | Fellow Involvement | Technique Used in Persistent Cannulation | Definition for Difficult Biliary Access/Failed Biliary Cannulation | Timing of Early Precut | Timing of Persistent Cannulation |
|---|---|---|---|---|---|---|---|---|
| **Tang et. al. (2005)** | Single-center (Canada) | RCT | NKP | Yes | Non-wire-guided sphincterotome | >12 min. cannulation (7 min. by fellow and 5 min. by endoscopist) | Precut after Failed Cannulation | 15 min. after randomization |
| **de Weerth et. al. (2006)** | Single-center (Germany) | RCT | NKP (Erlangen type sphincterotome on the papillary roof) | No | Wire-guided sphincterotome | >20 min. OR >3 PD cannulation | Immediate Precut | 20 min. OR 3 PD cannulation after randomization |
| **Zhou et. al. (2006)** | Single-center (China) | RCT | NKP/NKF | No | Wire-guided sphincterotome | >10 min. OR >3 PD cannulation | Precut after Failed Cannulation | N/A |
| **Khatibian et. al. (2008)** | Single-center (Iran) | RCT | NKF | No | Wire-guided sphincterotome | >15 min. cannulation | Immediate Precut | 15 min cannulation after randomization |
| **Cennamo et. al. (2009)** | Single-center (Italy) | RCT | NKP | No | Wire-guided sphincterotome | >5 min. OR >3 PD cannulation | Precut after Failed Cannulation | 20 min. after randomization |
| **Manes et. al. (2009)** | Multi-center (Italy) | RCT | NKF | No | Both wire- and non-wire-guided sphincterotome | >10 min. OR >5 PD injection | Precut after Failed Cannulation | 10 min. after randomization |
| **Swan et. al. (2013)** | Single-center (Australia) | RCT | NKP | Yes | Wire-guided sphincterotome | >10 min. OR >10 attempts OR >4 PD cannulation (fellow + consultant) | Precut after Failed Cannulation | 10 min. after randomization |
| **Mariani et. al. (2016)** | Multi-center (Italy) | RCT | NKF | No | Wire-guided sphincterotome | >5 min. OR >3 MPD cannulation | Precut after Failed Cannulation | 10 min. or 3 MPD cannulation after randomization |
| **Zagalsky et. al. (2016)** | Multi-center (Argentina) | RCT | NKP | No | Wire-guided sphincterotome | >8 min. OR >3 PD cannulation | Precut after Failed Cannulation | N/A |
| **Takano et. al (2018)** | Single-center (Japan) | Retrospective Cohort | NKP | No | Wire-guided sphincterotome | within 20 min. | Precut within 20 min. from initial cannulation | 20 min. after randomization |

Table 1. Characteristics of Included Studies

| | Study Group | No. of Patients | Mean Age, years | Male/Female | Cannulation Success Rate with Salvage Therapy (%) | Primary Cannulation Success Rate w/o Salvage Therapy (%) | Overall Procedure-related Adverse Event | PEP | Bleeding | Perforation | Cholangitis |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tang et. al. (2005)** | Early Precut | 32 | 64.6 ± 13.3 | 15/17 | 31 (97) | 24 (75) | 4 | 2 | 1 | 0 | 1 |
| | Persistent Cannulation | 30 | 67.2 ± 12.7 | 14/16 | 28 (93) | 22 (73) | 2 | 2 | 0 | 0 | 0 |
| **de Weerth et. al. (2006)** | Early Precut | 145 | 66 | 50/95 | 145 (100) | 145 (100) | 3 | 3 | 0 | 0 | 0 |
| | Persistent Cannulation | 146 | 64 | 50/96 | 145 (99) | 104 (71) | 5 | 4 | 1 | 0 | 0 |
| **Zhou et. al. (2006)** | Early Precut | 43 | 62.7±11.5 | 26/17 | 39 (91) | 39 (91) | 2 | 1 | 1 | 0 | 0 |
| | Persistent Cannulation | 48 | 64.3±10.6 | 29/19 | 36 (75) | 36 (75) | 2 | 2 | 0 | 0 | 0 |
| **Khatibian et. al. (2008)** | Early Precut | 106 | 56.6 ± 17.9 | 49/57 | 105 (99) | 88 (83) | 3 | 2 | 0 | 1 | 0 |
| | Persistent Cannulation | 112 | 55.9 ± 17.2 | 37/75 | 111 (99) | 100 (89) | 3 | 3 | 0 | 0 | 0 |
| **Cennamo et. al. (2009)** | Early Precut | 36 | 68 (38-84) | 16/20 | 36 (100) | 33 (92) | 3 | 1 | 1 | 1 | 0 |
| | Persistent Cannulation | 110 | 71 (34-88) | 51/59 | 110 (100) | 104 (95) | 7 | 6 | 1 | 0 | 0 |
| **Manes et. al. (2009)** | Early Precut | 77 | 66 (29-94) | 50/27 | 71 (92) | 63 (81) | 7 | 2 | 5 | 0 | 0 |
| | Persistent Cannulation | 74 | 65 (26-95) | 48/26 | 71 (96) | 66 (89) | 14 | 11 | 2 | 1 | 0 |
| **Swan et. al. (2013)** | Early Precut | 39 | 59 ± 17.6 | 11/28 | 34 (87) | 34 (87) | 9 | 8 | 1 | 0 | 0 |
| | Persistent Cannulation | 34 | 59 ± 17.6 | 11/23 | 29 (85) | 12(35) | 8 | 6 | 2 | 0 | 0 |
| **Mariani et. al. (2016)** | Early Precut | 185 | 70.4 ± 14.2 | 88/97 | 179 (97) | 168 (91) | 18 | 10 | 4 | 3 | 1 |
| | Persistent Cannulation | 190 | 68.2 ± 16.0 | 77/113 | 183 (96) | 176 (93) | 36 | 23 | 7 | 4 | 2 |
| **Zagalsky et. al. (2016)** | Early Precut | 50 | 52 ± 15.1 | 16/34 | 49 (98) | 49 (98) | 4 | 2 | 1 | 1 | 0 |
| | Persistent Cannulation | 51 | 49 ± 16.68 | 36/15 | 49 (96) | 49 (96) | 2 | 2 | 0 | 0 | 0 |
| **Takano et. al (2018)** | Early Precut | 17 | 78 (59-90) | 10/7 | 16 (94) | 16 (94) | 2 | 1 | 1 | 0 | 0 |
| | Persistent Cannulation | 46 | 76 (32-95) | 24/22 | 32 (70) | 32 (70) | 4 | 4 | 0 | 0 | 0 |

Table 2. Baseline Characteristics and Procedure-related Adverse Events

**Figures**

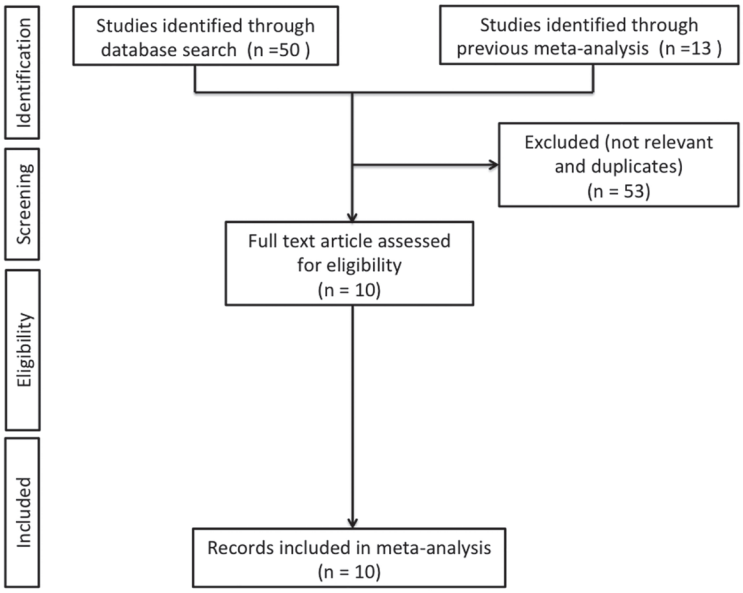


Figure 1. Flow Diagram of Eligible Studies

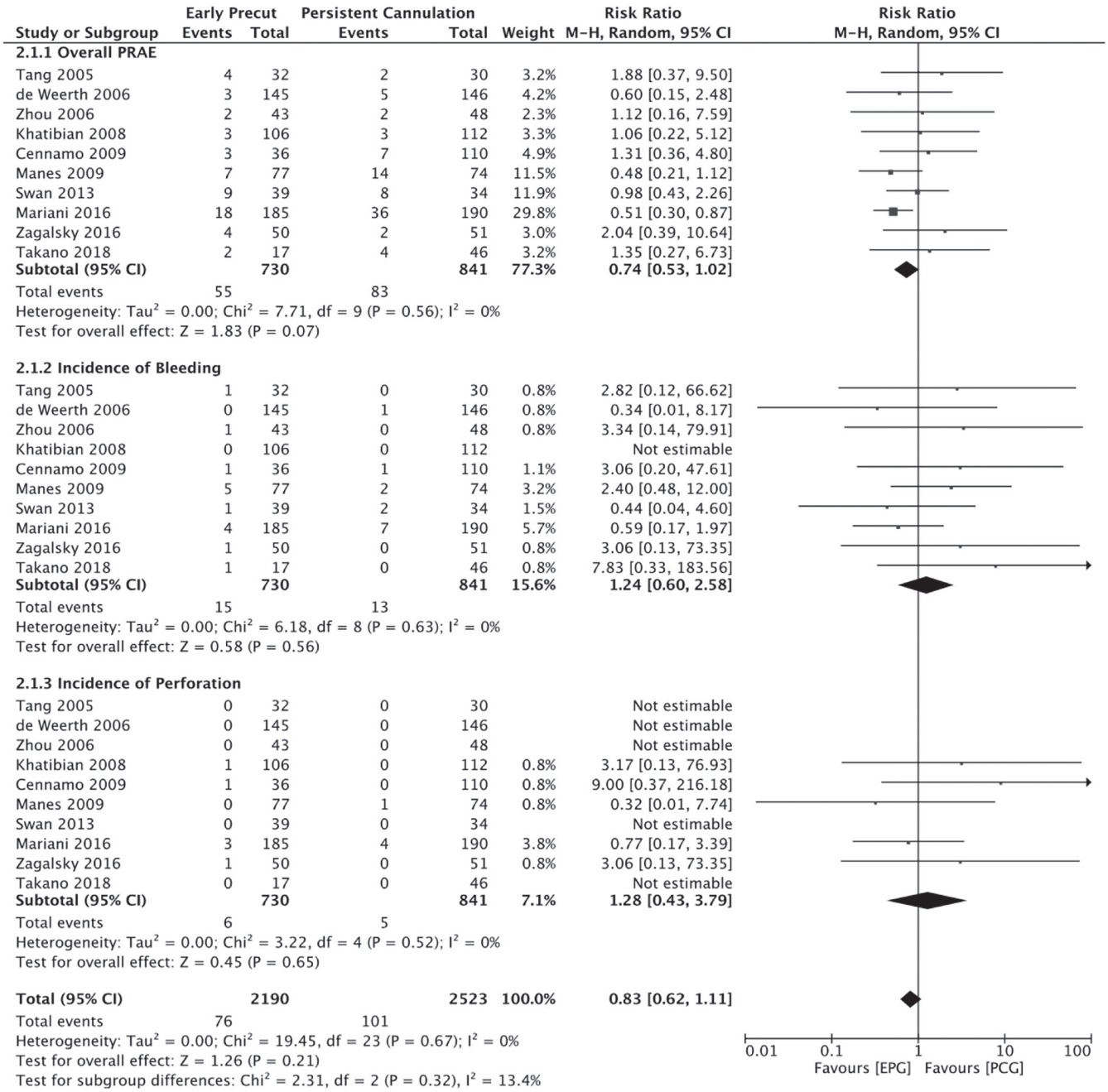


Figure 2. Forrest Plot for the Overall PRAE, Incidence of Bleeding and Perforation

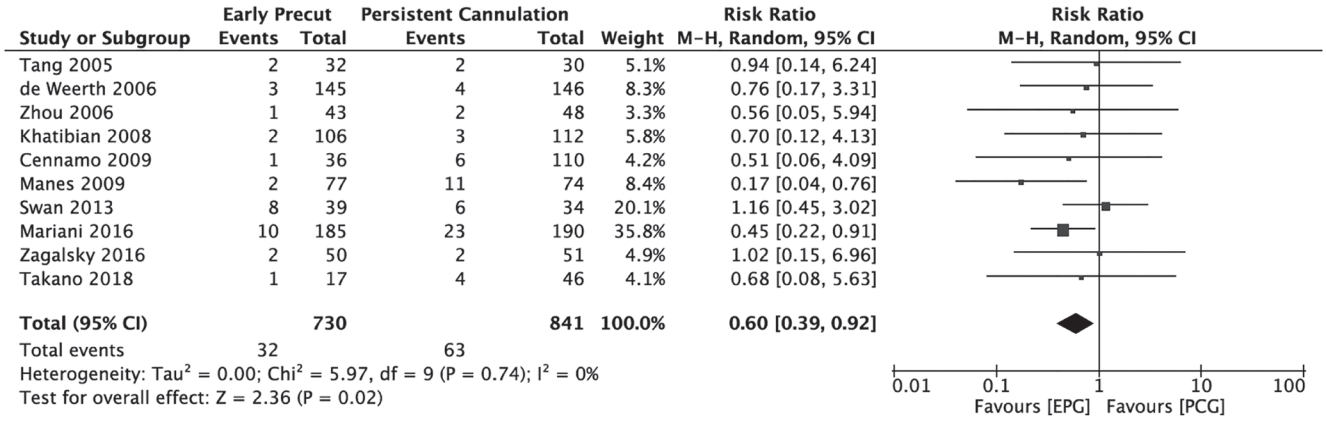


Figure 3. Forrest Plot for the Overall PEP Rate

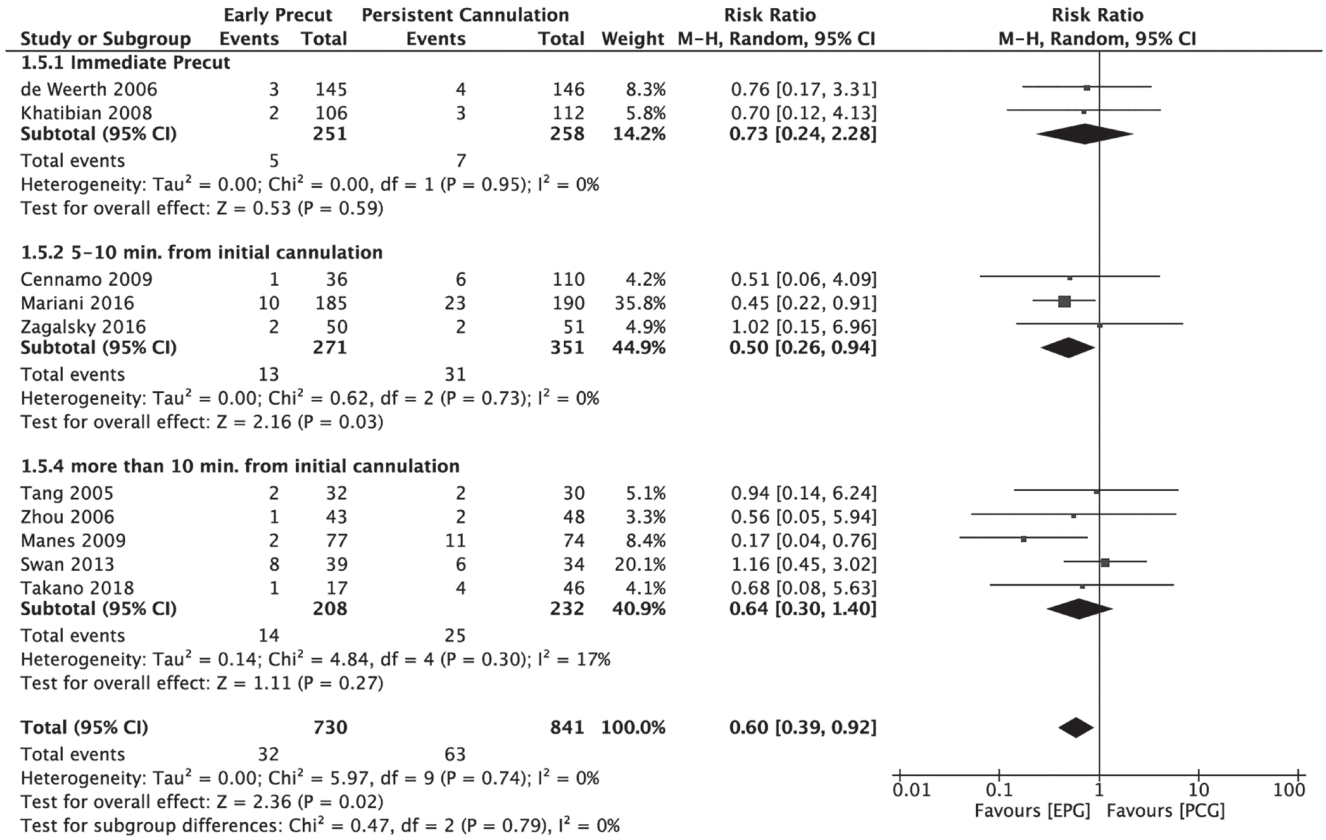


Figure 4. Forrest Plot for Rates of PEP based on the Timing of Precut Sphincterotomy

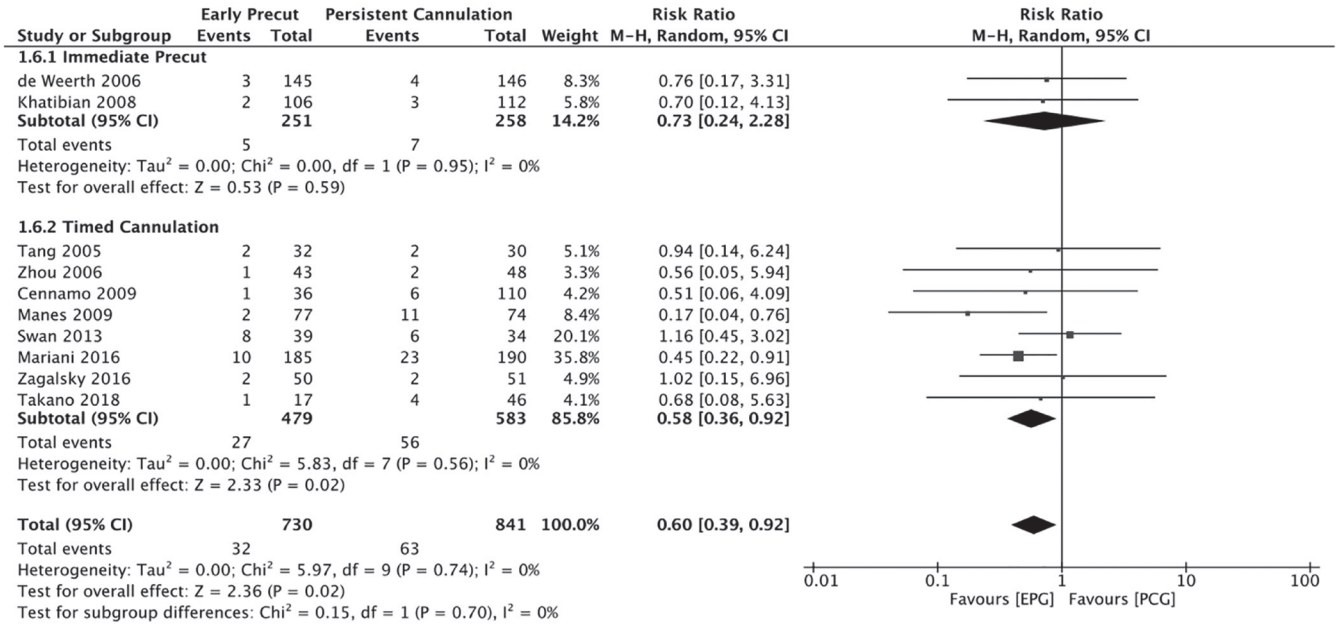


Figure 5. Forrest Plot for Rates of PEP based on the Timing of Precut Sphincterotomy (Immediate vs. Timed)

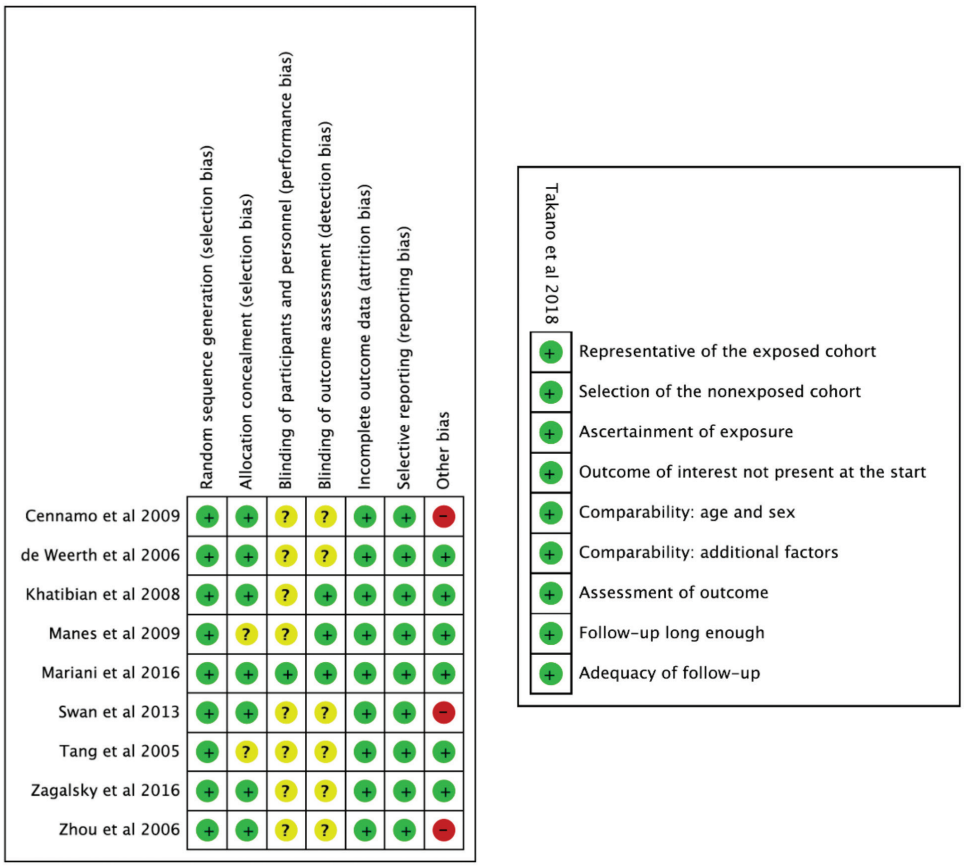


Figure 6. Risk of Bias Summary for Randomized Control Studies and Cohort Study

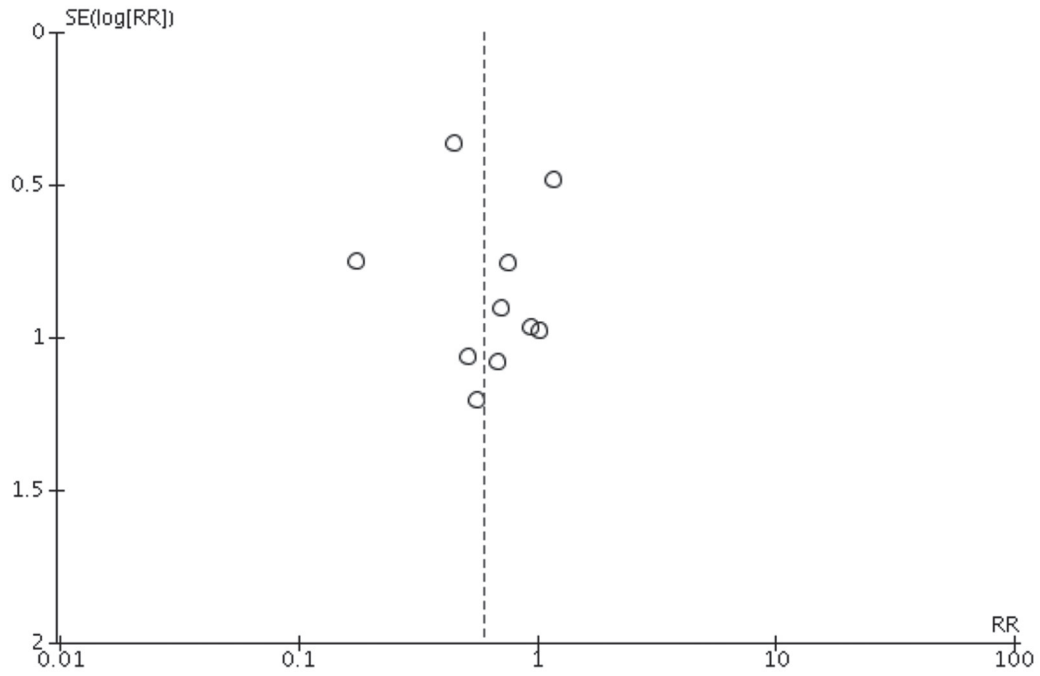


Figure 7. Funnel Plot of Included Studies

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