

World Journal of *Meta-Analysis*

World J Meta-Anal 2019 May 31; 7(5): 184-258





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The WJMA is now abstracted and indexed in Emerging Sources Citation Index (Web of Science), China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (CSTJ), and Superstar Journals Database

**RESPONSIBLE EDITORS
FOR THIS ISSUE**

Responsible Electronic Editor: Yun-Xiaojian Wu Proofing Editorial Office Director: Jin-Lei Wang

NAME OF JOURNAL

World Journal of Meta-Analysis

ISSN

ISSN 2308-3840 (online)

LAUNCH DATE

May 26, 2013

FREQUENCY

Irregular

EDITORS-IN-CHIEF

Giuseppe Biondi-Zoccai

EDITORIAL BOARD MEMBERS

<https://www.wjnet.com/2308-3840/editorialboard.htm>

EDITORIAL OFFICE

Jin-Lei Wang, Director

PUBLICATION DATE

May 31, 2019

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Pancreatic stents to prevent post-endoscopic retrograde cholangiopancreatography pancreatitis: A meta-analysis

Mitsuru Sugimoto, Tadayuki Takagi, Rei Suzuki, Naoki Konno, Hiroyuki Asama, Yuki Sato, Hiroki Irie, Ko Watanabe, Jun Nakamura, Hitomi Kikuchi, Mika Takasumi, Minami Hashimoto, Takuto Hikichi, Hiromasa Ohira

ORCID number: Mitsuru Sugimoto (0000-0002-4223-613X); Tadayuki Takagi (0000-0003-0696-5973); Rei Suzuki (0000-0002-4049-0484); Naoki Konno (0000-0001-9830-4317); Hiroyuki Asama (0000-0002-0102-0404); Yuki Sato (0000-0001-8000-0972); Hiroki Irie (0000-0002-4805-6244); Ko Watanabe (0000-0003-3895-7636); Jun Nakamura (0000-0001-6006-1778); Hitomi Kikuchi (0000-0003-0583-1623); Mika Takasumi (0000-0002-6025-8084); Minami Hashimoto (0000-0002-5750-7182); Takuto Hikichi (0000-0002-9815-1557); Hiromasa Ohira (0000-0003-4331-0634).

Author contributions: Sugimoto M designed and performed the study; Sugimoto M, Takagi T and Ohira H analyzed the data; Sugimoto M, Takagi T and Ohira H wrote the paper; Suzuki R, Konno N, Asama H, Hikichi T, Watanabe K, Nakamura J, Kikuchi H, Takasumi M, Sato Y, Hashimoto M and Irie H provided clinical advice; and T.H. and H.O. supervised the study.

Conflict-of-interest statement: We have no financial relationships to disclose.

PRISMA 2009 Checklist statement: The authors have read the PRISMA 2009 Checklist, and the manuscript was prepared and revised according to the PRISMA 2009 Checklist.

Open-Access: This article is an open-access article which was

Mitsuru Sugimoto, Tadayuki Takagi, Rei Suzuki, Naoki Konno, Hiroyuki Asama, Yuki Sato, Hiroki Irie, Ko Watanabe, Jun Nakamura, Hitomi Kikuchi, Mika Takasumi, Minami Hashimoto, Hiromasa Ohira, Department of Gastroenterology, Fukushima Medical University, School of Medicine, Fukushima City, Fukushima Prefecture 960-1295, Japan

Ko Watanabe, Jun Nakamura, Hitomi Kikuchi, Minami Hashimoto, Takuto Hikichi, Department of Endoscopy, Fukushima Medical University Hospital, Fukushima City, Fukushima Prefecture 960-1295, Japan

Corresponding author: Tadayuki Takagi, MD, PhD, Associate Professor, Department of Gastroenterology, Fukushima Medical University, 1 Hikarigaoka, Fukushima City, Fukushima Prefecture 960-1247, Japan. daccho@fmu.ac.jp

Telephone: +81-24-5471202

Fax: +81-24-5472055

Abstract

BACKGROUND

Endoscopic retrograde cholangiopancreatography (ERCP) plays a major role in the investigation and treatment of pancreaticobiliary diseases. However, post-ERCP pancreatitis (PEP) is a severe adverse effect. Prior meta-analyses have shown that prophylactic PS was useful for preventing PEP. However, abstract reports and patients who underwent endoscopic ampullectomy were included in the previous analyses. In addition, two meta-analyses involved non-randomized controlled trials (RCTs). The efficacy of PS for preventing severe PEP was different in each meta-analysis. Therefore, we performed the current meta-analysis, which included only full-text articles, and added new findings.

AIM

To reveal the efficacy of prophylactic pancreatic stent (PS) placement for preventing PEP.

METHODS

We searched the MEDLINE, Cochrane Library and PubMed databases for related RCTs. Among the reports retrieved, 11 studies were included in this meta-analysis. All full-text articles were published between 1993 and 2016. A total of 1475 patients were enrolled in the included studies; of these patients, 734 had a PS inserted, and 741 did not have a PS inserted. PEP and severe PEP occurrence were evaluated in this meta-analysis.

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Manuscript source: Unsolicited manuscript

Received: March 4, 2019

Peer-review started: March 4, 2019

First decision: March 27, 2019

Revised: May 7, 2019

Accepted: May 11, 2019

Article in press: May 11, 2019

Published online: May 31, 2019

P-Reviewer: Chawla S, Ljubicic N, Lv XP, Sperti C

S-Editor: Ji FF

L-Editor: A

E-Editor: Wu YXJ



RESULTS

PEP was observed in all studies and occurred in 39 (5.3%) patients who received a PS. On the other hand, PEP occurred in 141 (19%) patients who did not receive a PS. The occurrence of PEP was significantly lower in the patients who underwent PS placement than in the patients who did not receive a PS (OR = 0.32; 95%CI: 0.23-0.45; $P < 0.001$). In addition, the occurrence of severe PEP was evaluated. Notably, the occurrence of severe PEP was not observed in the stent group; however, the occurrence of severe PEP was observed in 8 (1.3%) patients who did not have a PS inserted. Severe PEP occurred significantly less often in the stent group than in the no stent group (OR = 0.24; 95%CI: 0.06-0.94; $P = 0.04$).

CONCLUSION

In conclusion, prophylactic PS placement is useful for preventing PEP and severe PEP.

Key words: Endoscopic retrograde cholangiopancreatography; Pancreatic stent; Post-endoscopic retrograde cholangiopancreatography pancreatitis; Meta-analysis

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Core tip: Endoscopic retrograde cholangiopancreatography (ERCP) plays a major role in the investigation and treatment of pancreaticobiliary diseases. However, post-ERCP pancreatitis (PEP) is a severe adverse effect. To prevent PEP, prophylactic pancreatic stent (PS) placement was recommended in some randomized controlled trials (RCTs). We performed this meta-analysis that included only RCTs with full-text articles to evaluate the efficacy of prophylactic PS for preventing PEP. As a result, the rates of PEP and severe PEP occurrence were statistically lower in the stent group than in the no stent group. Prophylactic PS was efficient in preventing PEP.

Citation: Sugimoto M, Takagi T, Suzuki R, Konno N, Asama H, Sato Y, Irie H, Watanabe K, Nakamura J, Kikuchi H, Takasumi M, Hashimoto M, Hikichi T, Ohira H. Pancreatic stents to prevent post-endoscopic retrograde cholangiopancreatography pancreatitis: A meta-analysis. *World J Meta-Anal* 2019; 7(5): 249-258

URL: <https://www.wjgnet.com/2308-3840/full/v7/i5/249.htm>

DOI: <https://dx.doi.org/10.13105/wjma.v7.i5.249>

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) occupies an important place in the endoscopic treatment and investigation of pancreatic and biliary diseases. However, post-ERCP pancreatitis (PEP) is a severe adverse event. Several past studies have reported that the occurrence of PEP was observed in 0.4%–5.6% of patients^[1-8]. Additionally, the fatality rate of PEP was 0%–0.1%^[4,6-8].

The risk factors shown to influence PEP occurrence in past reports were previous history of pancreatitis or PEP, two or more pancreatography procedures, sphincter of Oddi dysfunction (SOD), age younger than fifty years, female sex, difficulty of biliary cannulation, biliary sphincter balloon dilation, and precut sphincterotomy^[7-15]. However, the usefulness of pancreatic stent (PS) placement for PEP has been reported in these high-risk patients^[16-55]. Several prospective randomized controlled trials (RCTs) were discussed in these reports. Some RCTs showed the efficacy of PS placement in preventing PEP^[19,20,22,26,27,30,45,51-53,55]. In addition, six meta-analyses were performed on this topic. The insertion of a PS was recommended in all of the meta-analyses^[35,38,56-59]. However, the RCTs involved in these meta-analyses were varied. In addition, two meta-analyses involved non-RCTs^[38,59]. In a study included in the two meta-analyses, the no stent group was not randomized^[31]. Therefore, we performed a meta-analysis limited to full-text articles and excluding any RCTs of special cases (for example, ampullectomy cases, only abstracts, *etc.*). In addition, we included new RCTs in this meta-analysis.

MATERIALS AND METHODS

Literature search

We conducted a meta-analysis data search according to PRISMA statement guidelines^[60]. MS and TT performed literature retrieval using the MEDLINE, PubMed, Cochrane Library databases. The retrieval was limited to reports written in English. The following keywords were used for the search: “pancreatic stent” and “post-ERCP pancreatitis”.

Study selection

The studies that met the following criteria were selected: (1) RCTs comparing patients who received a PS for the prevention PEP and patients who did not receive a PS during ERCP; (2) Full-length articles; and (3) Articles written in English. We excluded studies that met the following criteria: (1) Case reports; (2) Case series; (3) Retrospective case control studies; and (4) Studies on endoscopic ampullectomy, because the procedure considerably changes the form of the Vater papilla. Moreover, we performed a manual search of reports cited in the extracted articles to discover any additional reports.

Data extraction

The data extracted were as follows (Tables 1 and 2): (1) Study data (first author, year of publication, country); (2) Patient characteristics (age, sex, number of patients who received a PS, number of patients who did not receive a PS); and (3) Factors related to ERCP procedures (type of PS, success rate of PS insertion, occurrence of PEP, severity of PEP, severity criteria of PEP).

Evaluation of bias

The publication bias for the obtained data was assessed using funnel plots.

Statistical analysis

The meta-analysis was performed using The EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan)^[61]. The homogeneity of each study was judged by determining the I^2 value. An I^2 value $\leq 25\%$ was considered to have no statistical heterogeneity. An I^2 value of 25%-50% was treated as low statistical heterogeneity, and an I^2 value of 50%-75% was treated as moderate statistical heterogeneity. An I^2 value $> 75\%$ was considered to have high statistical heterogeneity. A fixed-effects model was used if extracted studies had low heterogeneity. A random-effects model was used if the extracted studies were heterogeneous. A P value < 0.05 indicated a significant difference.

RESULTS

Selection of eligible studies

A total of 369 articles were identified by searching MEDLINE, Cochrane Library and PubMed. Of these reports, 80 studies were excluded because of duplication. In addition, 279 studies were excluded according to the selection criteria described above, as determined from the title and abstract. Finally, 11 studies were included in this meta-analysis (Figure 1).

All of these studies were RCTs published between 1993 and 2016. A total of 1475 patients were included in the studies, and of whom, 734 patients underwent insertion of PS, and 741 patients did not have a PS inserted. In some studies, proteinase inhibitors or antibiotics were administered as other prophylaxis; however, rectal indomethacin was not used in any study. All patient characteristics are shown in Table 1, and ERCP-related procedures are shown in Table 2.

The definition of PEP and severity of PEP

In the RCTs, with the exception of two studies by Smithline *et al*^[55] and Fazel *et al*^[52], PEP was defined according to Cotton's criteria^[62]. In these RCTs, new abdominal pain after ERCP with elevated serum amylase no less than three times the normal upper limit in 24 h was diagnosed as PEP. In the study by Smithline *et al*^[55], abdominal pain with elevated serum lipase or amylase no less than two times the normal upper limit was diagnosed as PEP. In the study by Fazel *et al*^[52], epigastric and umbilical pain with elevated serum amylase no less than two times the normal upper limit was diagnosed as PEP.

The severity of PEP was classified according to Cotton's criteria in almost all RCTs^[62] (Table 2). In the criteria, mild pancreatitis was defined as an extension of planned hospitalization of two to three days. Moderate pancreatitis was defined as an

Table 1 Patient characteristics of selected studies

Ref.	Country	Sample number		Mean age		Sex (male / female)		Patients
		Stent	No stent	Stent	No stent	Stent	No stent	
Smithline <i>et al</i> ^[55] , 1993	United States	43	50	46	47	19/81	22/78	SOD, CBD < 10 mm
Tarnasky <i>et al</i> ^[51] , 1998	United States	41	39	45.7	46.4	NA	NA	SOD
Fazel <i>et al</i> ^[52] , 2003	United States	38	36	45.8	43.6	4/32	6/32	SOD, difficult cannulation
Sofuni <i>et al</i> ^[19] , 2007	Japan	98	103	67.0	66.0	60/38	64/38	NA
Tsuchiya <i>et al</i> ^[20] , 2007	Japan	32	32	65.0	69.0	19/13	22/10	NA
Ito <i>et al</i> ^[22] , 2010	Japan	35	35	68	70	19/16	20/15	Difficult cannulation
Sofuni <i>et al</i> ^[27] , 2011	Japan	213	213	NA	NA	NA	NA	Risk factors, such as SOD, history of pancreatitis
Pan <i>et al</i> ^[26] , 2011	China	20	20	61.0	57.0	9/11	10/10	High-risk patients
Kawaguchi <i>et al</i> ^[30] , 2012	Japan	60	60	66.0	68.0	27/33	25/35	SOD, previous PEP
Lee <i>et al</i> ^[53] , 2012	South Korea	50	51	57.3	57.9	17/33	21/30	Difficult cannulation
Yin <i>et al</i> ^[45] , 2016	China	104	102	57.2	57.4	59/45	55/47	High-risk patients

SOD: Sphincter of Oddi dysfunction; CBD: Central bile duct; NA: Not available; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis.

extension of planned hospitalization of four to ten days. Severe pancreatitis was defined as an extension of planned hospitalization of more than ten days with or without bleeding or a pseudocyst requiring intervention.

Meta-analysis

PEP was observed in all studies; it occurred in 39 (5.3%) patients who underwent PS insertion, and on the other hand, it occurred in 141 (19%) patients who did not have a PS inserted. The heterogeneity among the included studies was low ($I^2 = 31\%$, $P = 0.15$); therefore, we selected a fixed-effects model. The occurrence of PEP was significantly lower in patients who received a PS than in the patients who did not receive a PS (OR = 0.32; 95% CI: 0.23-0.45; $P < 0.001$; Figure 2).

We also evaluated severe PEP between the stent group and the no stent group. The occurrence of severe PEP was not observed in the stent group; however, the occurrence of severe PEP was observed in 8 (1.3%) patients who did not undergo PS insertion. Statistical heterogeneity was not seen in the included studies ($I^2 = 0\%$, $P = 0.99$); therefore, a fixed-effects model was chosen. The occurrence of severe PEP was significantly lower in the stent group than in the no stent group (OR = 0.24; 95% CI: 0.06-0.94; $P = 0.04$; Figure 3).

Publication bias

Egger's test of funnel plot asymmetry showed publication bias ($P = 0.009$; Figure 4). The funnel plot was asymmetric, and we found that negative studies with a smaller number of subjects were missing.

DISCUSSION

In this meta-analysis, prophylactic PS placement was efficient for preventing PEP. This result is the same as that in each previous RCT that was included in this meta-analysis. In addition, this meta-analysis proved that prophylactic PS placement prevented the occurrence of severe PEP.

In the eleven RCTs in this meta-analysis, ten RCTs indicated that prophylactic PS placement decreased the occurrence of PEP^[19,20,22,26,27,30,45,51-53]. However, Smithline *et al*^[55] reported that prophylactic main pancreatic duct stenting is not recommended for the prevention of PEP^[55]. The different results among the RCTs was influenced by the small sample size. In addition, there were far fewer patients with severe PEP. Therefore, the occurrence of severe PEP was not significantly different between the stent group and the no stent group in any of the included studies. On the other hand, severe PEP was not observed in the stent group in the included RCTs. These results indicated that prophylactic PS might prevent not only total PEP but also severe PEP.

The efficacy of prophylactic PS for preventing severe PEP was not statistically proven in any RCT. However, six meta-analyses were previously performed on

Table 2 The factors related to the endoscopic retrograde cholangiopancreatography procedures of selected studies

Ref.	ERCP procedure	Pancreatic stent	Success rate (%)	PEP n (%) stent/ no stent	Criteria of PEP severity
Smithline <i>et al</i> ^[55] , 1993	Precut EST	Double-barbed 5 or 7fr, 2 or 2.5 cm	90	Total 6 (14)/9 (18) Mild 5 (12)/5 (10) Moderate 1 (2)/2 (4) Severe 1 (2)/2 (4)	Cotton
Tarnasky <i>et al</i> ^[51] , 1998	EST	5 or 7Fr, 2 or 2.5 cm	NA	Total 1 (2)/10 (26) Mild 0 (0)/5 (13) Moderate 0 (0)/5 (13) Severe 0 (0)/0 (0)	Cotton
Fazel <i>et al</i> ^[52] , 2003	EST	5fr nasopancreatic catheter or Double-barbed 5fr, 2 cm	95	Total 2 (5.3)/10 (28) Mild 2 (5.3)/5 (14) Moderate 0 (0)/2(6) Severe 0 (0)/3 (8)	Cotton
Sofuni <i>et al</i> ^[19] , 2007	EST, EPBD, IDUS, biopsy, sphincter of Oddi manometry, POCS	5Fr, 3 cm with 2 flanges on the duodenal side	97	Total 3 (3)/14 (13.6) Mild 2 (2)/8 (7.8) Moderate 1 (1)/6 (4.6) Severe 0 (0)/0(0)	Cotton
Tsuchiya <i>et al</i> ^[20] , 2007	EST, IDUS, EPBD, sphincter of Oddi manometry	5fr, 3 or 4 cm duodenal pig tail stent without inner flange	100	Total 1 (3.1)/4 (12.5) Mild 1 (3.1)/2 (6.3) Moderate 0 (0)/1 (3.1) Severe 0 (0)/1 (3.1)	Cotton
Ito <i>et al</i> ^[22] , 2010	EST, IDUS, EPBD, biopsy	5fr, 4 cm with a single duodenal pig tail	97	Total 1 (2.9)/8 (23) Mild 1 (2.9)/8 (23) Moderate and severe 0	Cotton
Sofuni <i>et al</i> ^[27] , 2011	EST, EPBD, ENBD, IDUS, biopsy	5Fr, 3 cm with 2 flanges on the duodenal side	88	Total 20 (9.4)/31 (15.2) Mild 16 (7.5)/22 (14.6) Moderate 4 (1.9)/8 (3.8) Severe 0 (0)/1 (0.5)	Cotton
Pan <i>et al</i> ^[26] , 2011	ERCP	5fr single pig tail	NA	Total 4 (20)/14 (70) Mild, moderate, severe NA	Cotton
Kawaguchi <i>et al</i> ^[30] , 2012	Precut EST, pancreatic sphincterotomy, biopsy, IDUS	5fr, 3 cm with two flanges on the duodenal side	100	Total 1 (1.7)/8 (13.3) Mild 1 (1.7)/8 (13.3)	Modified Cotton
Lee <i>et al</i> ^[53] , 2012	EST, precut EST, IDUS, biopsy	Unflanged 3fr, 4, 6, or 8 cm duodenal pig tail stent	96	Total 6 (12)/15 (29.4) Mild 5 (10)/12 (23.5) Moderate 1 (2)/2 (3.9) Severe 0 (0)/1 (2)	Cotton
Yin <i>et al</i> ^[45] , 2016	EST, EPBD	5Fr, 5, 7, or 9 cm	NA	Total 8 (7.7)/18 (17.7) Mild, Moderate, severe NA	NA

PEP: Post-ERCP pancreatitis; EST: Endoscopic sphincterotomy; NA: Not available; EPBD: Endoscopic papillary balloon dilation; IDUS: Intraductal ultrasonography; POCS: Peroral cholangioscopy.

prophylactic PS to prevent PEP. Additionally, two of the six meta-analyses also reported that prophylactic PS did not significantly prevent severe PEP^[56,58]. As more cases about prophylactic PS were reported, two meta-analyses performed by Mazaki *et al*^[57,59] proved that prophylactic PS was efficient for preventing severe PEP. The second recent meta-analysis was carried out by Shi *et al*^[35] and involved only full-text articles and excluded reports with only abstracts. However, the efficacy of prophylactic PS for preventing severe PEP was not shown in the meta-analysis. In the current meta-analysis, we included only full-text articles. As a result, PS was found to be efficient for preventing severe PEP. The addition of new RCTs and exclusion of RCTs on special cases such as ampullectomy^[63] may have contributed to the definitive results of this meta-analysis.

This study has some limitations. First, all RCTs involved in this meta-analysis were written in English. Second, the type of PS was different in each RCT. Third, publication bias existed in this study. In the future, we hope that the accumulation of a greater number of relevant RCTs will overcome this bias.

In conclusion, prophylactic PS was useful for preventing not only PEP but also severe PEP.

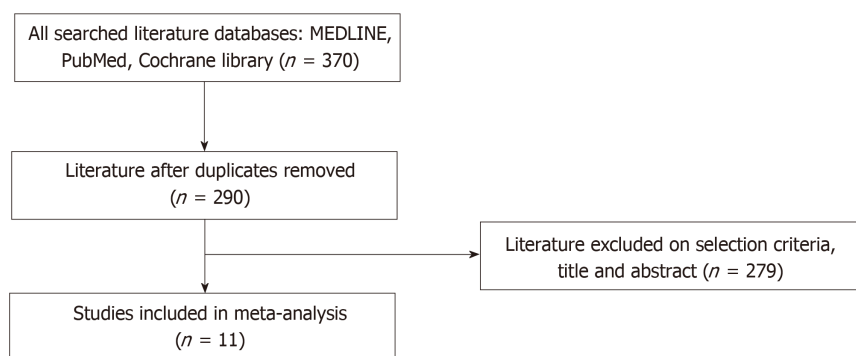


Figure 1 The flowchart of the article selection process.

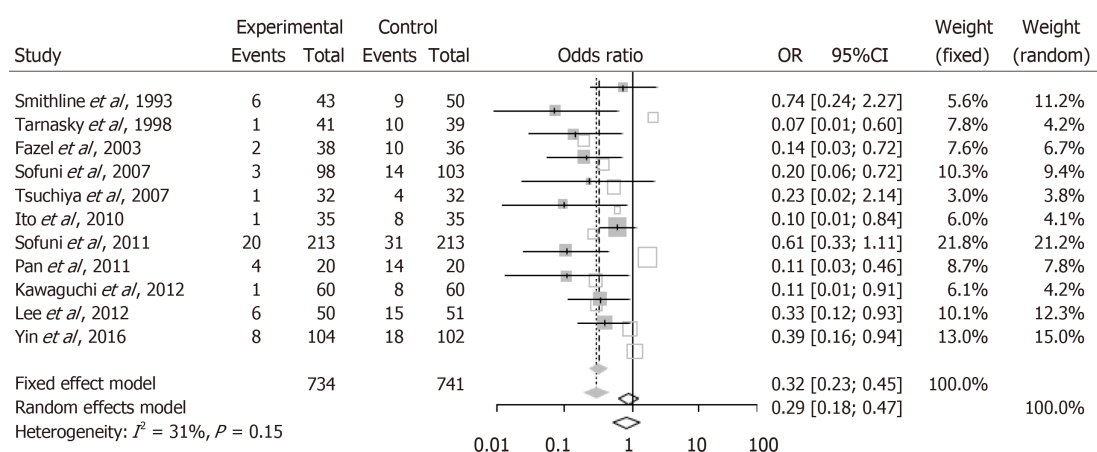


Figure 2 Forest plot of post-endoscopic retrograde cholangiopancreatography pancreatitis.

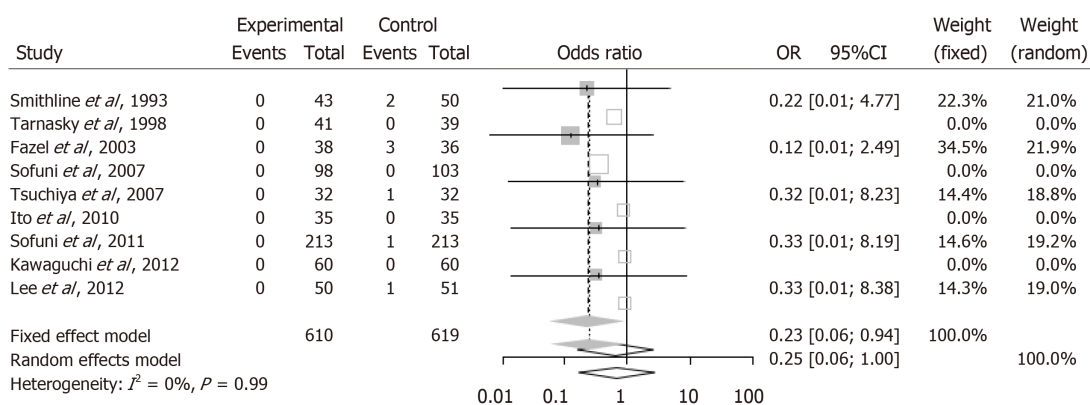


Figure 3 Forest plot of severe post-endoscopic retrograde cholangiopancreatography pancreatitis.

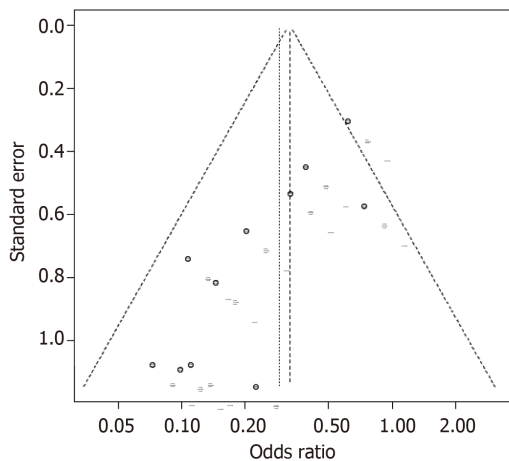


Figure 4 Funnel plot of post-endoscopic retrograde cholangiopancreatography pancreatitis occurrence.

ARTICLE HIGHLIGHTS

Research background

Endoscopic retrograde cholangiopancreatography (ERCP) occupies an important place in the endoscopic treatment and investigation of pancreatic and biliary diseases. However, post-ERCP pancreatitis (PEP) is a severe adverse effect. To prevent PEP, prophylactic pancreatic stent (PS) placement has been recommended based on the results of several randomized controlled trials (RCTs).

Research motivation

Prior meta-analyses have shown that prophylactic PS was useful for preventing PEP. However, abstract reports and patients who underwent endoscopic ampullectomy were included in the previous analyses. The efficacy of PS for preventing severe PEP was different in each meta-analysis. Therefore, we performed the current meta-analysis, which included only full-text articles, and added new findings.

Research objectives

In this meta-analysis, we evaluated the efficacy of prophylactic PS for the prevention of PEP.

Research methods

We identified the included RCTs by searching MEDLINE, Cochrane Library and PubMed. Among the retrieved reports, 11 studies were included in this meta-analysis. The occurrence of PEP and severe PEP was evaluated.

Research results

The rates of PEP and severe PEP occurrence were significantly lower in patients who received a PS than in patients who did not receive a PS.

Research conclusions

Prophylactic PS was useful not only for preventing PEP but also for preventing severe PEP.

Research perspectives

This meta-analysis proved that prophylactic PS prevented severe PEP. This result will contribute to a reduction in PEP and severe PEP in patients undergoing ERCP.

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