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Endoscopic palliative treatment versus surgical bypass in malignant low bile duct obstruction: A systematic review and meta-analysis

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ABSTRACT

Aims: Despite technological advances, only about 20% of periampullary tumors are found to be resectable at the time of presentation. Biliary tree obstruction and consequent jaundice occur in 70–90% of those patients and has important consequences for a patient's quality of life. Relief of biliary tree obstruction is the main goal for treatment, and few options for palliative therapy of biliary tree obstruction can be performed, including surgical bypass, percutaneous stenting, and endoscopic stenting. Objective: The aim of the present study was to acquire and analyze data to compare the success of procedures, procedure-related complication, mortality in 30 days, recurrent-jaundice rates in endoscopic, and surgical palliative techniques. Methods: Two independent reviewers searched the following electronic databases: Medline, EMBASE, Cochrane, LILACS, BVS, SCOPE, and CINAHL (EBSCO). Inclusion criteria included studies involving patients with distal biliary obstruction due to periampullary tumors who underwent endoscopic therapy or a surgical procedure for palliation. Results: No differences were observed for success of procedures; differences were observed with better outcomes for endoscopy therapy with regards to mortality associated with procedure, complication associated with procedure, and mortality in 30 days. Also, differences were observed with better outcomes for surgery therapy for recurrent-jaundice. Conclusion: Endoscopic palliative drainage is associated with a lower rate in complication, mortality associated with procedure, and mortality in 30 days. Recurrent-jaundice analysis demonstrated an overall lower rate in surgical bypass procedures. No differences were found for the success of procedures.

Keywords: Periampullary tumors, Bile duct cancer, Cholangiocarcinoma, Pancreatic carcinoma, Endoscopy, Gastrointestinal, Surgical procedures

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INTRODUCTION

Jaundice due to biliary obstruction is usually the main symptom at the time of diagnostic in periampullary cancers. Despite technological advances, only about 20% of periampullary tumors are found to be resectable at the time of presentation. Biliary tree obstruction and consequent jaundice occur in 70–90% of those patients and has important consequences for a patient's quality of life. Palliation remains the principal management in such patients because of this dismal natural history, and relief of biliary tree obstruction is a prime concern [1, 2].

Few options for palliative therapy of biliary tree obstruction can be performed, including surgical bypass, percutaneous stenting, and endoscopic stenting. Although initial results with surgical bypass demonstrated low rates of recurrent jaundice (2–5%), the surgery itself carries an appreciable risk of post-operative morbidity and mortality, up to 24% in some trials [3, 4]. Surgical decompression has been advocated in patients who at the time of laparotomy for planned tumor resection are found to have unresectable disease as well as in occasional patients with longer projected survival [5, 6]. Advances in minimally invasive therapy have led to the development of luminal stents whose insertion can relieve jaundice and hence avoid the need for surgery [7–9].

Early biliary stents came in the form of a plastic prosthesis that was inserted across the obstructing mass to provide drainage of the biliary tree; however, bilioduodenal reflux and food fibers result in stent blockage. Various changes in plastic stent design and adjunctive therapy such as antibiotics have failed to significantly improve their patency [10]. With a wider bore than plastic stents, several studies have shown that they exhibit superior patency to plastic stents [11–13].

Obstructive jaundice due to malignant distal biliary obstruction can thus be relieved by surgery or endoscopic metal or plastic stents [14, 15]. A number of randomized controlled trials (RCTs) have compared various combinations of these interventions [16, 17]. Endoscopic stents appear to offer a less invasive option, but the many designs and stent types available have made selecting the ideal stent for individual patients complicated. This paper reviews the outcomes associated with surgery and endoscopic therapies.

OBJECTIVES

The aim of the present study is to acquire and analyze data to compare success of procedure, procedure-related complication, mortality in 30 days, and recurrent-jaundice rates in endoscopic surgical procedures in patients with distal biliary obstruction due to periampullary tumors (i.e., pancreatic neoplasms or low bile duct carcinoma).

MATERIALS AND METHODS

Protocol and Registration

PROSPERO 2015 CRD42015017792 [18]

Guidelines http://www.prisma-statement.org/statement.htm

Eligibility Criteria

a) Types of studies: Randomized clinical trials, controlled clinical trial, and cohort studies.

b) Types of participants: Patients with distal biliary obstruction due to periampullary tumors (i.e., pancreatic neoplasms or low bile duct carcinoma).

c) Types of intervention: Comparison between endoscopic palliative stents and surgical palliative procedures.

d) Types of outcome measures: The main outcome measures were the following: success of procedure, procedure-related complication, mortality in 30 days, and recurrent-jaundice rates.

In this literature search, we do not limit ourselves by year of publication or by language.

Information sources include MEDLINE as well as the Cochrane Controlled Trials Register, EMBASE, EBSCO, LILACS, Library University of Sao Paulo, Research website BVS, and SCOPE.

Search

Medline:

P: "(Periampullary Tumors OR Biliary Tract Neoplasms OR Biliary Tract Cancer OR Biliary tract tumors OR Bile Duct Cancer OR Pancreatic Neoplasms OR Cholangiocarcinoma OR Pancreatic Carcinoma) AND

I: (Endoscopy OR Endoscopy, Gastrointestinal) AND

C: (Surgery OR Surgical Procedures, Operative)".

Embase:

P: Pancreatic neoplasms OR bile duct neoplasms AND

I: endoscopy AND

C: surgery AND

('clinical trial' OR 'controlled study' OR 'major clinical study' OR 'prospective study' OR 'retrospective study'))".

Cochrane, LILACS, Scopus and CINAHL:

P: pancreatic neoplasms OR bile duct neoplasms AND

I: endoscopy AND

C: surgery

Study Selection

Eligibility assessment was performed independently in an unblinded, standardized manner by two reviewers. Assessment included a thorough reading of the abstract to identify studies that compare endoscopic with surgical techniques. Studies selected were read in their entirety and excluded according criteria JADAD [19], NEWCASTLE OTTAWA [20] and Methodology Check List SIGN [21]. Studies that did not report the results in absolute numbers and those not written in English, Spanish, or Portuguese were excluded. Disagreements between reviewers were resolved by consensus.

Data Collection Process and Items

We extracted data by a detailed reading of the results of each study. This included information on the success of the procedure, procedure-related complication, mortality in 30 days, and recurrent-jaundice rates. We only included absolute numbers reported in the text of the article or with the analysis of graphs. We excluded an article for not reporting the results in absolute numbers. One review author extracted the following data from included studies, and the second author checked the extracted data. Disagreements were resolved by discussion between the two reviewers; we did not contact authors for further information.

Data items

The following information was extracted from each included study: Characteristics of population (type and location of tumors); type of intervention, considering different modalities of techniques in endoscopic treatment (plastic stents, metallic stents, covered or uncovered stents) versus surgical approach (hepaticojejunostomy, cholecystojejunostomy, choledocojejunostomy and gastrojejunostomy associated); type of outcome measure including complications, success of procedure, morbidity, mortality, survival in 30 days, recurrent-jaundice, and hospitalization rates.

Risk of Bias In Individual Studies

Since both cohort and randomized studies were included, the risk of bias in individual studies was assessed using the Newcastle-Ottawa Quality Assessment for cohort studies [20] and JADAD Scale for randomized trials [19] as well as the Methodology Check List: SIGN for both [21, 22].

We extracted data into a table of all studies with the identification of all potential bias of each study. Then, different factors were identified as individual generators of biases, including age, comorbidities, techniques used, prevalence, and experience.

Summary Measures

Individual analysis for each study included the following: experiment events rate (EER), control event rate (CER), number needed to treat (NNT), and absolute risk (ARR).

Synthesis of Results

We performed a meta-analysis with the software RevMan5 [23] using the following characteristics: dichotomous data type, statistical method of Mantel-Haenszel, fixed effect model analysis, effect measure risk difference, study confidence interval 95%, total confidence interval 95%, and year of study.

Risk of bias across studies.

To identify true heterogeneity and cause for publication bias between studies, we conducted both a graphic funnel plot and a I2 analysis. We noted a value of I2 greater than 50% as having high heterogeneity. If the study was outside the funnel plot it was regarded as publication bias, but if it was inside the funnel plot it was considered as having true heterogeneity.

RESULTS

Study Selection

We identified 8238 studies through MEDLINE, We identified 1941 studies through COCHRANE, LILACS, SCOPUS, and CINAHL. Eliminating repeated studies, we found 9179 studies in total. We excluded studies that did not have information about periampullary cancers. We chose eight studies that we reviewed with JADAD [19], NEWCASTLE OTTAWA [20], and the methodology check list: Cohort and clinical trial studies SIGN [21]. We excluded a study that was written in French. We included seven studies for qualitative analysis and five studies for quantitative analysis (Figure 1).

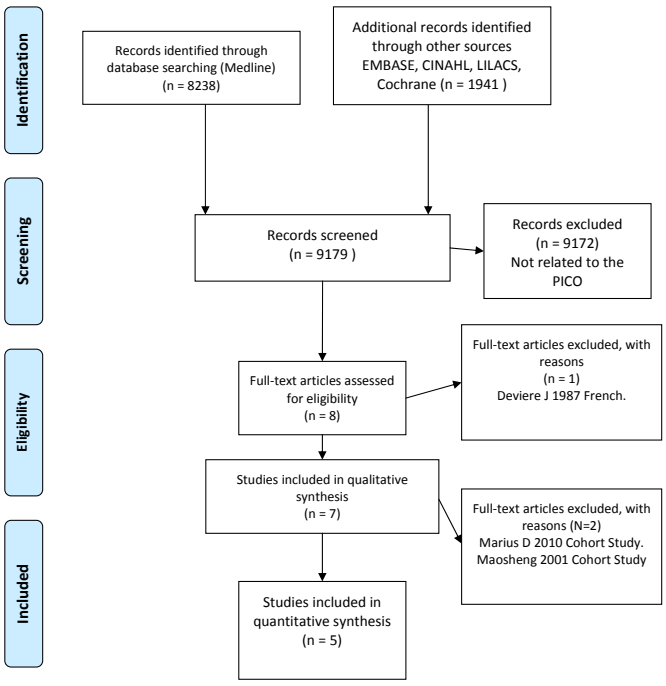

Figure 1: Flow Diagram.

Study Characteristics

The characteristics of the studies are summarized in Table 1. Table 2 describes the oncologic diagnosis analyzed, the number of interventions for each treatment group, and the report in absolute numbers for each outcome of interest extracted. The survival and hospital stay was expressed in mean without standard error, was no topic under analysis [24–29].

Risk of Bias Within Studies

We identify biases selected for qualitative analysis studies and evaluate them according criteria from the JADAD, Methodology check list: SIGN, and NEWCASTLE OTTAWA [19–21] (Table 2).

Summary Measures

Individual analysis for each study included the following: experiment events rate (EER), control event rate (CER), number needed to treat (NNT), and absolute risk (ARR) (Table 3).

Results of Individual Studies and Synthesis of Results

Procedure Success

Five clinical trial reported procedure success, and the heterogeneity test indicated a $\chi 2$ of 4.09 and a I2 of 2%, demonstrating low heterogeneity. The fixed-effects model was adopted, and the RD was 0.02 (95% CI: -0.04, 0.07) (Figure 2). Analysis of the pooled data revealed no statistically significant differences in procedure success between the two therapies.

Mortality associated with procedure

Mortality associated with procedure: two clinical trials reported mortality associated with procedure, and the heterogeneity test indicated a $\chi 2$ of 2.57 and a I2 of 61%, demonstrating high heterogeneity. The fixed-effects model was adopted, and the risk difference was -0.10 (95 % CI: -0.16, –0.03) (Figure 3a). Analysis of the pooled data revealed differences in mortality associated with procedure with significant risk of bias. The funnel plot analysis identified true heterogeneity, and by consensus of reviewers we opted to perform the meta-analysis using the risk ratio.

Table 1: Study Characteristics.

STUDY	POPULATION	INTERVENTION	Succ	Mor proc	Mor 30d	Comp	Surv	Re-jaund	Hos-stay
Marius Distler 2010 Cohort Study [24]	Obst Jaudance Palliative ADPH-TB N247	P Stent N138			3	7	5.1 mo	0	
		P Stent + HJ Bypass N68			0	12	9.4 mo	0	
		HJ Bypass N41			1	6	6.3 mo	3	
Artifon 2006 Clinical Trial 01-04 [8]	Obst Jaudance Palliative ADPH-TB N30	M Stent 15	15	0	0	6	5,2 mo	4	2
		HJ HCJ Bypass 15	15	0	0	9	6,5 mo	1	9
Maosheng 2001 Cohort Study 83-99 [25]	Obst Jaudance Palliative ADPH N60	M (Cov Unc) Stent 19	18		1	9	6.6 mo	5	12
		HJ HCJ + or - Bypass 41	41		0	13	7.5 mo	2	32
Smith 1994 Clinical Trial [26]	Obst Jaudance Palliative ADPH-TB N201	P Stent N101	95	3	8	29	5.2 mo	36	19
		HJ HCJ + or - Bypass N100	94	14	15	58	6.5 mo	2	26
Andersen 1989 Clinical Trial [27]	Obst Jaudance Palliative ADPH-TB N50	P Stent N25	24		5	9	2.7 mo	1	26
		HJ HCJ Bypass N25	22		6	5	3.2 mo	3	27
Shepherd 1988 Clinical Trial [28]	Obst Jaudance Palliative ADPH-TB N52	Stent N23	19		3	7	5.1 mo	7	
		Bypass N25	23		5	14	4.2 mo	0	
Bornman 1986 Clinical Trial [29]	Obst Jaudance Palliative ADPH N53	Stent N23	21		2	7	4.7 mo	8	18
		Bypass N25	19		5	8	3.7 mo	3	24

HJ Hepatojejunostomy
HCJ Hepatocholedocojejunostomy
ADPH Pancreatic adenocarcinoma head
TB Biliary Tree
Succ Success
Mor proc Mortality procedure
Mor 30d Mortality in 30 days
Comp complication
Surv survival
Re-jaund recurrent-jaundice
hstay hospital Stay
mo month

Table 2: Risk of blas within studies.

WORK	POPULATION	INTERVENTION	Other bies	NEW CASTEL	JADAD	SIGN
Marius Distler 2010 Cohort Study [24]	Obst Jaudance Palliative ADPH-TB N247	P Stent N138	63y 2,2 mean enchange	8		accept
		P Stent + HJ Bypass N68	63y			
		HJ Bypass N41	63y			
Artifon 2006 Clinical Trial 01-04 [8]	Obst Jaudance Palliative ADPH-TB N30	M Stent 15	64.2y, succes reduction 50% B		3	accept
		HJ HCJ Bypass 15	61.4y Dont lost			
Maosheng 2001 Cohort Study 83-99 [25]	Obst Jaudance Palliative ADPH N60	M Stent 19	67.5y, MS 8-10mm 6-8cm, B13.7 (1.2), success redution B 2 week 16 preprocedure drainage 8 P Stent Hstay 12	8		accept
		HJ HCJ CJ + or - Bypass 41	66.0y, B8.8 (1), success redution B 2 week 34 preoperative drainage 3 P Stent Hstay 32.			
Smith 1994 Clinical Trial [26]	Obst Jaudance Palliative ADPH-TB-AM-VA N201	P Stent N101	70y B270; TS 3; Percutaneos if CPRE fail, PS10FR, Intention to treat success redution 20% B 5 day, 19 RENDESVOUZ, 4.5m mean enchange		3	accept
		HJ HCJ + or - Bypass N100	70y B 311, TS 3.6, intention to treat, success redution 20% B 5 day LOST 3%			
Andersen 1989 Clinical Trial [27]	Obst Jaudance Palliative ADPH-TB N50	P Stent N25	77y, succes reduction 50% B, 7-10Fr OS,		3	accept
		HJ HCJ CD Bypass N25	76y, 19 treated according to randomisation, 10% lost.			
Shepherd 1988 Clinical Trial [28]	Obst Jaudance Palliative ADPH-TB N52	Stent N23	LOST 10%		3	accept
		Bypass N25				
Bornman 1986 Clinical Trial [29]	Obst Jaudance Palliative ADPH N53	Stent N25	61y treated according to randomisation, 10% lost.		3	accept
		Bypass N25	61y			
HJ Hepatojejunostomy HCJ Hepatocholedocojejunostomy			ADPH Pancreatic adenocarcinoma head TB Biliary Tree			

Table 3: Summary Measures

WORK	population	succ	CER EER	ARR NNT	Mor proc	CER EER	ARR NNT	mort 30d	CER EER	ARR NNT	com	CER EER	ARR NNT	r-jaun	CER EER	ARR NNT
Marius Distler 2010 Cohort Study	P Stent N138							3	0.02 ; 0.009	0.01 3 ; 77	7	0.05 1 ; 0165	-0.114 ; -9	0	0 ; 0.028	-0.028 ; -23
	P Stent + HJ Bypass N68							0			12			0		
	HJ Bypass N41							1			6			3		
Artifon 2006 Clinical Trial 01-04	M Stent 15	15	1.0 ; 1.0	0.0	0	0	0.0	0	0	0.0	6	0.4 ; 06	-0.2 ; -5	4	0.267 ; 0.067	0.2 ; 5
	HJ HCJ Bypass 15	15			0			0			9			1		
Maosheng 2001 Cohort Study 83-99	M (Cov Unc) Stent 19	18	0.947 ; 1.0	-0.053 ; -19				1	0.053 ; 0	0.053 ; 19	9	0.47 ;0.31	0.15 ; 6	5	0.26 ; 0.04	0.2 ; 5
	HJ HCJ CJ + or - Bypass 41	41						0			13			2		
Smith 1994 Randomised Trial	P Stent N101	95	0.94 ; 0.94	0.001 ;1000	3	0.03 ;0.14	-0.110 ; -9	8	0.07 ; 0.15	-0.071 ; -14	29	0.287 ; 0.580	-0.293 ; -3	36	0.35 ; 0.02	0.33 ; 3
	HJ HCJ CJ + or - Bypass N100	94			14			15			58			2		
Andersen 1989 Clinical Trial	P Stent N25	24	0.96 ; 0.88	0.08 ; 13				5	0.20 ; 0.24	-0.04 ; -25	18	0.72 ; 0.4	0.3 ; 3	1	0.04 ; 0.12	-0.08 ; - 13
	HJ HCJ CD Bypass N25	22						6			10			3		
Shepherd 1988 Clinical Trial	Stent N23	19	0.82 ; 0.92	-0.09 ; -11				3	0.13 ; 0.2	-0.07 ; -14	7	0.30 ; 0.50	-0.25 ; -4	7	0.30 ; 0	0.30 ; 3
	Bypass N25	23						5			14			0		
Bornman 1986 Clinical Trial (29)	Stent N23	21	0.91 ; 0.76	0.15 ; 7				2	0.087 ; 0.20	-0.11 ; -9	7	0.304 ; 0.320	0.016 ; -62	8	0.34 ; 0.12	0.22 ; 4
	Bypass N25	19						5			8			3		
Succ Success Mor proc Mortality procedure Mor 30d Mortality in 30 days Comp complication Re-jaund recurrent-jaundice									CER control event rate EER experimental event rate ARR Absolute risk reduction NNT Number needed to treat							

Mortality associated with procedure: two clinical trials reported mortality associated with procedure; the heterogeneity test was not applicable. The fixed-effects model was adopted, and the risk ratio was 0.21 (95% CI: -0.16, –0.03) (Figure 3b). Analysis of the pooled data revealed differences in mortality associated with procedure that favored endoscopy therapy, with potential bias in this statement.

Mortality 30 Days

Mortality at 30 days: Five clinical trials reported mortality at 30 days; the heterogeneity test indicated a χ2 of 1.44 and a I2 of 0%, demonstrating homogeneity. The fixed-effects model was adopted, and the RD was -0.07 (95 % CI: -0.13, 0.00) (Figure 4). Analysis of the pooled data revealed statistically significant differences in mortality at 30 days between the two therapies and favors endoscopy therapy.

Complication associated with procedure

Complication associated with procedure: five clinical trials reported complication associated with procedure; the heterogeneity test indicated a χ2 of 12.10 and a I2 of 67%, demonstrating high heterogeneity. The fixed-effects model was adopted, and the RD was -0.19 (95 % CI: -0.28, –0.09) (Figure 5a). Analysis of the pooled data revealed differences mortality associated with procedure, with potential bias in this statement. In the funnel plot analysis, the study Andersen (1999) was identified as a source of heterogeneity for publication bias. By consensus of reviewers, we opted to withdraw this work from the meta-analysis complication associated with procedure (Figure 5b).

Complication associated with procedure for endoscopy and surgery therapies: four studies reported complication associated with procedure; the heterogeneity test indicated a χ2 of 3.50 and an I2 of 14%, demonstrating low heterogeneity. The fixed-effects model was adopted, and the RD was -0.24 (95% CI: -0.34, –0.24) (Figure 5b). Analysis of the pooled data revealed statistically significant differences in complication associated with procedure and showed better outcomes for endoscopy therapy.

Recurrent-Jaundice

Recurrent-Jaundice: five clinical trials reported Recurrent-Jaundice; the heterogeneity test indicated a χ2 of 22.53 and an I2 of 87%, demonstrating high heterogeneity. The fixed-effects model was adopted, and the RD was 0.25 (95% CI: 0.18, 0.32) (Figure 6a). Analysis of the pooled data revealed differences for Recurrent-Jaundice with significant risk of bias in does this affirmation. In the funnel plot analysis, the study Andersen (1989) was identified as a source of heterogeneity for publication bias. By consensus of

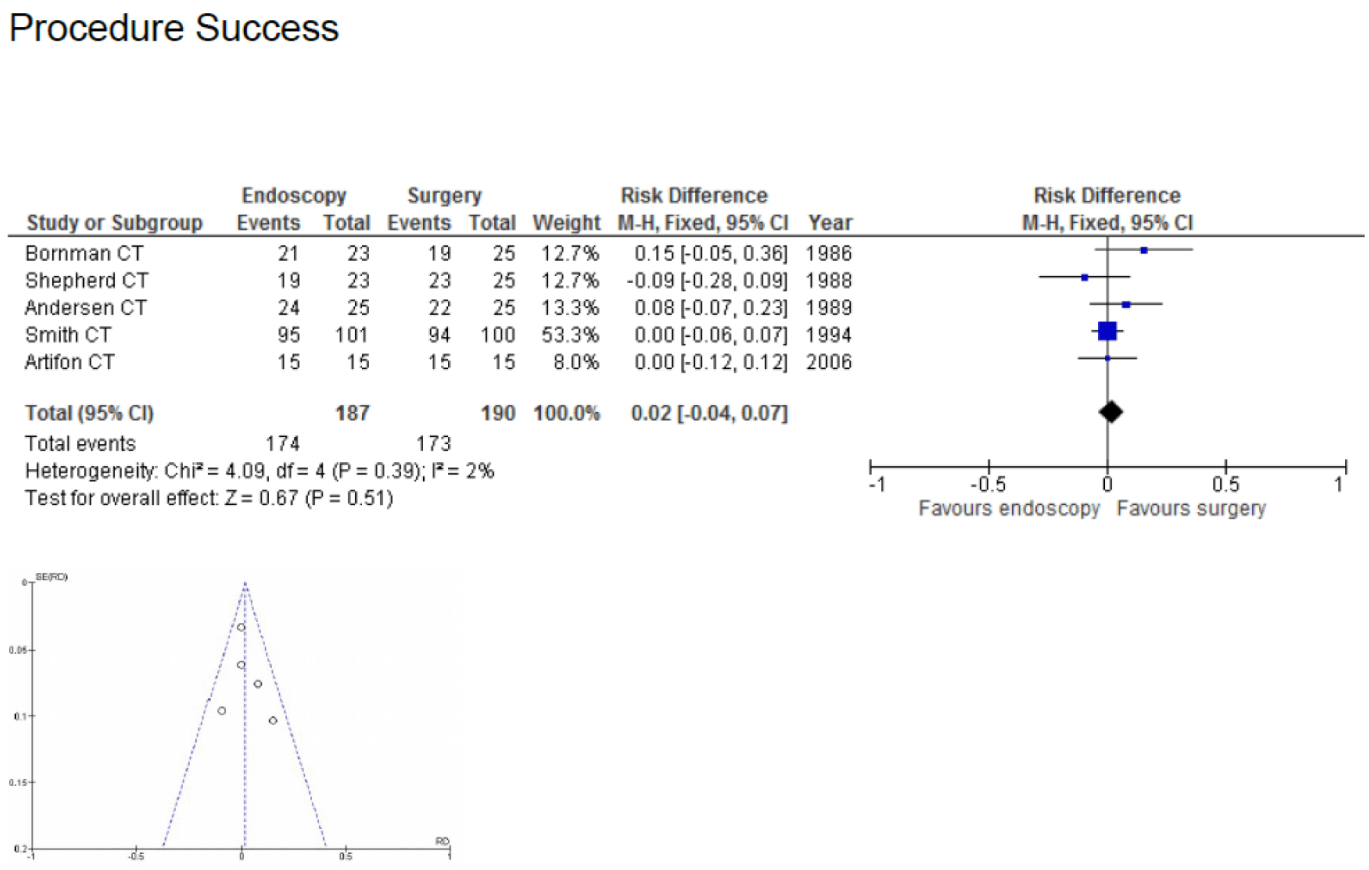

Figure 2: Risk Difference in procedure success.

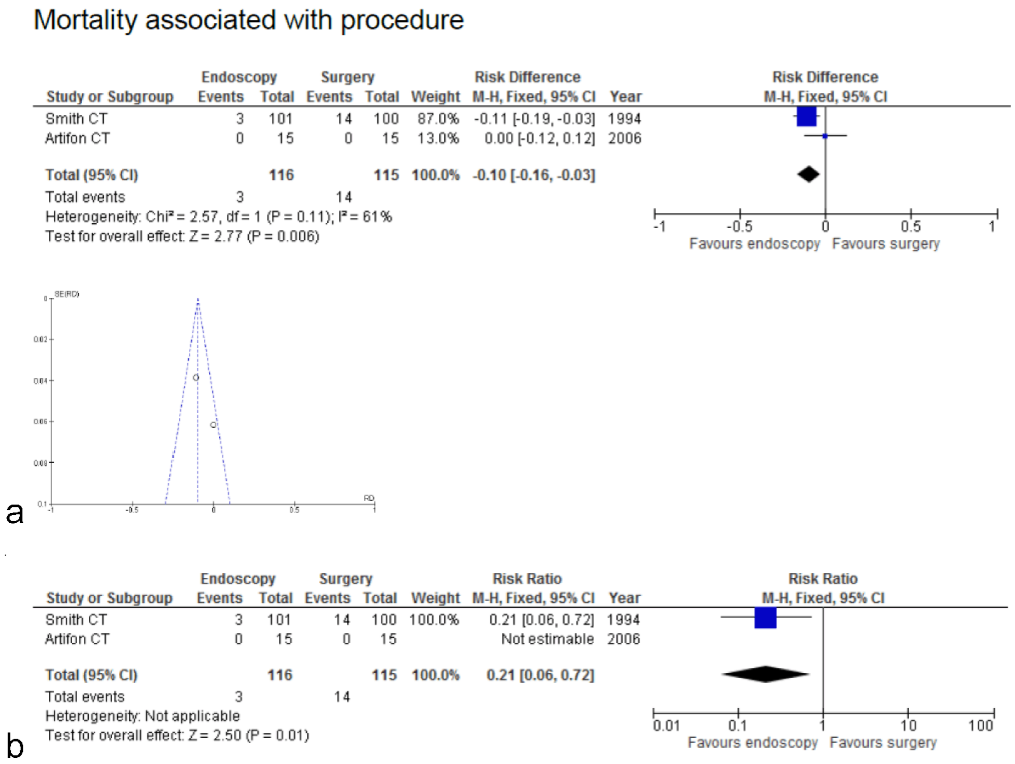

Figure 3: (a) Risk difference in mortality associated with procedure for endoscopy and surgery therapies. (b) Risk ratio in mortality associated with procedure for endoscopy and surgery therapies.

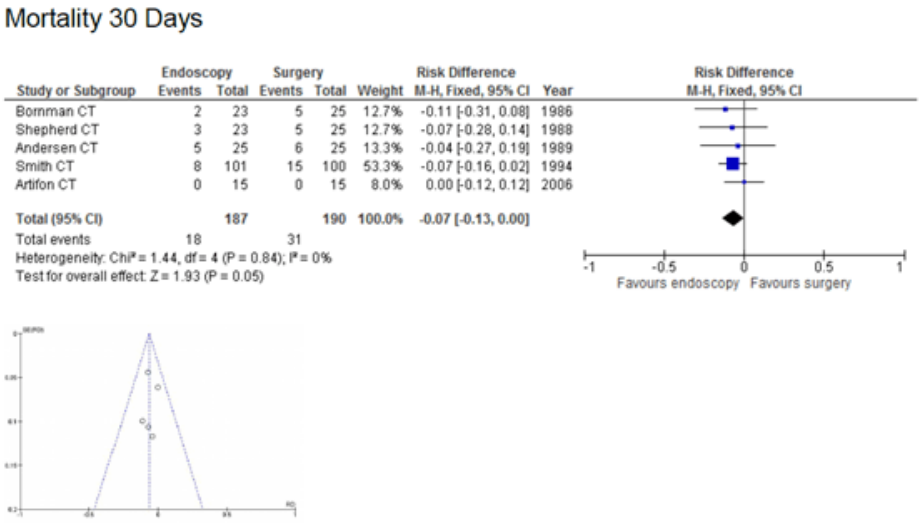

Figure 4: Risk Difference in mortality 30 days.

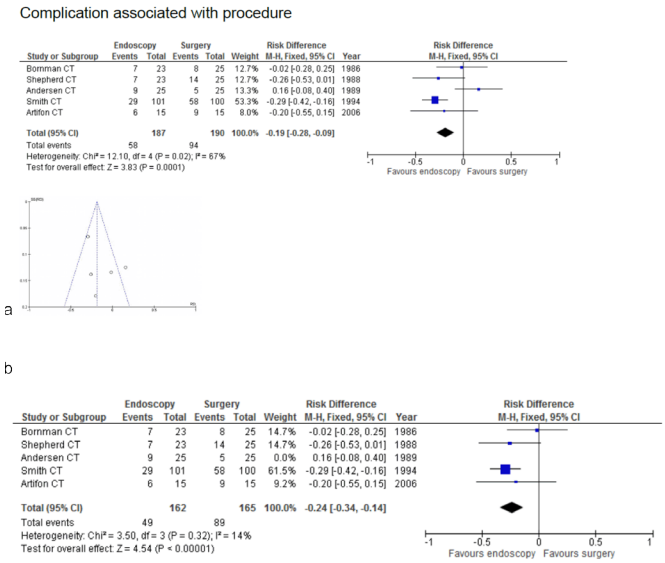

Figure 5: (a) Risk difference in complication associated with procedure for endoscopy and surgery therapies. (b) Risk difference in complication associated with procedure for endoscopy and surgery therapies.

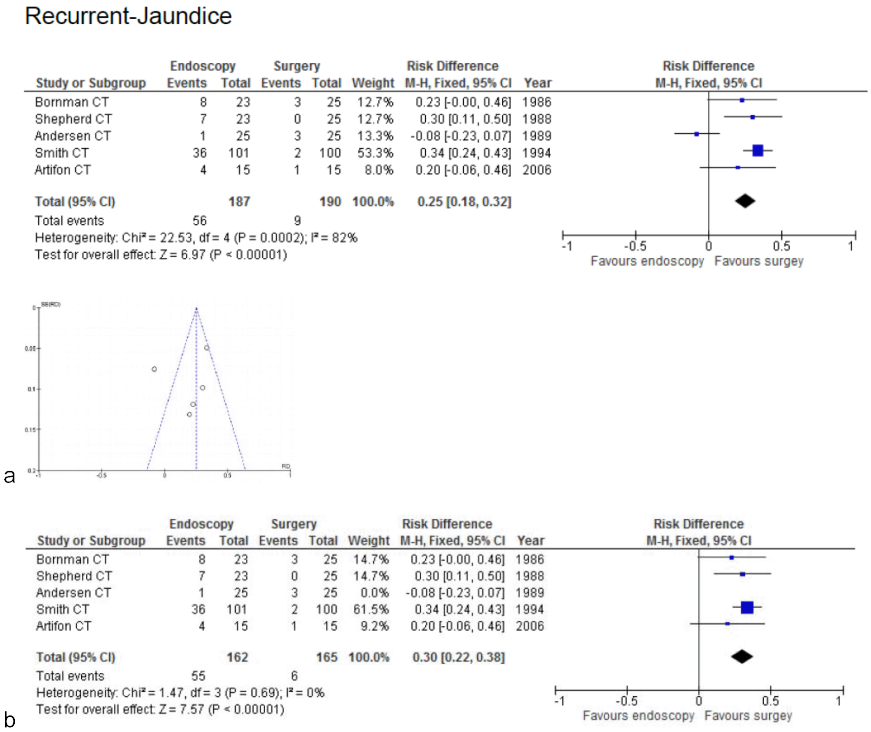

Figure 6: (a) Risk difference in Recurrent-Jaundice. (b) Risk difference in Recurrent-Jaundice for endoscopy and surgery therapies.

reviewers, we opted to withdraw this work from the meta-analysis of Recurrent-Jaundice (Figure 6b).

Recurrent-Jaundice for endoscopy and surgery therapies: four clinical trials reported Recurrent-Jaundice; the heterogeneity test indicated a χ2 of 1.47 and an I2 of 0%, demonstrating homogeneity. The fixed-effects model was adopted, and the RD was 0.30 (95 % CI: 0.22, 0.38) (Figure 6b). Analysis of the pooled data revealed statistically significant differences for Recurrent-Jaundice and showed better outcomes for surgery therapy.

Risk of Bias Across Studies

Although the results of success of the procedure were homogeneous between the studies, and no difference was found between the procedures in clinical trials, there is substantial risk of bias because the concept of success is different for each study. Although all are based on a percentage of reduction of bilirubin, the percentages that determined a successful procedure were different.

Mortality at 30 days was homogeneous between the studies, and statistically significant differences were found between the two therapies that favored endoscopy

therapy. We believe this result is one of the most solid because it was exposed in all studies in absolute numbers and because the concept of death is unlikely subject to interpretation bias.

With regard to complication associated with procedure, Andersen (1999) was identified as a source of heterogeneity for publication bias. Excluding this study, we analyzed four studies demonstrating low heterogeneity and found statistically significant differences (with low probability of bias) in complication associated with procedure that showed better outcomes for endoscopy therapy.

With regard to Recurrent-Jaundice, Andersen (1999) was identified as a source of heterogeneity for publication bias. Excluding this study, we analyzed four studies demonstrating homogeneity and revealed statistically significant differences (with low probability of bias) in Recurrent-Jaundice analysis that showed better outcomes for surgery therapy.

DISCUSSION

Summary of Evidence

About 70% of patients with periampullary tumors have evidence of obstructive jaundice at the time of presentation. Therefore, the main goal of palliative therapy in those patients is to resolve the biliary obstruction. Five randomized controlled trials comparing the outcomes of endoscopic stent placement versus surgical bypass for palliation therapy was analyzed.

No statistically significant differences were found in procedure success between the two therapies. Differences were found between mortality associated with procedure that favored the endoscopy therapy. There was significant risk of bias in this affirmation, and the risk ratio was 0.21. Statistically, significant differences (NNT 14) in mortality at 30 days between the two therapies favors endoscopy therapy. This is perhaps the most striking result unidentified in previous reviews. Also, statistically significant differences (NNT 4) in complication associated with procedure between the two therapies favors endoscopy therapy. Finally, statistically significant differences (NNH 3) were found for Recurrent-Jaundice and showed better outcomes for surgery therapy.

LIMITATIONS

Several limitations of the present study need to be considered. The characteristics of patients were not comparable in some studies. Although the studies were homogeneous in age, some studies had different average ages, which may lead to a significant bias in the results. Several endoscopic therapies including plastic stent and metallic stent (covered or uncovered) were used, and may be bias generator. The type of operation used was also different in all studies and may cause some biases. Finally, publication bias might exist when including published studies because positive results are more likely to be published than negative results.

CONCLUSION

Endoscopic palliative drainage is associated with a lower rate of complication as well as mortality associated with procedure and mortality within 30 days. Recurrent-jaundice analysis demonstrated an overall lower rate in surgical bypass procedures.

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Author Contributions

Silvia Lucia Alves de Lima – Conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Fabio Alberto Castillo Bustamante – Conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Eduardo GuimarãesHourneaux de Moura – Conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Wanderley Marques Bernardo – Conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

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Dalton Marques Chaves – Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Tomazo Antonio Prince Franzini – Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Carlos Kiyoshi Furuya Junior – Analysis and interpretation of data, Drafting the article, Critical revision of the article, Final approval of the version to be published

Guarantor

The corresponding author is the guarantor of submission.

Conflict of Interest

Authors declare no conflict of interest.

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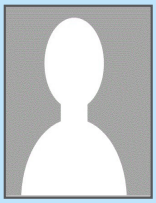

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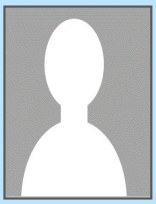

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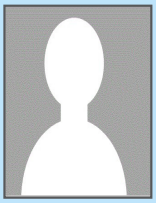

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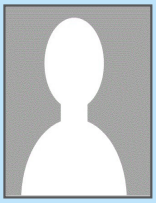

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