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Endosonography-Guided Biliary Drainage versus Percutaneous Transhepatic Biliary Drainage in the Falls of Endoscopic Retrograde Cholangiopancreatography: Systematic Review and Meta-Analyses

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Abstract

Background and Aims: The Endoscopic Retrograde Cholangiopancreatography (ERCP) is currently used for therapeutic purposes. In experienced hands the success rate is over 95%. The failure of ERCP to drain the bile duct in patients with biliary obstruction varies between 6% and 7%. In order to remedy failures, alternative techniques have emerged, such as Percutaneous Transhepatic Biliary Drainage (PTBD) and Endosonography-guided Biliary Drainage (EUS-BD). The objective of this systematic review was to assess which of the two techniques would be the best choice after ERCP failure.

Materials and Methods: We searched the databases, such as MEDLINE, Embase and Cochrane Central Library. Literature articles comparing EUS-BD *vs.* PTBD were included: randomized, prospective, non-randomized and retrospective trials.

Results: Fourteen articles were selected among them: randomized clinical trials (3), retrospective (10) and non-randomized prospective (1). Overall, we obtained 1,281 patients: 759 allocated to the EUS-BD group (intervention) and 522 to the PTBD group (comparison). Technical and clinical success was not statistically significant. And in relation to the number of adverse events, it had better statistical significance in the cases of RCTs. In technical success the risk difference IC 95%: 0.03 (-0.05, 0.11) with p>0.05 with heterogeneity of 26%, in clinical success the risk difference IC 95%: 0.00 (-0.12, 0.13) with p>0.05 with 0% heterogeneity. And in adverse events the risk difference IC 95%: -0.23 (-0.36, -0.09) with p<0.05 with 0% heterogeneity.

Conclusion: Technical success and clinical success did not have statistical significance, but with adverse events, the technique through endosonography had a decrease with adverse events.

Keywords: Endoscopic retrograde cholangiopancreatography; Drainage; Percutaneous; Failed and endoscopic ultrasonography

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Introduction

Until the 1980s, the treatment of biliary obstructions was open surgery, which had high rates of morbidity and mortality, prolonged periods of hospitalization and discouraging clinical results [1]. The development of Endoscopic Retrograde Cholangiopancreatography (ERCP), in subsequent years as a minimally invasive technique to be compared to surgery, improved the diagnosis and treatment of patients with biliary obstruction. The good results have made it the method of choice for treating this clinical condition. In experienced hands the success rate is over 95% [2]. The failure of ERCP to drain the bile duct in patients with biliary obstruction varies from 6% to 7% [3].

Regardless of the cause when biliary obstruction jaundice is not resolved, there is fat malabsorption, malabsorption of fat-soluble vitamins, malnutrition, cachexia and itching, which affects the quality of life of patients. Its progression to cholangitis and liver failure leads to multiple organ failure, and even death [1]. These facts demonstrate the importance of draining the obstructed bile duct as quickly as possible.

Until recently, Percutaneous Transhepatic Biliary Drainage (PTBD) was an optional method for ERCP failure, but some important points in the treatment chart for this disease should be highlighted: Performing the procedure on another day, sending the patient to the radiology service and the use of another medical team. In addition, this technique has high and negligible morbidity and mortality rates [4].

Recently, the development of Endosonography-Guided Biliary Drainage (EUS-BD) as an optional method after the failure of ERCP in an attempt to decompress the bile duct has become an attractive method. As an advantage, it stands out: Its performance immediately after the failure of the ERCP, with a rate of AEs supposedly lower than the other available techniques and with similar results [5].

The objective of this systematic review was to assess which of the two techniques would be the best choice, evaluating the technical, clinical success and the rate of AEs after ERCP's failure to decompress the main bile.

Method

Protocol and registration

This systematic review and meta-analysis was carried out in accordance with the recommendations of the Cochrane manual, following the items of the preferred reports for systematic reviews and Meta-Analyzes (PRISMA) [6]. The review was registered in the international database PROSPERO - International Prospective Register of Systematic Review, under registration number 218756 [7]. And the one approved by the Ethics Committee of Hospital Moriah/ São Paulo - Brazil dates from November 14, 2019.

Inclusion and exclusion of studies

Articles that compared the EUS-BD and PTBD techniques were analyzed. Retrospective articles randomized clinical trials and non-randomized prospective studies were selected, showing a number of articles to be evaluated for the present study. There was no restriction on the language and date of publication until October 2020.

The studies, which did not compare the drainage of the bile duct using the two techniques described above, such as: Abstracts without the publication of the complete article, those that showed results only with EUS-BD or PTBD alone, those whose scope was drainage by ERCP, review articles, comments and published case series, were excluded from the study.

Inclusion and exclusion of participants

We included patients >18 years old, with biliary obstruction, both sexes, with the signed Informed Consent form (IC) signed and who had failed the ERCP. We excluded those who refused to sign the informed consent form, those with anatomical fistulas, severe TGI stenosis, coagulopathies, portal hypertension and multiple organ dysfunctions, which prevented the performance of any type of endoscopic procedure.

Database and search strategy

The database was searched using MEDLINE/PubMed, EMBASE and Central Cochrane Library. Gray literature databases such as Google literature, endoscopy books and statistics books were not used.

The keywords or "Mesh Terms" used in the MEDLINE/ PubMed database were: (Retrograde Cholangiopancreatography, Endoscopic) and (Drainage) and (Percutaneous) and (Failed) and (Endosonographies). The keywords used in the search in the virtual library of EMBASE and Cochrane were made with simple terms such as: (ERCP) and (Drainage) and (Percutaneous) and (Failed) and (Endoscopic Ultrasonography).

Methodological quality assessment

The studies were classified by methodological quality according to the JADAD design in Randomized Clinical Trials (RCTs). A separate analysis of retrospective and non-randomized studies was carried out to assess methodological quality, which considers the blinding of patients and researchers to randomization and adequacy [8], in addition to the description of exclusions and losses.

Data extraction and outcome

The data were extracted using a specific form previously prepared by the reviewers, for the data extraction protocol. Two reviewers independently extracted data from selected studies. In case of disagreement between the reviewers, consensus was established through discussion between them and at least one third reviewer, if necessary and after they were confirmed, there was a group analysis to define the conclusion of the present manuscript.

The data were considered subject to extraction when made available in the text, in tables or graphs and the extraction of the data through intervention and treatment analysis (AIT). When evaluating the articles for the present manuscript, it had consensus with the analysis of technical and clinical success and description of the AEs.

Data analysis

The data were extracted based on the intention to treat information. For all outcomes with RCTS, the absolute risk difference was considered and for retrospective risk ratio and analysis with a 95% Confidence Interval (95% CI), considering a significance level of $p<0.05$. The difference between the outcomes and analysis of each outcome was calculated through the fixed effect and along with dichotomous variables. The analysis was performed with the RevMan 5.3 software using the Mantel-Hantzel (M-H) test.

Heterogeneity was considered by I2, with a 50% cut-off. When a value ≥ 50% was found, sensitivity analysis was performed to try to identify a study with a higher probability of publication bias ("outlier"), through graphic expression through the Egger test through the "funnel plot" and in case of heterogeneity >50%, we exchange the fixed effect for a random effect and interpret the heterogeneity as substantial or true.

Results

Inclusion and exclusion of studies

The total number of articles after applying the keywords in MEDLINE/PubMed and Embase/Cochrane with: (Drainage) and (Percutaneous) and (Failed) and (Endoscopic Ultrasonography) OR (Endoscopic retrograde cholangiopancreatography) allowed the identification of 274 and 11 studies, respectively. After 139 duplicate

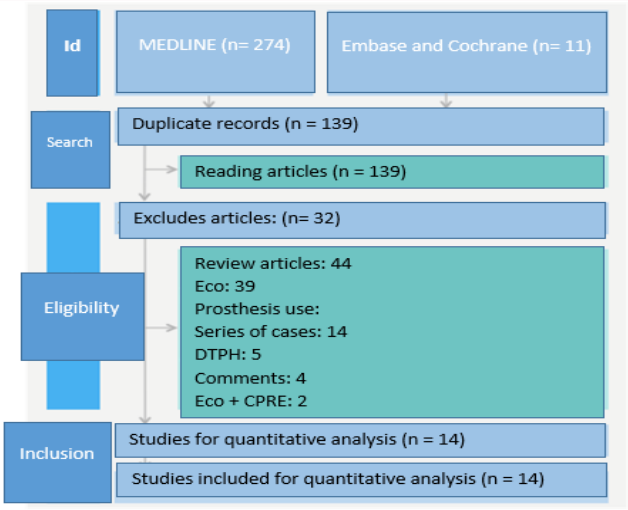

Figura 1: Fluxograma PRISMA.

articles were excluded, 146 were considered eligible, 132 were excluded (44 reviews, 39 titles on the EUS-BD alone, 24 studies on implantation of prostheses, 14 case series, 5 comments on studies, 4 titles on isolated PTBD and 2 studies dealing with EUS-BD and ERCP, after applying the exclusion criteria, this systematic review reached consensus after analyzing the 2 independent reviewers, resulting in a total of 14 articles that were included and analyzed by the PRISMA flowchart (Figure 1), comprising 10 retrospective studies [11-20], 3 randomized clinical trials and 1 prospective non-randomized trial [5,9,10,21].

Inclusion and exclusion

After applying the exclusion criteria, a total of 1,281 patients were reached, 759 underwent EUS-BD (intervention) and 522 underwent PTBD (comparison). The table of study characteristics included: References, year of publication, country, type of study, and total number of patients, patients (n) in the intervention group, patients (n) in the comparison group and the different types of drainage. The description of the studies shown in Table 1.

Table 2 describes the characteristics of each of the articles eligible for analysis. Reference, randomization, allocation, blinding, losses, prognosis, intention-to-treat analysis were included using the JADAD design, which was used specifically for only RCTs. Table 3 shows retrospective and non-randomized studies.

Outcomes

Technical success: The 14 articles included in the study showed that 759 patients underwent EUS-BD (intervention) and 522 underwent PTBD (comparative group). Three RCTs were found, of which 67 patients were submitted to EUS-BD (intervention group) and 65 to PTBD (comparison group). The technical success rate in this group was 64/67 (95.5%) in the intervention group and 60/64 (93.7%) in the comparison group. The risk difference 95% CI: 0.03 (-0.05, 0.11) with p>0.05 with 26% heterogeneity. The Forest Plot and funnel plot are shown in Figure 2 and 3.

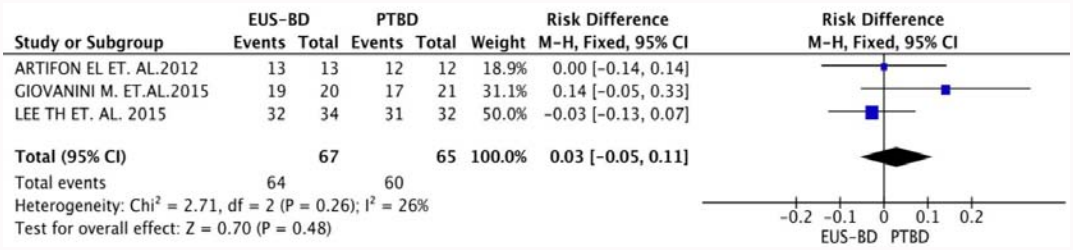

Figure 2: RCT Forest Plot showing technical success.

Table 1: Description of the studies.

Reference	Year	Country	Type of Study	Population	Intervention	Comparison	Types of Drainage
Albert JG et al. [10]	2014	Germany	Retrospective	33	6	27	NA
Artifon EL et al. [8]	2012	Brazil	Randomized	25	13	12	EUS-CD
Bapaye A et al. [11]	2013	India	Retrospective	51	25	26	EUS-CD, EUS-HG, EUS-AG
Bill J et al. [12]	2015	USA	Retrospective	50	25	25	EUS-RN
Giovanini M. et al. [5]	2015	France	Randomized	41	20	21	EUS-DO, EUS-HG, EUS-AG
Huang P et al. [13]	2017	China	Retrospective	66	36	30	EUS-CDS, EUS-HGS
Kashab MA et al. [14]	2014	USA	Retrospective	73	22	51	EUS-CD, EUS-HG,EUS-RN
Lee TH et al. [9]	2015	Koreia	Randomized	66	34	32	EUS-CD, EUS-HG
Nam K et al. [20]	2018	Koreia	Retrospective	313	251	62	NA
Paik WH et al. [16]	2017	Koreia	Retrospective	324	184	140	EUS-HGS
Sharaika RZ et al. [17]	2016	USA	Retrospective	60	47	13	EUS-CD, EUS-HG
Sportes A et al. [18]	2017	France	Retrospective	51	31	20	EUS-HG
Téllez Ávila FI et al. [19]	2018	Mexico	Retrospective	62	30	32	EUS-HGS, EUSCDS
Torres-Ruiz MF et al. [15]	2016	Mexico	Retrospective	66	35	31	NA

Table 2: Characteristics of RCTs.

Reference	Randomization	Allocation	Blindness	Losses	Prognosis	Ait	Jadad
Artifon EL et al. [8]	Yes	Yes	No	No	Homogeneous	Yes	3
Giovanini M et al. [5]	Yes	No	No	No	Homogeneous	Yes	3
Lee TH et al. [9]	Yes	Yes	No	No	Heterogeneous	Yes	3

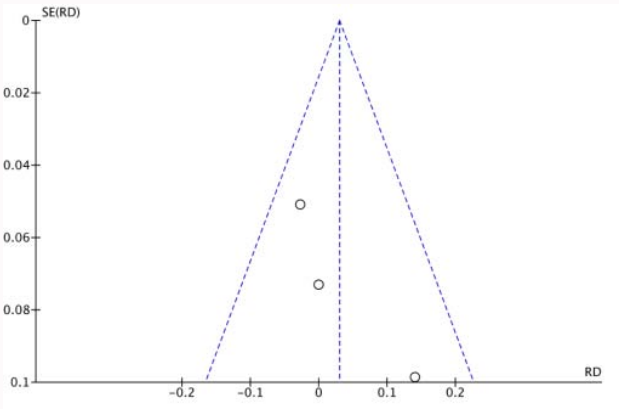

Figure 3: RCTs Funnel Plot showing technical success.

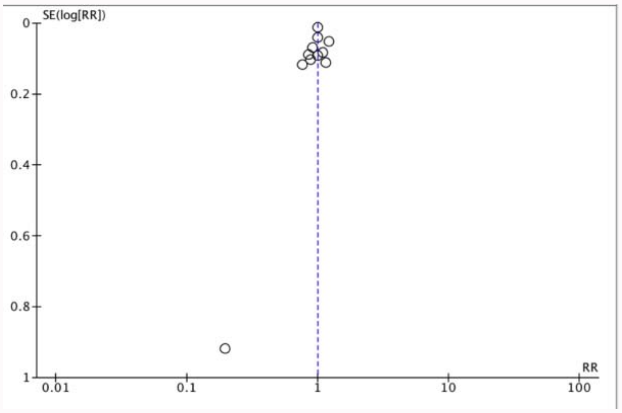

Figure 5: Funnel Plot of retrospective and prospective studies showing technical success.

Ten retrospective and 1 prospective studies were found, of which 692 patients were submitted to EUS-BD (intervention group) and 457 to PTBD (comparison group). The technical success rate in this group was 647/692 (93.49%) in the intervention group and 405/457 (88.62%) in the comparison group. The risk ratio 95% CI: -0.99 (0.92, 1.06) without statistical significance. The Forest Plot and funnel plot are shown in Figure 4 and 5.

Clinical success: Of the 14 articles 9 described the clinical success rate. With 264 patients in the intervention group and 237 in the comparison group. Two RCTs described the findings in 45 patients (intervention) and 43 (comparison). The clinical success rate in the intervention and comparison group was 41/45 (91.1%) and 39/43 (90.7%), respectively. The risk difference 95% CI: 0.00 (-0.12, 0.13) with p>0.05 with 0% heterogeneity. The Forest Plot and funnel plot are shown in Figure 6 and 7.

Seven retrospective studies allocated 219 patients in the intervention group and 194 in the comparison group, with a clinical success rate of 180/219 (82.2%) and 137/194 (70.61%), respectively. The risk ratio 95% CI: 1.30 (0.98, 1.73) without statistical significance. The Forest Plot and funnel plot are shown in Figure 8, 9.

Adverse events: Of the 14 articles 11 described as in a total of 320 patients (intervention) and 291 (comparison). Of the 3 RCTs, 67 (intervention) and 65 patients (comparison) were allocated. The AEs occurrence rate was 16/67 (23.9%) for the intervention group and 31/65 (47.1%) for the comparison group. The risk difference 95% CI: -0.23 (-0.36, -0.09) with p<0.05 with 0% heterogeneity. The Forest Plot and funnel plot are shown in Figure 10 and 11.

Regarding the 8 retrospective studies, 253 patients were allocated to the intervention group and 226 to the comparison group. The AEs rate in the intervention group was 53/253 (20.94%) and in the comparison group it was 87/226 (38.49%). The risk ratio 95% CI: -0.59 (0.29, 1.20) without statistical significance. The Forest Plot and funnel plot are shown in Figure 12, 13.

Discussion

The gold standard technique for accessing the biliary tree is ERCP, with a success rate of 90%, in cases of normal gastrointestinal anatomy [15]. Surgery and PTBD are indicated in patients who have anatomical variants, ampular pathology (stones, stenosis and tumor infiltration), periampular diverticulum, gastric obstruction, internal duodenal stent or gastric bypass, situations that hinder and sometimes prevent ERCP [1,22,23].

After PTBD several AEs are reported in the literature due to the presence of internal/external drainage. The main ones are occlusion, detachment of the drain in relation to the bile ducts and cholangitis,

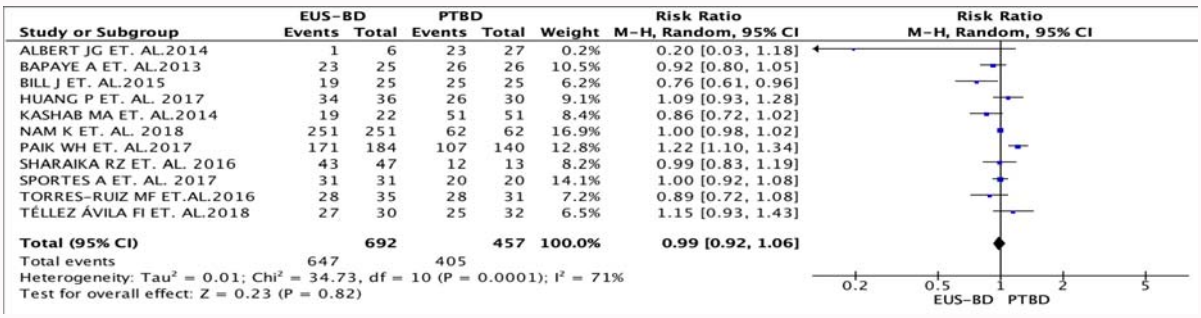

Figure 4: Forest Plot of retrospective and prospective studies showing technical success.

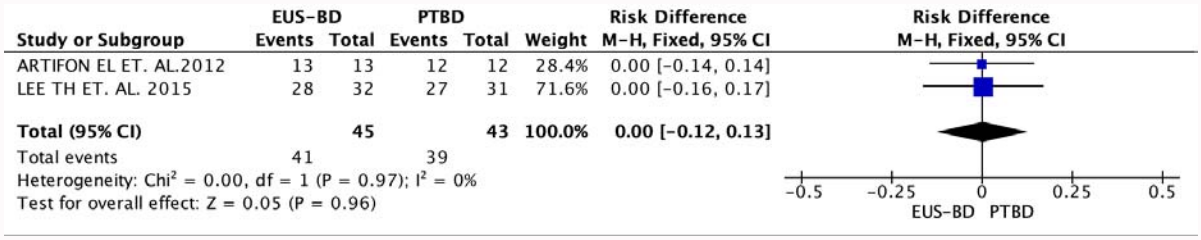

Figure 6: RCTs Forest Plot showing clinical success.

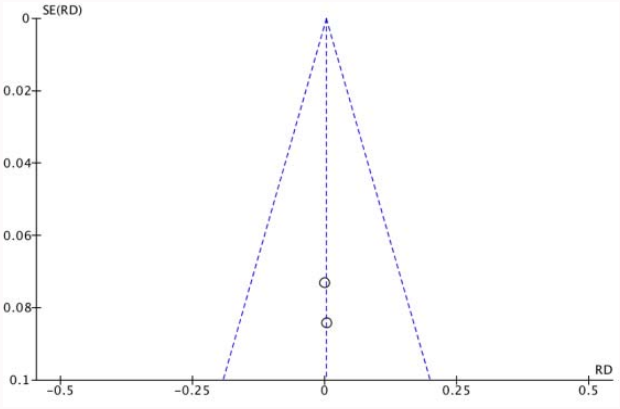

Figure 7: RCT Forest Plot showing clinical success.

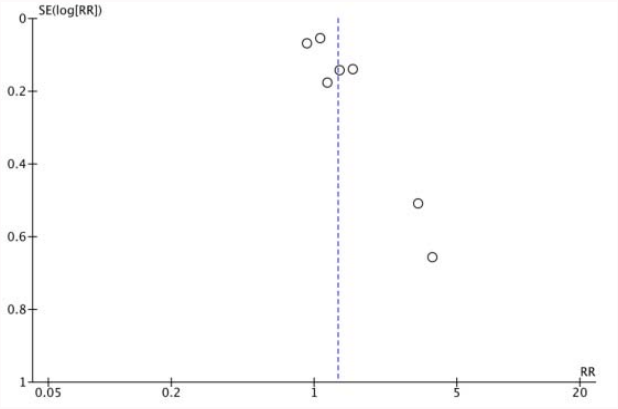

Figure 9: Funnel Plot of retrospectives showing clinical success.

the most common AEs. In addition, PTBD imposes a longer hospital stay and decreases patients' quality of life, due to the maintenance of an internal/external drain through the percutaneous orifice. In recent years, EUS-BD has become a safe, effective and less invasive solution compared to PTBD [24].

EUS-BD is a procedure performed to access biliary structures through the lumen of the gastrointestinal system, creating a fistula under direct vision guided by echoendoscopy and fluoroscopy together [25].

In the present systematic review and meta-analysis we found that the occurrence of AEs was lower in patients undergoing EUS-BD compared to PTBD obtained statistical significance both from the RCTS group (Figure 10) and also in the retrospective work group (Figure 12). Therefore, 1 in 4 patients who undergo EUS-BD after ERCP failure will benefit from an important reduction in the number of adverse events already reported after EUS-BD.

So far, PTBD is indicated as an alternative means of access to the biliary tract in cases of failure in drainage by ERCP or surgical means. After successful PTBD, the patient is sent home with a percutaneous drain. The constant output of bile causes nutritional malabsorption with loss of electrolytes. This problem does not occur with the EUS-BD, which is a more physiological method, providing better nutritional absorption and preventing the loss of electrolytes. In addition, the EUS-BD requires fewer reinterventions and avoids stress for the patient, who does not go home with the percutaneous drain.

Table 3: Characteristics of retrospective and non-randomized studies.

Reference	Randomization	Part of the Retrospective Study	Comparable Groups
Albert JG et al. [10]	No	Yes	Yes
Bapaye A et al. [11]	No	Yes	Yes
Bill J et al. [12]	No	Yes	Yes
Huang P et al. [13]	No	Yes	Yes
Kashab MA et al. [14]	No	Yes	Yes
Nam K et al. [20]	No	No	No
Paik WH et al. [16]	No	Yes	Yes
Sharaika RZ et al. [17]	No	Yes	Yes
Torres-Ruiz MF et al. [15]	No	Yes	Yes

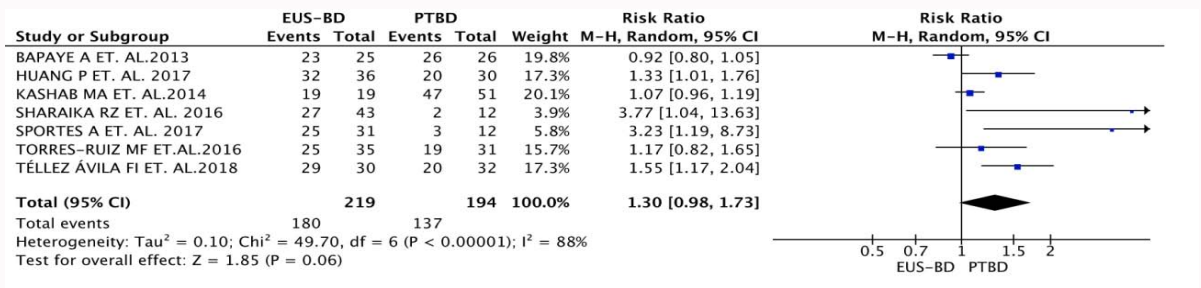

Figure 8: Forest Plot retrospectives showing clinical success.

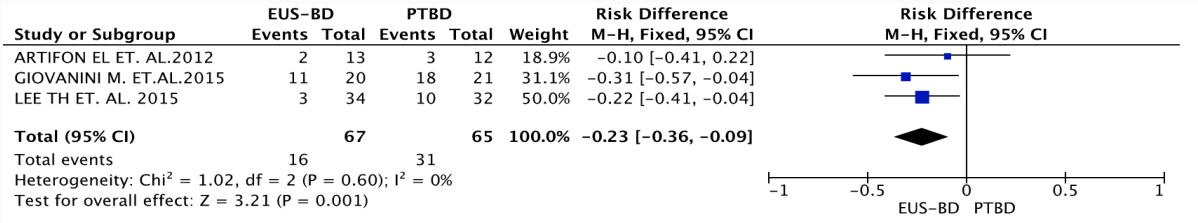

Figure 10: RCT Forest Plot showing adverse events.

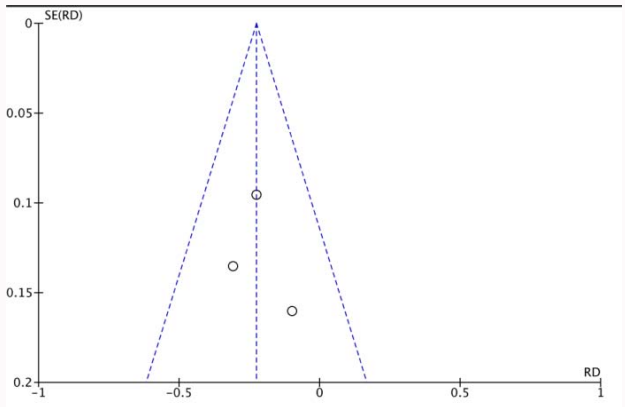

Figure 11: Funnel Plot of RCTs showing adverse events.

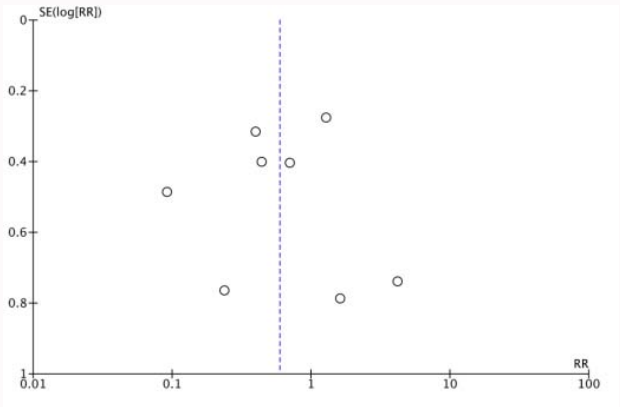

Figure 13: Funnel Plot of retrospectives showing adverse events.

The present study showed that the technical success for drainage of the bile duct after ERCP failure is similar for both the use of PTBD and EUS-BD, without showing statistical significance (Figure 2, 4). On the other hand, a problem reported in several articles is that because the EUS-BD is a complex procedure it can present a higher rate of AEs when performed by inexperienced endoscopists, this makes the EUS-BD operator dependent, as well as the PTBD that it is also an operator-dependent technique. This fact corroborates that both techniques must be performed by experienced doctors with good technical knowledge and anatomy of the biliary tree [26].

This study revealed that in experienced hands, both technical and clinical success between the two techniques did not show statistical significance, both in RCTs and in retrospective studies (Figure 6, 8). This means that when referring the EUS-BD or PTBD in experienced hands, the success of one or the other is similar and good.

The RCTs that were part of our study were made in centers where there are all implements within the endoscopy sector, such as interventional radiology, that is, they were performed in tertiary centers. An important advantage in favor of the EUS-BD is that the drainage fistula of the bile duct can be performed with the gastric or duodenal wall, facilitating the patient's lifestyle. In turn, PTBD is more invasive, as it leaves stents for internal drainage and external drainage. This fact determines the increase in hospitalization days, increasing the at least theoretical risk of infection after stent insertion [27].

It also stands out, as well as what is found in all guidelines that within the field of endoscopy, it is always up to the endoscopist to decide which technique he prefers, in addition to being explained in a clear and objective way. An algorithm was delivered to standardize the conduct in the case of obstruction of the bile duct with increased bilirubin and cholangitis.

The algorithm shows that after ERCP failure with dilated intrahepatic biliary tract, treatment should be with prosthetic insertion. Initially, an attempt should be made to approach the gastric chamber *via* hepatica and in the event of failure, a choledoduodenostomy is performed. On the other hand, in case the intrahepatic bile duct does not present dilation, the main procedure must be transduodenal extrahepatic [28]. It was not possible during

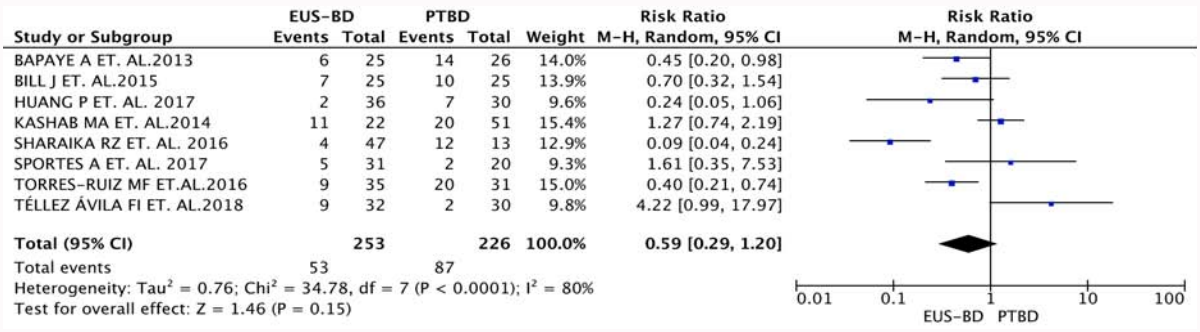

Figure 12: Forest Plot of retrospectives showing adverse events.

this study to identify the correct algorithm for adequate drainage of the bile duct with the techniques described by the EUS-BD.

Strengths and Limitations

This systematic review and meta-analysis is the first to evaluate all articles found in the literature. The number of studies included was adequate for the topic. Fourteen papers were included and among them, we had RCTs, retrospective and non-randomized with a number of patients that surpassed the 1,000 patients. We evaluated and thought about the best way to evaluate the two drainage methods and chose to analyze the technical, clinical success and the occurrence of AEs.

In the present study it was not possible to determine the types of prostheses used, the forms of dilation performed and whether there was use of other equipment, since the articles did not define these data to perform an adequate meta-analysis. The test of identification of publication biases (outliers) through the Funnel Plot was used through the random effect by the Egger test. The random effect for the risk difference was removed, maintaining the high heterogeneity of the sample. In the presence of a high heterogeneity, the weight of each study should be considered, from the smallest weight (4.7%) to the largest weight (11.3%), which these weights determine the function of true or substantial heterogeneity, since it is the number total articles showing bile duct drainage after ERCP failure.

Data are available in the current literature by adding randomized and prospective studies, by the number of patients evaluated, so our evidence can be considered moderate. We believe that more work should be carried out, especially RCTs, so that there is a better rate of evidence.

Despite these limitations, the two procedures are effective and have similar technical and clinical success. Tertiary hospitals should prepare for their technological suitability and availability in relation to EUS-BD, as this technique has a wide technological availability and that training in these procedures must be carried out by experienced physicians and in the future they can choose this technique. As first-line in the treatment of occluded biliary tract after ERCP failure.

In view of the results obtained in this systematic review and meta-analysis, we can conclude that there is no statistical difference between the two techniques studied EUS-BD and PTBD in relation to clinical and technical success. On the other hand, the occurrence of AEs was lower after EUS-BD when compared to PTBD.

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