Original Article

Risks and Protective Factors of Post-Endoscopic Retrograde Cholangiopancreatography Complication in Patients Undergoing Liver Transplantation: A Systematic Review and Meta-analysis

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ABSTRACT

Background:
Liver transplantation is a critical treatment option for end-stage liver disease, albeit associated with potential complications. Among the most common post-transplant complications are biliary issues, including leaks, strictures, and obstructions. Endoscopic retrograde cholangiopancreatography (ERCP) is frequently employed to manage these complications despite its inherent risks. While the complications of ERCP in the general population are well-documented, specific risks and protective factors for liver transplant recipients have not been extensively studied.

Materials and Methods:
We conducted a systematic review and meta-analysis in accordance with PRISMA guidelines. In order to find relevant studies published between 1/1/2011 and 1/3/2023, two independent researchers conducted searches (MT, I SH). A literature search of English language publications was conducted using MEDLINE through PubMed, EMBASETM through Ovid, the Cochrane Library, and Trip. In addition to Magiran and SID, we searched KoreaMed and LILACS for literature published in other languages. Endoscopic retrograde cholangiopancreatography OR ERCP, OR liver Transplantation, OR Complication are terms used in the search strategy. The Newcastle-Ottawa Scale (NOS) was used to assess the quality of the studies, and data were independently extracted by two researchers.

Results:
A total of 274 studies were selected. After analyzing their correspondence with the required criteria, a final review of eleven studies was conducted. Our meta-analysis identified several risk and protective factors for complications following ERCP in liver transplant patients. Protective factors included male sex and intraoperative stenting, which were associated with reduced complications. Conversely, high serum bilirubin and creatinine levels and a history of hepatitis B were found to increase the likelihood of complications or failure after ERCP. Factors such as age, history of diabetes, serum Alanine Aminotransferase (ALT) level, steroid administration, Mammalian Target of Rapamycin (mTOR) inhibitor use, and sphincterotomy did not significantly impact ERCP outcomes and complications.

Conclusion:
This systematic review and meta-analysis provide valuable insights into the risk and protective factors associated with complications following ERCP in liver transplant recipients. These findings can inform clinical decision-making and guide healthcare providers in optimizing the management of post-transplant biliary complications.

Keywords: Liver transplantation, Endoscopic retrograde cholangiopancreatography (ERCP), Complications, Risk factors, Systematic review

please cite this paper as:
Sivandzadeh GR, Taghavi AR, Ejtehadi F, Afshari M, Delaramnasab M , Tahani M, Shahramian I. Risks and Protective Factors of Post-Endoscopic Retrograde Cholangiopancreatography Complication in Patients Undergoing Liver Transplantation: A Systematic Review and Meta-analysis. *Govaresh* 2024; 29: 44-52

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Received: 19 Nov. 2023
Revised: 10 Mar. 2024
Accepted: 11 Mar. 2024

INTRODUCTION

Liver transplantation is one of the treatment methods in the final stage of liver disease. This surgical procedure can be risky and associated with possible complications (1). One of the common complications after liver transplantation is related to biliary complications, which most often include leakage, anastomotic or non-anastomotic strictures, and biliary obstruction with stones and mud (2).

Advancements in liver transplantation techniques started significantly worldwide after the first transplantation by Thomas Starzel in 1963, and since then, liver transplantations have been increasing worldwide (3). With the improvement of surgical methods and post-operative care, the amount of complications after surgery has decreased, but there are still complications after surgery, which most of the time require investigation and appropriate action (4).

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the methods used to manage biliary and pancreatic diseases, especially after liver transplantation complications (5). ERCP carries risks such as cholangitis, pancreatitis, bleeding, and perforation, possibly leading to death in rare cases. The rate of complications reported in the general population varies between 4% to 12%. Some studies indicate that the rate of complications in liver transplant patients is similar to that of the general population. Despite the studies conducted, the rate of complications of this procedure in liver recipients has not been investigated in detail (6).

In this study, we analyzed the risk factors and protective factors of complications after ERCP in liver transplant recipients analytically and systematically in related studies.

MATERIALS AND METHODS

A systematic search of the literature was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline (7). The following search technique was used between 1/1/2011 and 1/3/2023 to find the eligible studies. Two researchers (MT, I SH) searched for the pertinent papers published between 1/1/2011 and 1/3/2023. The Cochrane Library, Ovid, and Trip databases searched for English-language publications in MEDLINE, EMBASETM, and MEDLINE via PubMed. Our search for articles written in different languages included national databases (Magiran, SID), KoreaMed, and LILACS. For literature saturation the list of included references or relevant reviews was examined. The Health Sciences Librarian website was used to develop unique search techniques focused on systematic review searches using MESH terms and open phrases in compliance with the PRESS criteria. Results from searches in other databases were contrasted with those from the MEDLINE approach after it had been finalized (MT, I SH).

Similarly, PROSPERO was looked up to locate recent or active systematic reviews. The terms ERCP OR liver transplantation OR Complication were utilized in the search approach. The database of earlier study materials and systematic reviews was also explored to find the published research (MT, I SH). A search for unpublished data and abstracts (MT) was also conducted on all papers that met the inclusion criteria.

Eligibility Criteria

The addition of cross-sectional, case-control, cohort, case reports, and review publications with the availability of full text were the articles that met the criteria for the systematic review. Non-random sample size, lack of relevance to the issue, duplicate studies, and inadequate data were among the exclusion criteria. Two researchers carried out each of the stages mentioned above independently to prevent bias in the study. Finally, the agreement of the results obtained by the third researcher was examined.

Study Selection and data extraction

All pertinent publications were initially gathered, and a list of abstracts was created to help special investigations. The complete text of the publications was given to the researchers after the specifics, such as the name of the journal and the author, had been concealed. Two researchers independently examined each publication; if the article was rejected, the reason was stated. In the event of a dispute between the two researchers, a third researcher evaluated the paper.

Quality control of studies

The risk of bias was assessed using NOS (The New-Castle-Ottawa Scale) containing three sections (selection, comparability, and exposure) with 0-9 scores (four scores for selection, two scores for comparability, and three scores for exposure section). All papers with scores less than 5 were excluded from the meta-analysis. The assessment was conducted independently by two methodologists (M A, M DN).

In the next step, two researchers independently extracted data from the final selected studies. This information included the following:

The name of the first author, the date of publication of the article, the frequency of complications after ERCP, the odds ratio and the confidence interval related to each of the investigated factors, the frequency of each of the investtigated factors in the two groups with and without ERCP complications, the average difference of the quantitative factors investigated in the two groups. In the

groups with and without ERCP complications, the mean and standard deviation of each quantitative factor were investigated.

Statistical Analysis

First, in the primary studies that did not directly report the odds ratio or mean difference from the mean and standard deviation or the frequency of the investigated factors in two groups with and without complications, the odds ratio or mean difference was calculated along with the corresponding confidence intervals and standard deviation (17). The degree of heterogeneity between the results of primary studies was checked using the Cochrane test and the I square index. In case of significant heterogeneity, the random effects model was used, and in the absence of heterogeneity, the fixed effect model was used to combine the results. The points and combined results of the studies were displayed with the help of a table and a forest plot diagram. In this graph, each box's size indicates the study's weight, and the horizontal lines indicate the 95% confidence interval. All analyses and meta-analyses were done using Stata version 11 software. It should be noted that meta-analysis was performed only for factors whose effects were investigated and reported in at least three primary studies (18).

RESULTS

In the first phase of our comprehensive search, 275 studies were retrieved. By reviewing the titles and abstracts, 75 studies were excluded. After a complete review of the text and considering the inclusion/exclusion criteria, 53 studies were excluded, and finally, nine studies were chosen as appropriate for systematic review and meta-analysis (figure 1). The study's general information (first author, nation, and year of publication), and study information (Study design, percentage of female participants compared to male participants, participant count, statistical index used, and factors examined) were all extracted (table 1).

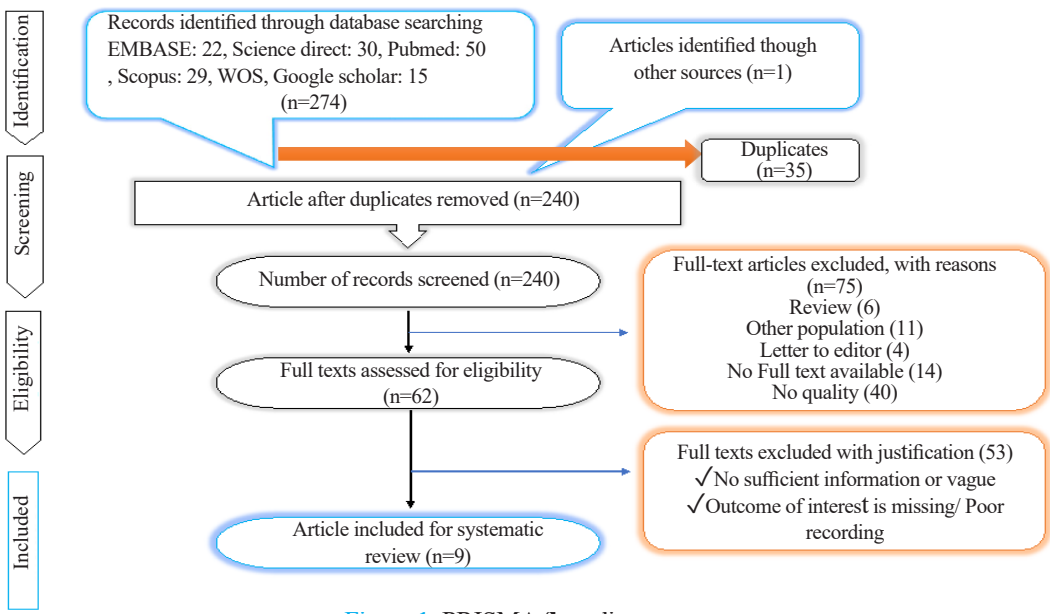

Figure 1. PRISMA flow diagram

Table 1. Summary of included studies

Author	Year	Country	Study design	Female to male	Participants(n)	Statistical index used	Factors examined
RB Ambrus(8)	2015	Denmark	Retrospective	0.95	292	OR(95% CI)	Stent use
Espinosa(9)	2021	Taiwan	Retrospective	0.19	652	OR(95% CI) / mean difference(SE)	Sphincterotomy, steroid use, creatinin, mTORI use
Domingo Balderramo(10)	2011	Spain	Retrospective	0.42	243	OR(95% CI) / mean difference(SE)	Sex, age, stent, sphincterotomy, steroid use, creatinin, mTORI use, diabetes, hepatitis, bilirubin, ALT

Daniel Pievsky(11)	2016	US	Retrospective	0.30	219	OR(95% CI) / mean difference(SE)	Sex, age, stent, sphincterotomy, steroid use, creatinin, mTORI use, diabetes, hepatitis, bilirubin, ALT
Guo-Zhen Li(12)	2018	China	Retrospective	-	1786	OR(95% CI) / mean difference(SE)	Sex, age, sphincterotomy, steroid use, creatinin, diabetes, hepatitis, bilirubin,
Giacomo Faleschini(13)	2015	Italy	Retrospective	0.32	360	OR(95% CI) / mean difference(SE)	Stent use
Piotr Czubkowski(14)	2018	Poland	Retrospective	0.57	189	OR(95% CI) / mean difference(SE)	Age, hepatitis, bilirubin, ALT
Ana Rita Alves(15)	2017	Portugal	Retrospective	0.55	120	OR(95% CI) / mean difference(SE)	Sex, Age
Ayman El Nakeeb(16)	2016	Egypt	Retrospective	0.79	996	OR(95% CI) / mean difference(SE)	Sex, age, bili

1.Examining the role of sex in the occurrence of complications after ERCP

As Figure 2 and Table 2 show, the results of five studies (10-12,15,16) investigated the relationship between sex and complications after ERCP, and the combination of their results showed that the odds ratio of complications in men was equal to 0.70, which was statistically significant (P=0.015). According to Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=3.29, P=0.510). Therefore, the results were combined using the fixed effect model. This indicates that the male sex reduces the occurrence of complications.

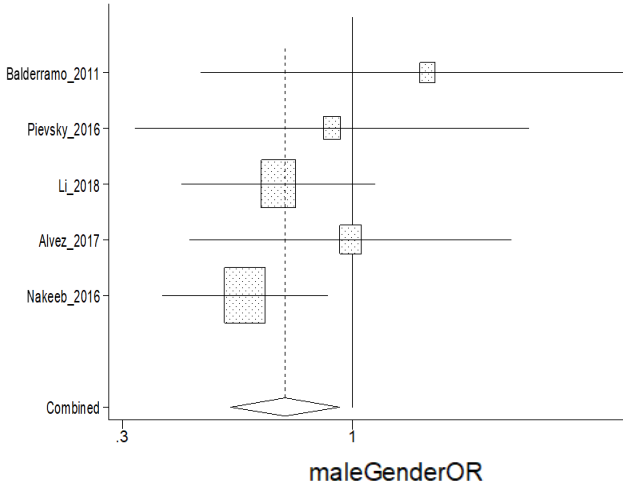

Figure 2. Point and pooled estimates of the effect of male sex on post-ERCP complications

Table 2. Point and pooled estimates of the effect of male-sex on post-ERCP complications

Study	Odds ratios	Lower	Upper	Pvalue
Balderramo_2011	1.48	0.45	4.83	
Pievsky_2016	0.9	0.32	2.52	
Li_2018	0.68	0.41	1.13	
Alvez_2017	0.99	0.43	2.3	
Nakeeb_2016	0.57	0.37	0.88	
Pooled OR	**0.703**	**0.528**	**0.935**	**0.015**

2. Examining the role of patients' age in complications after ERCP

The results of six studies (10-12,14-16) investigated the role of age in the occurrence of complications after ERCP, and the combination of their results showed that the average age of the group with complications was about 0.005 years less than the group without complications, but this difference was not statistically significant. According to Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=3.85, P=0.571). Therefore, the results were combined using the fixed effect model (Figure 3).

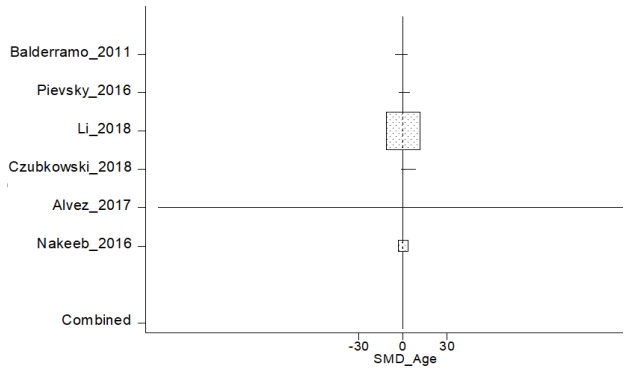

Figure 3. Point and pooled estimates of the effect of age on post-ERCP complications

3. The role of the stent in complications after ERCP

The results of four studies (8,10,12,13) investigated the relationship between stenting and complications after ERCP, and the combination of their results showed that the odds ratio of complications in the group with stents was about 80% lower than in the group without stents, which was statistically significant (P<0.001). According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=3.34, P=0.342). Therefore, the results were combined using the fixed effect model (Figure 4). This shows that placing a stent reduces the occurrence of complications.

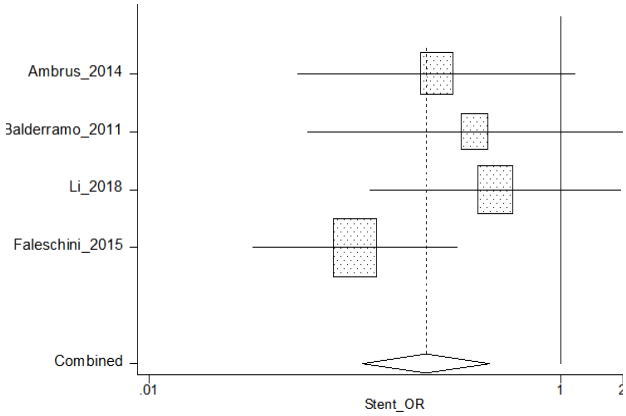

Figure 4. Point and pooled estimates of the effect of stent insertion on post-ERCP complications

4. The role of sphincterotomy in complications after ERCP

The results of four studies (9-12) investigated the relationship between sphincterotomy and complications after ERCP, and the combination of their results showed that the odds ratio of complications following sphincterotomy was equal to 1.07, which was not statistically significant (P=0.745). According to the results of Cochran's statistics, there was significant heterogeneity between the results of primary studies (Q=9.98, P=0.019). Therefore, the combination of results was done using a random effect model (Figure 5).

This indicates that sphincterotomy did not play a role in the occurrence of complications.

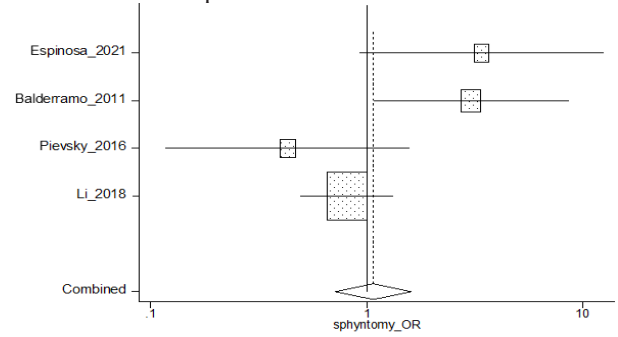

Figure 5. Point and pooled estimates of the effect of sphincterotomy on post-ERCP complications

5. The role of serum creatinine level in complications after ERCP

The results of four studies (9-12) investigated the role of serum creatinine level in the occurrence of complications after ERCP, and the combination of their results showed that the average creatinine of the group with complications was about 0.7 mg/dL more than the group without complications, which was statistically significant. According to the results of Cochran's statistics, there was significant heterogeneity between the results of primary studies (Q=38.59, P<0.001). Therefore, the combination of results was done using a random effect model (Figure 6).This indicates the role of high serum creatinine in complications after ERCP.

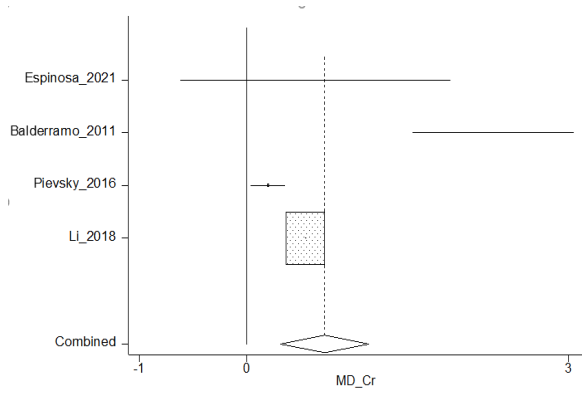

Figure 6. Point and pooled estimates of the effect of serum creatinine on post-ERCP complications

6. The role of steroid administration in complications after ERCP

The results of three studies (9-11) investigated the relationship between steroid administration and complications after ERCP, and the combination of their results showed that the odds ratio of complications following steroid injection was 1.13, which was not statistically significant (P=0.892). According to the results of Cochran's statistics, there was significant heterogeneity between the results of primary studies (Q=11.44, P=0.003). Therefore, the combination of results was done using a random effect model (Figure 7). This indicates that steroid injection did not play a role in complications.

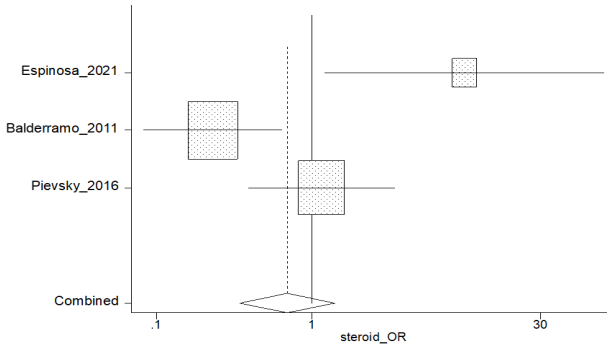

Figure 7. Point and pooled estimates of the effect of steroid Fuse on post-ERCP complications

7. The role of using mTORi, mammalian target of rapamycin inhibitors in complications after ERCP:

The results of three studies (9-11) investigated the relationship between mTORI administration and complications after ERCP, and the combination of their results showed that the odds ratio of complications following mTORI administration is equal to 1.52 (Figure 8), which was not statistically significant (P=0.372).

According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=3.18, P=0.204). Therefore, the results were combined using the fixed effect model.

This indicates that the administration of mTORI did not play a role in the occurrence of complications.

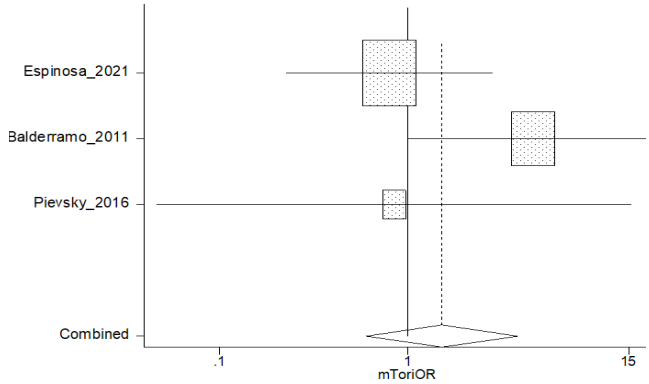

Figure 8. Point and pooled estimates of the effect of mTORI use on post-ERCP complications

8. The role of history of diabetes in complications after ERCP

The results of three studies (10-12) investigated the relationship between diabetes and complications after ERCP, and the combination of their results showed that the odds ratio of complications in diabetic people was equal to 1.24, which was not statistically significant (P=0.394).

According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=0.928, P=0.629). Therefore, the results were combined using the fixed effect model (Figure 9).

This indicates that the history of diabetes did not play a role in the complications.

9. The role of history of hepatitis B disease in complications after ERCP

The results of 3 studies (10,12,14) investigated the relationship between hepatitis B and complications after ERCP, and the combination of their results showed that the odds ratio of complications in people with hepatitis B is

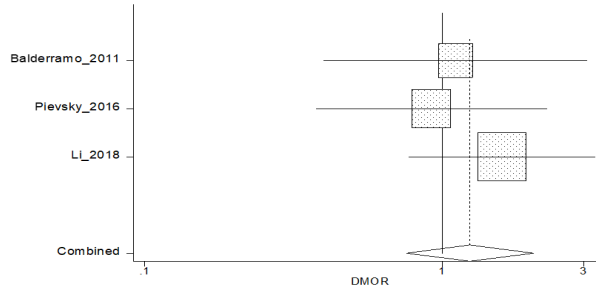

Figure 9. Point and pooled estimates of the effect of diabetes mellitus on post-ERCP complications

equal to 1.95, which was statistically significant (P=0.032 Figure10). According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=1.86, P=0.395). Therefore, the results were combined using the fixed effect model.

This indicates that the history of hepatitis in people increases the chance of complications after ERCP.

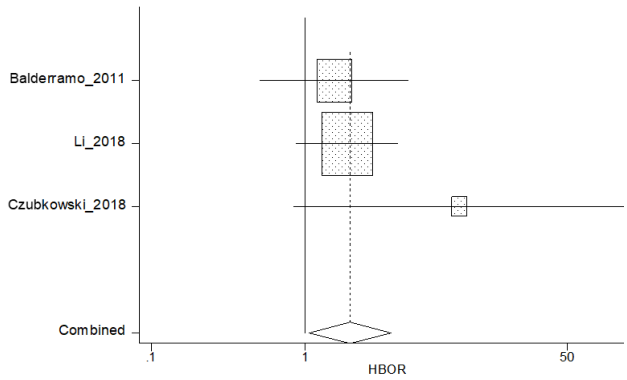

Figure 10. Point and pooled estimates of the effect of hepatitis B infection on post-ERCP complications

10. The role of serum bilirubin level in complications after ERCP

The results of five studies (10-12,14,16) investigated the role of serum bilirubin levels in the occurrence of complications after ERCP, and the combination of their results showed that the average bilirubin in the group with complications is about 0.55 mg/dL more than the group without complications, which is a statistically significant difference (P<0.001). According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=0.891, P=0.926). Therefore, the results were combined using the fixed effect model (Figure 11).

This indicates the role of high serum bilirubin in complications after ERCP.

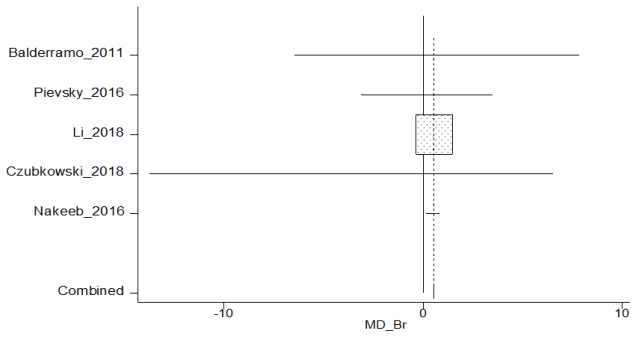

Figure 11. Point and pooled estimates of the effect of serum bilirubin on post-ERCP complications

11. The role of serum ALT level in complications after ERCP

The results of three studies (10,11,14) investigated the role of serum ALT level in the occurrence of complications after ERCP, and the combination of their results showed that the average ALT of the group with complications was about 0.05 mg/dL lower than the group without complications. This difference was not statistically significant (P=0.658). According to the results of Cochran's statistics, there was no significant heterogeneity between the results of primary studies (Q=3.65, P=0.161). Therefore, the results were combined using the fixed effect model (Figure 12).

This shows the lack of effect of high serum ALT on complications after ERCP.

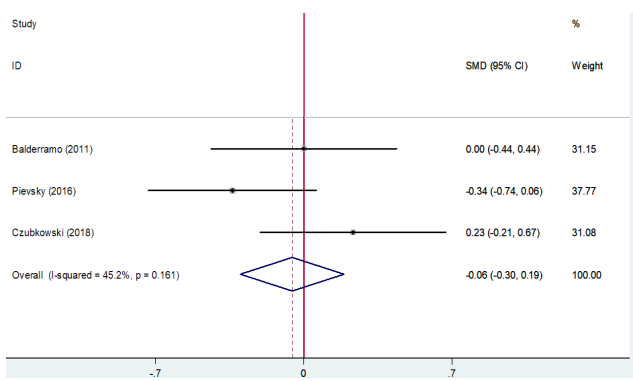

Figure 12. Point and pooled estimates of the effect of ALT on post-ERCP complications

DISCUSSION

Despite the progress made in liver transplant surgery, unfortunately, in some cases, they lead to complications after the surgery, which requires compensatory measures to correct and improve the patient's condition. If corrective measures are not taken after surgery, it can even lead to a threat to patients' lives. One of the common complications in patients after surgery is biliary complications. In mostcases, these complications can be managed through ERCP, and biliary diseases caused by liver transplant complications can be corrected.

The results of this study show that sex affects complications after ERCP, and according to the studies conducted, the ratio of the chance of complications in men is equal to 0.70, which was statistically significant (P=0.015). Therefore, it can be said that male sex reduces the incidence of ERCP complications. The average age of the group with complications is about 0.005 years less than the group without complications, but this difference was not statistically significant. It can be concluded that age does not affect complications after ERCP. We examined the relationship between stenting and complications after ERCP, which showed that the odds ratio of complications in the group with stents was about 80% lower than in the group without stents, which was statistically significant (P<0.001).

In the study conducted by McFarlane (19) on the complications of ERCP, the results showed that a group of patients in whom the stent was not used developed complications such as obstruction of the bile duct after liver transplantation. By examining the relationship between sphincterotomy and complications after ERCP, the findings indicate that the odds ratio of complications after sphincterotomy is equal to 1.07, which was not statistically significant (P=0.745).

Fei Du and colleagues stated that patients undergoing hilar biliary compression or endoscopic retrograde biliary drainage are more likely to develop post-ERCP cholangitis. The number and diameter of biliary stents may influence post-ERCP cholangitis. Sample size and clinical heterogeneity are two intractable problems, and a larger sample size should be collected to confirm risk factors for screening (22).

This indicates that sphincterotomy did not play a role in the occurrence of complications. After examining the role of serum creatinine level in complications after ERCP, the combination of their results showed that the average creatinine of the group with complications was about 0.7 mg/dL more than the group without complications, which was statistically significant. These cases show the role of high serum creatinine in the occurrence of complications after ERCP. They investigated the relationship between steroid administration and complications after ERCP, and the combination of their results showed that the odds ratio

of complications following steroid injection was equal to 1.13, which was not statistically significant (P=0.892). It can be concluded that steroid injection had no role in complications.

After investigating the relationship between mTORI administration and complications after ERCP, their results showed that the odds ratio of complications following mTORI administration was 1.52, which was not statistically significant (P=0.372). This indicates that the administration of mTORI did not play a role in the occurrence of complications. By examining the relationship between diabetes and complications after ERCP, their results showed that the odds ratio of complications in patients with diabetes was equal to 1.24, which was not statistically significant (P=0.394). This indicates that the history of diabetes did not play a role in the occurrence of complications.

In examining the relationship between hepatitis B and complications after ERCP, the combination of their results showed that the odds ratio of complications in people with hepatitis B is equal to 1.95, which was statistically significant (P=0.032).

This indicates that the history of hepatitis in people increases the chance of complications after ERCP. After investigating the role of serum bilirubin level in the occurrence of complications after ERCP, the results showed that the average bilirubin in the group with complications was about 0.55 mg/dL more than the group without complications, which was statistically significant (P<0.001). This indicates the role of high serum bilirubin in complications after ERCP.

Examining the role of serum ALT level in complications after ERCP showed that the average ALT of the group with complications is about 0.05 mg/dL lower than the group without complications, which was not statistically significant (P=0.658). This shows the lack of effect of high serum ALT on complications after ERCP.

Ilaria Tarantino and colleagues stated that although ERCP is a highly effective procedure for the management of post-transplant bile duct complications, a significant number of patients require other types of approaches (20). On the other hand, Mohammad Alomari and co-workers concluded that the rate of post-ERCP complications in liver transplant recipients was comparable to the general population. Therefore, intraoperative evaluation and management may follow the current standards of care in this patient population (21).

CONCLUSION

The results of this study showed the protective role of the male sex and the intention of intraoperative stenting in the occurrence of complications after ERCP. On the other hand, the results showed that high serum bilirubin and creatinine levels and a history of hepatitis B increase the chance of complications or failure after ERCP. Also, our results showed that factors such as age, history of diabetes, serum ALT level, steroid administration, and mTORI, as well as performing sphincterotomy, do not affect ERCP results and complications.

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