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DOI: 10.17235/reed.2019.6284/2019

Link: [PubMed \(Epub ahead of print\)](#)

Please cite this article as:

Egea Valenzuela Juan, Jijón Crespín Roxanna, Serrano Jiménez Andrés, Alberca de las Parras Fernando. Endoscopic retrograde cholangiopancreatography in the management of biliary complications after orthotopic liver transplantation. Rev Esp Enferm Dig 2019. doi: 10.17235/reed.2019.6284/2019.



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OR 6284

Endoscopic retrograde cholangiopancreatography in the management of biliary complications after orthotopic liver transplantation

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Received: 26/3/2019

Accepted: 29/05/2019

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ABSTRACT

Background: biliary complications are frequent after orthotopic liver transplantation and the management of these complications with endoscopic retrograde cholangiopancreatography (ERCP) is available. The aims of the study were to analyze the experience in the endoscopic management of biliary complications after liver transplantation in a third level center. Furthermore, the factors associated with higher rates of technical and clinical success were determined.

Methods: this was an observational retrospective study of ERCPs performed in patients with biliary complications after liver transplantation between February 2012 and January 2017. The factors analyzed were: demographics, time between transplantation and ERCP, indications for ERCP, strategy of stenting (only plastic stents, only self-expandable metallic stents, plastic followed by metallic stents and metallic followed by plastic stents), technical and clinical success and complications.

Results: one hundred and sixty-eight endoscopies were performed in 58 patients. Thirty-three patients (56.9%) presented with early complications. The most frequent indication for ERCP was

anastomotic stenosis (57.8%). Technical success in the first ERCP was achieved in 43 patients (74.1%). Early onset of biliary complications was associated with higher rates of technical success (OR: 6.49; p: 0.036). Clinical success was obtained in 36 cases (62.1%). Patients with early complications had a higher probability of having good clinical response (OR: 11.16; p: 0.033). The results were worse in patients with only plastic stents (50% of clinical success). Eleven complications were observed among 168 ERCPs (6.54%), including two pancreatitis, five bleeding events, three cholangitis and one micro-perforation.

Conclusions: ERCP is safe and useful in the management of biliary complications after liver transplantation. Early onset of complications is associated with better results. Some patients will need repeated procedures to obtain a good clinical response.

Key words: Anastomotic stenosis. Biliary leaks. Metallic self-expandable stents. Plastic stents. Cholestasis.

INTRODUCTION

Liver transplantation is essential in the management of patients with end stage cirrhosis and acute liver failure. The most frequent type is orthotopic liver transplantation (OLT) and biliary complications are the most frequent (10-45%) (1-5). Biliary stenosis (2-28%) can be anastomotic or non-anastomotic and are divided in two groups: early, which occur during the first year after transplantation and are ischemic, and late, which are produced by immunological mechanisms, more fibrotic and difficult to treat. Anastomotic strictures can be managed with endoscopic retrograde cholangiopancreatography (ERCP), but surgical management is preferred in non-anastomotic stenosis. However, there is also reported experience of the endoscopic management of non-anastomotic strictures (6). Other frequent complications after OLT are anastomotic leaks, choledocolithiasis and redundant bile ducts, which may present with altered liver enzymes and cholestasis (7,8).

The aim of the present study was to analyze our experience and results in the endoscopic management of the biliary complications of OLT.

METHODS

Study design

This was an observational retrospective study of consecutive ERCPs performed in liver transplantation recipients from February 2012 to January 2017. All the patients included in the study had an OLT with end-to-end biliary anastomosis.

Endoscopic procedures

All the ERCPs were performed by experienced endoscopists under deep sedation, which was controlled and administered by an anesthesiologist. The decision to perform a sphincterotomy, to dilate a stenosis and the use of plastic or self-expandable metallic stents (PS or SEMS) was made by the endoscopist and depended on the endoscopic and radiologic findings and the characteristics of the patient. Patients that received SEMS were re-evaluated after six months and patients with PS, after three months. Every strategy was used as an alternative after the failure of the other one. Thus, there were patients with no stent, patients with only SEMS, only PS, SEMS followed by PS and PS followed by SEMS. All the patients received antibiotic prophylaxis with cephalosporins and those with native papilla also had rectal indomethacin. Antithrombotic drugs were managed according to the current national guidelines (9,10).

Factors analyzed

The factors analyzed included: age, gender, time between OLT and the initial ERCP, indications, strategy of stenting, technical and clinical success and complications. Complications were classified as early, in the first year after OLT and late, after the first year. Indications for ERCP were stenosis, leaks, cholestasis, choledocolithiasis and stent removal. The first four indications have been included in the study when analyzing the technical success of the first ERCP or clinical success after follow-up. Stent withdrawal was also included when analyzing the technical success of all the ERCPs in the database.

A technical success after ERCP was considered as the endoscopic treatment of the biliary complication: dilation of a stenosis, correct placement of the stent to treat a stenosis or leak, extraction of stones or cleaning up of the bile duct and successful retrieval of the stent when indicated. A clinical success was considered when the biliary complication was resolved after the necessary ERCP and stability of the patient after at least six months.

Complications were defined according to the standard classics in ERCP (11), including bleeding, perforations, acute pancreatitis and cholangitis. We have also analyzed the incidence of migration

and obstruction of the stents.

RESULTS

One hundred and sixty-eight ERCPs were performed in 58 patients (1 to 7 procedures; 2.95 ± 1.68 ERCPs per patient) were included in the study. The mean time between OLT and the first ERCP was $872.05 \pm 1,526.61$ days (10 to 8,400 days). Demographics and indications are presented in table 1 and the indications for the first ERCP at the time of presentation are summarized in table 2.

The agreement between the initial indication for ERCP based on radiology and the findings during the endoscopic procedure was analyzed, with only a complete agreement of 56.8% between both. In nine cases (15.5%), the radiologic diagnosis was incomplete, biliary abnormalities were observed by ERCP after normal radiologic studies in eight patients (13.8%) and four patients (6.9%) had normal ERCP after an altered radiology. This is summarized in figure 1.

Regarding the initial ERCP, technical success was achieved in 43 cases (74.1%) and more frequently in patients with early complications (81.8% vs 64%, $p: 0.041$). However, there were no differences in the mean time between OLT and ERCP in the group of procedures with a technical success or failure ($806.16 \pm 1,306.26$ days vs $1,060 \pm 2,078.02$ days, $p: 0.258$). There were no differences in technical success in the first ERCP among the different indications: 77.1% in stenosis, 55.6% in biliary leaks, 83.3% in cholestasis and 50% in patients with choledocolithiasis ($p: 0.404$). Finally, there were no differences in the mean age of the patients regarding technical success in the first ERCP ($57.27 [52.90-61.63; 95\% CI] \pm 7.88$ years old vs $54.91 [51.04-58.77; 95\% CI] \pm 12.56$ years old, $p: 0.403$). According to the multivariate logistic analysis, only early onset of the biliary complications was associated with a higher probability of technical success, OR: 6.49 (1.13-37.22; 95% CI), $p: 0.036$ (Table 3).

The distribution of the indications among the total number of ERCPs is shown in table 4. There were no differences in terms of technical success with regard to the different indications ($p > 0.1$). Clinical success was obtained in 36 cases (62.1%). There were no differences in the mean age of patients with or without clinical success (54.92 ± 11.64 years vs 56.50 ± 11.50 years, $p: 0.5$). Furthermore, there were no differences between patients with early or late complications (72.7% vs 48%, $p: 0.055$). This was close to statistical significance and the mean time between OLT and the first ERCP was shorter in patients with clinical success ($60,786 \pm 1,138.25$ days vs $1,304.36 \pm 1,962.38$ days, $p: 0.02$). There were no differences in terms of clinical success among the different indications; 68.6%

in stenosis; 55.6% in anastomotic leaks, 50% in cases of cholestasis and 50% in patients with choledocolithiasis (p: 0.647).

A total of 44 patients received some type of stenting for the treatment of stenosis and leaks; 28 patients (63.6%) had only SEMs, four (9.2%) had only PS, six (13.6%) had SEMs followed by PS and six (13.6%) had PS followed by SEMs. The patients in the group of only SEMs had a clinical success of 70%, 50% in the only PS group, 100% in individuals who received SEMs followed by PS and 85.7% in the PS followed by SEMs group. Significant differences were found among the rates of clinical success, p: 0.001. According to the multivariate analysis, only the early onset of the biliary complications was associated with a higher probability of achieving clinical success, OR: 11.168 (1.220-102.264), p: 0.033 (Table 5).

There were eleven complications among the 168 ERCPs (6.54%): two cases of post-ERCP pancreatitis, five cases (2.9%) of bleeding (three early and two late hemorrhages), three post-ERCP cholangitis and one patient presented with a micro-perforation after the ERCP. Thirty-three ERCPs were performed due to complications related to previously placed stents. The stent produced biliary sludge and was cleaned up or removed in 13 cases, there were eight cases of external and five of internal stent migration, a metallic stent was retained in seven cases and all were treated with a stent-in-stent technique. All these stent-related complications were resolved endoscopically, except one retention that required surgery. No patients were under antithrombotics (four patients were under antiplatelets and seven patients were under anticoagulants) presented bleeding events. Clinical success was not achieved in 22 patients after endoscopic therapy. Ten patients required Roux-en-Y hepaticojejunostomies due to a persistent anastomotic stenosis after endoscopic management. Two patients required re-OLT due to persistent common bile duct stenosis. A conservative management was applied in the rest of patients.

DISCUSSION

According to our results, ERCP is safe and effective in the management of biliary complications after OLT. Early onset of the biliary complications is associated with better results. Biliary complications are frequent after OLT (1,2) and endoscopic management has become a first-line treatment (3,5). The most frequent complications in our study were stenosis and leaks and 12% of the patients developed both, which is similar to reported data in the literature (4,5,12).

It has been proposed that the gold standard for the diagnosis of biliary stenosis after OLT should be ERCP, percutaneous cholangiography or intraoperative direct confirmation (13). However, patients are referred for ERCP after radiologic diagnosis in the daily practice (ultrasonography, CT-scan and magnetic resonance). We found a weak correlation between radiology and endoscopic findings. The indication of ERCP should be supported not only by abnormal radiology, but also by altered laboratory tests and clinical data must be considered as a global understanding of the patients is required in this setting.

We found a technical success in the first ERCP of 74.1% and the clinical response was 62.1% during follow-up. In both cases, the probability of achieving good results was higher in the patients with early complications. These results are consistent with previously published data, a clinical success of 60% was reported in a large series of 1,188 liver transplantations (3). Poor outcomes after ERCP have been described in elderly patients, non-anastomotic stenosis, multiple stenosis and long standing biliary leaks (14). We did not find any cases of multiples stenosis and non-anastomotic strictures were managed surgically. In our series, ERCPs were performed immediately after the diagnosis of a leak, with good results in all the cases. We did not find any other factor such as gender, indication or age that predicted response. This is also consistent with other studies (15).

Different strategies in terms of stenting were followed. All had similar results, except for the patients that received only PS, which was the group with worse outcomes. Data in the literature regarding this topic are variable. A recent meta-analysis reported that the use of SEMS reduced the number of endoscopic procedures and the total time of treatment, but it did not affect the final response or the recurrence rates (16). A different study showed that SEMS were associated with a lower number of complications (17). The outcomes are similar when the results from studies in referral centers using PS and SEMS were compared, with 84% (63-100%) vs 75% (53-81%) of stenosis resolved respectively (18). In a meta-analysis of eight controlled but non-randomized studies, PS presented lower recurrence rates after 12 months (19). Moreover, other studies report better results when using PS (20-24). On the other hand, a European multicenter group reported good results using SEMS for 4-6 months, with a clinical response of 63.4% (25). In addition, SEMS have proved to be useful after failure of treatment with PS (26). There is wide variability among all these series and it is difficult to obtain conclusions. In our opinion and according to our experience, the type of stent should be chosen depending on the lesion (stenosis, leak, lithiasis, etc.) and the characteristics of the bile duct. As previously described (26), good results were also found when

using SEMS as an alternative after failure of PS and vice versa. The lack of response after initial stenting should not be considered as a failure of the endoscopic management, although the use of a different type of stent in subsequent ERCPs should be considered.

Four cases of post-OLT choledocolithiasis occurred in our series and obstruction of the SEMS due to biliary sludge occurred in 13 patients. These data could support the prophylactic use of ursodeoxycholic acid in a group of high risk patients with previous biliary disease, serum cholesterol > 200 mg/dl and triglycerides > 150 mg/dl, as previously proposed (27,28).

The limitations of this approach include the need for multiple ERCPs, the rate of complications, the impact on quality of life and cost. However, lower mortality rates have been described for endoscopic management compared with surgery (3). A mean of 2.95 procedures per patient was found in our series, which is lower than previously published data (3-8 per patient). Regarding complications, the rate in this study was 6.54%, which is similar to the results of other groups (6-12%) (29-31). All cases of complications related to the stents (obstruction or misplacement) were successfully managed endoscopically.

In conclusion, ERCP is useful in the management of different biliary complications after OLT, especially in those with an early onset and a low rate of complications. Among these, the most frequent are those related to obstruction or misplacement of the SEMS, but they can be resolved endoscopically in most of the cases with a low impact. Endoscopy can be technically difficult and challenging in OLT recipients and should be performed in referral centers and by experienced endoscopists.

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Accepted

Table 1. Demographics and indications

		n (%)
Patients	Total (age: 55.52 ± 11.51 years)	58
	Female (age: 52.31 ± 9.87 years)	14 (24.13%)
	Male (age: 58.22 ± 13.46 years)	44 (75.87%)
ERCPS	Total	168
	Stenosis	97 (57.7%)
	Leaks	11 (6.5%)
	Cholestasis	22 (13.1%)
	Choledocolithiasis	4 (2.4%)
	Stent removal	34 (20.2%)

Table 2. Distribution of the indications in the first ERCP regarding the moment of presentation

	<i>Early complication</i> <i>n (%)</i>	<i>Late complication</i> <i>n (%)</i>	<i>Overall</i> <i>n (%)</i>
Stenosis	20 (34.5%)	15 (25.8%)	35 (60.3%)
Leaks	9 (15.5%)	0	9 (15.5%)
Cholestasis	4 (6.9%)	8 (13.8%)	12 (20.7%)
Choledocolithiasis	0	2 (3.5%)	2 (3.5%)
Overall	33 (56.9%)	25 (43.1%)	58 (100%)

Percentages are referred to the total number of patients (n: 58).

Table 3. Multivariate analysis of the association of different variables with technical success (95% CI)

	<i>Odds ratio</i>	<i>p</i>
Age	0.986 (0.917-1.060)	0.708
Onset of biliary complication: early	6.492 (1.132-37.223)	0.036
Indication: stenosis	1.457 (0.076-28.019)	0.803
Indication: leak	0.194 (0.006-6.648)	0.363
Indication: cholestasis	3.587 (0.145-88.888)	0.435
Indication: choledocolithiasis	0.953 (0.801-1.109)	0.491

Table 4. Distribution of the indications among the total number of ERCPs. Rate of technical success in every indication

	<i>n (%)</i>	<i>Technical success</i>
Stenosis	97 (57.8%)	71 (73.2%)
Leaks	11 (6.5%)	9 (81.9%)
Cholestasis	22 (13.2%)	15 (68.3%)
Choledocolithiasis	4 (2.3%)	3 (75%)
Retrieval of stents	34 (20.2%)	32 (94.1%)
Overall	168 (100%)	130 (77.4%)

Table 5. Multivariate analysis of the association of different variables with clinical success

	<i>Odds ratio</i>	<i>p</i>
Age	1.050 (0.979-1.125)	0.170
Onset of biliary complication: early	<i>11.168 (1.220-102.264)</i>	<i>0.033</i>
Indication: stenosis	0.785 (0.028-21.703)	0.886
Indication: leak	0.053 (0.01-3.544)	0.171
Indication: cholestasis	1.336 (0.024-74.461)	0.888
Indication: choledocolithiasis	1.166 (0.755-1.569)	0.491
Strategy: only SEMS	1.041 (0.447-1.922)	0.509
Strategy: only PS	1.099 (0.522-2.101)	0.094
Strategy: SEMS followed by PS	0.993 (0.395-2.044)	0.664
Strategy: PS followed by SEMS	0.806 (0.662-1.077)	0.371

95% CI. $p < 0.05$ is considered as significant.

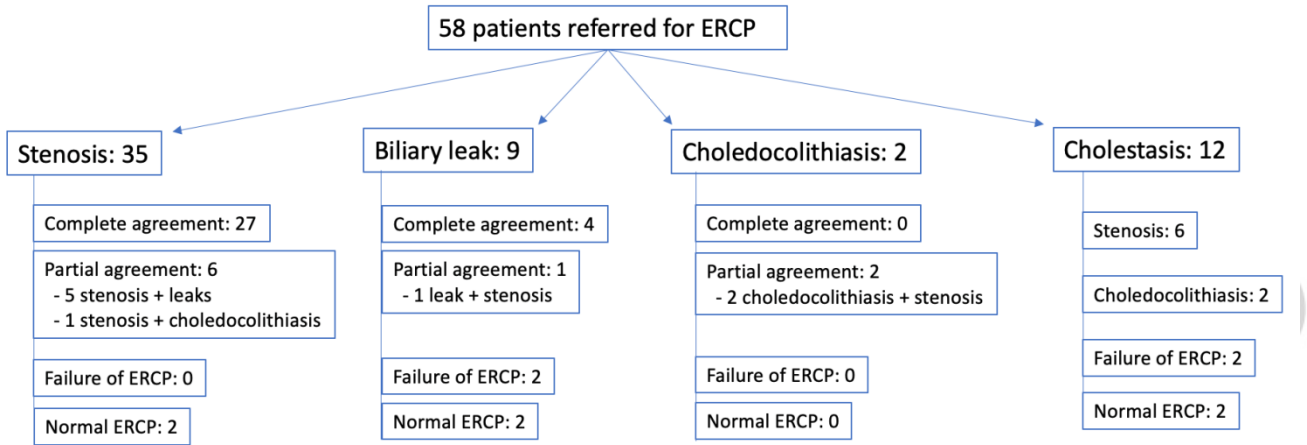


Fig. 1. Indications for ERCP and correlation between radiologic and endoscopic findings.