Surgery or EUS-guided choledochoduodenostomy for malignant distal biliary obstruction after ERCP failure

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ABSTRACT

Background and Objectives: Endoscopic retrograde cholangiopancreatography (ERCP) is the method of choice for drainage in patients with distal malignant biliary obstruction, but it fails in up to 10% of cases. Percutaneous transhepatic cholangiography (PTC) and surgical bypass are the traditional drainage alternatives. This study aimed to compare technical and clinical success, quality of life, and survival of surgical biliary bypass or hepaticojejunostomy (HJT) and endoscopic ultrasound (EUS)-guided choledochoduodenostomy (CDT) in patients with distal malignant bile duct obstruction and failed ERCP. Patients and Methods: A prospective, randomized trial was conducted. From March 2011 to September 2013, 32 patients with malignant distal biliary obstruction and failed ERCP were studied. The HJT group consisted of 15 patients and the CDT group consisted of 14 patients. Technical and clinical success, quality of life, and survival were assessed prospectively. Results: Technical success was 94% (15/16) in the HJT group and 88% (14/16) in the CDT group (P = 0.598). Clinical success occurred in 14 (93%) patients in the HJT group and in 10 (71%) patients in the CDT group (P = 0.169). During follow-up, a statistically significant difference was seen in mean functional capacity scores, physical health, pain, social functioning, and emotional and mental health aspects in both techniques (P < 0.05). The median survival time in both groups was the same (82 days). Conclusion: Data relating to technical and clinical success, quality of life, and survival were similar in patients who underwent HJT and CDT drainage after failed ERCP for malignant distal biliary obstruction.

Key words: Biliary duct neoplasms, drainage, endoscopic ultrasound, obstructive jaundice, palliative treatment, pancreatic neoplasms

INTRODUCTION

Malignant distal bile duct obstruction is an extremely aggressive condition. Most cases are diagnosed at an advanced stage. At the time of diagnosis, approximately 37% of patients have biliary obstruction and approximately 85% of patients are no longer candidates for curative surgical treatment.¹⁻⁴ Due to this advanced stage at presentation, such patients have poor performance status. Relief of obstructive jaundice becomes critical because biliary stasis (direct bilirubin higher than 15 mg/dL) can lead to comorbidities and early death.⁴

Endoscopic retrograde cholangiopancreatography (ERCP) with biliary stent placement is the method of choice for initial palliative treatment of obstructive jaundice, with a success rate of 90-95%.⁵⁻⁶ In cases of ERCP failure, surgical bypass is an alternative method, though with recurrent jaundice in 2-5% and a mortality rate of up to 24%.⁷ Percutaneous transhepatic biliary drainage is another alternative method for relief of biliary obstruction; however, the rate of complications can reach 30% due to biliary fistulas, bleeding, and hepatic...
Furthermore, some patients require long-term external biliary drains, which poorly affects quality of life. Combining endoscopic ultrasound (EUS) therapy with basic techniques of conventional ERCP, a new alternative to biliary decompression has been described: EUS-guided biliary drainage (EBD). This novel technique carries a technical success rate of 95%. EBD has not been compared specifically to conventional surgical techniques. In this study, we sought to determine outcome differences between two biliary drainage techniques in patients with distal malignant biliary obstruction and failed ERCP.

PATIENTS AND METHODS

From March 2011 to September 2013, a total of 1,549 therapeutic ERCPs were performed at the University of Sao Paulo. All patients with distal malignant biliary obstruction undergoing ERCP were consented for possible EBD. In case of ERCP failure, the patient was included in the study according to the inclusion and exclusion criteria. The following two groups were created: The surgical hepaticojejunostomy (HJT) group and the EUS-guided choledochoduodenostomy (CDT) group. The allocation of each included patient to his/her group was found on revealing a sealed envelope, containing the patient’s allocation, just after the ERCP failure. Inclusion criteria included age ≥18 years, unresectable distal malignant obstruction of distal bile duct, and failed standard ERCP. Patients from whom consent had not been obtained and patients with severe coagulopathy were excluded from the study. The institution’s ethical committee review board (IRB) approved the study and informed consent forms were presented to all patients. Informed consent was obtained from all subjects after explaining the HJT and EUS-guided CDT techniques, the novel nature of EUS-guided CDT technique, and discussing the risks, complications, alternatives, and possible benefits. The clinical trials registry identified for this study is NCT01522573.

Tumors were classified as unresectable based on MRI results, computerized tomography, and EUS-guided technique (invasion of mesenteric-portal axis to at least 50%, invasion of the superior mesenteric artery, celiac trunk invasion, and evidence of distant metastasis). After ERCP failure, patients were randomized into either of two groups (HJT and CDT), with 16 patients in each group. Patients in the HJT group underwent surgery 1 or 2 days after ERCP failure. The patients in the CDT group underwent EUS-guided CDT immediately after failed ERCP under the same anesthesia session. Patients in the HJT group were monitored by medical assistants in the Department of Surgery, Faculty of Medicine, University of Sao Paulo. Patients in the CDT group were followed up at the Department of Gastrointestinal Endoscopy, Hospital das Clinicas, University of Sao Paulo. All CDT procedures were performed by one endoscopist experienced in ERCP and EUS (ELAA).

Surgical technical success was defined as a successful construction of hepatojejunal anastomosis in Roux-en-Y fashion. The success of EUS-guided technique was characterized by nonanatomical biliary recanalization through the placement of a self-expandable metal stent through the duodenal wall into the bile duct. Clinical success was defined by a reduction of total serum bilirubin (BT) by at least 50% from the initial value after 7 days. BT was measured before and after biliary drainage (7 days, 30 days, 60 days, and 90 days). Quality of life was assessed using the Medical Outcomes Study 36 Index- Item Short-Form Health Survey (SF-36). Median survival time was estimated at up to 3 months according to each technique, with respective intervals with 95% confidence, using the Kaplan-Meier function.

Duodenal invasion of tumor was defined through endoscopic findings (lack of distensibility, mucosal friability, and linear areas in the mucosa located in the middle of the second part of the duodenum and/or bulb with or without decreasing intestinal light) and by EUS (loss of hyperechoic interface between the lesion and the duodenal wall, hypechoic thickening and loss of echo layers of the duodenal wall under the lesion, and intense neovascularization seen through color Doppler). All patients in the HJT group underwent gastrojejunal bypass (with or without endoscopic signs of duodenal invasion). In the CDT group, patients with endoscopic evidence of duodenal obstruction due to tumor invasion underwent endoscopic placement of enteral self-expanding metallic stent.

Surgical complications assessed included dehiscence of the hepatojejunal anastomosis and gastroenteroraoanastomosis, anastomotic ulcer bleeding, hemobilia, cholangitis, and intra-abdominal abscess. EUS-guided drainage complications assessed included abscess formation, abdominal pain, gastrointestinal perforation, hemorrhage, cholangitis, acute pancreatitis, biliary fistula, and stent migration.
After the procedure, patients were followed up for 90 days for clinical complications, laboratory, quality of life, and survival.

**Surgical hepaticojejunostomy [Figure 1]**

All procedures were performed under general anesthesia. Intravenous cefazolin (1 gm) was administered prophylactically 1 h before the procedure. A cross section of jejunal loop was taken and a termino-lateral jejuno-jejunal anastomosis (3-4 cm opening) was constructed between the proximal and distal jejunal pouches using 3-0 nylon monofilament suture on a single plane [Figure 1d]. Construction of termino-lateral hepaticojejunal anastomosis with total separate stitches using mononylon 5-0 surgical wire [Figure 1a] was performed. Then construction of latero-lateral gastrojejuno anastomosis with distal segment of the proximal jejunal loop was performed [Figure 1b]. The anastomosis was located at the greater gastric curvature with a 6-cm aperture using 3.0 catgut wire on two levels: The first being with continuous seromuscular stitches and the second, total, also with continuous stitches. Construction of latero-lateral jejuno-jejunal anastomosis between the proximal jejunal and jejunal loop that makes up the Roux-en-Y [Figure 1c] was performed. Temporary drainage of the abdominal cavity was achieved by placing a 20-Fr Penrose drain.

**EUS-CDT [Figure 2]**

General anesthesia with tracheal intubation was used to prevent bronchoaspiration. Before the procedure, a single dose of antibiotics was administered.

The dilated common bile duct was identified from the transduodenal route, with the linear echo-endoscope positioned in the duodenal bulb. Color Doppler was used to identify any vascular structures in the path of the needle. Transduodenal puncture of the dilated common bile duct with a 19-gauge needle was performed, and the intraductal position confirmed by aspiration of bile and subsequent cholangiography, delineating biliary anatomy and the stenotic lesion. A 0.035-inch hydrophilic guide wire was passed through the needle.

The needle was then withdrawn, leaving the guide wire in the intraductal position. Dilation of the choledochooduodenal fistula was done using a needle-knife with electrocautery. A self-expandable metallic biliary stent (partially covered) with the distal end positioned in the biliary and proximal end in the duodenal bulb was then placed under endoscopic and fluoroscopic guidance.

All patients remained in fasting and were hospitalized for 1 night for observation.

**Statistical analysis**

Block randomization was performed using Microsoft Excel 2007 software to randomly allocate patients. Sealed, numbered envelopes were prepared in advance that contained the allocation of each patient. The patient allocations were revealed from the envelopes immediately after ERCP failure. Quantitative personal characteristics were described according to groups using Student’s *t*-tests summary and comparative measurements between techniques. Fisher’s exact test or the chi-square test
was used to assess the existence of associations, when applicable. Laboratory tests and quality of life scores in each domain were described according to technique and time of evaluation using summary measures, and comparative measurements were made between the techniques and times using generalized estimating equations with a self-regression correlation matrix of order 1 between times, with a normal marginal distribution and logarithm link function to correct high variability. For models that present statistical significance, the analysis was followed by Bonferroni multiple comparison testing in order to evaluate differences between techniques or time differences.

RESULTS

Of the 32 enrolled patients, three (9%) were excluded due to technical failure, one (3%) from the HJT group, and two (7%) from the CDT group. Thus the technical success rate was 93.75% (15/16) in the HJT group and 87.5% (14/16) in the CDT group ($P = 0.598$). The causes of failure in conventional anatomical access by ERCP are shown in Table 1.

The demographic characteristics of the patients included in this study are presented in Table 2.

Palliative biliary drainage was performed by means of Roux-en-Y HJT in all patients in the HJT group (15/15). EBD was performed in all patients in the CDT group (14/14) according to the EUS-guided CDT technique.

The mean procedure time in the HJT group was 107 min and in the CDT group was 45.3 min ($P = 0.027$) [Table 3].

Clinical success was achieved in 24/29 patients (83%), i.e., 14 patients (93%) in the HJT group and 10 (71%) in the CDT group ($P = 0.169$) [Tables 4 and 5].

The behavior of laboratory findings according to technique over the follow-up time are depicted in Graphs 1 (BT), 2 [gamma-glutamyl transferase (GGT)], and 3 [alkaline phosphatase (AP)].

Duodenal invasion was observed in five (33.3%) patients in the HJT group. All of them underwent gastric bypass. In the CDT group, duodenal invasion

![Graph 1. Average profiles of TB and their standard errors according to techniques](image1)

![Graph 2. Average profiles of GGT and their standard errors according to techniques](image2)

![Graph 3. Average profiles of AP and their standard errors according to techniques](image3)

**Table 1. Causes of failure in ERCP**

| Causes of failure ERCP          | Technique    | Total |
|--------------------------------|--------------|-------|
|                                | HJT          | CDT   | n | % | n | % | n | % |
| Difficulty with IV cannulation | 8            | 10    | 18 | 62|
| Neoplastic infiltration of the papilla | 3           | 3     | 6  | 20.6|
| Neoplastic infiltration of the duodenum | 2           | 1     | 3  | 10.3|
| Previous surgeries (No access to papilla) | 1           | 1     | 1  | 3.4|
| Intradiverticular papilla     | 1            | 7     | 1  | 3 |
Complications occurred in two (13.33%) patients in the HJT group: One case of severe bacteremia and one case of gastric bleeding arising from gastroenterostomy. These were successfully treated endoscopically. In the CDT group, three (21.42%) cases of complications were observed: A bleeding duodenal wall, which was treated endoscopically; an early biliary fistula promoting a subhepatic collection of 4 cm, which was successfully treated by nonoperative means; and one case of early stent migration into the abdominal cavity, which was treated surgically. There was no statistically significant difference in the complication rates between techniques ($P = 0.651$).

The median survival time of patients in the HJT group was 82.27 days, and in the CDT group was 82.36 days. In the HJT group, 60% of the patients died 90 days

was seen in four patients (28.57%), in which cases enteral metallic stents placed were placed without major complications ($P < 0.999$).

Regarding quality of life, all areas showed statistically significant improvement (functional capacity, physical health, pain, and social and emotional aspects) independent of the technique used, except for the “general health” and “vitality” technical areas ($P > 0.05$) [Table 6].

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**Table 2. Demographic characteristics of the 29 patients**

| Variable                  | HJT     | CDT     | Total    | $P$       |
|---------------------------|---------|---------|----------|-----------|
| **Gender**                |         |         |          |           |
| Female                    | 8       | 7       | 15       | 53.3      |
| Male                      | 7       | 7       | 14       | 46.7      |
| **Pain**                  |         |         |          |           |
| No                        | 6       | 2       | 8        | 40.0      |
| Yes                       | 9       | 12      | 21       | 60.0      |
| **Jaundice**              |         |         |          |           |
| Yes                       | 15      | 14      | 29       | 100.0     |
| **Fever**                 |         |         |          |           |
| No                        | 14      | 13      | 27       | 93.3      |
| Yes                       | 1       | 1       | 2        | 6.7       |
| **Ascites**               |         |         |          |           |
| No                        | 10      | 13      | 23       | 66.7      |
| Yes                       | 5       | 1       | 6        | 33.3      |
| **Previous operation**    |         |         |          |           |
| No                        | 8       | 13      | 21       | 53.3      |
| Yes                       | 7       | 1       | 8        | 46.7      |
| **Immediate Complications** |   |         |          |           |
| No                        | 13      | 11      | 24       | 86.7      |
| Yes                       | 2       | 3       | 5        | 13.3      |
| **Age (years)**           |         |         |          |           |
| average (SD)              | 68.1 (19.5) | 65.9 (12.2) | 67.0 (16.2) |
| median (min.; max.)       | 74 (34; 95)  | 66 (51; 86)  | 70 (34; 95)  |
| **Weight loss (kg)**      |         |         |          |           |
| average (SD)              | 7.27 (3.65)  | 10.93 (4.89) | 9.03 (4.61)  |
| median (min.; max.)       | 8 (0; 14)   | 10 (3; 20)   | 10 (0; 20)  |
| **Gall diameter preprocedure** | |         |          |           |
| average (SD)              | 21.5 (5.2)   | 21.1 (4.0)   | 21.3 (4.6)  |
| median (min.; max.)       | 22 (10; 30)  | 20 (15; 30)  | 22 (10; 30) |
| **Time (min)**            |         |         |          |           |
| average (SD)              | 107     | 45.3    | 45.3     | 12.0      |
| median (min.; max.)       | 44.5     | 25 (25; 66) | 44.5 (25; 66) |
| **Total**                 | 15       | 100     | 14       | 100       |

Results of Fisher’s exact test, *Results of the chi-square test, Result **Student t-test, SD: standard deviation

**Table 3. Technical data in HJT and CDT groups**

| Variable                  | Techniques | $P$   |
|---------------------------|------------|-------|
| Bile duct diameter (mm)   | HJT 22     | 0.793 |
| Average procedure time (min) | 107      | 0.027 |
| Duodenal invasion (N)     | 5          | 0.999 |
after surgery, whereas in the CDT group, 42.9% died during the same period ($P = 0.389$) [Graph 4].

**DISCUSSION**

For a long period, surgical bypass has been the main modality in the palliation of obstructive jaundice in patients with failed ERCP. However, high rates of morbidity and mortality led to the search for and development of nonsurgical methods for palliative biliary drainage.[15]

Surgical palliation of tumors of the distal bile duct should be performed through the creation of a biliary-enteric anastomosis. However, there is controversy about the choice of the best palliative technique in the malignant obstruction of distal bile duct. In this context, we highlight the HJT, because of the low morbidity and reduced recurrence of jaundice associated with it in the medium term. Cholecystojejunostomy is still a palliative bypass that can be used because it is simple to perform, effective, and presents less morbidity; however, it is limited to patients with intact gallbladder. In this technique, there is the possibility of tumor invasion of the cystic duct, resulting in early biliary obstruction; therefore, it should be used when the estimated survival is, at most, 4-6 months.[18]

Biliary bypass with duodenum is more physiological and is an alternative, besides permitting future endoscopic biliary interventions. However, for malignant lesions, this approach may not be as effective, because there is the risk of anastomosis tumor invasion.[19]

Patients who underwent cholecystojejunostomy presented with lower survival and required more biliary surgery interventions (4.4 × more) compared to those who underwent anastomosis through the principal biliary tract.[20] Of patients with pancreatic head cancer who underwent palliative surgical treatment, 30% required future treatments resulting from duodenal obstruction, thus highlighting why prophylactic gastroenteral bypass is still controversial.[21]

In a meta-analysis published in 2013, patients with malignant pancreatic neoplasm with low surgical risk were most benefited when they underwent surgery, due to the lower rate of recurrent jaundice and subsequently a shorter hospital stay, when compared to patients who underwent bile stent placement.[22]
Table 5. Results of multiple comparisons between times for BT, GGT, FA in both groups

| Variable                  | Techniques | Comparison | Average difference | Standard error | P Inferior | IC (95%) |
|---------------------------|------------|------------|--------------------|----------------|------------|----------|
| Total bilirubin           | HJT Group  | Pre-7 days | 11.87              | 0.94           | <0.001     | 10.03    |
|                           |            | Pre-30 days| 13.13              | 1.07           | <0.001     | 11.04    |
|                           |            | Pre-60 days| 13.48              | 1.12           | <0.001     | 11.29    |
|                           |            | Pre-90 days| 13.49              | 1.45           | <0.001     | 10.66    |
|                           |            | 7 days-30 days| 1.26              | 0.94           | 0.178      | -0.57    |
|                           |            | 7 days-60 days| 1.62              | 1.09           | 0.136      | -0.51    |
|                           |            | 7 days-90 days| 1.62              | 1.44           | 0.259      | -1.20    |
|                           |            | 30 days-60 days| 0.35              | 0.96           | 0.713      | -1.53    |
|                           |            | 30 days-90 days| 0.36              | 1.41           | 0.799      | -2.41    |
|                           |            | 60 days-90 days| 0.01              | 1.32           | 0.997      | -2.59    |
| CDT Group                 |            | Pre-7 days | 7.65               | 0.97           | <0.001     | 5.75     |
|                           |            | Pre-30 days| 10.36              | 1.10           | <0.001     | 8.20     |
|                           |            | Pre-60 days| 10.96              | 1.21           | <0.001     | 8.59     |
|                           |            | Pre-90 days| 10.97              | 1.39           | <0.001     | 8.24     |
|                           |            | 7 days-30 days| 2.71              | 0.97           | 0.005      | 0.81     |
|                           |            | 7 days-60 days| 3.31              | 1.18           | 0.005      | 1.00     |
|                           |            | 7 days-90 days| 3.32              | 1.39           | 0.017      | 0.60     |
|                           |            | 30 days-60 days| 0.60              | 1.05           | 0.572      | -1.47    |
|                           |            | 30 days-90 days| 0.61              | 1.36           | 0.653      | -2.05    |
|                           |            | 60 days-90 days| 0.02              | 1.28           | 0.991      | -2.49    |
| Gamma-glutamyl transferase| HJT Group  | Pre-7 days | 814.49             | 68.36          | <0.001     | 680.51   |
|                           |            | Pre-30 days| 849.29             | 73.78          | <0.001     | 704.69   |
|                           |            | Pre-60 days| 855.99             | 75.93          | <0.001     | 707.18   |
|                           |            | Pre-90 days| 871.22             | 98.39          | <0.001     | 678.39   |
|                           |            | 7 days-30 days| 34.80             | 68.36          | 0.611      | -99.18   |
|                           |            | 7 days-60 days| 41.50             | 75.09          | 0.580      | -105.67  |
|                           |            | 7 days-90 days| 56.73             | 98.28          | 0.564      | -135.89  |
|                           |            | 30 days-60 days| 6.70              | 69.77          | 0.923      | -130.04  |
|                           |            | 30 days-90 days| 21.93             | 97.63          | 0.822      | -169.42  |
|                           |            | 60 days-90 days| 15.23             | 94.29          | 0.872      | -169.58  |
| CDT Group                 |            | Pre-7 days | 523.07             | 70.76          | <0.001     | 384.39   |
|                           |            | Pre-30 days| 620.50             | 76.37          | <0.001     | 470.82   |
|                           |            | Pre-60 days| 682.41             | 80.34          | <0.001     | 524.95   |
|                           |            | Pre-90 days| 683.84             | 94.45          | <0.001     | 498.73   |
|                           |            | 7 days-30 days| 97.43             | 70.76          | 0.169      | -41.25   |
|                           |            | 7 days-60 days| 159.34            | 79.49          | 0.045      | 3.55     |
|                           |            | 7 days-90 days| 160.77            | 94.33          | 0.088      | -24.11   |
|                           |            | 30 days-60 days| 61.91             | 74.11          | 0.403      | -83.34   |
|                           |            | 30 days-90 days| 63.34             | 93.61          | 0.499      | -120.12  |
|                           |            | 60 days-90 days| 1.43              | 90.90          | 0.987      | -176.72  |
| Alkaline phosphatase      | HJT Group  | Pre-7 days | 451.07             | 39.30          | <0.001     | 374.03   |
|                           |            | Pre-30 days| 467.27             | 39.07          | <0.001     | 390.69   |
|                           |            | Pre-60 days| 465.00             | 39.77          | <0.001     | 387.06   |
|                           |            | Pre-90 days| 464.53             | 51.69          | <0.001     | 363.22   |
|                           |            | 7 days-30 days| 16.20             | 39.30          | 0.680      | -60.83   |
|                           |            | 7 days-60 days| 13.94             | 39.76          | 0.726      | -64.00   |
|                           |            | 7 days-90 days| 13.46             | 51.69          | 0.795      | -87.85   |
|                           |            | 30 days-60 days| -2.26             | 39.99          | 0.955      | -80.64   |
|                           |            | 30 days-90 days| -2.74             | 51.69          | 0.958      | -104.04  |
|                           |            | 60 days-90 days| -0.48             | 52.40          | 0.993      | -103.17  |
| CDT Group                 |            | Pre-7 days | 315.86             | 40.68          | <0.001     | 236.12   |
|                           |            | Pre-30 days| 385.21             | 40.44          | <0.001     | 305.95   |
|                           |            | Pre-60 days| 389.53             | 42.10          | <0.001     | 307.02   |

Continued
Table 5. (Continued)

| Variable       | Comparison | Average difference | Standard error | P Inferior | IC (95%)  |
|----------------|------------|--------------------|----------------|------------|-----------|
|                |            | Pre- 90 days       |                |            | Inferior  |
|                |            |                    |                |            | Superior  |
|                |            | 388.47             | 49.53          | <0.001     | 291.38    |
|                |            |                    |                |            | 485.56    |
| 7 days-        |            | 69.36              | 40.68          | 0.088      | −10.38    |
|                |            |                    |                |            | 149.09    |
| 7 days-        |            | 73.67              | 42.09          | 0.080      | −8.83     |
|                |            |                    |                |            | 156.18    |
| 7 days-        |            | 72.61              | 49.54          | 0.143      | −24.47    |
|                |            |                    |                |            | 169.70    |
| 30 days-       |            | 4.32               | 42.33          | 0.919      | −78.64    |
|                |            |                    |                |            | 87.27     |
| 30 days-       |            | 3.26               | 49.53          | 0.948      | −93.83    |
|                |            |                    |                |            | 100.34    |
| 60 days-       |            | −1.06              | 51.11          | 0.983      | −101.24   |
|                |            |                    |                |            | 99.12     |

Table 6. Description of scores of quality of life (SF36) according to techniques during follow-up

| Variable       | Moment (Day) | Average | DP | Median | Minimum | Maximum | N |
|----------------|--------------|---------|-----|--------|---------|---------|----|
|                | HJT          | Technique | CDT | Average | DP | Median | Minimum | Maximum | N |
| Functional Capacity | 0           | 26.3     | 9.9 | 30      | 0       | 40      | 15     |
|                | 7           | 33.7     | 15.1 | 30      | 0       | 60      | 15     |
|                | 30          | 40.7     | 15.2 | 40      | 0       | 60      | 15     |
|                | 60          | 44.3     | 9.6  | 45      | 25      | 60      | 14     |
|                | 90          | 57.5     | 88   | 60      | 45      | 70      | 6      |
| Physical Health | 0           | 5.0      | 10.4 | 0       | 0       | 25      | 15     |
|                | 7           | 21.7     | 20.8 | 25      | 0       | 50      | 15     |
|                | 30          | 31.7     | 24.0 | 25      | 0       | 75      | 15     |
|                | 60          | 28.6     | 19.3 | 25      | 0       | 50      | 14     |
|                | 90          | 45.8     | 18.8 | 50      | 25      | 75      | 6      |
| Pain           | 0           | 60.2     | 34.6 | 41      | 22      | 100     | 15     |
|                | 7           | 78.0     | 22.5 | 74      | 52      | 100     | 15     |
|                | 30          | 76.7     | 20.1 | 74      | 51      | 100     | 15     |
|                | 60          | 70.4     | 18.5 | 74      | 41      | 100     | 14     |
|                | 90          | 88.7     | 14.4 | 92      | 64      | 100     | 6     |
| HGS            | 0           | 41.0     | 10.7 | 35      | 25      | 55      | 15     |
|                | 7           | 42.1     | 6.4  | 45      | 30      | 50      | 15     |
|                | 30          | 40.7     | 11.1 | 42      | 20      | 62      | 15     |
|                | 60          | 38.4     | 5.3  | 38.5    | 30      | 45      | 14     |
|                | 90          | 34.8     | 10.9 | 32.5    | 25      | 55      | 6      |
| Vitality       | 0           | 38.7     | 10.9 | 35      | 15      | 65      | 15     |
|                | 7           | 38.0     | 11.3 | 35      | 20      | 60      | 15     |
|                | 30          | 40.3     | 13.3 | 40      | 25      | 70      | 15     |
|                | 60          | 42.9     | 14.0 | 42.5    | 25      | 70      | 14     |
|                | 90          | 32.5     | 12.6 | 30      | 20      | 50      | 6      |
| Social Asp.    | 0           | 30.0     | 15.5 | 25      | 0       | 62.5    | 15     |
|                | 7           | 45.8     | 12.2 | 50      | 25      | 62.5    | 15     |
|                | 30          | 54.2     | 12.2 | 62.5    | 37.5    | 75      | 15     |
|                | 60          | 43.8     | 14.5 | 43.75   | 25      | 75      | 14     |
|                | 90          | 52.1     | 9.4  | 50      | 37.5    | 62.5    | 6      |
| Emotional Asp. | 0           | 8.9      | 15.3 | 0       | 0       | 33      | 15     |
|                | 7           | 35.6     | 19.8 | 33.3    | 0       | 67      | 15     |
|                | 30          | 46.7     | 27.6 | 33.3    | 0       | 100     | 15     |
|                | 60          | 40.5     | 26.7 | 33.3    | 0       | 100     | 14     |
|                | 90          | 38.9     | 25.1 | 33.3    | 0       | 67      | 6      |
| Mental Health  | 0           | 45.9     | 13.2 | 48      | 12      | 68      | 15     |
|                | 7           | 44.0     | 10.4 | 48      | 28      | 60      | 15     |
|                | 30          | 39.7     | 11.4 | 44      | 16      | 56      | 15     |
|                | 60          | 45.1     | 11.9 | 44      | 20      | 60      | 14     |
|                | 90          | 42.7     | 10.3 | 42      | 28      | 56      | 6      |

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Regarding survival, patients who underwent palliative surgical biliary drainage, survived, on average, 65 days.[23]

The technical success of EBD by transmural access proves to be 92-95%,[13,14,25] while the clinical success, mainly in the CDT, is 75-100%.[14,24,25]

A landmark study published in 2012 revealed that there was no significant difference in quality of life among patients with obstructive jaundice caused by malignant biliary disease who underwent CDT and DPHT percutaneous access during the follow-up period of 3 months.[26]

As regards biliary stents, the metallic ones cost more than the plastic stents; however, the patency period of a metallic stent is significantly higher. In addition, partially and fully covered stents seem to be similar in their effectiveness.[27]

The complication rate in CDT is approximately 23%,[25] which can be due to pneumoperitoneum, occlusion of stent, stent migration, and bile leakage.[33,42,29] Bile leaks occur more frequently when plastic stents are used (11%).[13]

It is necessary to highlight that EUS-guided drainage is safe and effective when the recommended approaches are followed.[28]

CONCLUSION

This study demonstrates that surgical HJT and EUS-guided CDT in patients with distal malignant biliary obstruction and failed ERCP are similar regarding the studied outcomes.

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