

Clinical characteristics, treatments, and outcomes of difficult biliary stones in a reference hospital in Colombia

Características clínicas, tratamientos y desenlaces en cálculo biliar difícil en un centro de referencia en Colombia

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Recibido: 06/12/2022 - Aprobado: 22/04/2023

ABSTRACT

The local experience and the success rate of different available treatments for difficult biliary stones in Colombia are poorly described. We made an observational study reporting patients treated for difficult biliary stones, at Hospital Universitario San Ignacio in Bogotá, Colombia between January 2015, and November 2021. Clinical characteristics, endoscopic retrograde cholangiopancreatography (ERCP) findings, and outcomes are presented. Additionally, the success rates of Endoscopic Sphincterotomy Plus Large Balloon Dilation (ESLBD), Mechanical Lithotripsy (ML), temporary stenting (TS), cholangioscopy-guided laser lithotripsy (CGLL), and surgery are described. A total of 146 patients were included (median age 69 years, IQR 58.5-78.5, 33.8% men). The median stone diameter was 15 mm (IQR 10 – 18 mm). One stone was presented in 39.9%, two stones in 18.2%, and ≥ 3 stones in the remaining stone. A 67.6% disproportion rate was observed between the stone and distal common bile duct. Successful stone extraction was achieved in 56.2% in the first procedure, 22.6% in the second, 17.1% in the third, 3.4% in the fourth, and 0.7% in the fifth procedures. The successful extraction rates were 56.8% for ESLBD, 75% for ML, 23.4% for TS, 57.7% for CGLL, and 100% for surgery. Endoscopic management of difficult stones is usually successful, although it usually requires 2 or more ERCPs procedures. The surgical requirements were low. ESLBD is an effective technique unlike TS. Few patients required advanced techniques such as ML or CGLL. Endoscopic procedures are associated with a low rate of complications.

Keywords: Gallstones; Choledocholithiasis; Lithotripsy; Laser; Biliary Tract Surgical Procedures (source: MeSH NLM).

RESUMEN

La tasa de éxito de diferentes tratamientos de Cálculo Biliar Difícil (CBD) en Colombia no está descrita. Hemos realizado un estudio descriptivo observacional sobre el tratamiento de CBD en el Hospital Universitario San Ignacio en Bogotá, Colombia entre enero 2015 y noviembre 2021. Se presentan las características clínicas, hallazgos en la Colangiopancreatografía Retrógrada Endoscópica (CPRE) y desenlaces asociados. Adicionalmente, se describe la tasa de éxito de los pacientes tratados mediante esfinterotomía asociada a dilatación endoscópica con balón grande (EDEBG), litotripsia mecánica (LM), stent temporal (ST), litotripsia con láser guiada por colangioscopia (LLGC) y cirugía. 146 pacientes fueron incluidos (Mediana de edad 69 años, RIC 58,6-78,5). 33,8% eran hombres. La mediana del tamaño del CBD fue de 15 mm (RIC 10-18 mm). 39,9% tenían un solo cálculo, 18,2% tenían 2 y el resto ≥ 3 cálculos. 67,6% tenían desproporción entre el cálculo y el colédoco distal. La extracción exitosa se logró en 56,2% en el primer procedimiento, 22,6% en el segundo, 17,1% en el tercero, 3,4% en el cuarto y 0,7% en el quinto procedimiento. La tasa de extracción exitosa fue de 56,8% con EDEBG, 75% con LM, 23,4% con ST, 57,7% con LLGC y 100% con cirugía. El manejo endoscópico del CBD es usualmente exitoso. Sin embargo, requiere usualmente ≥ 2 CPRE. El tratamiento quirúrgico no es común. EDEBG es una técnica efectiva a diferencia del ST. Pocos pacientes requirieron técnicas avanzadas como LM o LLGC. Los métodos endoscópicos presentan una baja tasa de complicaciones.

Palabras clave: Cálculos Biliares; Coledocolitiasis; Litotricia; Litotripsia por Láser; Procedimientos Quirúrgicos del Sistema Biliar (fuente: DeCS Bireme).

Citar como: Lombo-Moreno CE, Muñoz-Velandia OM, Leguizamo AM, Larotta D, Vargas R. Clinical characteristics, treatments, and outcomes of difficult biliary stones in a reference Hospital in Colombia. Rev Gastroenterol Peru. 2023;43(2):120-6. doi: 10.47892/rgp.2023.432.1446

INTRODUCTION

Bile duct stones treatment is usually performed by ERCP (endoscopic retrograde cholangiopancreatography) with balloon or basket extraction^{1,2}. However, in 10-15% of cases, bile duct stones cannot be extracted using conventional methods³. This condition is known as difficult biliary stones (DBS). In our hospital, 1,446 ERCPs were performed between 2015 and 2021 and 10.1% corresponded to DBS.

Different types of specialized therapeutic procedures are available for DBS¹. Although the success rates of these procedures in Latin America have been reported^{4,5}, local Colombian reports are scarce⁶. DBS treatment requires expensive technology and highly specialized personnel. Therefore, local studies are required to optimize the resource allocation.

In this study, we describe the clinical characteristics, laboratory findings, ERCP findings, treatments, outcomes, and subsequent treatments performed in patients with DBS treated at a reference hospital in Colombia.

METHODS

A descriptive observational study was conducted including patients with DBS diagnosed at the Hospital Universitario San Ignacio between January 2015 and November 2021. The inclusion criteria were patients older than 18 years, with DBS diagnosis defined as: 1) unsuccessful bile duct clearance by ERCP plus sphincterotomy (associated with a balloon or basket extraction attempt), or 2) disproportion between the size of the distal bile duct and the stone (DBDS), with a difference greater than 2 mm⁶. The exclusion criteria were pregnancy, altered coagulation or platelet function without an active infectious process, cholecystostomy prior to ERCP, and referral to another hospital. Ethical approval was granted by the Institutional Review board (FM-CIE-0006-22).

Sociodemographic data were collected systematically during patient care. Variables regarding comorbidities, laboratories, ERCP findings, adverse events, Intensive Care Unit requirement, in-hospital mortality, hospitalization length stay and unscheduled readmission in the following 30 days were obtained from electronic medical records. Mortality rate at 6 months was evaluated using the National ADRES database (acronym in Spanish, which translates General Social Security Health System Resources Administrator), a public database which reports mortality date (https://aplicaciones.adres.gov.co/bdua_internet/Pages/ConsultarAfiladoWeb.aspx).

DBS treatment success was defined as bile duct clearance because of the therapeutic procedure. Procedures available for DBS treatment were Endoscopic Sphincterotomy Plus Large Balloon Dilatation (ESLBD)

(Boston Scientific CRE™ balloon, Massachusetts, United States), Mechanical lithotripsy (ML), (Lithotriptor GF500, G-FLEX, Belgium), Temporary Stent (TS) (Flexima™, Boston Scientific, Massachusetts, United States), Cholangioscopy-guided laser lithotripsy (CGLL) (Spyglass, Boston Scientific, Massachusetts, United States), or surgery. These procedures were performed according to international guidelines recommendations¹. Patients with unsuccessful bile duct clearance after the first ERCP with balloon or basket extraction could be treated with a therapeutic procedure for DBS in the same ERCP time or scheduled at a later visit to receive another therapeutic procedure. The therapeutic procedure selection was decided by the endoscopist.

Patients with pending DBS resolution (PDBSR) were defined as patients with DBS who required a new therapeutic procedure but were within the six-month window after the last procedure. Follow-up losses were defined as patients with DBS who required a new therapeutic procedure but did not consult within the next six-month windows after the last procedure. Where possible, telephone follow-up was done to find out if lost patients had been treated at another hospital. Patients who reported extra-institutional DBS treatment were asked to share their clinical record information to determine treatment success. Patients who could not provide extra-institutional clinical records were considered as follow-up losses.

STATISTICAL ANALYSIS

To describe qualitative variables, absolute and relative frequencies were reported. The central tendency and dispersion measures were calculated for quantitative variables. Mean and standard deviation for variables with normal distribution, and median and interquartile range for variables with non-normal distribution. The Kolmogorov-Smirnov test at a significance level of 5% ($p < 0.05$) was used to assess the normal distribution. A descriptive analysis of patients treated with CGLL and comparison between groups with or without complete follow-up was done (Supplementary Table 1. A t-test, Mann Whitney U test, or chi-squared test was used to compare groups according to variable characteristics. Statistical analysis was performed using STATA (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC).

RESULTS

A total 146 patients with DBS were included in this study (Table 1). The median age was 69 years (interquartile range 58.5 – 78.5). Fifty patients (33.8%) were male. The median comorbidity Charlson Index score was 3 (IQR 1 – 5). 42 patients (28.4%) had a previous ERCP and 56 (37.8%) had cholangitis at admission. The median largest stone diameter was 15 mm (IQR, 10 – 18 mm), 72 (48.9%) were ≥ 15 mm. Of the patients, 39.9% had one stone, 18.2%

Table 1. Clinical data, initial ERCP findings, and outcomes in patients with difficult biliary stones.

Variable	n = 146
Age, median (IQR)	69 (58.5 - 78.5)
Male sex, n (%)	50 (33.8)
Charlson index, median (IQR)	3 (1 - 5)
Previous cholecystectomy, n (%)	50 (33.8)
Previous ERCP, n (%)	42 (28.4)
Pancreatitis, n (%)	10 (6.8)
Cholangitis, n (%)	56 (37.8)
Admission laboratories	
AST, median (IQR)	120 (65 - 187.5)
ALT, median (IQR)	218 (86.5 - 333)
Total Bilirubin, median (IQR)	8 (5.5 - 14)
Alkaline phosphatase, median (IQR)	397 (322.5 - 523)
Initial ERCP data	
Endoscopist experience ≥ 5 years, n (%)	132 (89.2)
Larger stone diameter, mm, median (IQR)	15 (10 - 18)
Larger stone diameter ≥ 15 mm, n (%)	72 (48.9)
Number of stones, n (%)	
1	59 (39.9)
2	27 (18.2)
≥ 3	62 (41.9)
Impacted biliary stone, n (%)	
Impacted in biliary duct	21 (14.4)
Impacted in common hepatic duct	5 (3.4)
Impacted in left or right hepatic duct	0 (0)
Biliary duct anatomic alteration, n (%)	13 (8.8)
DSDBDS, n (%)	100 (67.6)
Basket or Balloon extraction attempt, n (%)	71 (48)
Outcomes	
ICU hospitalization, n (%)	11 (7.4)
ICU length stay, days median (IQR)	2 (2 - 4)
Adverse events, n (%) *	5 (3.4)
Hospitalization mortality, n (%)	4 (2.7)
Hospitalization length stay, median (IQR)	5 (2 - 8)
Unscheduled readmission 30 days, n (%)	13 (8.8)

Acronym: IRC, interquartile range; AST, aspartate amino transferase; ALT: alanine amino transferase; ERCP, Endoscopic retrograde Cholangiopancreatography; DSDBDS, disproportion between the size of distal bile duct and the stone ; ICU, Intensive Care Unit. * Adverse events defined as post-ERCP, bleeding that required blood cells transfusion, pancreatitis, cholangitis or perforation.

had two stones, and 41.9% had ≥3 stones. DSDBDS was observed in 100 (67.6 %) patients. Four (2.7%) patients died during hospitalization and 13 (8.8%) had an unscheduled readmission within 30 days.

The most commonly used procedures as the first therapeutic option were ST (53.4%) and ESBLD (37.7%). 82 patients (56.2%) had successful DBS extraction in the first therapeutic procedure (after unsuccessful ERCP associated with balloon or basket extraction). 33 (22.6%) patients were successful in the second procedure, 25 (17.1%) in the third, 3 (2.1%) in the fourth, and 1 (0.7%) in the fifth procedure. Four (2.7%) patients died during the follow-up period. Eight patients treated with TS (6.5%) were classified as having PDBSR and 24 (19.4%) were lost to follow-up. Supplementary Figure 1 shows a flowchart of the treatments received by patients. Table 2 reports the success rates according to the therapeutic procedures performed. The overall success rates were 56.8% for ESLBD, 75% for ML, 23.4% for TS, 57.7% for CGLL and 100% for surgery procedures (Table 2).

Patients who required at least one session of CGLL had a higher prevalence of previous ERCP (44.4%) and larger stones (18 mm). After successful CGLL, fragments were retrieved with a Dormia Basket (GF1615, G-FLEX, Belgium). The characteristics and outcomes of patients treated with Cholangioscopy Guided Laser Lithotripsy are presented in Table 3).

Considering the high frequency of loss to follow-up in the TS group, we compared patients with or without complete follow-up. The group loss to follow-up presented a trend toward older age (75.5 vs 67.0 years, p: 0.122), higher comorbidity (median Charlson index score 4 vs 3, p=0.232) and higher mortality at 6 months (7 vs 1, p=0.011) (Supplementary Table 1).

Table 2. Success extraction rate in difficult biliary Stone according to procedure and treatment session.

Procedure	First session		Second session		Third session		Fourth session		Fifth session		Total	
	n = 146	Success, n (%)	n = 64	Success, n (%)	n = 31	Success, n (%)	n = 6	Success, n (%)	n = 1	Success, n (%)	n = 248	Success, n (%)
Temporary stent, n (%)	78 (53.4)	19 (24.4)	34 (53.1)	5 (14.7)	8 (25.8)	4 (50)	3 (50)	1 (33.3)	1 (100)	1 (100)	124 (50.0)	29 (23.4)
In-hospital mortality	3 (3.8)	-	1 (2.9)	-	0 (0)	-	0 (0)	-	-	-	4 (3.2)	-
Pending stent revision	5 (6.4)	-	2 (5.9)	-	0 (0)	-	1 (33.3)	-	-	-	8 (6.5)	-
Follow-up los	15 (19.2)	-	6 (17.6)	-	2 (25.0)	-	1 (33.3)	-	-	-	24 (19.4)	-
ESLBD, n (%)	55 (37.7)	29 (52.7)	13 (20.3)	9 (69.2)	6 (19.4)	4 (66.7)	-	-	-	-	74 (29.8)	42 (56.8)
CGLL, n (%)	5 (3.4)	3 (60.0)	13 (20.3)	6 (46.2)	7 (22.6)	5 (71.4)	1 (16.7)	1 (100)	-	-	26 (10.5)	15 (57.7)
Surgery, n (%)	6 (4.1)	6 (100)	4 (6.3)	4 (100)	9 (29.0)	9 (100)	1 (16.7)	1 (100)	-	-	20 (8.1)	20 (100)
Mechanical lithotripsy, n (%)	2 (1.4)	2 (100)	-	-	1 (3.2)	1 (100)	1 (16.7)	0 (0)	-	-	4 (1.6)	3 (75)

Acronym: ESLBD, Endoscopic Sphincterotomy Plus Large Balloon Dilation; CGLL, Cholangioscopy Guided Laser lithotripsy; NA, Not applied.

Table 3. Clinical, sociodemographic, ERCP findings and treatment success rate in patients with difficult biliary stones treated with Cholangioscopy Guided Laser Lithotripsy.

Variable	Total
	n = 18
Age, median (IQR)	63 (52.5 - 73)
Male sex, n (%)	5 (27.8)
Charlson index, median (%)	2 (1 - 3.7)
Previous cholecystectomy, n (%)	13 (72.2)
Previous ERCP, n (%)	8 (44.4)
Pancreatitis, n (%)	0 (0)
Cholangitis, n (%)	4 (22.2)
Admission laboratories	
AST, median (IQR)	167.5 (94.5 – 303.7)
ALT, median (IQR)	233 (103.2-404)
Total Bilirubin, median (IQR)	2.7 (1.6 – 4.9)
Alkaline phosphatase, median (IQR)	292.5 (156.5 – 449.2)
ERCP data	
Endoscopist experience ≥5 years, n (%)	17 (94.4)
Larger Stone diameter, n (%)	18 (11 - 20)
Stones number, n (%)	
1	9 (50.0)
2	2 (11.1)
≥ 3	7 (38.9)
Impacted biliary stone, n (%)	2 (11.1)
Bile duct anatomic alteration, n (%)	1 (5.6)
DSDBDS, n (%)	14 (77.8)
Mortality at 6 months, n (%)	0 (0)
CGLL required sessions. n (%)	
1 session	12 (66.7)
2 sessions	4 (22.2)
3 sessions	2 (11.1)

Acronyms: CGLL, Cholangioscopy Guided Laser lithotripsy; IQR, interquartile range; AST, aspartate amino transferase; ALT: alanine amino transferase; ERCP, Endoscopic retrograde Cholangiopancreatography; DSDBDS, disproportion between the size of distal bile duct and the stone ICU, Intensive Care Unit.

DISCUSSION

This study describes the clinical characteristics, laboratory findings, ERCP findings, outcomes, and subsequent management in patients with DBS in a reference hospital in Colombia. Our results suggest: 1) >50% of DBS patients had ≥2 common duct bile stones 2) A moderate (50-70%) success rate is expected in the first therapeutic DBS procedure (after failed ERCP), with nearly 50% of patients requiring ≥2 sessions. 3) A moderate success rate of several endoscopic procedures is expected in the next sessions.

We found a moderate success rate in DBS patients treated with ESLBD. Additionally, ESLBD success rate was consistent in different session times (between 52.7 and 69.2%). A 2019 meta-analysis⁷EMBASE, and the Cochrane Library database to identify relevant available articles

until July 19, 2018. Complete common bile duct stone (CBDS reported variable success rates, in a range between 66.7-97.7% in the initial intervention and 29-92% in the following sessions. Success rate variability depended on stones characteristics (mean number of stones between 2 and 4, stone diameter between 10 mm and 16.5 mm) with a lower success rate for stones ≥15 mm⁸. Our relatively lower ESLBD success rates could be associated with our larger median stone size (15 mm).

In our study, ML had a 75% DBS success rate. However, only four patients were treated with this procedure. ML has been reported as a therapeutic option for DBS patients. A study reported success rates near to 70% in a single session and 90% in subsequent sessions for stone size diameter ≥15 mm⁹. That study reported that unsuccessful ML procedures were associated with a stone diameter of ≥21.9 mm. Other studies reported unsuccessful ML procedures associated to impacted biliary stones, stone size >30 mm or DSDBDS¹⁰. Besides, ML is associated with major complications (basket entrapment or basket fracture). These technical complications can occur in 3.5% of procedures in the bile duct¹¹. Therefore, in our hospital we prefer ESLBD as a therapeutic option. In conclusion, ML has a moderate success rate and is a good therapeutic option in reference centers with specialized personnel.

Half of our DBS patients were initially treated with TS. The European Society of Gastrointestinal Endoscopy (ESGE) guideline recommends TS as a temporal treatment to relieve biliary obstruction and before a subsequent attempt to stone extraction¹. Evidence suggests that TS exerts a shearing force¹², reducing the volume and number of stones in the common bile duct¹³ facilitating next extraction attempts. TS is frequently performed as the first option in our setting because it is readily available and other specialized DBS therapeutic procedures require prior insurance authorization. However, our results showed a low overall TS success rate (23.4%). Prospective studies have reported a TS success rate between 55%¹⁴ and 75%¹⁵, which is higher than our results. Our results may differ because nearly 25% of our patients were PDBSR or follow-up losses. Second, DBS fragile patients could have died or could have been unfit for another ERCP¹⁶. That hypothesis is supported by our results: Our lost to follow-up group had a trend toward older age, higher comorbidity, and a higher 6-month mortality rate.

Patients with DBS treated with CGLL presented a moderate success rate, which was consistent across different session times. Maydeo *et al.* reported a DBS success rate of 77.5% in the first CGLL procedure¹⁷. They also reported a 90% success rate in DBS diameter size between 16 – 30 mm and 65% success rate for stones ≥ 30 mm. Additionally, unsuccessful CGLL procedures were associated with large stones, multiple stones, and patients with a history of previous unsuccessful ERCP. In our study, CGLL was performed in 18 patients in one or more sessions (Table 3 and Supplementary Figure 1). A total of 44.4% of the patients had a history of previous ERCP. The median

stone size was 18 mm and half of the patients had ≥ 2 stones. These factors are related to unsuccessful extraction and may explain our lower success rate. Therefore, CGLL is a useful therapeutic procedure for DBS patients with a stone diameter ≥ 15 mm, multiple stones, or a history of previous ERCP. However, one third of patients will require more than one CGLL session.

In our study, surgery for DBS patients was always successful. Previous studies have reported no mortality or morbidity differences between endoscopic and surgical treatment¹⁸. However, there is a tendency to carry out an endoscopic treatment in choledocholithiasis¹⁹. Therefore, surgery is usually performed in selected patients or after multiple unsuccessful therapeutic procedures. This study reported that only 20 patients required surgery for DBS within 6 years, 70% after unsuccessful endoscopic procedures and 30% as the first therapeutic alternative. Those patients had multiple stones associated with a severe DSDBDS. A medical board, including the surgical team and an experienced endoscopist, made surgical decisions on a case-by-case basis. In conclusion, different endoscopic therapeutic procedures are effective for DBS management. However, surgery may be an option considering the local experience and available resources.

This study describes clinical, sociodemographic and ERCP characteristics and success rates of different therapeutic procedures in a large local DBS cohort. Our data reflect the decision-making process faced by an endoscopist in everyday practice. Some limitations, need to be considered: 1) Guidelines have reported different DBS diagnostic criteria based on stone size and bile duct characteristics^{1,2}, and different definitions make it difficult to compare the results of different groups. We decided to use a definition that has been used in other studies^{17,20} and carefully described the biliary stones and bile duct characteristics to facilitate the comparison of our results with those of other studies 2) Treatment allocation depended on endoscopist criteria. However, there was no difference in the efficacy between the different therapeutic procedures. Therefore, our results represent real world evidence about DBS treatment decisions and could present data to improve subsequent studies.

Our methodology presents a descriptive and retrospective design; therefore, our data should be interpreted as a hypothesis generator and does not demonstrate any therapeutic procedure superiority in DBS patients. Clinical trials are required to compare different treatment options and to assess the best sequential approach. Additionally, TS presented a significant follow-up loss which difficult the success outcome evaluation. Although telephone contact was attempted in these patients, there was a high prevalence of loss to follow-up. Therefore, TS therapeutic procedure data must be carefully considered.

In conclusion, our results suggest a moderate DBS success rate with different alternative therapeutic

procedures. However, several treatment sessions are usually required in DBS patients.

Funding: No funding is reported in this study.

Conflicts of interest: No conflict of interest is reported.

Participation in study report

Carlos Ernesto Lombo-Moreno: Study design, Data collection, statistical analysis, text writing.

Oscar Mauricio Muñoz-Velandia: Study design, statistical analysis, text writing.

Ana María Leguizamo: Study design, text writing.

David Larotta: Data collection, text writing.

Rómulo Vargas: Study design, text writing.

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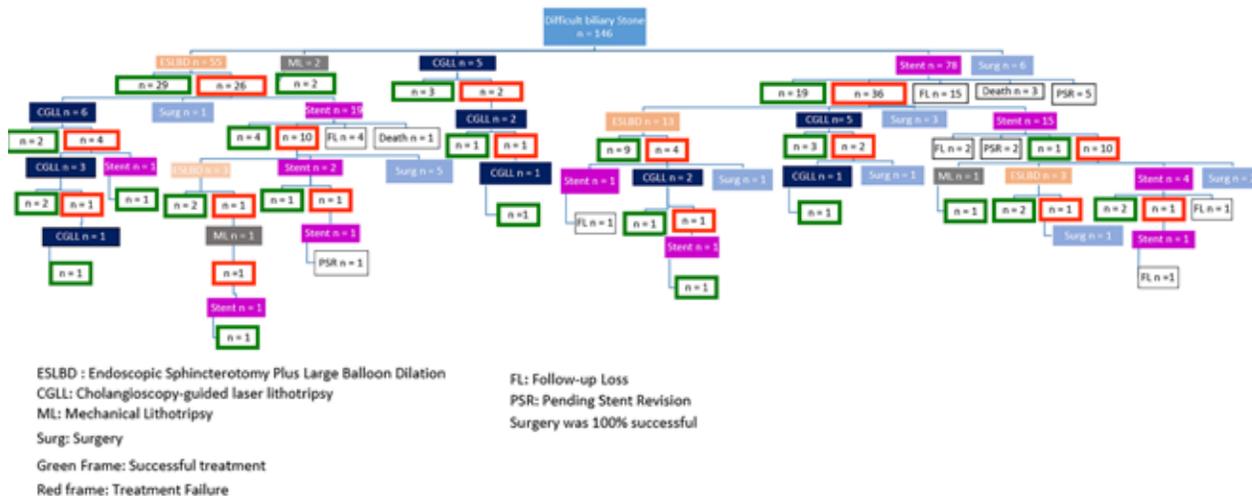
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Supplementary

Supplementary figure 1. Difficult biliary stones treatment flowchart in patients treated at Hospital Universitario San Ignacio (2015 – 2021).



Supplementary table 1. Clinical, sociodemographic and ERCP findings in patients with difficult biliary stone treated with temporal stent according to follow-up completeness.

	Follow-up loss n = 24	Complete follow-up n = 29	p
Age, median (IQR)	75.5 (63.2 - 84)	67 (61 - 76)	0.122
Male sex, n (%)	10 (41.7)	11 (37.9)	0.782
Charlson index, median (%)	4 (2 - 5.7)	3 (2 - 4.5)	0.232
Previous cholecystectomy, n (%)	6 (25)	8 (27.5)	0.832
Previous ERCP, n (%)	3 (12.5)	9 (31)	0.109
Pancreatitis, n (%)	2 (8.3)	2 (6.9)	0.844
Cholangitis, n (%)	8 (33.3)	13 (44.8)	0.394
Admission laboratories			
AST, median (IQR)	132 (71 - 234)	145 (87 - 202)	0.925
ALT, median (IQR)	151 (93 - 264)	186 (92.5 - 291)	0.670
Total Bilirubin, median (IQR)	2.39 (1.23 - 3.67)	5.3 (1.52 - 9.8)	0.037
Alkaline phosphatase, median (IQR)	332 (271.5 - 558)	262 (135.7 - 452)	0.189
ERCP data			
Endoscopist experience ≥5 years, n (%)	23 (95.8)	25 (86.2)	0.233
Larger Stone diameter, n (%)	13.5 (8.7 - 18)	12 (9.7 - 18)	0.779
Stones number, n (%)			
1	10 (41.7)	5 (17.2)	0.490
2	7 (29.2)	4 (13.8)	0.170
≥ 3	7 (29.2)	20 (68.9)	0.004
Impacted biliary stone, n (%)	5 (20.8)	8 (27.6)	0.570
Bile duct anatomic alteration, n (%)	2 (8.3)	4 (13.8)	0.532
DSDBDS, n (%)	12 (50)	17 (58.6)	0.394
Mortality at 6 months, n (%)	7 (29.2)	1 (3.4)	0.011

Acronyms: IQR, interquartile range; AST, aspartate amino transferase; ALT: alanine amino transferase; ERCP, Endoscopic retrograde Cholangiopancreatography; DSDBDS, disproportion between the size of distal bile duct and the stone.