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CLINICAL INVESTIGATION

Percutaneous Treatment of Biliary Cast Syndrome After Orthotopic Liver Transplantation: Comparison of Mechanical Versus Hydraulic Rheolytic Cast Extraction

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Abstract
Purpose Biliary cast syndrome (BCS) is the presence of casts within the intrahepatic or extrahepatic biliary system after orthotopic liver transplantation. Our work compares two percutaneous methods for BCS treatment: the mechanical cast-extraction technique (MCE) versus the hydraulic cast-extraction (HCE) technique using a rheolytic system.
Materials and Methods A total of 24 patients were included in the study. Six patients were referred for HCE, and 18 patients were treated with MCE. A statistically significant larger number of sessions was required in the MCE group (21.0, range 11 to 72 sessions) ($p = 0.033$).
Results Median therapy duration was shorter in the HCE group at 2.4 months (range 2 to 5) compared with 6.7 months (range 3 to 39) in the MCE group ($p < 0.001$). Both patient acceptance was better and costs for total therapy were 40% less in the HCE group. No significant differences where found concerning clinical and biochemical improvement or graft and patient survival.
Conclusion The use of the hydraulic rheolytic system decreased total therapy time, thereby decreasing the induced inflammation time of the biliary tree. A significant benefit of HCE has been observed in our patients when we compare our results with those of MCE.

Keywords Liver/heptic · Gall stones · Non-Vascular interventions

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Introduction

Biliary cast syndrome (BCS) occurring after orthotopic liver transplantation (OLT) is the presence of casts within the intrahepatic or extrahepatic biliary system, resulting in secondary bilary duct obstruction and cholangitis [1, 2]. The casts are a hardened material, composed primarily of bilirubin but also collagen, bile acids and cholesterol, that take the shape of the biliary ducts. The presence of casts is associated with increased morbidity, graft failure, need for retransplantation, and mortality [3].

BCS has been reported to be successfully treated by endoscopic or percutaneous methods (with basket extraction, biliary irrigation, and appropriate use of stents) in ≤60% of patients; however, multiple procedures are often required. Patients who cannot be successfully treated by endoscopic or percutaneous means require surgery, or even retransplantation, to remove of the casts [4].

The objective of this work was to compare efficacy between two methods of biliary cast extraction: the mechanical cast-extraction (MCE) technique versus the hydraulic cast-extraction (HCE) technique using the AngioJet Rheolytic Thrombectomy System (Possis Medical, Minneapolis, MN) in patients with BCS.

Assayed variables between both groups were total duration of therapy, total number of interventional sessions, clinical and biochemical improvement, pain experienced during intervention, retransplantation rate, and total cost of the interventional therapy.

Materials and Methods

Patient Selection

A longitudinal study was conducted at a tertiary-care liver transplantation facility (Heidelberg University Clinic, Heidelberg, Germany) between 2004 and 2008. The protocol was reviewed and approved by the Institutional Review Board. Twenty-four patients were included in our study. Inclusion criteria were patients with proven clinical, biochemical, and imaging BCS criteria. According to the study of Gor et al. [4], patients were excluded if they had any of the following criteria: cholangitis originating from other aetiologies (i.e., previous history of sclerosing cholangitis), cholestasis due to anatomic stenosis, and/or presence of biliary stones and living donor liver transplantations. BCS was initially suspected because of a patient's clinical and biochemical deterioration and sonographic appearance. In most of the patients, computed tomography (CT) or magnetic resonance imaging (MRI) studies were performed as part of the initial diagnostic evaluation to exclude other aetiologies of liver failure (hepatic artery stenosis, vascular thrombois, liver hypoperfusion) and to corroborate of the diagnosis of cholestasis.

Percutaneous biliary interventions were initially performed in patients with a biliodigestive anastomosis or secondary to an endoscopic retrograde cholangiographic approach when the intrahepatic biliary branches could not be reached. Those with choledocho–choledocal anastomoses were referred for endoscopic evaluation. Patients were triaged between MCE or HCE treatments in an aleatory manner.

Applicable laboratory parameters were examined in all BCS patients, and values at the time of BCS diagnosis and after successful cast removal were compared. Blood samples were tested for alkaline phosphatase, total bilirubin levels, aspartate aminotransferase (GOT), gamma-glutamyl transferase (GGT), C-reactive protein (CRP), and leucocytes levels.

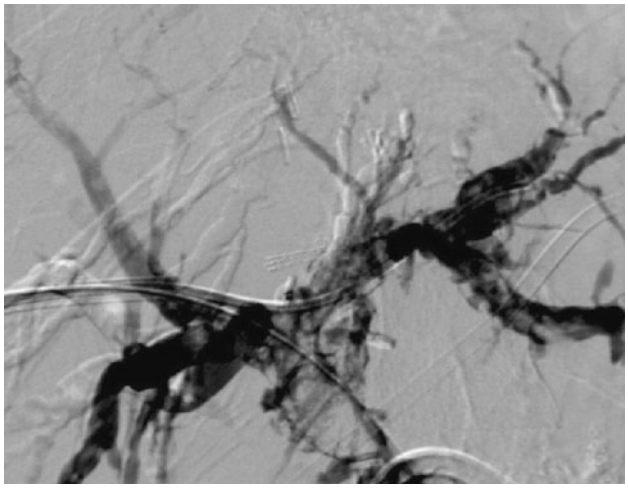

Fig. 1 Typical cholangiographic appearance of BCS. Multiple defects are demonstrated within the intrahepatic biliary branches as is the consequent cholestasis

Technique

In all cases, signed agreement was obtained. Bilateral percutaneous transhepatic drainage (PTD) of the biliary tree was established in conventional intercostal (right biliary branches) and subxiphoidal (left biliary branches) approaches. Using 8F drains (Skater; Angiotech, Vancouver, Canada), the biliary system was drained for a period of 3 to 5 days to decrease the acute cholestasis (Fig. 1).

In a second procedure (48 to 72 h after the first PTD implantation), all interventions were performed using a mild sedation with a mixture of 2.5 mg midazolam and 25 mg pethidin, administered intravenously, as well as local anaesthesia (100 mg prilocainhydrochloride [Xilonest1%; AstraZeneca GmbH, Wedel, Germany]).

The 8F biliary drains were exchanged for 8F × 24-cm introducers (right and left) (Terumo, Leuven, Belgium) to enable biliary access. In addition, a 0.035-inch × 180-cm Amplatz super-stiff wire (Boston Scientific, Miami, FL) was employed through the biliary tree into the small intestine from both sides as a "security wire."

In parallel to the security wire and through the same 8F sheath ("tandem technique") a 5F Vertebral catheter (Terumo) was used for selective catheterization of the intrahepatic and extrahepatic biliary branches using a 0.035-inch soft guidewire (Radiofocus; Terumo). This basic approach was the same in both groups before MCE or a HCE was attempted.

MCE

Once an obstructed biliary branch could be catheterized selectively, cast removal was performed using a six-wire Dormia basket (Angiomed, Karlsruhe, Germany) as well as

4- to 6-mm–diameter balloon catheters (Cordis, Bridgewater, NJ) utilising the inverted Fogarty technique (i.e., pushing casts into the bowel, not pulling them back). In every obstructed branch, a gentile flushing with sterile water was performed to remove debris. When postinterventional cholangiography showed a significant decrease or absence of debris, another branch was catheterized, and the MCE was repeated. Stenotic segments were dilated during the procedure with the same balloon using a maximum of 8 atm for at least 120 s. Each MCE session lasted between 90 and 120 min. Finally, new 8F biliary drains were deployed with internal and external outflows.

HCE

The rheolytic Angiojet system consists of three primary components: the catheter, the pump device, and the drive unit. The dual-lumen catheters come in sizes 4F to 7F and may be used over a 0.035-inch guidewire. The drive unit produces a high-speed (400 km/h) saline jet at the catheter tip, which is directed backwards into the effluent lumen. The result is a low-pressure stream exposed to the vessel lumen that disrupts and removes debris by Venturi effect. No direct mechanical manipulation is used to remove debris from the vessel lumen. Because extraction of particulates is performed indirectly by creation of a negative pressure stream, potential injury to the vessel or ductal walls may be minimized. The over-the-wire design and low profile allowed us to achieve good manoeuvrability and tractability in a tortuous biliary tree [10].

We used a 6F diameter catheter system in each patient. The tip of the Angiojet catheter was positioned as distal as possible in every obstructed branch (Fig. 2). Once activated, the catheter was slowly pulled back from distal to proximal to remove the casts and to avoid injury to the biliary lumen by pushing the catheter. The region where the flush is generated can be identified by two radio-opaque metal marks in the tip of the catheter. Sterile water, 150 ml at 35 to 37°C, was applied in every biliary branch treated. Because most of the injected fluids are aspired by the catheter, it is possible to use ≤ 4 litres saline solution without side effects, such as vomiting, diarrhoea, or electrolyte imbalance. After the selected biliary branches were treated, new biliary drains were deployed. Although small amounts of blood could frequently be recognized during the intervention (minimally stained water), no haemoglobin decrease was registered after the intervention in any case, inferring lack of damage to vascular structures. Each HCE session lasted between 60 and 90 min.

End Points

In each group (MCE and HCE), therapy was considered successfully completed when the clinical condition of the patient was normal (defined as absence of fever and jaundice), the biochemical parameters (bilirubin, alkaline phosphatase, GGT, GOT, leucocytes) were within normal range (for bilirubin this was defined as a normalization of total bilirubin levels or at least a three-fold decrease compared with the initial level), and the radiologic control showed a significant improvement without the presence of intrahepatic cholestasis.

In contrast, if after 4 weeks of therapy the patient's condition was tending toward deterioration despite treatment, therapy was considered unsuccessful and therefore discontinued.

Pain Measurement

Patients were asked to rate the severity of pain they experienced during one session on a scale of 1 to 6 using the international Verbal Description Scale to describe pain

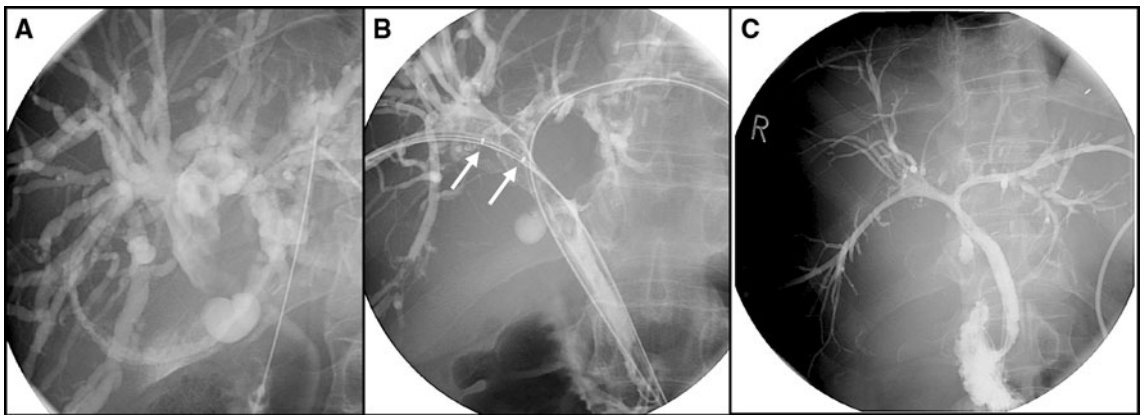

Fig. 2 **A** Cholangiographic appereance of BCS. **B** A bilateral approach was performed to remove the intrahepatic casts with the Angiojet system catheter (white arrows). **C** Result after HCE shows no evidence of casts in the biliary tree. Biliary drains remain in situ

levels: 0 = no pain, 1 = mild pain, 2 = discomforting, 3 = distressing, 4 = intense, and 5 = excruciating. In every case, pain was estimated using the pain scale by Mundipharma Laboratories (http://www.mundipharma.de/schmerztherapie/therapie/schmerz-messen.html).

Cost Calculation

Costs were estimated depending on the type and quantity of the deployed material in each interventional session (catheters, guidewires, sheaths, drains, and special materials, such as Angiojet catheter, Dormia baskets, or balloons). The cost of one session was multiplied by the total number of required sessions in a complete therapy. Costs were estimated in Euros according to the given prices of the buying department of our institution corresponding to the month of June 2009.

Complications

Complications were subdivided into major and minor complications. Major complications included problems derived from the BCS intervention that required subsequent correction by a surgical or interventional procedure (i.e., pneumothorax, embolization of bleeding related to punctures). Acute pain during the intervention requiring increased intravenous analgesics and sedative medications, transinterventional chills, minor bleeding, nausea, vomiting, and diarrhoea were considered minor complications.

Statistical Analysis

All patient data were entered into a dedicated database (Excel: Mac 2008, Version 12.2.3 (091001), Microsoft Corporation, Redmond, WA, USA). Laboratory test results are provided as median values with the range in brackets. Mann–Whitney U test was used to assess statistical significance where applicable using SigmaPlot for Windows version 11.0 (Systat Software GmbH, Erkrath, Germany). A level of $p \leq 0.05$ was considered statistically significant.

Results

A total of 24 patients were included in the study. Six patients (2 women) were referred to HCE, and 18 patients (6 women) were treated by MCE. Median age at the time of the first procedure was 55 years (range 51 to 65) in the HCE group and 49 years (range 17 to 68) in the MCE group. In all cases, the procedures were performed as planned, reaching a technical success of 100% for the both groups (Table 1).

Table 1 Results

Assayed variable	MCE	HCE
Total no. interventional sessions (median)	21[a]	16.5[bd]
Therapy duration (mo)	6.7	2.4[d]
Normalization of bilirrubin levels (%)	28.6	66.6
Six-month graft survival rate (%)	100	66[c]
Six-month patient survival rate (%)	66	66
Patient peri-interventional pain compliance on a scale of 0 to 6 (median)	3.05	1.3[d]
Total cost (Euros 2009)	13,568.00	6079.04

[a] Ten to 17 sessions were specifically attempted to perform mechanical cast extraction with balloons or baskets. The rest of the sessions were cholangiographic controls and drainage exchanges

[b] Only 4 sessions were specifically attempted to remove the casts hydraulically. The rest of the sessions were cholangiographic controls and drainage exchanges

[c] Of this group, 33.3% of patients underwent re-liver transplantation in optimal clinical condition

[d] Statistically significant ($p \leq 0.05$)

Total Number of Interventional Sessions and Duration of Therapy

A median number of 16.5 procedures (range 9 to 18) were required for successful HCE; however, only in a maximum of 4 sessions was the Angiojet system used. The rest of the sessions consisted of cholangiographic controls and drain exchanges. A significantly larger number of sessions were performed in the MCE group (21.0 sessions [range 11 to 72]; $p = 0.033$). As a result, median therapy duration was shorter in the HCE group at 2.4 months (range 2 to 5) compared with 6.7 months (range 3 to 39) in the MCE group ($p < 0.001$).

Clinical and Biochemical Improvement

Detailed analysis of applicable laboratory parameters showed no significant differences between the HCE and MCE groups at each time point. However, there was a trend toward HCE being more effective in decreasing bilirubin levels. Before interventional treatment was performed, median total and conjugated bilirubin levels (in U) were, respectively, 6.2 and 6.0 mg/dl (range 3.3 to 8.3 and 2.8 to 7.3) for HCE and 3.4 and 2.9 mg/dl (range 1.9 to 11.7 and 1.0 to 10.0) for MCE (not significant in Mann–Whitney U test). Normalization of bilirubin levels (total bilirrubin $\leq$1.0 mg/dl) was achieved in 4 of 6 patients (66.6%; median 1.0 mg/dl [range 0.6 to 7.5]) by the time HCE therapy was finished, whereas bilirubin was normalized by MCE in only 4 of 14 patients (28.6%; median 4.7 mg/dl [range 0.7 to 9.2]) (Fig. 3).

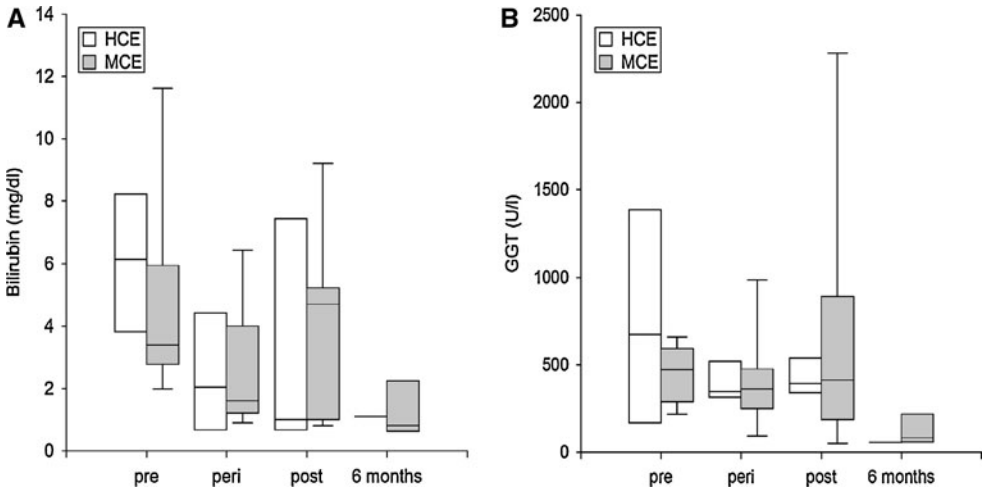

Fig. 3 Box plots of blood tests for (*right*) bilirubin and (*left*) GGT. Median is given by the central line; the 25th to 75th percentile is given by the box; and whiskers mark the 10th and 90th percentile. Blood tests were performed before, during- and after the intervention as well as at 6-month follow-up. A large variability within a small patient collective did not allow significant differences between the two groups. In both, a trend toward normalization of bilirubin and GGT levels after successful treatment can be observed

Graft Survival and Patient Mortality

Both graft and patient survival were analyzed with a median follow-up time of 6 months after the last intervention. Overall survival was identical in both groups and reached 66.6%. Despite a high technical success rate, repeat OLT was necessary in 2 (33.3%) patients in the HCE group; however, these patients were in doubtless better clinical condition (afebrile, blood tests with decreased inflammatory signs, normal blood cultures) compared with patients in the MEC group. In the MCE group, no retransplantation was possible within the first 6 months after the interventional therapy because despite technical success, the patients requiring repeat OLT were, compared with the HCE group, still not fit enough for surgery. Deaths in both groups were not related to the interventional procedures; in all cases, mortality was caused by histopathologic proven liver rejection and progressive and fulminant liver failure.

Periprocedural Pain

Patient compliance, in terms of pain experienced after the procedure, was measured using Mann–Whitney U test. Those patients treated in the HCE group recorded statistically significant lower values on the pain scale. Patients in the HCE group recorded an average of 1.33 points (median 1 [range 1 to 2]) on the pain scale, whereas the MCE group recorded an average of 3.05 points (median 3 [range 1 to 5]) ($p = 0.05$) on the pain scale.

Total Costs

Tables 2 and 3 list an overview of the standard costs of a single procedure in each group. Costs resulting from individual therapies, such as application of stents to stenotic segments or volume of contrast medium, were not considered part of the HCE or MCE accounting. Median total costs for a complete individual therapy (counting from the first to the last radiologic intervention) were calculated

Table 2 Material costs in the HCE group

Material	Price (Euros)	Amount	Totals
Angiojet system	1230.00	1	1230.00
Cobra 5F	13.68	1	13.68
J-wire	9.55	1	9.55
Terumo wire	16.00	1	16.00
Amplatz wire	24.80	2	49.60
8F sheath	10.12	2	20.24
8F biliary drainage	90.14	2	180.28
Total			1519.35

Table 3 Material costs for the MCE group

Material	Price (Euros)	Amount	Totals
Cobra 5F	13.68	1	13.68
Monorail balloon	76.16	2	152.32
Skipper wire	113.05	2	226.10
Opta Pro Ballon	83.30	1	83.30
Terumo wire	16.00	1	16.00
Amplatz wire	24.80	2	49.60
8F sheath	10.12	2	20.24
Basket system	106.48	1	106.48
8F biliary drainage	90.14	2	180.28
Total			848

as 6,079.04 Euros for the HCE group and 13,568 Euros for the MCE group.

Complications

Mild complications were frequent and equally distributed between both groups. Only one ipsilateral iatrogenic pneumothorax was registered as a major complication in the MCE group and occurred when the initial PTCD was attempted.

Table 4 Currently described applications of the Angiojet system with references

Acute pulmonary embolism [12]
Thrombolysis in hemodialysis grafts [13]
Treatment of acute peripheral arterial occlusive disease [14]
Thrombolysis in renal arteries [15]
Central and peripheral vein thrombosis [16, 17]
Thrombectomy of deep venous thrombosis [18]
Carotid and vertebrobasilar artery thrombectomy [19, 20]
Acute myocardial infarction [21]
Massive coronary air embolism [22]

Discussion

Biliary cast syndrome, first described by Waldram in 1975, remains a serious complication after OLT, with substantially variable incidence rates with reports ranging from 3 to 18% [1–3, 5–7]. The pathogenesis of cast formation is not clearly understood. Proposed etiological factors for BCS include acute cellular rejection, hepatic ischemia, prolonged cold ischemic time, deployment of biliary drains, biliary infections or sepsis, and biliary obstruction [3].

Percutaneous techniques have previously been used to treat BCS, usually in failed cases of endoscopic retrograde cholangiopancreatography. Standard therapy for BCS is usually ERCP with biliary sphincterotomy and balloon extraction of the biliary casts. Variable success rates ranging from 25 to 60% have been reported using various techniques [8, 9]. In the series by Gor et al., the median number of biliary procedures required to treat each patient with BCS was 3 (range 0 to 6). However, despite these interventions, 22% of the BCS patients required repeat OLT and had a significantly worse graft survival as well as a trend toward worse patient survival compared with control patients. These findings question the efficacy of non-surgical approaches in the treatment of BCS [4].

Our initial experience with mechanical cast extraction was more promising, but we still wanted to improve our technique to optimise our outcomes. As a result, we investigated the possible use of alternative fragmentation devices, such as the rheolytic Angiojet system. This device was originally designed for thrombolytic purposes (Table 4).

To date, only 149 electronic references can be obtained after searching the word "Angiojet" in the PubMed database. The majority are reports of singular cases describing its employment in the vascular system. Loehr et al. [10] were the first and until now the only ones to report the use of the Angiojet system in the biliary tree. Their work describes one case of impacted intrahepatic ductal debris in a patient with a choledocal cyst and its successful removal using this system [10]. Further investigation into this valuable application of the Angiojet system, however, had not been repeated in a series of patients until now by our group. Clinical and biochemical success were achieved after several sessions with both the MCE and HCE techniques. In addition, pruritus was completely eliminated in both groups.

Statistically significant differences were noted in the total duration of therapy, required number of interventional sessions, costs, and periprocedural pain. The total duration of therapy and the number of sessions required before achieving a clinical and biochemical success was almost three times less in the HCE group compared with the MCE group (Table 1). GGT levels were increased in most of the patients for long periods even if bilirubin, GOT, and GPT levels were normal. This phenomenon was thought to result from the long-term use of external drains, which were placed to maintain percutaneous access. This evoked local insult to the biliary tree, resulting in increased GGT levels whilst decreasing bilirubin. The effect of this phenomenon can be suggested from our results: As therapy time decreased (and hence there was decreased time of induced inflammation of the biliary tree), in particular with the Angiojet system, decreased inflammation was demonstrated by a continuous decrease in GGT. In those patients in whom the time of percutaneous treatment was >6 months, a substantial increase in liver parameters was observed, suggesting a vicious cycle of inflammatory reaction. Those patients with decreased therapy time (in either group), and thus no sustained increase in liver enzymes, had a more favourable follow-up.

Small and central casts can be treated by mechanical technique with good results, whereas the Angiojet system seems to be more effective in cases when BCS is also compromising the peripheral branches and in complicated situations, e.g., when central casts cannot be extracted by the MCE approach. In the HCE group, there were no patients in whom the system failed to remove all casts; however, in the MCE group complete cast extraction failed in some patients with segmental casts.

The hepatic artery plays an important physiologic role in providing a blood supply to both the liver parenchyma and bile duct system, especially in the early postoperative period [11]. The occurrence of stenoses after cast removal remained unaffected by cast treatment in either group, possibly due to previous ischemic damage to the biliary duct wall. In both groups, stenoses were dilated using angioplasty balloons. Stents were required in only two patients (both in the MCE group) due to a stenosis in the biliary (biliodigestive) anastomosis. Stents were not applied to intrahepatic biliary branches. Repeat OLT was required in our study group in only three situations that could not be resolved by percutaneous methods: (1) confirmed liver rejection, (2) unresolvable associated complications (e.g., total hepatic artery thrombosis, graft rejection demonstrated by biopsy), and (3) cases complicated by infection (e.g., cholangitis or biliary abscess). Nonetheless, percutaneous treatment allowed affected patients to wait for retransplantation in a better clinical state, thereby avoiding acute sepsis.

Another important aspect of rheolytic cast clearance is the fact that patients experienced significantly less pain during the intervention, thereby decreasing the total amount of analgesics (hence decreasing costs) as a consequence. With decreased procedural pain, patient aversion to repeated interventions also decreased.

The initial concern regarding the Angiojet system was expense: The cost of a single HCE session is nearly twice that of MCE. This lead to the slightly increased number of MCE procedures compared with HCE procedures. We found over time, however, that these costs were more than compensated for by a dramatic decrease in the number of procedures necessary to complete the therapy and, therefore, more HCE procedures could be performed.

Our study demonstrated that this therapy is a relatively safe procedure with a low complication rate. Iatrogenic pneumothorax occurred only once in the MCE group when the initial biliary drains were deployed.

Conclusion

In our short series, the rheolytic Angiojet system decreased total therapy time. In addition, side effects, such as pain and febrile reactions, tend to decrease in patients treated with this new method. A significant benefit of HCE has been observed in our patients when we compare our results with those of MCE and even with other short series evaluating endoscopic approaches in treating BCS. Given the negative impact of BCS on liver transplant outcomes and the limited number of controlled trials on this subject, further large-scale studies appear justified.

Conflict of interest We don't have any financial disclosures.

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