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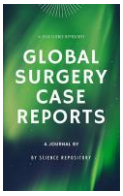

Research Article

Treatment of Complex Whole Liver Intrahepatic Ductal Stones Using a Patented Stone-Clearance Sheath Combined with Nephroscopic Holmium Laser Lithotripsy

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ABSTRACT

Purpose: To investigate the clinical efficacy of nephroscopic laser lithotripsy with the aid of a patented suctioning sheath in treating complicated whole-liver dispersed intrahepatic ductal stones.

Methods: From September 2013 to September 2017, 150 patients who were diagnosed with whole-liver dispersed intrahepatic ductal stones were included in this study and were divided into two groups randomly. The control group consists of 75 patients who were treated by traditional surgery combined with choledochoscopic laser lithotripsy. The observation group consists of the other 75 patients who were treated by traditional surgery combined with nephroscopic laser lithotripsy with the aid of the patented sheath. Related treatment outcome parameters were compared.

Results: There were no significant differences in first surgery operative time, first surgery bleeding amount, complication and stone clearance rates (P>0.05). However, the second surgery operative time was (63.58±9.84) min while the complication rate was 7.5% in the observation group, significantly less than that of control group (P<0.05). There were significantly higher first-stage and second stage sinus ductal stone clearance rates and final stone clearance rate in the observation group compared to that of control group (P<0.05), while operative times, hospitalization duration and cost, and one year stone recurrent rate were significantly lower (P<0.05).

Conclusion: The efficacy of using the patented stone-clearance sheath combined with nephroscopic holmium laser lithotripsy was significant, warrants more extensive clinical adoption.

Introduction

Hepatolithiasis is a common disease in our country. It treatment principles are to remove stone completely, relieve obstruction, drain smoothly, and prevent recurrence [1]. Using traditional approach to remove diseased side liver lobe plus T tube drainage can manage most unilateral lobar hepatolithiasis. However, the rate of postoperative residual stone could be as high as 30.14% and the rate of reoperation could be as high as 11% [2]. For whole liver hepatolithiasis, the rate of postoperative residual stone would be even higher [3]. In this study, we found that the treatment outcome using traditional surgery plus nephroscopic lithotripsy with the aid of a patentedly designed suctioning stone clearance sheath was good. We therefore report our study as below.

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Data and Methods

I Study Object

150 patients who were diagnosed with total hepatolithiasis in our hospital from September 2013 to September 2017 were selected for this study. The diagnosis criteria included upper abdominal non-contrast CT, contrast enhanced CT, or MRI verified total hepatolithiasis, which were in accordance with Type II hepatic and ductal stone criteria proposed by Group of Bile duct surgery, Division of Surgery, Chinese Medicine Association, with or without accompanied common bile ductal stones [4]. Exclusion criteria included inoperable patients who are extremely old aged, with uncorrectable generalized bleeding disorder, acute bile ductal infection, liver function Child-Pugh grade C, uncontrollable hypertension or diabetes, serious cardiovascular disease, or pulmonary insufficiency. The studied patients were randomly divided into two groups, control group and observation group. The 75 patients in the control group were treated by traditional surgery combined with choledochoscopic holmium laser lithotripsy. The other 75 patients in the observation group were treated with traditional surgery plus patentedly designed percutaneous minimally invasive suctioning stone lithotripsy and nephroscopic holmium laser lithotripsy with the aid of the patentedly designed suctioning stone clearance. There were no significant differences on general demographic data (P>0.05) and they were statistically comparable (Table 1).

Table 1: General Data Comparison between the Groups.

Group	Case (n)	M/F	Age(year）	Type IIa	Type IIb	Type IIc
Observation	75	38/37	53.74±11.03	31	27	17
Control	75	39/36	54.12±10.58	30	29	16
Statistical value		$\chi 2$=2.14	t=1.241	T=1565.5		
P value		P=0.351	P=0.286	P=0.149		

II Surgical Methods

In the control group for patients with Type IIa and Type IIb stones, choledocholithotomy and severe side lateral hepatectomy were performed, followed by traditional choledochoscopic laser lithotripsy through common bile duct and cross-section hepatic ducts. At the end of the surgery, a T-tube was indwelled, which was changed to a sinus supporting tube (drainage tube) for patients underwent second stage stone removal. For the patients with Type IIc stones, choledocholithotomy was performed, followed by traditional choledochoscopic laser lithotripsy. In the above-mentioned surgical patients, if residual stones were present by reexamination after surgery, traditional choledochoscopic laser lithotripsy will be used for sinus stone extraction when the sinus tracts become sturdy after 6-8 weeks of surgery. Should the outcome of stone clearance after the sinus tract lithotripsy not yet be satisfactory after the second surgery, the patented stone-clearance sheath assisted nephroscopic laser lithotripsy will be used. These cases were still included in the control group as cases with residual stones but were not included in the observation group for data analysis. In the observation group, for patients with type IIa and IIc stones, choledocholithotomy was performed, followed by patented stone-clearance sheath assisted nephroscopic lithotripsy for stone removal through the common bile duct.

At the end of the surgery, common bile duct indwelling T-tube over 20 gauges was placed following the principle of “coarse, short, and straight”. The T tube came out through the abdominal wall being connected for drainage. For type IIb patients, choledocholithotomy and severe side lateral hepatectomy were performed, followed by patented stone-clearance assisted nephroscopic laser lithotripsy through common bile duct and cross-section hepatic ducts. T-tubes and bile duct supporting tubes (Drainage tube) were placed at the end of surgery. In the above-mentioned surgical patients, if residual stones were present by reexamination after surgery, the patented stone-clearance sheath assisted nephroscopic laser lithotripsy will be used for sinus stone extraction when the sinus tracts become sturdy after 6-8 weeks of surgery. In most cases 1-2 surgeries were needed to clear stones with satisfactory results.

III Observation Indexes

Indexes including the first and second operation time, complication rate, initial hemorrhage, postoperative hospitalization days, hospitalization costs, number of operations, first-stage stone clearance rate, first-stage sinus stone clearance rate, second stage sinus stone clearance rate, the total stone clearance rate, and the recurrence rate at one year after the operation were compared for the two groups of patients. The stone removal effect standard, that is, complete removal: T-tube or bile duct supporting tube cholangiography and CT showed no residual stones; almost complete clearance: T-tube or biliary supporting tube cholangiography and CT showed that the main bile duct stones have been cleared, only a small amount of stones in the terminal bile duct (grade III or more bile duct); partially removed: T-tube or biliary support tube cholangiography and CT showed significant residual hepatic stones. Complete removal and almost complete clearance were considered complete removal of stones.

IV Statistics

SPSS22.0 statistical software was used for data analysis and processing. The measurement data was represented by (±s), and the count data is represented by the number of cases (percentage). For measurement data, t test was used; for count data, chi-square test or rank sum test were used. P <0.05 was defined as the difference was statistically significant.

Results

The comparison of the basic indexes of the two groups is shown in (Table 1). There was no significant differences between the initial operation time and the initial blood loss of the observation group compared with the control group (P>0.05), but the reoperation time, total length of hospital stay and expenses were significantly less than the control group (P<0.05). In the primary surgeries for the observation group, there were 2 cases of postoperative bleeding, 2 cases of postoperative cholangitis, and 3 cases of biliary fistula. In the control group, there were 2 cases of hepatic hemorrhage, 2 cases of postoperative cholangitis, and 4 cases of hepatic section edge biliary fistula. All these complications were controlled after conservative therapies. There were no significant differences in the complications of the first surgery between the observation group and the control group (P>0.05). However, in the reoperations, 9 cases of postoperative cholangitis occurred in the control group, which was significantly higher than that of 3 cases in the observation group (P<0.05).

Comparison of the outcomes of stone clearance in the two groups is shown in (Table 2). The observation group was significantly lower than the control group in the number of operations and the recurrence rate of stone at one year (P<0.05). The rates of stone clearance in the first operations were not significantly different between the two groups (P>0.05), but the first stage sinus clearing rate, the second stage sinus clearing rate and the total stone clearance rate were significantly higher than in the control group (P<0.05).

Table 2: Stone Clearance Outcome Comparison.

Group	Number of operation （n）	First operation stone clearance rate	First-stage Sinus Tract Stone clearance rate	Second-stage Sinus Tract Stone Clearance Rate	Total stone clearance rate	Stone clearance rate at 1 year
Observation	1.24±0.32	35（46.7）	24/40(60.0)	12/16(75.0)	71(94.7)	5/71(7.1)
Control	1.97±0.47	33（44.0）	12/42(28.6)	13/30(43.3)	58(77.3)	12/58(20.7)
Statistical value	t=6.124	$\chi2$=1.862	$\chi2$=12.537	$\chi2$=14.763	$\chi2$=7532	$\chi2$=8.694
P value	P=0.035	P=0.283	P<0.001	P<0.001	P=0.021	P=0.016

Discussion

Epidemiology shows that the incidence of hepatobiliary stones in China is as high as 20% [5]. It mainly occurs in the hepatobiliary ducts or gallbladder. After the formation of stones, it can stimulate the body's vascular cells to produce acute inflammation. Severe abdominal pain is the main clinical symptom. The treatment generally requires a comprehensive approach, and the main treatment is surgery [6]. At present, most biliary surgeons widely believe that liver resection is the most effective treatment for the treatment of hepatolithiasis. It can not only remove stones, but also can remove atrophic liver parenchyma and narrow bile ducts and reduce the recurrence of stones and the risk of bile duct cell carcinoma [7]. However, liver resection has high requirements for liver reserve function and general conditions of patients and has the disadvantages of large surgical trauma and high technical requirements. It is reported that the residual stone rate after operation is still 20 to 30%, and the reoperation rate is as high as 37.1%, especially for patients with whole liver stones and marked biliary cirrhosis it is almost impossible to deplete [8].

Therefore, for total hepatic bile duct stones namely type II patients, its usage is quite limited. For the treatment of type IIa and IIb stones, multiple surgical procedures and adjuvant therapy are often required [9]. In recent years, the newly developed choledochoscopic lithotripsy as a combined approach have greatly reduced the rate of postoperative residual stones, which brings hope for patients with type IIa, especially type IIc. However, conventional choledochoscopes generally can only enter Class II bile ducts, and it is difficult to remove stones from small bile ducts. Moreover, flexible choledochoscopes have the disadvantages of difficult handling and lack of fulcrum when lithotripsy is performed. Gravels are often retrieved by baskets or stone clamps. Stone removal is therefore inefficient, time-consuming, and technically demanding [10].

In this study, we used Holmium laser lithotripsy in treating complex hepatic intrahepatic bile duct stones with the aid of a patent-designed stone breaking and suctioning sheath combined with a rigid nephroscope, which is normally used in percutaneous nephrolithotomy. The holmium laser is currently the latest surgical laser. The principle is that the energy generated by the helium laser vaporizes the water between the optical fiber and the stone, and the generated bubbles transmit energy to the stones and crush the stones [11]. Holmium laser lithotripsy is gradually applied to the treatment of hepatolithiasis lithotripsy. Compared with hydraulic lithotripsy and pneumatic biliary lithotripsy, it has a good effect of cutting and smashing stones, and the thermal injury and mechanical damage is minimal. Its other advantages include lightness and flexibility with coagulation and hemostasis function during surgery [12].

The patent stone sheath is supplemented with a negative pressure suction system on the basis of minimally invasive surgery. It can actively attract and clear stones during operation. Combined with holmium laser nephroscopic lithotripsy, large stones can be rapidly broken into small pieces of stones. Being able to perform lithotripsy and suctioning clearance simultaneously using the patented sheath, gravels less than 2mm can be sucked directly through the scabbard cavity, 2-5mm stones can be aspirated from the sheath funnel cavity by withdrawing the scope, which can avoid the repeated stone removal using a stone basket and the high pressure water flow, which can significantly shorten the operation time and improve the surgical efficiency [13]. For intrahepatic bile duct stones complicated by bacterial infections, routine use of cholecystoscopy with high perfusion pressure can easily make bacteria or toxins being absorbed into the blood to cause bacteremia or sepsis. However, using the patented stone sheath the pressure inside the biliary system can be adjusted to positive and negative according to the needs

using the negative pressure switch, which improves the surgical safety of patients with stones complicated by biliary tract infections [14]. Simultaneously, the patented stone clearance sheath can use the sheath's hard front to perform touching, scraping, pressing and other manipulations in the biliary tract under surveillance. The small stones in the corners of the biliary tract can be carefully pulled out, and the inflammatory necrotic tissue flocculated in the biliary wall can also be scraped and sucked away. The negative pressure suctioning stone removal has high efficiency, and it can remove the gravel in time with the biliary clearing system. It needs almost no forceps or net basket for stone removal, which greatly shortens the operation time and effectively reduces the surgical trauma.

Although the initial operation time, blood loss, complications, and stone clearance rate did not differ significantly, using the patented stone clearance sheath combined with nephroscopic laser lithotripsy for treatment of complex total hepatic intrahepatic bile duct stones achieved less reoperation time, significantly reduced incidence of complications, higher first-stage sinus stone clearance rate, higher second-stage sinus stone clearance rate, and higher total stone clearance rate, compared to the traditional surgery combined with cholangioscopic laser lithotripsy. Other surgically related parameters were also superior to the traditional surgical methods.

In summary, in this study used the patented technology of Urology in an interdisciplinary way to treat complex whole liver intrahepatic bile duct stones. The results showed the advantages of high efficiency, minimal trauma, low residual stone rate, quick recovery, and is worthy of clinical recommendation.

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Author Contributions

Protocol/project development: Xie Y, Song Hu; Data collection or management: Zhong Deng, Ye Xiao; Data analysis: Deng Zhong; Manuscript writing/editing: Xie D.

Consent

Written informed consent was obtained from the patients for publication of this report and any accompanying images.

Ethical Approval

Ethical and regulatory approvals were sought and obtained from the Affiliated Ganzhou Hospital of Nanchang University

Conflicts of Interest

None.

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