

Magnetic Anastomosis for Biliojejunostomy: First Prospective Clinical Trial

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Abstract

Background Magnetic compression anastomosis (magnamosis, MCA) has been verified safe and effective by us and others in animal bilioenteric anastomosis (BEA). The objective of the present study was to introduce clinical application of magnetic compression bilioenteric anastomosis (MC-BEA) with a unique device in series of patients.

Methods Patients with obstructive jaundice with an indication of BEA were prospectively enrolled from 2012 to 2015. After dissection of bile ducts, the mother ring and drainage tube were placed in the proximal bile duct and the purse-string suture was tightened over the drainage tube. The drainage tube was introduced into the jejunal lumen at the anastomotic site and used to guide the daughter ring to assemble with the mother ring. All the patients were routinely followed up for magnets discharge or any complications associated.

Results Forty-one patients were included. Thirty-four (82.9%) patients had a malignant primary disease, while seven (17.1%) had benign disease. The median time for MC-BEA was 10.5 min (interquartile range [IQR] 8.3–13.0 min). No perioperative morbidity or mortality associated with MC-BEA was observed. The median time for a patent bilioenteric anastomosis formation was 19.0 days (IQR 14.5–23.0 days), and the magnets were discharged with a median postoperative duration of 35.0 days (IQR 28.0–43.0 days). With a median follow-up of 547.5 days (range 223–1042 days), no patients had biliary fistula, while two (4.9%) developed anastomotic stricture at 4 months and 14 months after surgery, and underwent reoperation for reconstruction of BEA.

Conclusions MCA is a safe, effective, and time-saving modality for biliojejunostomy.

Xue-Min Liu, Xiao-Peng Yan, and Hong-Ke Zhang have contributed equally to the work.

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Introduction

Bilioenteric reconstruction is a routine procedure for reconstruction of internal bile flow when indicated. However, unlike enteroenterostomy, bilioenteric anastomosis is a more complicated procedure with a relatively higher risk

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of postoperative leakage (8–10%) or stricture (5–8%) after traditional hand-sewn [1–4], which increases readmission rate and decreases the quality of patient's life. Therefore, simplification and optimization of this procedure is a field of interest and endeavor for many hepato-pancreatic-biliary surgeons.

Magnetic compression anastomosis (magnamosis, MCA) is a promising anastomotic technique [5]. Since being first described in 1978 by Obora [6], MCA has been initially attempted in treatment of esophageal atresia [7] and diverticula [8], diversion of gastrointestinal tract [9, 10], and recanalization of the biliary stricture [11–16], etc. Recently, Graves et al. [10] reported successful utilization of magnetic compression for side-to-side small bowel anastomosis in patients. In fact, the technique of MCA was mostly confined to anastomosis between the same organs and/or a side-to-side anastomosis as reported previously. In 1995, Cope et al. [17] reported successful magnetic compression cholecystogastric and cholecystojejunal anastomosis in swine. Avaliani and the colleagues reported magnetic compression biliary-duodenal side-to-side anastomosis as a palliative treatment for obstructive jaundice due to advanced peri-ampullary carcinoma [1]. Recently, Saito et al. [18] reported a successful biliary-duodenal anastomosis using magnetic compression in a living-donor liver transplantation patient. In fact, magnetic compression anastomosis has been also used for bilioenteric anastomotic stricture [12, 14]. In contrast, whether and how magnetic anastomosis can be successfully achieved in bilioenteric reconstruction remains largely unevaluated.

For more than 10 years, we have developed different types of magnets, and performed substantial preclinical studies on utilization of magnetic compression method in vascular, intestines, and biliary lumens connection or anastomosis, which indicates a promising and broad application prospect of MCA [19–30]. Specifically, the magnets for BEA comprises of two neodymium-iron-boron (NdFeB) rings [20, 21, 26]. One is placed in the proximal bile duct, and the other is placed in the jejunal lumen where the anastomosis is desired. The two rings are mated when getting close on a drainage tube, and the interposed tissue between the two rings is compressed, causing ischemia, necrosis and anastomosis formation. The mated magnets are then expelled via the intestines. After extensive preclinical testing in canine models and progressive optimization of the magnets design, magnetic force and anastomotic procedure, we developed this unique magnetic anastomosis device and reported the first clinical study of magnetic compression bilioenteric anastomosis (MC-BEA) in series of patients.

Patients and methods

Study cohort

Patients indicated for bilioenteric anastomosis were prospectively enrolled in the study at *Department of Hepatobiliary Surgery, The First Affiliated Hospital of Xi'an Jiaotong University of China* from July 2012 to December 2015. The study was approved by the ethics committee of the hospital, and written consent was obtained from all patients before operation. All the surgical procedures were performed by the same surgical team (Y. Lv).

Magnetic device

The magnetic device used in this study consists of two magnetic rings (mother and daughter ring) and an 8-Fr nasogastric tube (Fig. 1a, b). The magnetic rings are made of neodymium-iron-boron (NdFeB, N45) and nickel plated. The outside diameter (OD) of magnetic rings ranges from 8 to 15 mm, and the inside diameter and height are 4 mm and 6 mm, respectively. In the device, a nasogastric tube passes through the mother ring and is tightly fixed to mother ring (Fig. 1a, b). This nasogastric tube is used as a stent and drainage tube before complete formation of anastomotic stoma.

The magnetic force relative to distance between the two magnets were measured by an Electronic Universal Testing Machine (UTM6202; Shenzhen Suns Technology Stock CO., LTD, Shenzhen, China) (Fig. 2). The thickness of the interposed biliary and intestinal tissue between the two magnets ranges from 1.5 to 2.5 mm. The magnetic flux density was measured with Gauss Meter HT20 (Shanghai Hengtong magnetic technology CO., LTD, Shanghai, China), which ranges from 1430 to 2340 GS. The magnetic pressure (P) was calculated as P (kPa) = F (N)/ S (mm²) [2]. When the thickness of the tissue between the two magnets is constant, the pressure of the different sized magnets on the interposed tissue is similar. For example, the pressure of different magnets (8–5 mm, OD) ranges from 27.4 to 32.3 kPa when the tissue thickness is 2 mm.

Surgical procedure

For the enrolled patients, conventional surgical procedures were performed except bilioenteric anastomosis by utilization of our magnetic compression device. The magnetic size was selected according to the diameter of bile ducts. MC-BEA was performed between the common bile duct or first branch of left/right hepatic duct and the jejunum. The procedure of MC-BEA was described briefly (Fig. 3,

Supplementary Digital Content 1. Wmv). A purse-string suture (Fig. 3a) was prepared with absorbable thread at the biliary stump. A mother magnetic ring and drainage tube was implanted into the bile duct, and the purse-string suture was then tightened over the drainage tube (Fig. 3b). Saline solution was infused into the bile duct through the drainage tube for water leak test. The drainage tube was introduced into the jejunal lumen via a hole by cautery at the anastomotic site and pulled out of the jejunal stump. A daughter magnetic ring was advanced in the jejunal lumen via the drainage tube toward the mother ring (Fig. 3c). The daughter and mother magnets were then mated at the anastomotic site (Fig. 3d). A simple pull test and water leak test were performed to ensure the tight combination of the two magnets and no leak between. The drainage tube was introduced out of the jejunal wall as an external biliary drainage tube, which was also used to perform cholangiography postoperatively (Supplementary Digital Content 1. Wmv). This drainage tube was finally introduced out of the body and fixed at the abdominal wall. The time duration between magnets placement in biliary tract and fixation of the drainage tube was recorded as the MCA procedure time.

Postoperative follow-up

After surgery, the drainage tube was used for biliary decompression before complete formation of BEA. Cholangiography via drainage tube was routinely performed to evaluate the status of anastomotic remodeling at 3 and 7 days after surgery (Fig. 4a). After discharge, all patients were routinely followed till the end of the study. Cholangiography was undertaken depending on the change of volume and types of drained fluids. When the patent BEA was formed, the volume of bile drained would drop dramatically, or intestinal fluids would be drained via the tube. Contrast agents could pass the anastomosis site and flow into the intestine during cholangiography (Fig. 4b). Occasionally, an extra pull of the external drainage tube was required before cutting of the drainage tube at the abdominal wall, if the magnets could not completely fall

into the intestines. The two magnets will then be expelled (Fig. 4c) (Supplementary Digital Content 1. Wmv).

Results

In total, 41 patients (24 men and 17 women) were included in the current study, with a median age of 60 (interquartile range [IQR] 55–68) years. A majority of patients ($n = 34$, 82.9%) had a primary malignant disease, whereas 17.1% had benign diseases (Table 1). Among the 34 patients with malignant disease undergoing MC-BEA, 25 patients underwent pancreaticoduodenectomy, five patients received palliative cholangiojejunostomy, and 4 patients underwent radical resection of carcinoma with or without hepatectomy. All of the seven patients with benign diseases underwent Roux-en-Y MC-BEA.

Forty-four cholangiojejunostomies or hepaticojejunostomies were performed in all 41 patients. Specifically, 39 of the 41 patients received cholangiojejunostomy, one patient underwent left and right hepaticojejunostomy, and another one patient underwent left, right, and caudate hepaticojejunostomy, separately. The median procedure time of MC-BEA was 10.5 min (IQR 8.3–13.0 min, $n = 44$). The median biliary diameter which was measured by MR or CT before surgery was 15.0 mm (IQR 12.5–18.0 mm). The median OD of the magnetic rings used in the surgeries was 11.0 mm (IQR 10.0–12.0 mm), including 4 pairs of 8-mm rings, 12 pairs of 10-mm rings, 9 pairs of 11-mm rings, 15 pairs of 12-mm rings, and 1 pair of 15-mm rings.

The median hospital stay was 17.0 days, ranging from 7 to 64 days. No perioperative mortality was observed in the study cohort. The median time for a patent bilioenteric anastomosis formation was 19.0 days (IQR 14.5–23.0 days), and the median time for the magnets expulsion was 35.0 days (IQR 12–90 days). Among the 41 patients, six patients have experienced extra pull of the external drainage tube, as a cholangiography via the drainage tube showed both intrahepatic bile ducts and intestines, but the magnets had not completely fallen off.

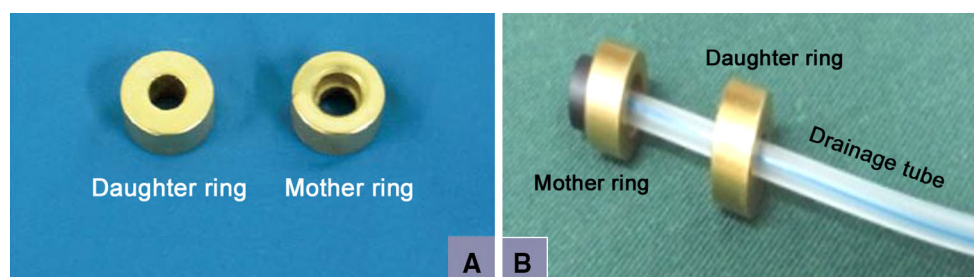


Fig. 1 Overview of the magnets (a) and magnetic device (b)

Fig. 2 Magnetic force curve according to the outside diameter of the magnets and distance between the mother and daughter ring

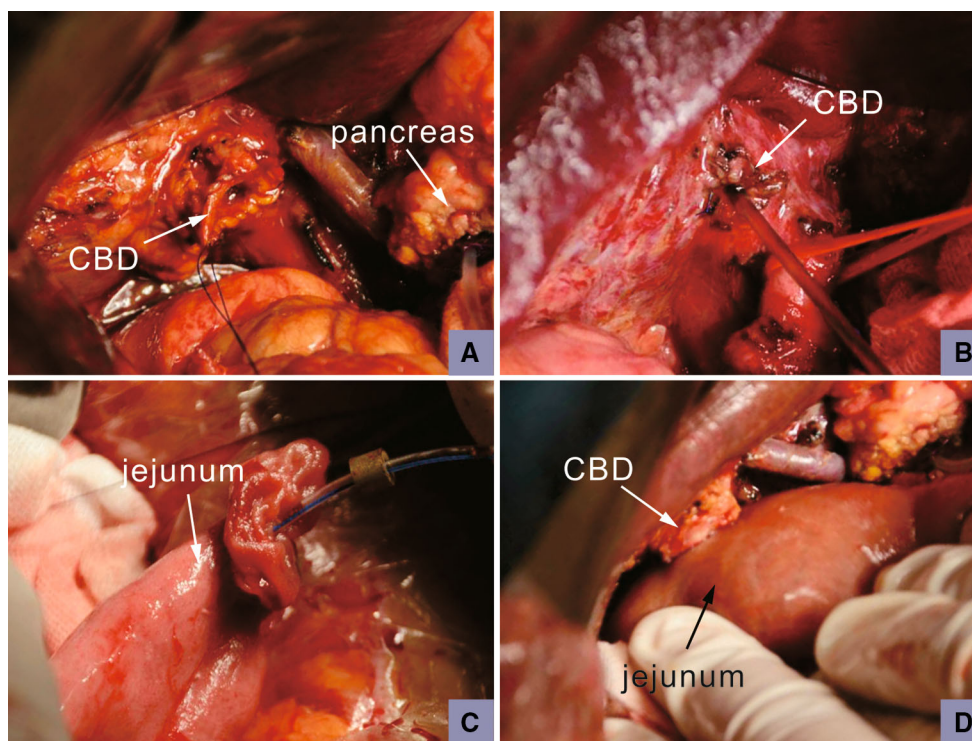
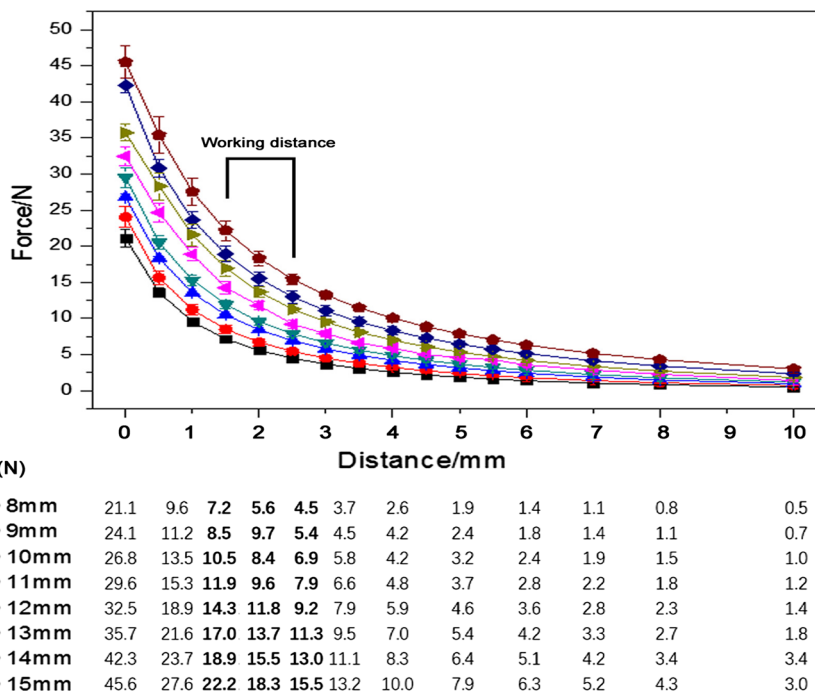


Fig. 3 Utilization of magnetic device in bilioenteric anastomosis. **a** Preparation of a purse-string suture at the biliary stump. **b** Implantation of a mother magnet into bile duct and tightening the purse-string suture over the drainage tube. **c** Advancement of a daughter

magnet via the drainage tube into the jejunum at the desired anastomotic site. **d** Bilioenteric anastomosis is achieved following the spontaneously assembling of the two magnets

With a median follow-up of 547.5 days (range 223–1042 days), cholangitis occurred in 3 (7.3%) patients before the magnets expulsion; two of them had the

complication in hospital stay, while one patient had the complication after discharge. In fact, all the three patients had preoperative cholangitis. Obstruction of drainage had

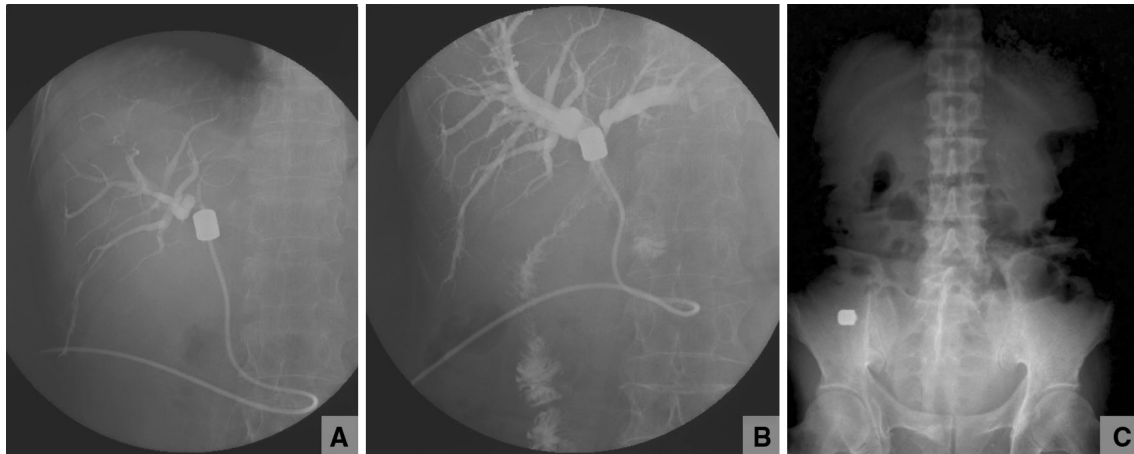


Fig. 4 Postoperative cholangiography via the drainage tube. **a** Early cholangiography showed that no contrast agent got into the jejunum. **b** Late cholangiography showed that the contrast agents passed the

anastomosis site into the jejunal lumen without magnets migration. **c** Abdominal X-ray plain film (day 30) showed that the magnets sloughed off from the anastomosis site into the colon

been suspected, thus drainage tube irrigation was performed gently. After anti-infectious treatment, the three patients recovered well. No cholangitis was observed after the magnets were discharged from the body. Of note, no patients developed postoperative biliary fistula in this cohort. Biliary anastomotic stricture occurred in two patients at 4 and 14 month after surgery, respectively. The primary disease of these two patients was pancreatic neuroendocrine tumor and pancreatic adenocarcinoma, respectively. Both patients underwent open surgery for dissection of scar at anastomotic stoma and reconstruction of a new hand-sewn BEA. Postoperative histological examination demonstrated fibrotic hyperplasia of bile ducts of anastomotic stoma with no evidence of tumor recurrence.

Discussion

The current study reported the first case series of MC-BEA in patients with different indications. MC-BEA was successfully performed in all 41 patients with objective jaundice. The incidence of postoperative bile leakage was null, while the incidence of anastomotic stricture was low (4.9%). This initial experience of clinical use of MC-BEA is important, as it strongly demonstrated the safety and effectiveness of bilioenteric anastomosis with utilization of a newly magnetic compression device.

MCA is an easy, time-saving, and less traumatic procedure that has been reported safely and effectively utilized in enteroenterostomy and recanalization of benign biliary stricture [10–16]. In fact, several previous cases series have reported successful utilization of magnets for creation of side-to-side biliary-enteric anastomosis as a palliative treatment of malignantly obstructive jaundice [1, 18]. In

contrast, we utilized a newly developed magnetic device for an end-to-side biliojejunostomy in the current study as a curative or palliative treatment for both malignant and benign disease. Of note, in our previous preclinical studies, series of magnetic devices have been developed with continuous optimization of the internal and external materials, magnetic pressure and bursting strength, etc. [19–22, 26, 30]. Although the magnetic force varies with distance and magnets diameter (Fig. 2), the pressure among different pairs of magnets was similar at a specific working distance. After the magnets were assembled, a simple pull test had been used to confirm tight compression.

The tight compression of the biliary and intestinal tissue by the two magnets allows simultaneous central tissue necrosis and surrounding tissue remodeling for establishment of a new channel between the bile duct and intestines [1, 20, 21, 26]. Of note, the compressive strength by magnetic device is continuous and increasing as the tissue between the magnets gets thinner after ischemia and necrosis (Fig. 2) [20–22]. Such tight compression significantly prevents bile leakage after surgery, even in malnourished or obese patients. After complete canalization between the bile duct and intestines, the magnetic device will fall into the bowel and be expelled naturally. Although the tissue specimen is unavailable in patients, we have verified in animal studies that anastomosed tissue by MC-BEA was smoother and had less inflammatory reaction and collagen deposition in comparison with that by hand-sewn [20–22].

In our previous canine model, the MCA device was expelled within 2 weeks [20, 21]. However, among the patients, the median time for magnets expulsion was about 1 month after surgery. This discrepancy might be multifactorial. For example, the length of bowel in human is

Table 1 Clinical characteristics and surgical procedures for magnetic compressive bilioenteric anastomosis

Variables	Number (percentage)/ median (IQR)
n	41
Age	60.0 (55.0–68.0)
Gender	
Male	24 (58.5%)
Female	17 (41.5%)
Primary disease	
Extrahepatic cholangiocarcinoma	16 (39.0%)
Pancreatic carcinoma	9 (22.0%)
Duodenal carcinoma	6 (14.6%)
Ampulla carcinoma	2 (4.9%)
Gallbladder carcinoma	1 (2.4%)
Hepatocholedocholithiasis	3 (7.3%)
Benign extrahepatic biliary stricture	4 (9.8%)
Surgical procedure	
Pancreatoduodenectomy	25 (61.0%)
Roux-en-Y choledochojejunostomy	16 (39.0%)
Diameter of the bile ducts for anastomosis (mm)	15.0 (12.5–18.0)
Outside diameter of magnetic rings (mm)	11.0 (10.0–12.0)
Time for magnetic anastomosis (min)	10.5 (8.3–13.0)
Hospital stay (days)	17.0 (12.0–27.0)
Time from surgery to stoma formation (days)	19.0 (14.5–23.0)
Time from surgery to magnetic rings discharged	35.0 (28.0–43.0)
Postoperative morbidity related	
Cholangitis	3 (7.3%)
Biliary stricture	2 (4.9%)
Reoperation	2 (4.9%)

IQR interquartile range

longer than canine, which may account for a longer time before magnets being discharged. The malnutrition status of patients in the study cohort may prevent physiological motility of gastrointestinal tract. Most patients were discharged before magnets expulsion. Some of them were unaware of the exact magnets expulsion time, but was found no magnets by abdominal X-ray plain film during follow-up, which caused a prolonged expulsion time calculation.

After modification and proficiency of MCA procedure, the average time for BEA was only about 10 min in the current study cohort, which was significantly reduced versus 44 min in canine model of our previous reports [21]. In fact, the average time for hand-sewn biliojejunostomy was about 20 min in our department. As such, this easy-performing MC-BEA could save operation time, and more importantly, can be accomplished by junior surgeons after practice.

Of note, no patients developed bile leakage after MC-BEA in the current study. In contrast, bile leakage after hand-sewn BEA has highly occurred in about 8–10% of patients [4]. The null incidence of biliary fistula after MC-BEA is attributed to tight compression of tissue between the magnets. Anastomotic stricture was noted in 2 (4.9%) patients during follow-up. Percutaneous transhepatic bile drainage was performed in one patient, but failed in the other patient due to insignificant dilation of the intrahepatic bile ducts. A balloon dilation or stent placement was not successfully performed as a result of complete obstruction of the anastomosis. Subsequently, the two patients underwent reoperation with a hand-sewn reanastomosis. The incidence of anastomotic stricture after MC-BEA was comparable to or moderately lower than hand-sewn of 5–8% [2, 3]. In fact, the two patients had a potent anastomotic stoma after surgery. No tumor recurrence at anastomotic site was verified during the second operation. Therefore, hyperplasia of biliary intima due to local inflammation, rather than MCA itself, might be a possible cause of anastomotic stricture.

There were several limitations of the current study, including small sample size evaluated, single-center conduction, and lack of synchronous comparison with hand-sewn technique. However, to our best knowledge, the present study is the largest clinical study in demonstrating the safety and effectiveness of magnamosis for biliojejunostomy. With interdisciplinary collaboration between medical and engineering science, the current study yields important findings and provides encouraging experience in magnetic anastomosis for biliojejunostomy. First, the optimal magnetic force and pressure for BEA with different size of magnets were calculated based on the previous preclinical and the current clinical studies [20–22, 26]. Second, a unique magnetic device has been developed for effective biliojejunostomy. Third, protocol for operation procedures and postoperative management were clearly established. In addition, this initial experience of MC-BEA in obstructive jaundiced patients will provide strong evidence in pursuing laparoscopic MC-BEA with antimagnetic surgical instruments, and advanced anastomosis between multiple biliary orifice and intestines.

Conclusions

Based on previous preclinical studies, we designed a new type of MC-BEA device, and demonstrated that this magnetic device successfully formed an end-to-side bilioenteric anastomosis in all the included patients. No biliary fistula occurred after surgery. The promising results of the present study encourage future utilization of magnetic anastomosis in hepato-pancreatic-biliary surgery.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no disclosures to report.

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