



Magnetic Compression Anastomosis Is a Good Treatment Option for Patients with Completely Obstructed Benign Biliary Strictures: A Case Series Study

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Abstract

Background Completely obstructed benign biliary strictures (BBS) is a difficult-to-treat condition. Surgery is the main treatment modality with high morbidity and mortality. Recently, the magnetic compression anastomosis (MCA) technique was employed in such cases with low complication rates.

Aims To evaluate the effectiveness of the MCA in completely obstructed BBS.

Methods 21 MCA procedures were performed in 19 patients with completely obstructed BBS. All patients had percutaneous biliary access. Magnets were located to the proximal side of the obstruction via percutaneous biliary sheath and the distal side endoscopically. The procedure was terminated as the magnets attracted. Either self-expandable fully covered metallic stent and/or a growing number of plastic stents were introduced after recanalization was achieved.

Result A total number of 19 patients with completely obstructed BBS resulting from cholecystectomy or liver transplant underwent 21 MCA procedures. Among those, 19 (90.5%) interventions were successful. The median stricture length that had been measured after magnet attraction was 4 mm (range 1–10 mm). The median magnet coupling time in successful cases was 9 days (range 4–27 days). No correlation was found between magnet coupling time and stricture length ($p=0.27$). Complications were observed in 6 (cholangitis:1, magnet migration:2, magnet entrapment:3) of 19 successful MCA procedures. Fifteen of the 19 successful procedures had at least a period of stent-free follow-up. Recurrence of stenosis occurred in 7 procedures, of which 4 remained stent-free with retreatment. Eventually, 12 procedures had stent-free last status.

Conclusions MCA is an effective and safe treatment option in completely obstructed BBS. Further studies are required for procedural standardization.

Keywords Biliary tract diseases · Magnets · Extrahepatic biliary stasis · Surgical anastomosis · Cholestasis

Introduction

One of the most common reasons for benign biliary strictures is surgical procedures, including that due to bile duct injury during laparoscopic cholecystectomy and stomal stricture following duct-to-duct anastomosis performed for liver transplantation [1]. It is mainly treated via an endoscopic or

percutaneous route with balloon dilatation and stent application [2]. To do so, crossing the stenotic area with a guidewire is required to carry therapeutic instruments to the pathological site [2]. If the stenosis is too narrow or completely obstructs the passage, endoscopic or interventional radiologic methods fail and surgery becomes the main treatment, however, it harbors high morbidity and mortality rates [1].

Magnetic compression anastomosis (MCA) is a recent technique described by Yamanouchi et al. providing sutureless passage construction for tubular organs [3]. There is a considerable amount of case reports/series in which MCA was used successfully to treat biliary obstructions [4]. It is mainly preferred when a guidewire and contrast medium cannot be passed through the stenotic area via endoscopic or percutaneous route [2]. Its usage avoids complications of surgery [2]. However, patient selection criteria and

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technical issues are not yet standardized. Thus, more studies are needed to draw a frame of standards of the MCA technique. Herein, we present our experience on patients with completely obstructed benign biliary strictures (BBS) that underwent the MCA technique.

Materials and Methods

The current study was approved by Ankara City Hospital Scientific Research Assessment and Ethics Committee (Approval No: E.Kurul-E1-20-830). Informed consent was taken for each procedure from patients. Procedures were performed in Ankara Türkiye Yüksek İhtisas Teaching Hospital from November 2013 till February 2019. Since Ankara Türkiye Yüksek İhtisas Teaching Hospital was incorporated into Ankara City Hospital in February 2019, procedures belonging to patients numbered 8–19 and second attempt of the 7th patient were conducted in Ankara City Hospital by the same medical staff.

Study Population

A total number of 19 patients with completely obstructed BBS caused by biliary injury during cholecystectomy or liver transplant surgery were included in the study (Table 1) and 21 MCA procedures were conducted. All patients were hospitalized. Interventions to pass through the obstruction with a guidewire first with endoscopic retrograde cholangiopancreatography (ERCP) and then with percutaneous transhepatic cholangiography (PTC) were failed. Percutaneous biliary access was left in place for all patients to enable biliary drainage and avoid cholangitis. Simultaneous cholangiograms with both endoscopic and percutaneous ways were obtained to determine the features of the obstructed biliary segment for suitability of the MCA technique. Adult patients with obstructed biliary segments less than 20 mm were employed for the MCA procedure as experienced by previous authors in literature [2, 4, 5]. Patients in whom two sides of the obstruction did not align properly were not recruited for MCA application.

Magnets

The magnets used in this study were heterogeneous and evolved in time with the advancements in MCA usage. All of the magnets used were Nickel-coated cylindrical neodymium iron boron rare-earth magnets (Jiangmen Magsource New Material Co. Ltd. Shuangshui, Jiangmen, Guangdong, China). Two types of magnets were used: N35 (remanence: 11.7–12.1 kGs) and N52 (remanence: 14.4–15.0 kGs). All

of the N52 magnets were 2.5 mm in diameter and applied both percutaneously and endoscopically. Whereas diameters (inserted endoscopically + percutaneously, respectively) of the N35 magnets used in first, second, third, and fifth patients were 5 + 4 mm, 4 + 2 mm, 4 + 3 mm, and 3 + 2 mm, respectively (Table 1). Initially, magnets (N35) were devoid of holes. To insert magnets endoscopically, a pit in 2 mm depth was formed at the tip of the magnet. Fishline (or 2/0 prolene suture thread) 2–3 cm in length was attached at the pit by ethyl 2-cyanoacrylate (Pattex glue, Henkel, Düsseldorf, Germany) to enable transportation of the magnet at the tip of the endoscope by grasping with a snare (Fig. 1A). Due to the difficulty in carrying this type of magnets endoscopically, magnets were started to be redesigned with a hole through which a 0.035-inch guidewire can be inserted (Fig. 1B). The hole-through magnets had to be reduced in size to enable the through-the-scope (TTS) application, but when the diameter of the N35 magnets decreased, the attraction power decreased accordingly. In order to provide the same attraction force, N52 magnets that have higher remanence value were preferred instead.

Percutaneous Magnet Insertion

MCA procedures were conducted in the ERCP theatre. All endoscopic procedures were carried out by a single experienced endoscopist (Ödemiş B.). Patients accepted after 12 h fasting. Midazolam as a sedative, propofol as hypnotic, and fentanyl for analgesia were applied to patients by an anesthetist. All patients had an 8F percutaneous biliary sheath that had been placed during previous treatment attempts by an interventional radiologist. To determine the most proper location for magnet insertion by radiopaque examination, the 8F sheath was removed and an angled taper catheter was inserted over a 0.035-inch guidewire. For magnets devoid of holes, the catheter was replaced with a 10F/40 cm contralateral (crossover) designed vascular sheath (14F in patient #1) over a 0.035-inch stiff straight-tip guidewire. Before insertion, magnetic poles were marked with a board marker (Fig. 1B). The magnet was loaded to the vascular sheath and dragged to the proximal pouch of the obstructed area as approximate as possible with the help of a 5F pusher (Fig. 2). Because of the presence of metallic mesh within the body structure of the contralateral vascular sheath, the magnet may adhere to the wall of the sheath, and difficulty in magnet placement may be experienced. Therefore, if possible, the use of a hole-through magnet should be preferred. For hole-through magnets, an angled tip catheter was replaced with a 10F/23 cm vascular sheath over a 0.035-inch stiff straight-tip guidewire. The marked magnet was loaded to the sheath through the guidewire and dragged to

Table 1 Demographic data of the patients along with MCA-applied obstructed biliary segment and magnet insertion characteristics

Patient No	Age, years	Sex	Etiology & Date of Biliary Surgery	Date of MCA	Obstructed Biliary Segment	Stricture Length, mm	Magnet Diameter*, mm	Magnet Type	Endoscopic Magnet Insertion Technique	Success
1	44	F	Cholecystectomy, 2013	26.11.2013	LHD (Bsm 4)	4	5+4	N35	Snare	Yes
2	69	M	LDLT (RL, 1A), 2013	11.12.2014	RP	3	4+2	N35	Snare	Yes
3	78	F	Cholecystectomy, followed by HI, 2015	01.09.2016	HJ	1	4+3	N35	Snare	Yes
4	62	M	Cholecystectomy, 2016	08.12.2016	CHD (Bsm 2)	5	2.5+2.5	N52	TTS	Yes
5	47	M	Cholecystectomy, 2017	17.01.2018	CHD (Bsm 2)	3	3+2	N35	Snare	Yes
6	71	M	Cholecystectomy, 2017	01.06.2018	CHD (Bsm 2)	10	2.5+2.5	N52	TTS	Yes
7 - 1st attempt	50	F	LDLT (RL, 2A), 2013	24.01.2019	RP - Cystic anastomosis	10	2.5+2.5	N52	TTS	Yes
7 - 2nd attempt				04.02.2020	RP - Cystic anastomosis	10	2.5+2.5	N52	TTS	Yes
8	38	M	LDLT (RL, 2A), 2018	26.03.2019	RA	7	2.5+2.5	N52	TTS	Yes
9	61	M	LDLT (RL, 1A), 2018	25.03.2019	CHD	10	2.5+2.5	N52	TTS	Yes
10	66	M	DDLT (RL, 1A), 2018	12.04.2019	RP	2	2.5+2.5	N52	TTS	Yes
11 - 1st attempt	56	M	LDLT (RL, 2A), 2013	20.06.2019	RA (Seg. 5)	3	2.5+2.5	N52	TTS	Yes
11 - 2nd attempt				11.07.2019	RP	10	2.5+2.5	N52	TTS	No
12	64	F	Cholecystectomy, 2018	26.08.2019	CHD (Bsm 2)	4	2.5+2.5	N52	TTS	No
13	40	F	Cholecystectomy, 2019	04.11.2019	CHD (Bsm 2)	2	2.5+2.5	N52	TTS	Yes
14	24	M	LDLT (RL, 2A), 2018	08.11.2019	RP	4	2.5+2.5	N52	TTS	Yes
15	52	F	Cholecystectomy, 2019	13.11.2019	CHD (Bsm 2)	3	2.5+2.5	N52	TTS	Yes
16	35	F	DDLT (WL, 1A), 2019	20.01.2020	CHD	2	2.5+2.5	N52	TTS	Yes
17	73	M	Cholecystectomy, 2019	12.03.2020	CHD (Bsm 2)	3	2.5+2.5	N52	TTS	Yes
18	42	F	Cholecystectomy, 2020	13.04.2020	CHD (Bsm 2)	5	2.5+2.5	N52	TTS	Yes
19	38	F	Cholecystectomy, 2020	20.04.2020	CHD (Bsm 2)	2	2.5+2.5	N52	TTS	Yes

Bsm: Bismuth type, CHD: Common Hepatic Duct, DDLT: Deceased Donor Liver Transplantation, LDLT: Living Donor Liver Transplantation, LHD: Left Hepatic Duct, M: Male, MCA: Magnetic Compression Anastomosis, RA: Right Anterior, RL: Right Lobe, RP: Right Posterior, Seg.: Segment, TTS: Through-The-Scope, WL: Whole Liver, 1A: One Anastomosis, 2A: Double Anastomosis

*Diameters of the endoscopically and percutaneously inserted magnets are given respectively



Fig. 1 Magnet types used in the study. **a** Coupled N35 magnets with a pit at the tip of the magnet that enables 2–3 cm fishline (or 2/0 prolene suture thread) attachment with superglue. **b** Coupled hole-through N52 magnets marked at the opposite poles with a board marker

the previously decided biliary zone with the help of a 5F pusher (Fig. 3).

Endoscopic Magnet Insertion

Magnet insertion to the distal pouch of the obstruction was performed with a duodenoscope (TJF-260V and TJF-Q180V, Olympus, Japan). Exceptionally, the procedure was performed with a double-balloon enteroscope (over-the-scope) in the third patient who underwent Roux-en-Y hepaticojejunostomy for biliary injury caused by laparoscopic cholecystectomy and who had completely obstructed hepaticojejunostomy anastomosis. Endoscopic sphincterotomy with or without 12 mm transpapillary balloon dilatation was applied to all patients (except HJ anastomosis obstruction) either during the diagnostic ERCP session or MCA procedure. In addition to the provided biliary drainage for the obstructed segment with a percutaneous catheter, interventions to non-obstructed biliary branches to protect biliary flow during the MCA session till the MCA coupling date were stated in Table 2. Following this, magnets were loaded to the duodenoscope in a position to meet the opposite pole of the percutaneously loaded magnet and carried to the distal end of the obstruction by using two different methods: (1)

Over-the-scope method: Large N35 magnet devoid of hole was advanced up to the distal end of the obstruction by holding the fishline or prolene suture thread attached to the magnet with a snare at the tip of the endoscope. (2) Through-the-scope method: Smaller and more powerful hole-through N52 magnet were advanced up to the distal end of the obstruction through the scope with a 7F pusher. By approximation of the magnets on both sides, attraction and proper alignment of the magnets were observed fluoroscopically. The MCA procedure was terminated when the magnets kept their position upon release. The length between the attracted magnets were accepted as stricture length and analyses were performed accordingly.

Extraction of the Coupled Magnets

Patients were evaluated with daily fluoroscopic examinations at the ERCP theatre. The day magnets coupled, a cholangiogram via percutaneous catheter was obtained. In the presented study, the transition of radiopaque solution to the distal side of the obstruction was observed at the day magnets coupled. Then, coupled magnets were removed according to the magnet type. Grasping the fishline attached to the magnets with forceps was preferred for the ones devoid of holes (Fig. 2). For magnets used later (hole-through magnets), a special catheter named as “through-the-scope magnet extractor” (TTS-ME) was designed with a 2 × 10 mm Nickel-coated cylindrical neodymium iron boron rare-earth N52 magnet (Jiangmen Magsource New Material Co., Ltd. Shuangshui, Jiangmen, Guangdong, China) embedded at the tip of a 10F pusher (Micro-Tech [Nanjing] Co., Ltd., Nanjing, Jiangsu, China) after expanding the tip by heat treatment (Fig. 4). Colored TTS-ME catheters that have opposite magnetic poles at the tip were prepared. TTS-ME catheter was inserted through the papilla of Vater and coupling occurred between previously coupled MCA magnets and the magnet at the tip of TTS-ME (Fig. 5). Proper TTS-ME was used to extract coupled magnets as decided at the MCA session according to the positions of the magnets.

Treatment of the Newly Formed Stenosis and Follow-Up

Following magnet removal, the newly formed stenotic biliary segment was treated with balloon dilatation and stenting either with multiple plastic stents or fully covered self-expandable metallic stents (FCSEMS). In order to prevent dislocation of FCSEMS, 7F pigtail plastic stents were applied through it in some patients. Patients with multiple plastic stents only were followed with repeated ERCP sessions during which a growing number of stents were applied

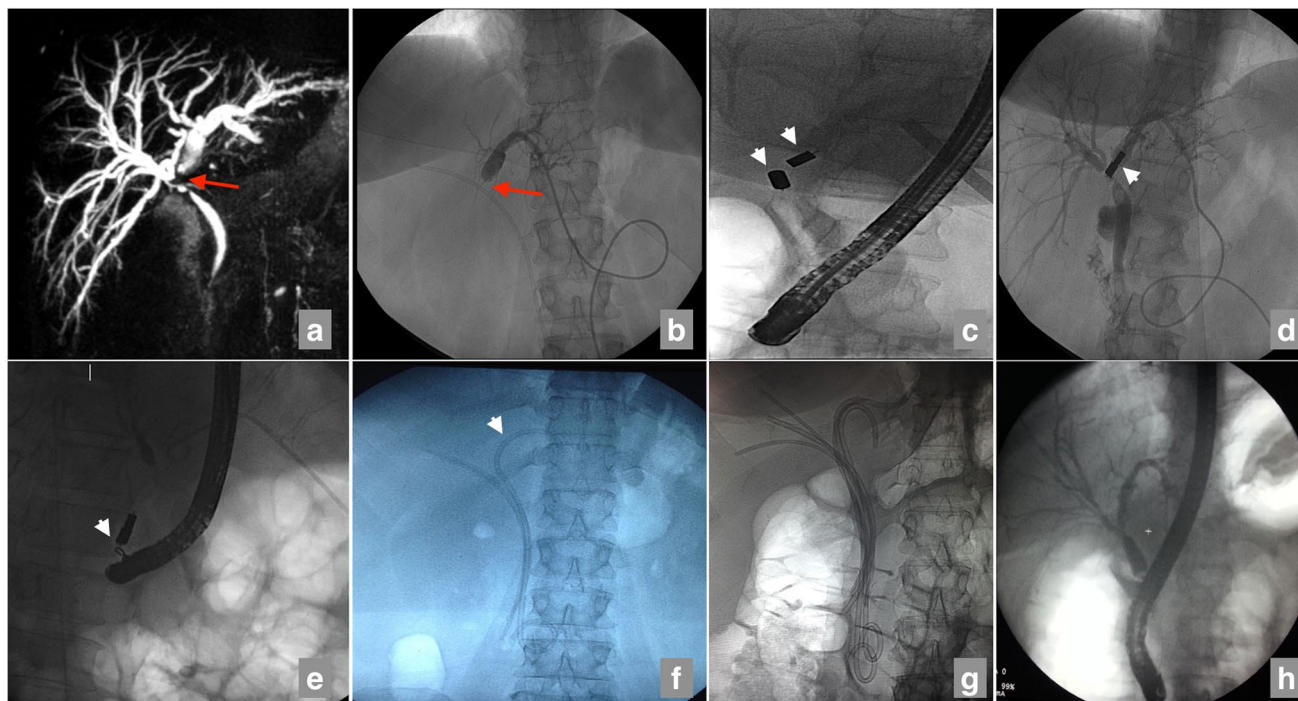


Fig. 2 MCA application in the 1st patient. **a** MRCP evaluation demonstrating loss of connection between the left hepatic duct and common hepatic duct (arrow). **b** Fluoroscopy image of percutaneous cholangiogram indicating total obstruction in the left hepatic duct (arrow). A plastic stent inserted into the right hepatic duct in a previous treatment attempt with ERCP can be seen as well. **c** Fluoroscopic image of the attracted magnets on the day of MCA application (arrowheads). **d** At the 21st day of MCA procedure, the magnets were seen coupled (arrowhead) and the radiocontrast agent passed to the

distal side of the obstruction zone. **e** Coupled magnets were taken out by grasping the fishline attached to the magnets with forceps (arrowhead). **f** A double pigtail stent was inserted into the newly formed stricture after successful MCA application (arrowhead) in addition to the stent application to incomplete stenosis area of the right hepatic duct. **g** Multiple plastic stents were inserted into the newly formed stricture. **h** Loss of stenosis were observed after 9-months treatment with multiple plastic stents

3 months intervals until the stenosis disappear. ERCP control and FCSEMS removal were performed 6–8 weeks later in patients with FCSEMS. Plastic stents or FCSEMS were applied if the stenosis persists. Patients who had no signs of stenosis, biliary stents were removed, and patients were followed with liver function tests with prolonged intervals if they yielded normal. Hepatobiliary ultrasonography was performed in those with abnormal laboratory results, and ERCP was performed if necessary.

Statistics

Statistical analysis was performed with the 26th version of Statistical Package for the Social Sciences (SPSS, IBM, Armonk, NY). Number and percentage were given for categorical data. Mean and standard deviation was used for continuous variables that were shown to be normally scattered. Median and interquartile range were used otherwise. Spearman correlation analysis was performed for non-parametric variables.

Results

Demographic Data of the Patients and Characterization of the Strictures

A total number of 19 patients with complete biliary obstruction resulting from cholecystectomy or liver transplant surgery underwent 21 MCA procedures (Table 1). The ages of the patients were ranged between 24 and 78 with a mean of 53.2 (Standard Deviation, SD: 15.1); and 10 (52.6%) of patients were male. While 11 (57.9%) of the patients had complete bile duct obstruction secondary to cholecystectomy, 8 (42.1%) patients had complete bile duct obstruction due to liver transplantation. All of the cholecystectomy procedures were performed laparoscopically due to cholelithiasis. Among patients with post-cholecystectomy injury, the most common injured biliary segment was the common hepatic duct (CHD) observed in 9 (81.9%) patients (Bismuth type 2 stricture). In the remaining 2 patients, one had left hepatic duct (LHD) obstruction (Bismuth type 4 stricture), while the other had an obstruction in Roux-en-Y hepaticojejunostomy anastomosis which had been performed to

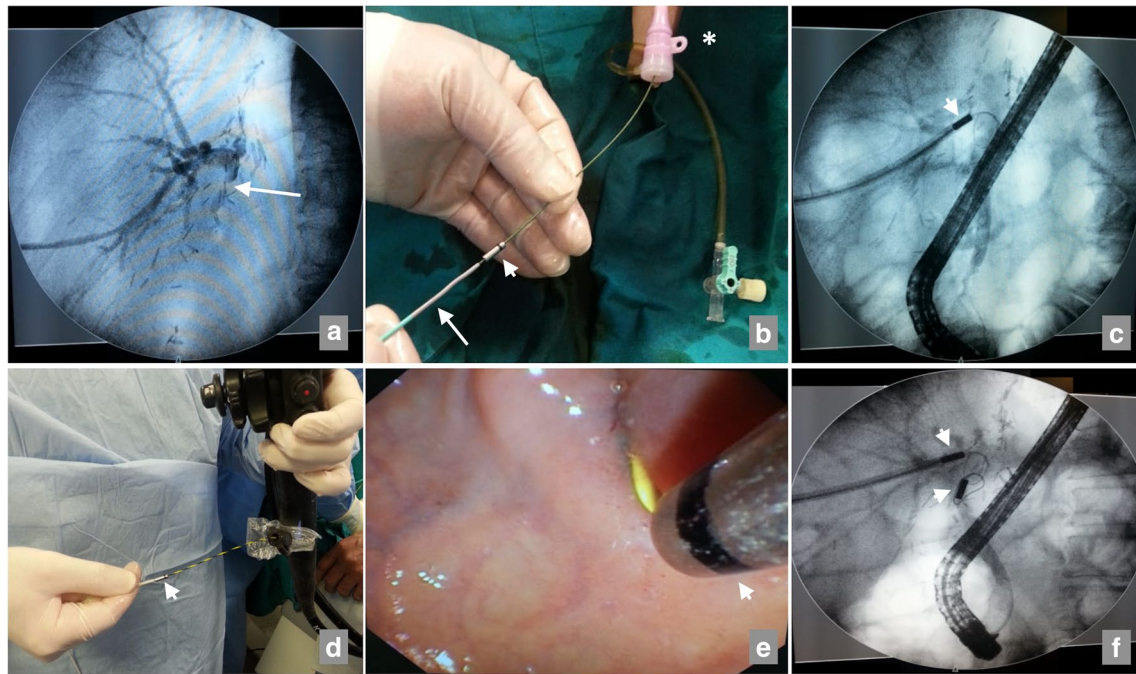


Fig. 3 Magnet insertion process in the 10th patient (arrowheads pointing magnets). **a** Fluoroscopic image performed with angled tip percutaneous catheter reveals total obstruction at the right posterior biliary duct (arrow). **b** The marked magnet (asterixis) through the guidewire and dragged to the previously decided biliary zone with the help of a 5F pusher (arrow).

c Fluoroscopic view of the percutaneous magnet insertion. **d** Magnet was loaded to the duodenoscope in a position to meet the opposite pole of the percutaneously loaded magnet and carried to the distal end of the obstruction via the TTS technique. **e** Endoscopic view of the magnet insertion through the ampulla of Vater. **f** Fluoroscopic view of both magnets just before the attraction

treat biliary injury secondary to laparoscopic cholecystectomy. In two patients (12th and 15th patients), a posterior aberrant bile duct draining distal to the obstruction site was observed. When the patients with a history of liver transplantation were evaluated, there was no cause found as etiology of cirrhosis in 3 patients (cryptogenic), while the cause of cirrhosis in each patient was primary biliary cholangitis (PBC), hepatitis B infection, and nonalcoholic steatohepatitis (NASH). In the remaining 2 patients, the etiologies of transplantation were toxic hepatitis and hepatocellular carcinoma. Among patients with liver transplantation, 6 (75%) had transplantation from living donors, while 2 (25%) from deceased donors. In 4 of the 6 patients with living donor liver transplantation (LDLT), the right anterior and right posterior branches were anastomosed separately, and in 2 of them, the right posterior branch was anastomosed to the cystic duct. In patients with deceased donor liver transplantation (DDLT), one had split (right lobe) transplantation and the other had whole liver transplantation. Among 6 patients having LDLT, complete biliary obstruction was observed in the right posterior branch (3 patients), right anterior branch (1 patient), CHD (1 patient), and simultaneous right anterior (segment 5) and right posterior branches (1 patient). In 2 patients with DDLT, complete biliary obstructions were observed in the right posterior branch and CHD.

Outcomes of the MCA Procedure

Nineteen (90.5%) of the 21 MCA interventions were successful. The median stricture length that had been measured after magnet attraction was 4 mm (ranged between 1 and 10, Table 1). Due to the retrospective nature of the study, preprocedural stricture lengths measured in cross-sectional imaging studies could be found only in 1st, 3rd, 4th, 7th (first attempt), 7th (second attempt), 9th, 10th, 14th, 15th, 16th and 18th patients and were 8 mm, 1 mm, 6 mm, 10 mm, 10 mm, 14 mm, 4 mm, 6 mm, 6 mm, 4 mm, and 10 mm, respectively. Preprocedural stricture lengths were longer than the measurements observed after magnet attraction. Analyses were performed with the lengths measured right after magnet attraction. The median magnet coupling time in successful cases was 9 days (ranged between 4 and 27). No correlation was found between magnet coupling time and stricture length ($p=0.27$). Median stricture length was 3 mm and median coupling time was 11 days in 4 successful procedures conducted with N35 magnets, while these numbers were 3.5 mm and 9 days in 15 successful procedures with N52 magnets, respectively.

In 19 successful procedures, magnets designed with fish-line and devoid of holes were used in 4 procedures and all were extracted with the help of forceps. In the remaining 15

Table 2 Features of the procedure and long-term follow-up data after MCA application

Patient No	Interventions to Non-Obstructed Segment	Magnet Coupling Time, days	Endoscopic Magnet Extraction Technique	Stent Type Applied to Newly Formed Stenosis	Complication	Total Follow-up Time [#] , days	Stent-free Follow-up Time, days	Recurrence	Last Status
1	Balloon Dilatation	21	Forceps	MPS	No	2676	2355	No	Stent-free
2	PD	11	Forceps	MPS	No	2295	1750	No	Stent-free
3	N/A	8	Forceps	Internal PD	No	1666	1568	Yes	Stent-free
4	N/A	11	Spontaneous	MPS	No	1510	1003	Yes	Stent-free
5	N/A	6	Forceps	FCSEMS	No	1163	469	Yes	Stent-free
6	N/A	27	TTS-ME	FCSEMS	No	1028	251	No	Stent-free
7 - 1st attempt	None	5	Stone Basket	FCSEMS	Magnet entrapment	370	310	Yes	Re-MCA
7 - 2nd attempt	None	14	TTS-ME	FCSEMS	No	337	0	–	Stented
8	None	7	TTS-ME	FCSEMS	No	730	269	Yes	Stent-free
9	N/A	7	TTS-ME	MPS	No	716	0	–	Stented
10	None	7	TTS-ME	MPS	No	712	301	No	Stent-free
11 - 1st attempt	PD (RP), None (Seg. 8)	12	TTS-ME	MPS	Cholangitis	82	0	–	Stented
11 - 2nd attempt	MPS	Failed	Combined*	–	–	–	–	–	–
12	None	21	Surgery	–	–	–	–	–	–
13	N/A	7	TTS-ME	MPS	No	506	218	No	Stent-free
14	None	11	TTS-ME	MPS	No	487	133	No	Stent-free
15	None	5	TTS-ME	FCSEMS	No	498	29	Yes	Stented
16	N/A	4	TTS-ME	MPS	Magnet migration	430	0	–	Stented
17	N/A	14	TTS-ME	MPS	Magnet entrapment	378	86	No	Stent-free
18	N/A	14	TTS-ME	FCSEMS	Magnet entrapment	346	225	No	Stent-free
19	N/A	9	TTS-ME	FCSEMS	Magnet migration	339	36	Yes	Stented

FCSEMS: Fully Covered Self Expandable Metallic Stent, MCA: Magnetic Compression Anastomosis, MPS: Multiple Plastic Stents, N/A: Non-applicable. PD: Percutaneous Drainage, RP: Right Posterior, Re-MCA: Repetition of MCA, Seg.: Segment, TTS-ME: Through-the-scope Magnet Extractor

* The distal magnet was removed endoscopically with TTS-ME. The proximal magnet that had been migrated to smaller biliary branches was extracted percutaneously through the 10F biliary sheath with the attraction of the magnet to a 0.035-inch stiff straight-guidewire

[#] The time period from MCA application to the date of the last follow-up

procedures, hole-through magnets were used and 11 of those magnets were extracted with TTS-ME alone. In the fourth patient, coupled magnets fell and were removed with the intestinal tract spontaneously. In the 14th patient, coupled magnets were dropped to the duodenum during extraction with TTS-ME. Since there was no risk of intestinal fistula formation due to already coupled magnets, the patient was followed daily with fluoroscopy till the magnets were discharged through stool. When the physical properties of endoscopically removed magnets were evaluated, significant

magnet erosion was not observed in any of the N52 magnets. However, significant erosion occurred on the suture-attached sides of the magnets in one of the four procedures which were used N35 magnets.

In the study, 2 of the total 21 MCA procedures were failed. Firstly, after successful MCA intervention to the right anterior branch (segment 5) in the 11th patient with liver transplantation, second intervention to the right posterior branch (stricture length was 10 mm) was failed. Although the magnets on the right posterior branch were re-aligned

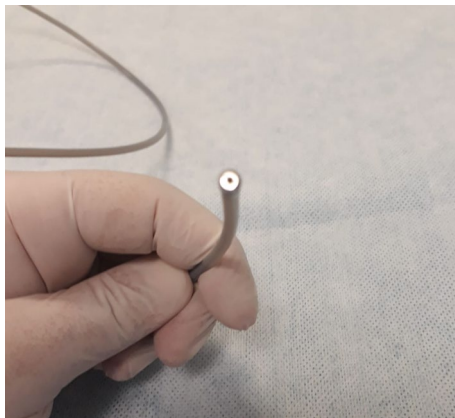


Fig. 4 Through-the-scope magnet extractor (TTS-ME) designed with a 2×10 mm Nickel-coated cylindrical neodymium iron boron rare-earth N52 magnet embedded at the tip of a 10F pusher after expanding the tip by heat treatment

twice in 8 days period during MCA application, the procedure was terminated because the magnets did not remain in the area of attraction of each other. The distal magnet was removed endoscopically with TTS-ME. The proximal magnet that had been migrated to smaller biliary branches was

extracted percutaneously through the 10F biliary sheath with the attraction of the magnet to a 0.035-inch stiff straight-guidewire. Since the patient did not attend follow-ups, other treatment options could not be tried. Secondly, MCA intervention to CHD in the 12th patient with cholecystectomy history (stricture length was 4 mm) was failed. Although the magnets were seen united on the 21 day, the MCA procedure was unsuccessful because the coupled magnets could not be removed endoscopically or percutaneously, and the patient was transferred to biliary surgery.

Stenting of the Newly Formed Stenosis

In successful MCA procedures, FCSEMS was applied to the newly formed biliary stenosis in 8 procedures, while multiple plastic stents were used in the 10, and percutaneous internal biliary catheter was used in the one with HJ anastomosis stenosis (Table 2). Patients numbered 5, 6, 7 (first and second attempts), 8, 15, 18, 19 had FCSEMS which were removed after a mean of 50.5 days (43, 48, 54, 48, 44, 53, 50, 64 days, respectively). In 4 (50%) procedures of all FCSEMS applied patients, a stent-free period was observed just after FCSEMS removal, although 3 (75%) of those

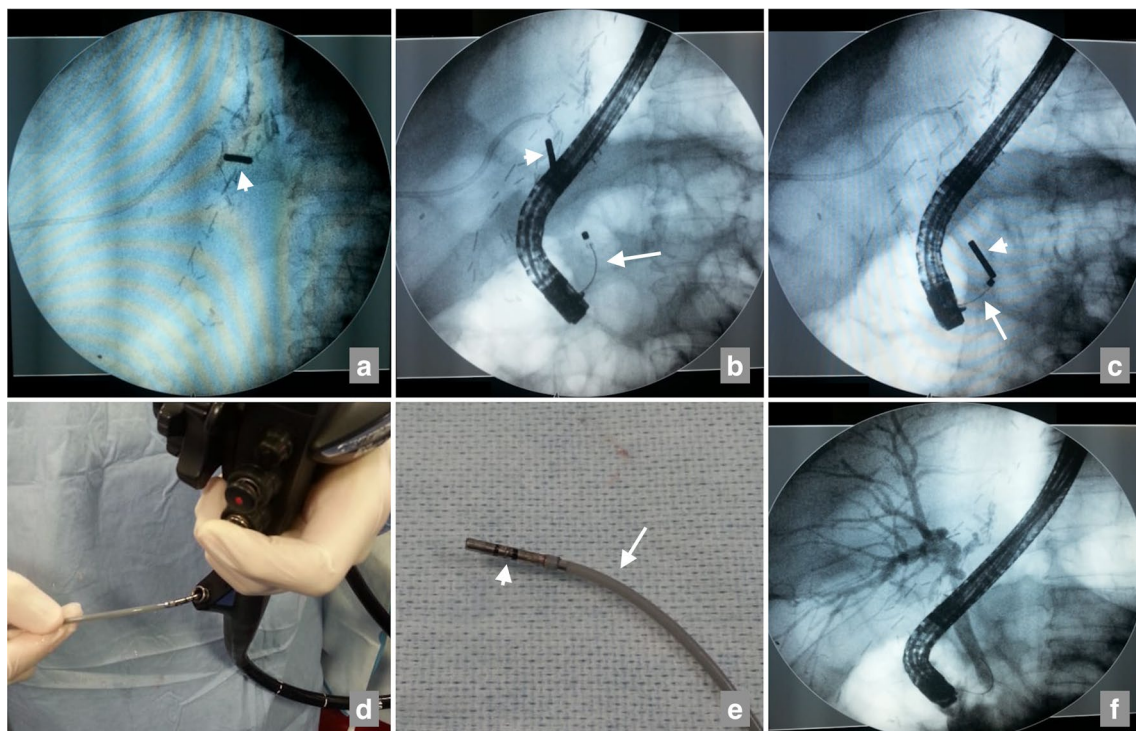


Fig. 5 Magnet extraction process in the 10th patient (arrowheads pointing magnets). **a** Fluoroscopic view of the coupling of the magnets at the day 7. **b** Fluoroscopic view of the insertion of the through-the-scope magnet extractor (TTS-ME) (arrow) endoscopically. **c** Coupling of the TTS-ME (arrow) with the previously coupled magnets.

d Taken out of the TTS-ME coupled with previously coupled magnets. **e** A picture of TTS-ME (arrow) coupled with previously coupled magnets. **f** Fluoroscopic view of the passage of the radiocontrast agent after successful MCA procedure

required further intervention later on due to recurrence of the stenosis. Growing amounts of plastic stents were applied to 2 patients with recurrence of stenosis and stent-free last status was achieved eventually. The last patient (seventh patient) with recurrence had another MCA procedure applied to the same biliary zone. In the remaining 4 procedures that had not had a stent-free period just after removal of FCSEMS, the seventh patient was followed with multiple plastic stents (MPS) just after the removal of another FCSEMS used again in the second MCA attempt. The sixth patient was left stent-free after follow-up with MPS applied upon removal of FCSEMS. The 15th patient had been followed with MPS after 29 days of stent-free period. The 19th patient did not attend her follow-ups. Eventually, 4 (50%) of the FCSEMS applied procedures had the last status of stent-free.

In successful procedures, 10 interventions were followed by increasing amounts of MPS without any FCSEMS application. Among those, patients numbered 1, 2, 4, 10, 13, 14, 17 were left stent-free after mean 321.5 days (300, 534, 198, 404, 281, 343, 278 days, respectively). Only one (14.3%) patient (fourth patient) had a recurrence of stenosis which was treated with another period of MPS application and ended up with stent-free last status. In the remaining 3 patients, the 9th and 16th patients had no stent-free period and the 11th patient did not attend the follow-ups. Eventually, 7 (70%) procedures among MPS applied patients without any FCSEMS insertion had stent-free last status.

The internal percutaneous drainage catheter, which was placed after removal of the coupled magnets was removed 62 days later in the patient with HJ stenosis.

Follow-Up

The median follow-up time of the successful MCA procedures, the period from MCA application to the date of the last follow-up, was 712 days (ranged between 82 and 2676). 15 of the successful procedures had at least one period of stent-free follow-up, of whom recurrence of the stenosis was observed in 7 procedures. 4 procedures were left stent-free after retreatment however, 3 procedures were still followed up with stents. Eventually, 12 (63.2%) of the successful 19 MCA procedures had the last status as stent-free with a median of 285 days (ranged between 86 and 2355) of stent-free follow-up.

Adverse Events

Complications were observed in 6 of 19 successful MCA procedures: 3 magnet entrapment, 2 magnet migration, and 1 cholangitis. Entrapment was observed in one patient during percutaneous magnet insertion, and in 2 patients after

magnet coupling was achieved. The magnet was stuck in the right branch during percutaneous insertion in the 18th patient. It could not be removed by the straight-tip guidewire advanced through the percutaneous sheath. The fishline-glued magnet was held with cholangioscopic forceps (Spy-Bite forceps, SpyGlass Direct Visualization Systems, Boston Scientific, Massachusetts, USA) and advanced over the 10F percutaneous sheath near the migrated magnet. After coupling of the magnets, they were pulled out. Then, a successful MCA procedure was performed through the left branch. In the first attempt of the 7th patient, coupled magnets were drifted into CHD with the help of tensed sphincterotome after 6 mm balloon dilatation applied to the cystic duct distal to the coupled magnets. Then, coupled magnets were grabbed and taken out with a stone basket. In the 17th patient after failed initial attempt to extract coupled magnets with TTS-ME, sequential application of 8 mm balloon dilatation, 7F bougie dilatation distal to the magnets, and pressurization via percutaneous radiopaque material injection were performed. Finally, entrapped magnets were extracted with TTS-ME. Among procedures in which magnet migration was observed, in the 16th patient, during the percutaneous insertion of the magnet, it migrated to the left biliary branch with the attraction of the magnet by the endoscope. Migrated magnet left in place and a second magnet was advanced percutaneously and attracted by the magnet placed with an endoscope. After recanalization was achieved, the migrated magnet was pulled with the help of a balloon catheter to the CHD where it was extracted by TTS-ME. In the 19th patient, coupled magnets had been migrated to the left hepatic duct (LHD). Although the radiopaque passage was present, the guidewire could not be advanced through the obstructed segment, and the rendezvous technique was employed to achieve endoscopic guidance. After balloon dilatation, coupled magnets were extracted with TTS-ME. A few days after MCA application to the right anterior branch (segment 5) in the 11th patient, cholangitis stemmed from unprotected biliary branch draining segment 8 was observed and intervened by application of a plastic stent.

Discussion

Complete biliary stenosis requires surgical treatment which has high morbidity and mortality rates [1]. Recently, the MCA technique has been employed to establish recanalization of the obstructed biliary segment with high success and low complication rate. It has begun to replace surgery in the treatment of completely obstructed BBS. With the MCA technique, recanalization of the complete stenosis can be achieved by compression of the area in between magnets resulting in ischemic necrosis and epithelization eventually [6]. The presented study is the second largest study in terms

of patient numbers, after Jang et al. [7], and is unique in measuring stricture length after magnet attraction. In literature, experiences on the MCA technique in completely obstructed BBS are limited to case series and reports [2, 5, 7–21]. The study conducted by Jang et al. with 39 patients appears to be the study with the highest number of patients having completely obstructed BBS [7]. In this study, the success rate of MCA was reported 100%. The median time of recanalization was 52 days. Another study with 12 patients was conducted in 2011 [5]. The success rate of MCA was 83.3% and the median recanalization time was 92 days. In the study with 9 posttransplant patients having complete biliary obstruction < 10 mm in length, Parlak et al. reported 77% successful MCA procedures after a mean recanalization time of 8.1 days [8]. Li et al. reported a 100% success rate in 9 patients with completely obstructed BBS measuring ≤ 10 mm long or incomplete ≤ 10 mm stenosis refractory to 3 sessions of ERCP [9]. The mean recanalization time was 16.3 days. In a study by Jang et al. [2] 5 MCA procedures out of 7 were successful with 36 days of a median magnet coupling time. In the presented study that performed in a relatively large number of patients including one with completely obstructed hepaticojejunostomy anastomosis, 19 (90.5%) out of 21 MCA procedures were successful with 9 days of a median magnet coupling time.

The difference in MCA success rate and magnet coupling time may stem from the patient and/or material-related factors. Since MCA is a developing technique, its effectiveness has not been sufficiently evaluated according to stricture properties. Most studies report that the stricture length should be below 15 or 20 mm [2, 5, 9–11]. In a study with success in 5 out of 7 patients, failure in 2 patients with stricture lengths of 15 and 17 mm may be an indication that patients with stricture lengths < 15 mm are eligible for MCA [2]. On the other hand, the 77% success rate was observed in the study of Parlak et al., where the stricture length in all patients was < 10 mm. In the presented study, stricture lengths measured after magnet coupling were ≤ 10 mm, and the success rate was 90.5%. These data indicate that stricture length is not the only factor in predicting MCA success. The shape of the bile duct, the directional pattern of both sides of the obstructed segment, magnet type, shape, attraction force, and diameter are the other factors affecting the procedural success [12, 22]. With the development of magnet technology, stronger and smaller magnets started to be used. While the optimal placement of the large magnets used before in the obstruction pouch was not always ensured, deeper insertion became more possible with smaller and more powerful magnets. Thus, concerns arising from an angular irregularity of both ends of completely obstructed BBS can be overcome with these new magnets. Transport of large magnets to the pathological site is possible with

the over-the-scope technique even with a double-balloon enteroscope as experienced in the 3rd patient of our study. However, it is not the preferred way because of the blockage of the endoscopic view and difficulty in proper magnet insertion. In most studies, unlike our study, a covered metallic stent was required to be placed through the ampulla of Vater to insert a magnet endoscopically [14, 18–20]. Because of these concerns, we recommend that through-the-scope insertion of smaller and more powerful hole-through magnets be used in the MCA procedure.

One issue regarding stricture length is that the stricture length measured during the simultaneous percutaneous and endoscopic cholangiograms can overestimate the true length. In our study, to overcome such overestimation, stricture lengths were measured just after the magnet approximation (Table 1). Although the results measured with the simultaneous cholangiograms were not specified in our study, it was observed that the length measured after magnet approximation was much shorter than the measurements performed in cross-sectional imaging studies. We think that this situation is due to overcoming the incomplete stenotic area in close proximity of the completely obstructed area with magnets, which the pressure applied with the simultaneous cholangiograms cannot exceed. Thus, the distance measured between the two magnets just after the magnet approximation represents distance between the beginning and end of the completely obstructed area and the success of MCA technique depends on the ischemic necrosis of this area. Because of these reasons, we believe that measurement of the stricture length after magnet approximation is more valuable to predict the outcome of the procedure.

MCA usage in completely obstructed BBS is relatively safe as stated in previous clinical series and reports [2, 5, 7–21]. Cholangitis appears to be the most frequent complication in literature [5, 7, 9]. Cholangitis can be easily prevented by providing drainage of patent bile branches by endoscopic stenting or percutaneous drainage in addition to already percutaneously protected obstructed segment. In our study, one patient had cholangitis and biliary drainage of the unprotected segment was enabled to overcome this complication. Magnet entrapment (3 patients) and migration (2 patients) were observed more frequently compared to cholangitis in our study, contrary to the literature. While TTS-ME designed by ourselves can be a beneficial and practical tool for magnet removal, entrapment and proximal migration of magnets make magnet removal quite challenging for endoscopists. In such cases, balloon or bougie dilatation distal to the magnets, percutaneous pressurization, manipulation of the magnets with various instruments and percutaneous cholangioscopic intervention can solve the problem in most cases. However, the surgical method can be considered when magnets cannot be removed with all these attempts, as occurred in the 12th patient.

During the MCA procedure, in order to prevent the percutaneously placed magnet to be pulled by the endoscope, as occurred in the 16th patient, and thus migrate to the proximal biliary tree, endoscopic magnet insertion should be placed first, and then percutaneously placed magnet should be released at the attraction zone of the distal one.

Another issue that can complicate the patient is the presence of magnets freely in the intestinal lumen. If only one magnet or coupled magnets, as experienced in our study, are present freely in the intestine, spontaneous discharge of the magnets with stool can be allowed with daily plain films. However, in the case of the presence of two or more magnets separately in the intestinal tract, serious complications, such as intestine-to-intestine fistula formation and perforation, can be faced. Thus, it is important that the magnets are not dropped into the intestine or trachea during the insertion or extraction process and TTS-ME used in our study can be a safer option for magnet extraction.

Moreover, magnetic resonance imaging is contraindicated in such patients. The MCA procedure should be performed by an experienced endoscopist and interventional radiologist to prevent and manage such complications.

There are different applications in the literature regarding the preservation of the patency of the newly formed stenotic area after recanalization with MCA. In some studies, an internal percutaneous drainage catheter was placed for six months [2, 7]. We believe that follow-up with percutaneous drainage after recanalization is uncomfortable and makes patients susceptible to infection. Furthermore, patients may need repeated interventions due to the percutaneous drainage catheter being dislodged by body movements. In our study, percutaneous drainage was left place out of necessity in the patient with hepaticojejunostomy stenosis. Thus, we support the usage of stenting with FCSEMS or a growing number of plastic stents in each ERCP session for the newly formed stenotic area. Although reports demonstrated the same effectiveness of FCSEMS and MPS application in postoperative benign biliary strictures, MPS usage scored over FCSEMS (stent free last status %70 vs. %50 respectively) in the presented study. Moreover, 7 out of the 19 successful procedures required re-stenting due to recurrence of the stenosis and this situation was observed less frequently in the MPS group compared to FCSEMS (14.3% vs. 75.0%, respectively). Additionally, the time to recurrence was shorter in the FCSEMS group and both patients (patients 15 and 19) who had recurrence within one month were in the FCSEMS group. However, we believe that these results may be stemmed from the short-term use of the FCSEMS and FCSEMS stenting time of 3–6 months can lead to better results in favor of metallic stent.

In the presented study, 7th (second attempt), 9th, 11th and 16th patients had no stent-free period and followed with MPS for 337, 716, 82 and 430 days, respectively. In these patients

and during stented periods of the patients with recurrences, control ERCP and stent replacement was performed approximately every 3 months. Neither cholangitis nor need of hospitalization were observed. Long stricture length and extra-anatomical anastomosis, such as right posterior and cystic duct anastomosis, in patients without any stent-free period were thought to be the reason for prolonged stenting times and stent-dependent follow-up.

MCA application in biliary tract is an evolving technique. Although there is more experience in surgical treatment of biliary injuries, less invasive methods are needed due to 10–20% stenosis recurrence rates and complications that reduce the quality of life, especially biliary leak, surgical site infections and abscess formation, reported after the surgery [23–27]. As seen in our study, the MCA technique could replace surgical repair in the future with the accumulation of experience, due to its high success rates, minimally invasive nature, rare and mostly endoscopically treatable complication profile. More studies are needed to standardize the MCA technique and directly compare it to surgical repair.

Our study has some limitations. Due to its retrospective nature, data belonging to stricture length measured during simultaneous cholangiograms or from preprocedural cross-sectional studies are lacking. Thus, the statistical representation of the significant decrease in stricture length observed just after the magnet approximation was not possible. Secondly, although our study is the second largest study regarding number of the procedures, it still harbors limited number of cases. Thirdly, long term follow-up was lacking in part of the patients. Furthermore, because of the retrospective nature and the design of the study, direct comparison with surgical arm could not be possible. Lastly, although any related complications with nickel-coated magnet have not been reported in the previous studies [8–10] and our study, we are concerned that there might still be a risk of nickel toxicity due to magnet erosion.

In conclusion, the MCA technique is an effective and safe option that should be considered as an alternative to surgery in the treatment of completely obstructed BBS. It avoids the morbidity and mortality burden of the surgery. Patient selection criteria, operational instructions, and materials must be standardized to optimize its effectiveness and safety with the help of further studies.

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Declarations

Conflict of interest Drs Bülent Ödemiş, Batuhan Başpınar, Muharrem Tola and Serkan Torun have no conflicts of interest or financial ties to disclose.

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