Double balloon enteroscopy improves ERCP successfulness in patients with modified small bowel anatomy

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ABSTRACT

OBJECTIVE: To evaluate the effect of endoscopic retrograde cholangiopancreatography (ERCP) using double balloon enteroscopy (DBE-ERCP) on ERCP procedure success in patients with surgically modified gastrointestinal (GI) tract anatomy.

METHODS: The medical records of the patients who underwent ERCP at the Gastroenterology Department of our University Hospital, between December 2008 to September 2014 were examined. In the patient group which has been planned to undergo DBE-ERCP, the procedures of patients who had undergone ERCP via standard duodenoscope or who had undergone DBE-ERCP during the same session because standard ERCP been failed were included. Procedure parameters, outcomes and complications related to the procedure were examined in both groups. Patients who have undergone DBE-ERCP procedure directly, those who have undergone push enteroscopy (PE) or gastroscopy to evaluate GI tract anatomy before ERCP day, and who have undergone DBE-ERCP on a different day from initial ERCP session were excluded. Afferent loop intubation, access to the major papilla, selective cannulation, therapeutic success rates and the effect of DBE on overall procedure success were evaluated.

RESULTS: Fifty-one patients with BII gastrojejunostomy and 11 patients with hepaticojejunostomy (with or without Roux-en-Y) were included in the study. In all patients included in the study, the process had been started with standard duodenoscope and if intubation of the afferent loop was unsuccessful, neither reaching the major papilla nor enterobiliary anastomosis failed, DBE had been used for the ERCP procedure. In 30 (48.4%) of the 62 patients whose GI tract was anatomically altered, the duodenoscope has been successfully advanced to the ampulla and 27 (43.5%) has been cannulated successfully. Thirty-one patients had been undergone DBE-ERCP. DBE has been reached to ampulla or enterobiliary anastomosis in 30 patients (96.8%) and selective choledocus cannulation has been achieved in all patients except 3 of them (1 patient with hepaticojejunostomy) (90%). The overall ERCP success rate increased from 43.5% (27/62) to 87.1% (54/62). Two perforations (1 during standard duodenoscopy and 1 with DBE-ERCP) were observed due to procedures.

CONCLUSION: The overall ERCP success rate increases in those whom ERCP was performed using the DBE in patients with small bowel anatomic variations that result from surgery.

Keywords: Billroth II gastric resection; double balloon enteroscopy; endoscopic retrograde cholangiopancreatography; hepaticojejunostomy; roux-en-Y reconstruction.

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When it is used for the management of hepatobiliary system and pancreatic diseases, endoscopic retrograde cholangiopancreatography (ERCP) is a very useful procedure. Although ERCP be performed successfully in 85–95% of patients who has unchanged small bowel anatomy [1], its successfulness in those have
Billroth II (BII) gastrojejunostomy, especially in patients with reconstruction of Roux-en-Y (R-en Y) which have long afferent limb, is lower (62–92%) [2–4]. Implementation of this kind of reconstruction is common after orthotopic liver transplantation (OLT) or biliary diversion procedures, the endoscope has to be advanced until the jejunojejunostomy is reached, and then additional 40 to 80 cm to the Roux limb [5, 6]. In case of R-en-Y existence, therapeutic choices for management of pancreatobiliary diseases are percutaneous transhepatic cholangiography (PTC), ERCP, or surgery.

Double-balloon endoscopy (DBE) is a very useful endoscopic technique that allows for complete visualization and also therapeutic interventions in the entire small intestine developed by Yamamoto and colleagues in 2001 [7–9]. Impact of DBE for management of hepatobiliary problems in persons with history of hepatobiliary or pancreatic surgery has been declared before [4, 5, 10–12]. If PTC or re-surgery are not valid options when the standard ERCP method been unsuccessful, DBE would be useful and life saving alternative for these patient's treatment [13].

In this paper, we aimed to describe our clinical results about the practice of DBE to perform ERCP (DBE-ERCP), including therapeutic actions, to increase total ERCP prosperity in persons with small bowel anatomy modified by surgery.

**MATERIALS AND METHODS**

The current study is a retrospective evaluation of prospectively entered data from a patient database of a single university center. The patients who have anatomically altered GI tract with or without Roux-en-Y and underwent ERCP in our unit between December 2008 and September 2014 were evaluated. Patients data were extracted from the registry system, where all data and follow-up results relating to ERCP procedure performed are prospectively entered and evaluated. In the group of patients who were planned to undergo DBE-ERCP, the procedures of patients who have undergone ERCP via standard duodenoscope or who have undergone DBE-ERCP during the same session because standard ERCP failed were prospectively entered and evaluated. In the group of patients who were planned to undergo DBE-ERCP, the procedures of patients who have undergone ERCP via standard duodenoscope or who have undergone DBE-ERCP during the same session because standard ERCP failed were enrolled in this study. Patients who have undergone DBE-ERCP procedure directly, those who have undergone push enteroscopy (PE) or gastroscopy to evaluate GI tract anatomy before ERCP day, and who have undergone DBE-ERCP on a different day from initial ERCP session were excluded. No distinction was made between patients referred from other centers for differential diagnosis and those patients directly attending our clinics. Demographic characteristics of the patients, results of the radiological, and biochemical evaluations performed prior to the procedure, procedure findings, data relating each procedure, histopathological diagnosis, clinical findings, and results were examined. Afferent loop entrance, access to the ampulla, cannulation of choledocus selectively, therapeutically success rates and the effect of DBE on overall procedure success were evaluated.

The DBE-ERCP technique and its risks have been explained to all patients, and informed consent has been obtained, including consent to the endoscopic treatment. Study approval was taken from local ethics committee of Kocaeli University (KU/GOAEK No: 2019/326 Date: November 13, 2019).

**Statistical Analysis**

All statistical analyses were performed using IBM SPSS for Windows version 20.0 (SPSS, Chicago, IL, USA). Descriptive statistics were reported as mean±standard deviation (SD) values. Categorical variables were summarized as counts (percentages). To compare proportions between two samples, Fisher’s exact test was used. Statistical analyses were carried out with 5% significance and a two-sided p-value <0.05 was considered as statistically significant.

**DBE-based ERCP**

The procedure had started with a side-viewing (standard) duodenoscope all the time. If afferent loop entrance or reaching the ampulla either biliary-pancreatic enteroanastomoses using the standard duodenoscope had not been not possible, DBE was tried for the ERCP process before referring the patient for PTC, or re-operation.

All DBE-ERCP procedures were performed under propofol sedation applied by anesthesiology team, by one experienced endoscopist, using by a 200-cm in length therapeutic double balloon endoscopy system which has 2.8-mm accessory channel (EN-450 T5, Fujinon Co. Ltd., Saitama, Japan). The DBE-ERCP was done using push-and-pull technique, starting in the left lateral position, and there after changing to the prone position as described by Yamamoto and other authors [3, 7, 8], under fluoroscopic guidance. Overtube and/or enteroscopy balloon has been often used to keep the scope stabilized during DBE-ERCP operation.
ERCP Procedures

Longer accessories usable with the long DBE are very limited in Turkey, although commercially available in some countries. Biliary cannulation of hepatobiliary system was achieved with a specific catheter (Glodip ERCP catheter, 320-cm, Cook Endoscopy, Winston-Salem, NC) and guide wire (Axcess 21, 650-cm, Cook Endoscopy, Winston-Salem, NC). After that, it has taken cholangiogram by administration of contrast medium and diagnostic study has been made. Later than, papillary balloon dilation or initial bougienage of a stenotic ostium of the hepaticojejunostomy has performed using by controlled radial expansion (CRE) balloon dilatation catheter (8–10 mm) (Boston Scientific Corporation, Natick, MA) if necessary.

When sphincterotomy (ES) was required, 0.021, 0.025 or 0.035 inch guidewire was advanced to the bile duct, and then ES was performed using different sphincterotomy advanced over the guidewire. Papillotomy (medwork, 260 cm, Hochstadt/Aisch, Germany) (with 0.021 guidewire), FTE-Papillotomies: F3QTEW1830250S (Fujinon, 250 cm, Saitama, Japan) (with 0.025 guidewire), F3YTEW2230250-FR7-5-S or F3YBEW2225250-FR7-5-15-S (Fujinon, 250 cm, Fujinon Co. Ltd., Saitama, Japan) (with 0.035 guidewire) have been used.

Besides, biliary stones have extracted with long biliary stone balloon (ESCORT II, 320-cm, Cook Endoscopy, Winston-Salem, NC).

When cannulation has failed, we alternated classic method to the PTC-rendezvous technique, followed by trans-ampullary access, as a rescue effort, in another session. After percutaneous puncture inside the intrahepatic bile system, 5-Fr sheath was entered via the guidewire in the bile duct and a 0.035 guidewire was then moved throughout the ampulla. Then, therapeutic DBE was inserted up to ampulla to carried out DBE-ERCP. We put a 7-Fr nasobiliary catheter the bile duct inside for at least 24 h to prevent bile leakage when this technique was used.

Antibiotics were not routinely given before the procedure. Complications were defined according to the criteria reported before by Cotton et al. [14].

### RESULTS

#### Patients

Fifty-one patients with BII gastrojejunostomy and 11 patients with hepaticojejunostomy (with or without Roux-en-Y) were included in the study. In all patients included in the study, process had been started with standard duodenoscope and if entrance of the afferent loop was unsuccessful, neither reaching the ampulla nor enterobiliary anastomosis failed, DBE had been used for the ERCP procedure. Among the 62 patients (41 male, 21 female; mean age 61±12 years, range 31–78 years) with GI tract’s anatomy which has been alternated, the standard duodenoscope has been successfully run out to the ampulla in 30 patients (48.4%) with incomplete gastrectomy (has Billroth II, but has not R-en-Y) and cannulation has perfectly performed in 27 patients (43.5%) (Table 1). The ampullary or anastomotic orifice was covered with the tumor in 2 patients. These two patients in whom selective biliary cannulation (3.2%) failed were successfully treated with PTC and drainage. Afferent loop perforation encountered in one patient which were recognized during the procedure. Last patient treated
with PTC rendezvous method, with following it the trans-ampullary process.

ERCP using a standard duodenoscope had been unsuccessful in the remaining 31 patients (50%), failed in afferent loop entrance in 6 (9.7%), or been unsuccessful reaching the ampulla because of a long afferent loop in 8 (12.9%) or failed in reaching pancreatobiliary anastomosis who have Roux-en-Y reconstruction in 17 (27.4%) (Table 1).

**Previous types of abdominal surgery**

In total, 17 patients had undergone R-en-Y reconstruction, before (27.4%). Among all post-surgical patients who have duodenoscope failed first access to the ampulla or anatomostic orifice, 11 patients (35.5%) had hepaticojejunostomy, while 20 patients (64.5%) still had a normal papilla. The location of pancreaticojejunostomy was not specifically sought. Anatomic features of patients and indications of DBE-ERCP are summarized in Table 2.

**Attainment to ampulla and anastomotic orifice with DBE**

Totally, a median of five (3–10) DBE cycles had to be done, till the ampulla or orifice were achieved by DBE. With DBE, access to ampulla or hepaticojejunostomy could be successfully carried out in 30 of 31 patients (96.8%).

The average operation time at initial session was 92 (41–122) minutes. While, the average time necessary to reach the ampulla or orifice was 41.7 (12–73) minutes. Fluoroscopic pictures of patients with BII were taken during ERCP using by standard duodenoscope are presented in Figures 1 and 2. Fluoroscopic pictures and endoscopic views of DBE-ERCP operation are presented in Figures 3, 4 and in Figures 5, 6, respectively.

![Figure 1. Normal cholangiogram image in a patient with billroth II gastric resection (using standard side-view duodenoscope).](image-url)
Failure of DBE in access to ampulla or hepaticojejunostomy

In one patient (3.2%), despite DBE-ERCP, attainment to the biliary canalicular system could not be obtained caused by perforation developed during the DBE-ERCP. This patient referred to operation and recovered uneventfully there after that.

Interventions

The DBE arrived to the ampulla in 30 patients (96.8%) and cannulation of common bile duct have been succeeded except 3 of them (87.1%). The ampullary orifice was covered with the tumor in 1 patient. This patient in whom selective biliary cannulation (3.2%) failed were successfully treated with PTC and drainage. Afferent loop perforation encountered in one patient which were recognized during the procedure. Last two patients treated with PTC rendezvous method, with following it the trans-ampullary process.
35 DBE-ERCPs were performed in 27 patients who could not completely investigated by standard ERCP. Endoscopic treatment was successful in all 27 patients (100%) Therapeutic interventions are showed in Table 2.

Complications
A patient who had Whipple with R-en-Y for pancreatic carcinoma have been undergone to surgery, because of small bowel perforation occurred during DBE-ERCP. In one patient who underwent sphincterotomy, and stone extraction using by balloon, retroperitoneal abscess developed. He was discharged after 3 weeks hospitalization, without permanent sequelae, thanks to interventional radiology department who performed abscess drainage along with antibiotic treatment.

Cholangitis, clinically significant post-ERCP pancreatitis or bleeding were not observed in DBE-ERCP patients' group.

No patient has been observed to die in relation to DBE-ERCP. No serious complication or sequelae were detected in the remaining patients.

The overall success rate of standard ERCP increases with DBE-ERCP from 43.5% (27/62) to 87.1% (54/62) in patients who have history of small bowel surgery (BII alone, BII or hepaticojejunostomy plus Roux-en-Y) (Table 2). This increase was statistically significant (p<0.001).

DISCUSSION
ERCP is more difficult in patients with anatomically changed GI tract. The challenges about reaching to the hepatobiliary and pancreatic canalicular system in these patients by endoscopically had been described, elsewhere [3, 6, 10].

The performance of ERCP carried out by a duodenoscope, in patients with previous surgical GI tract operation, have a tendency to be very variable (Billroth II, R-en-Y restoration, pancreaticojejunostomy, up to 92%, 33%, 8%, respectively) and high complication rates had been reported [15, 16]. Besides, it is often unfeasible to carry out ERCP, in patients with very long Roux limbs due to surgery, using by a normal duodenoscope, especially if accompanied adhesions exist.

In present study, the standard duodenoscope was reached up to the papilla in 30 patients (49.2%) with Billroth II (without R-en-Y) and therapeutic ERCP was successfully done in 27 (90%) patients. Two patients (6.4%) who failed in retrograde biliary drainage were treated successfully with the PTC. Last patient treated with PTC-rendezvous method, followed by with the transampullary technique as a rescue approach in another session.

While previously reported data revealed that cannulation success of a naive ampulla in R-en-Y reconstruction was 57% [17, 18], Wright et al. [19] published that they were able to perform therapeutic ERCP procedures in all cases without any problem if the ampulla was successfully reached by standard duodenoscope (67%).

In our study, among all patients (50%) who have duodenoscope failed initial access to the papilla or orifice (afferent loop entrance, attaining the ampulla or pancreaticojejunal anastomosis, 9.7%, 12.9% or 27.4% of the patients, respectively), DBE-ERCP proceeded towards near to the ampulla in thirty patients (96.7%) and therapeutic DBE-ERCP has been made possible in twenty-seven (87.1%) patients. So, cannulation rate of choledo -cus in patients who have been reached by DBE to the papilla or ostium, was high.

DBE is really labor and time-consuming procedure. However, as demonstrated in present study, this technique can also be used in patients who have altered small bowel. Thanks for DBE, when it has used with correct way, in most of time, anastomotic orifice or ampulla could be accessed and optimally detected visually. Our results are consistent with the other published data regarding double-balloon enteroscopy in the literature [3, 15, 16, 20].

Aabakken and his collegues described that the mean time to arrive the last point of the Roux limb was 40
(5–120) minutes [3]. These results were similar to ours (41.7 (12–73). In our patients in whom therapeutic actions were attempted, DBE-ERCP was successful in 87.1% (27/27) of cases.

ERCP for patients who have GI tract as reorganized anatomy with R-en-Y is accompanied with a high incidence of several complications such as perforation, and with technical difficulties. The total complication, perforation, and mortality ratios reported as 8–13%, 0.6–11%, and 1%, respectively [2, 21]. Most of these complications have been occurred in patients who have undergone B II gastrojejunostomy when performing ERCP by standard duodenoscope, and those are due to the angled afferent loop and over-pushing of the scope. Using by DBE, compression on the small intestine wall and sharp angulation of the anastomosis could be prevented and the enteroscope can be advanced more deeply caused for decreasing complications of standard ERCP technique, like perforation.

In a comparative study have published by Kim et al, authors showed that standard duodenoscope caused for markedly more bowel perforations in patients with BII compared to forward-viewing endoscope [22]. But we preferred to usage a standard side-viewing scope firstly, which allowed the operators to view the ampulla by staying in front of it, and we taken control of accessories much easier throughout the procedure, in this way. In our series, small bowel perforation occurred in one patient with Whipple, R-en-Y during DBE-ERCP and in another patient with cholecodolithiasis during standard ERCP. And these patients underwent to the surgery.

In case of failed ERCP in patients who have altered small bowel anatomy, as a nonsurgical option, was to perform PTC for biliary drainage, in the period of double balloon enteroscopy (DBE) nonexist. PTC is a logical choice for patients who are not suitable for surgery, although, it has some difficulties for patients who have not a dilated intrahepatic biliary canal or those have ascites. Moreover, it is contraindicated in patients who have tense ascites and coagulation defects [23]. Furthermore, PTC is not a good option for patients who have disorders of pancreas [11]. In these cases, DBE might be a unique management modality. The success rate, varies between 64% and 100% in the literature for reaching the ampulla or the bilio-enteric anastomosis, shows that it can be used for diagnostic and therapeutic ERCP in this population [3, 24–27].

Moreover, we know that PTC goes with more morbidity and mortality when it compares to the routine endoscopic process [28–31]. The risk of complications during DBE-ERCP seems to be lower than that of PTC procedures, which is around 5%, while therapeutic actions (balloon dilatation, biliary stent installation, or biliary stone therapy) have been performed successfully [30]. Thus, DBE-ERCP has important capacity to manage benign or malignant hepatobiliary and ampullary pathologies, even in patients who have history of small bowel surgery, and it can help to decrease the count of percutaneous procedures [3, 32, 33]. Our study confirms that successful DBE-ERCP with biliary drainage process caused for considerable decrease of cholestasis or cholangitis in 27 patients (87.1%). So, It has been possible to avoid of PTC in these 27 patients.

There are publications in the literature indicating that the naive ampulla or bilioenteric ostium might not been found even if the target point is reached with DBE [26, 27]. We used the transparent cap in all procedures, because it had been said that it may be aid to localize ampulla or bilioenteric orifice, exactly. Thus, we did not have any patient whom we could not find out his/her ampulla or bilioenteric ostium may be due to this effect of the cap we used.

In case of the DBE-ERCP collapsed because of ampulla or ostium has completely covered by tumor, this problem could be managed by performing PTC followed by DBE-rendezvous procedure. After input of the percutaneous catheter inside of the small bowel throughout the ampulla, this percutaneous cannula was successfully altered in two patients to internal cannula entered via DBE.

In total 17 patients who have R-en-Y reconstruction underwent 20 ERCP sessions with DBE. Diagnosis was obtained successfully in 15 of 17 cases (88.2%) (1 perforation and 1 cannulation failure) while therapeutic interventions have been able to success in all of these 15 cases. Our findings show that successful cholangiography and management can be achieved by DBE-ERCP in these patients as in compatible with the literature [3, 12, 20, 27].

In our point of view, cannulation and visualization of biliary tree with DBE in patients with a hepaticojejunostomy can be performed more easily with a CRE balloon. This method is similar to the conventional papillotomy technique in patients with normal anatomy and seems to be less dangerous [27, 33]. CRE balloons are marketing in different diameters and in time of our study 5-8 Fr prostheses had been used which can be advanced throughout the 2.8 mm in diameter working channel of the therapeutic DBE.
In our study, total success rates of duodenoscopic ERCP and DBE-ERCP in patients have anatomically altered GI tract was 43.5% and 87.1%, respectively. It is clear that the use of DBE-ERCP increases ERCP success.

Due to the increase in the number of patients undergoing biliary surgery and prolongation of life, DBE has become increasingly used for ERCP. Although it is less invasive and safer than surgery or PTC, it is effective in this group of patients [34, 35]. Our study results showed that this method can be used successfully and safely for the diagnosis and treatment of hepatobiliary system pathologies despite the complicated anatomy due to surgery in individuals who have undergone GI tract operation. Moreover, this results also points out that it is feasible to perform rendezvous technique using DBE in patients with PTC, although performed in just two patients at our reference center, as mentioned before.

On the other hand, the current new version of DBE has a new air pump system, and working channel 3.2 mm in wide, may be much more efficient in terms of performing ERCP procedure, easily [36]. Besides, another new version which shorter than normal version, which can be used with standard ERCP accessories, now available, also [37]. These two new DBE systems are needed to evaluate in terms of DBE-ERCP procedure’s overall success rate and feasibility. Such a study is still being carried out by our clinic.

We believe that our paper is important because this is the one of very few series that investigate impact of DBE-ERCP in patients who have alternate GI system in Turkey. But, our study has also some limitations. It was single-centered and performed with relatively few patients, as in other studies on this subject. This may be problematic with respect to generalization of the study results. Performing it as a retrospective style creates a bias risk and raises the possibility of evaluation problem arising from the study design. However, we believe that be evaluating the data collected prospectively was reduced this negativity. On the other hand, current study has not designed to assess of DBE-ERCP’s effect on the quality of life and clinical status of patients during follow-up period. Given the lack of evaluating of long-term follow up in patients, it can be speculated that the definitive efficacy of therapeutic DBE-ERCP is unclear. Patients included in this analysis have been done in a varied cohort of patients who have had several forms of surgical operation. Therefore, there might be heterogeneity among patients in terms of procedural accomplishment ratios.

Conclusion
DBE-ERCP can be used in patients who have anatomically altered GI tract (Hepaticojejunostomy or BII gastrojejunostomy plus Roux-en-Y) after be failed entering to afferent loop or reaching the ampulla either biliary-pancreatic enteroanastomosis using the standard duodenscope. This unique technique is a useful, secure and efficient procedure in patients with complicated anatomy secondary to previous surgery, permitting diagnostic and therapeutic actions. DBE-ERCP maximizes the total success ratio of ERCP in these patients, although complications can occur even in skilled and experienced hands.

REFERENCES
Sirin et al., Double balloon enteroscopy improves ERCP success