

ORIGINAL ARTICLE

Comparison of Conventional vs. Modified Seldinger Technique in Percutaneous Cholecystostomy and Evaluation of Procedural Efficiency and Safety

Perkütan Kolesistostomide Konvansiyonel ve Modifiye Seldinger Tekniklerinin Karşılaştırılması ve Prosedürel Etkinlik ve Güvenlik Değerlendirmesi

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ABSTRACT

Background/Aims: To assess the effectiveness and safety of a modified Seldinger technique (MST), bypassing consecutive dilatation steps, versus the conventional Seldinger technique (CST) in percutaneous cholecystostomy (PC).

Material and Methods: We conducted a retrospective cohort study at a tertiary healthcare facility in Turkey, analyzing de-identified data from January 2021 to January 2023. The study included 152 patients undergoing PC, comparing procedural times, complication rates, and pain scores between MST and CST groups. Statistical analyses included t-tests for continuous variables and chi-square tests for categorical variables, with significance set at $p < 0.05$.

Results: No significant differences were found regarding demographic, clinical, or laboratory characteristics between the CST and MST groups, indicating comparable patient profiles. The clinical efficacy rates were comparable between the CST and MST groups (85% and 88.5%, respectively; $p = 0.547$). The MST group had significantly shorter procedural time compared to the CST (4.24 ± 1.52 vs. 2.85 ± 1.31 , $p = 0.001$). Safety profiles were similar between groups ($p = 0.486$), with minor bleeding resolving spontaneously in one patient per group and no major complications observed. Pain during the CST procedure was significantly higher than in the MST group, though this difference did not persist at the 12-hour follow-up ($p = 0.01$ and 0.6 , respectively).

Conclusion: The utilization of the MST technique for PC demonstrated comparable efficacy and safety to the CST. However, MST was found to be associated with a lower incidence of complications related to the procedure, and required less time to perform, when compared to the CST.

Keywords: Bypass, percutaneous cholecystostomy, Seldinger technique

ÖZ

Amaç: Modifiye Seldinger tekniğinin (MST) ardışık dilatasyon aşamalarını atlayarak perkütan kolesistostomi (PC) üzerindeki etkinliği ve güvenliğini konvansiyonel Seldinger tekniği (CST) ile karşılaştırmak.

Materyal ve Yöntem: Türkiye'deki bir üçüncü basamak sağlık merkezinde retrospektif bir kohort çalışması gerçekleştirildi ve Ocak 2021 ile Ocak 2023 arasındaki anonimleştirilmiş verileri analiz ettik. Çalışmaya PC uygulanan 152 hasta dahil edildi ve MST ile CST grupları arasında işlem süreleri, komplikasyon oranları ve ağrı skorları karşılaştırıldı. İstatistiksel analizlerde sürekli değişkenler için t-testleri, kategorik değişkenler için ki-kare testleri kullanıldı ve anlamlılık düzeyi $p < 0.05$ olarak belirlendi.

Bulgular: CST ve MST grupları arasında demografik, klinik veya laboratuvar özellikleri açısından anlamlı bir fark bulunmadı, bu da hasta profillerinin benzer olduğunu gösterdi. Klinik etkinlik oranları CST ve MST grupları arasında benzerdi (%85 ve %88,5; $p = 0,547$). MST grubunda işlem süresi CST'ye kıyasla anlamlı derecede daha kısaydı ($4,24 \pm 1,52$ dakikaya karşı $2,85 \pm 1,31$ dakika, $p = 0,001$). Güvenlik profilleri gruplar arasında benzerdi ($p = 0,486$); her iki grupta birer hastada görülen hafif kanama kendiliğinden düzeldi ve ciddi bir komplikasyon gözlenmedi. CST prosedürü sırasında MST grubuna göre ağrı anlamlı derecede daha yüksekti, ancak bu fark 12 saatlik takipte ortadan kalktı ($p = 0,01$ ve $0,6$, sırasıyla).

Sonuç: PC için MST tekniğinin etkinlik ve güvenliğinin CST ile karşılaştırılabilir olduğu gösterilmiştir. Ancak, MST'nin prosedüre bağlı komplikasyonlarının daha düşük görülmesi ve daha kısa sürede tamamlanması ile ilişkilendirildiği bulunmuştur.

Anahtar Kelimeler: Baypas, perkütan kolesistostomi, Seldinger tekniği

Introduction

Acute cholecystitis (AC) is an inflammatory condition of the gallbladder that poses significant risks for morbidity and mortality (1). It is a frequently encountered emergency admission in surgical practice. The majority of AC cases, over 90%, are linked to gallstones and cholecystectomy is the established and widely accepted treatment for circumstances where the

patient is deemed suitable for surgery (2).

Early laparoscopic cholecystectomy is a safe and cost-effective method for AC treatment (3). However, emergency cholecystectomy mortality rates might reach 30% for patients with major comorbidities (4, 5). Therefore, high-risk patients may benefit from nonoperative treatment with systemic antibiotics,

either with or without decompression, to prevent perioperative morbidity (6).

Percutaneous cholecystostomy (PC) is a minimally invasive procedure that aims to decompress the gallbladder by draining. This method helps prevent the gallbladder from perforating and developing sepsis. PC can be used as an interim measure before surgery until the inflammation has reduced. However, it has also been proposed as a permanent treatment for AC in patients who are not suitable for surgery or for most patients with acute acalculous cholecystitis (2).

PC can be carried out utilizing the Seldinger technique, which has notable benefits and drawbacks. The Seldinger procedure is widely regarded as safe due to the use of a small-caliber 21-gauge needle for the first entry. This needle creates a little defect, hence minimizing the risk of harm to surrounding structures, particularly the liver and bowel, in the event of an accidental puncture. Although the treatment may typically be done with the help of ultrasound (US) to save time, many European institutions opt to complete the remaining phases of the process, consecutive dilations, with fluoroscopic guidance in the angiography suite for enhanced safety. However, while doing consecutive dilations bile leakage and peritonism may occur. Also, more post-interventional pain could be seen due to the nature of the CST (7).

To prevent bile leakage and peritonism and reduce post-operative pain, we propose a modification by bypassing the consecutive dilatation step and inserting the catheter directly through the guidewire to the gallbladder for the Seldinger technique. Therefore, we aimed to compare the efficacy and safety of the modified and conventional Seldinger technique in the paper.

Material and Methods

Study design

This retrospective analysis was conducted to include patients who underwent PC at a tertiary university hospital. The study was conducted in compliance with the Declaration of Helsinki. After obtaining approval from the institutional board, informed consent was acquired from all patients following a thorough explanation of the risks and advantages associated with the treatment.

Study sample

The study included all patients who underwent PC within 24 months from January 1st, 2021, to January 1st, 2023. The diagnosis of AC was made by considering the patient's medical history, clinical symptoms, and

signs (including fever, pain in the upper right quadrant, and the presence of Murphy's sign), as well as the results of laboratory tests (such as elevated levels of inflammatory markers like C-reactive protein (CRP), white blood cell count (WBC), and bilirubin levels), and imaging findings from ultrasound (US) or computed tomography (CT) scans. Both US and CT scans were consistently conducted to verify the suspected diagnosis and aid in the planning of the intervention.

The indications for PC were determined through a collaborative decision-making process involving surgeons and interventional radiologists. The study collected data on the basic demographic characteristics of the participants, as well as their comorbidities such as cardiac diseases, and malignancies. The presence of gallstones, potential gallbladder perforation at the time of diagnosis, and the possible coexistence of ascites were also recorded. Additionally, information on the imaging method used for diagnosis assessment, procedural details, and follow-up information was documented.

All patients in need of PC, regardless of the underlying cause, were eligible to be included in the study. Patients who had an international normalized ratio (INR) value below 2 and a platelet count of 50,000 cells/mm³ or greater were included in the study. Coagulation disorders that could not be corrected before the procedure (patients with an INR >2 or platelet count <50,000 cells/mm³) and patients with prior PC, gallbladder surgery, or other invasive gallbladder procedures were excluded from the study. Requisite actions, such as transfusions before the procedure, were carried out to rectify any abnormalities in the coagulation profile if needed. Nevertheless, PC was administered to patients suffering from acute sepsis, even when the aforementioned targets could not be reached even after receiving proper therapy.

Procedure

Before the procedure, all patients were administered antibiotic prophylaxis (ceftriaxone of 1000 mg) as determined by the attending physician. Two interventional radiologists, each possessing over two years of expertise in conducting the US-guided Seldinger method for PC, carried out the procedures. The patient was positioned in a supine or semi-lateral posture for transhepatic, subcostal catheter placement. When appropriate, a transperitoneal approach, intercostal approach, or a combination of both techniques were utilized.

In the group following the standard Seldinger procedure, the placement of the PC catheter was carried out under the administration of local anesthetic. The initial entry was achieved under the

guidance of the US. After inserting the 21-gauge, 15-cm needle and establishing bile drainage, the gallbladder was decompressed and a sample was collected for examination. Thereafter, a small amount of contrast medium (maximum 2 mL) was given to demonstrate the gallbladder and help position the guidewire (a 0.035-inch stiff guidewire (Amplatz Super Stiff Guidewire, Boston Scientific), as described in a previous study (8)). Thereafter, over-the-wire dilations were carried out using a 6 and 8-French dilator, and an 8-French pigtail catheter was placed over the wire with the aid of continuous fluoroscopic guidance. However, in the MST group, we omitted the dilatation phase and instead placed the pigtail directly using the guidewire. Technical success was defined as the confirmation of catheter placement into the gallbladder through imaging verification, followed by the aspiration of bile (8), while clinical success was determined by the steady decline of indicators such as signs, symptoms, and increased levels of inflammatory markers (9). Pain experienced during PC and at 12-h follow-up was assessed by visual analog score (0-10 points).

Statistical Analysis

Discrete variables are represented by count and percentage values, while continuous variables are represented by the median (interquartile range [the range between the 25th and 75th percentiles]) or mean (\pm standard deviation) values if they pass the normality test. The Kolmogorov-Smirnov test was employed to ascertain whether continuous data originated from normal distributions. If the variables passed the normality test, the unpaired t-test was used to determine the significance of the difference. However, for qualitative variables and continuous variables that did not fit into normal distributions, the Mann-Whitney test was used for nonparametric testing. A chi-square test of independence or Fisher's exact test was used to compare the proportions of different diagnostic methods between the two groups. The statistical analysis was conducted using the DATAtab online statistical program (DATAtab: Online Statistics Calculator. DATAtab e.U. Graz, Austria. URL <https://datatab.net>).

Results

PC was successfully conducted on all 152 patients who participated in the trial. Of them, 74 patients were in the CST group and 78 patients were in the MST group. Table 1 shows the demographics and clinical features of patients who had a PC procedure using either the CST or MST. No statistically significant differences were observed regarding sex, age, and the prevalence of diabetes mellitus, cardiac disease, hypertension, end-stage renal disease, cerebrovascular disease,

malignant disease, and calculous or acalculous cholecystitis between CST and MST groups. In addition, no statistically significant differences were observed in INR, WBC, or PLT count.

Table 1. Demographic and clinical characteristics of patients who had percutaneous cholecystostomy (PC) using either the conventional (CST) or modified Seldinger technique (MST).

Characteristic	CST (n=74)	MST (n=78)	p
Sex			
Male	37 (50)	37 (47.4)	0.081*
Female	37 (50)	41 (52.6)	
Age (years), mean \pm SD	75.16 \pm 12.56	74.91 \pm 11.84	0.126 ^a
Comorbidity			
Diabetes mellitus	32 (43.2)	33 (42.3)	0.380 ^a
Cardiac disease	21 (28.3)	25 (33.8)	0.768 ^a
Hypertension	43 (58.1)	39 (50)	0.383 ^a
End-stage renal disease	7 (9.4)	9 (11.5)	0.176 ^a
Cerebrovascular disease	24 (32.4)	26 (33.3)	0.139 ^a
Malignant disease	13 (17.5)	15 (19.2)	0.065 ^a
Cholecystitis			
Calculous	68 (92)	71 (91)	0.101 ^a
Acalculous	6 (8)	7 (9)	
Gallbladder rupture	12 (16.2)	14 (17.9)	0.083 ^a
Ascites	4 (5.4)	6 (7.6)	0.590 ^a
Diagnostic imaging technique			
US	62 (83.7)	61 (78.2)	0.430 ^a
CT	30 (40.5)	35 (44.8)	0.355 ^a
Laboratory			
INR, mean \pm SD	1.21 \pm 0.15	1.20 \pm 0.19	0.370 ^a
WBC, mean \pm SD	15.400 \pm 4410	15.850 \pm 3860	0.680 ^a
PLT, mean \pm SD	201.000 \pm 74.000	205.000 \pm 71.000	0.340 ^a

*chi-square test, a two-sample t-test, CST: Conventional Seldinger technique, CT: Computed tomography, INR: International normalized ratio, MST: Modified Seldinger technique, PC: Percutaneous cholecystostomy, PLT: Platelet, SD: Standard deviation, US: Ultrasound, WBC: White blood cell

Technical success was 100% for both groups and no need for a second effort to puncture was required in both groups. The average procedure time was significantly shorter in the MST group compared to the CST group (2.85 \pm 1.31 vs. 4.24 \pm 1.52 minutes; p=0.001). The CST group exhibited a higher incidence of procedure-related complications compared to the MST group (p=0.486). Within the CST group, one patient had minor bleeding, three patients experienced a bile leak, and one patient had a gallbladder rupture. Imaging

verified all complications. There were no instances of significant bleeding observed in either research group, however, one case of minor bleeding occurred in the CST and MST groups. There were no deaths due to the procedures. All procedures in our cohort were conducted using the subcostal technique, primarily through the transhepatic route. The mean pain during the CST procedure was significantly higher than in the MST group, although at 12-h follow-up no significant difference was observed. (Table 2).

Table 2. Comparison of Procedural Details for the Use of Conventional and Modified Techniques in Percutaneous Cholecystostomy

	CST (n=74)	MST (n=78)	p
Approach			
Transhepatic	62 (83.8)	70 (89.7)	0.279*
Transperitoneal	12 (16.2)	8 (10.3)	
Duration (min), mean \pmsd	4.24 \pm 1.52	2.85 \pm 1.31	0.001 ^a
Clinically successful			
Yes	63 (85)	69 (88.5)	0.547*
No	11 (15)	9 (11.5)	
Pain score, mean \pmsd			
During procedure	4.4 \pm 1.66	3.2 \pm 1.9	0.01 ^a
At 12 h of follow-up	2.4 \pm 1.35	2.6 \pm 1.21	0.6 ^a
Complications			
Minor bleeding	1	1	1 ^b
Major bleeding	0	0	N/A
Bile leak	3	1	0.356 ^b
Abscess formation	0	0	N/A
Bowel perforation	0	0	N/A
Gallbladder rupture	1	1	1 ^b
Pneumothorax	0	0	N/A
Death	0	0	N/A

*Chi-square test, ^aT-test, ^bFischer's- exact test, N/A: Not applicable, CST: Conventional Seldinger technique, MST: Modified Seldinger technique,

The clinical success rate was comparable between the two trial groups, with 88.5% for the MST group and 85% for the CST group (p=0.547). A comparable proportion of patients in both study groups experienced mortality either during their hospital stay or within the 3-month follow-up period. Specifically, 11 out of 74 patients (14.8%) in the CST group and 14 out of 78 patients (18%) in the MST group died (p=0.666).

Discussion

The potential for morbidity and mortality of AC continues to pose a significant challenge in surgical practice, frequently requiring emergent intervention. Although cholecystectomy is the standard treatment for eligible patients, high-risk individuals may benefit

from nonoperative methods, such as PC. The objective of this investigation was to evaluate the safety and efficacy of the CST and the MST for PC. The study results demonstrate that our proposed model, which modifies the usual Seldinger procedure, achieved comparable levels of safety and efficacy. Furthermore, it resulted in a reduced number of complications and operation time, while maintaining equivalent rates of technical and clinical success.

The trocar or Seldinger technique is the primary method used to perform PC. The pigtail drainage catheters that are inserted into the gallbladder are typically 8 or 10 French in diameter, but they may be larger if necessary due to the viscosity of the contents, according to either technique. During the performance of PC using the trocar approach, the complete trocar system is inserted into the gallbladder while real-time image guidance is provided using US. The system consists of the needle, which is enclosed within the stylet, which is then covered by the pigtail drainage catheter. Once the US has verified the exact positioning of the trocar system in the gallbladder lumen, the needle is removed, and the pigtail drainage catheter is advanced over the stylet while keeping it still (10). On the other hand, the Seldinger approach involves using a smaller needle (typically 18 gauge) to gain initial access into the gallbladder lumen, with the guidance of real-time US imaging. Once the needle is confirmed to be correctly inserted into the gallbladder and bile is observed flowing through it, the contents of the gallbladder are suctioned and a sample is collected for culture and analysis. Subsequently, under the continued oversight of the US, a 0.035-inch guidewire is inserted through the needle and guided to form loops within the gallbladder. After removing the needle, the guidewire is utilized to advance pigtail drainage catheter placement with serial dilations (11). However, serial dilations can lead to bile spills and peritonism, which can prolong the procedural duration, while the trocar technique enables the entire system to be inserted into the gallbladder using US guidance in one phase, without the need for dilations and over-the-wire exchanges. This makes the trocar procedure faster and easier to perform. In this study, therefore, we drew inspiration from the Trocar technique to adapt the MST. Our hypothesis posited that circumventing serial dilations would lead to a reduction in procedure duration and complications.

In the literature, technical success rates of the Seldinger technique are aligned with our findings (95.8-100%) (7, 12, 13). Our findings indicate that both MST and CST achieved technical success in all cases, with no notable disparity. Our findings indicate that the modified technique, which skips consecutive dilation phases and directly inserts the catheter through

the guidewire, is equally effective as the traditional method in accomplishing gallbladder decompression. Furthermore, the fact that there was no requirement for a second attempt to puncture in both groups highlights the practicality and dependability of both approaches.

Reppas et al. demonstrate that the mean procedural time for the Seldinger technique in patients requiring PC was 4.88 ± 2.68 (13). Similarly, in the TROSELIC II trial, the mean time to perform PC with the Seldinger technique was 4.41 ± 2.68 . (7) Although our results align with the literature regarding the Seldinger technique (4.24 ± 1.52), the variance in procedure duration between the two techniques was one of the most significant findings of our investigation. The MST group had an average procedure time that was significantly shorter than that of the CST group (2.85 ± 1.31). This decrease in procedure time with MST can be attributed to the omission of consecutive dilatation stages, which simplifies the procedure. In our study, both CST and MST were performed under local anesthesia, which is generally well-tolerated by patients and avoids the risks associated with general anesthesia. However, it is important to note that in some centers, percutaneous cholecystostomy (PC) is performed under general anesthesia, which may increase the procedural risks, especially in high-risk patients with significant comorbidities

A key factor in assessing PC safety is procedure-related complications. While not statistically significant, our analysis revealed a tendency toward fewer problems in the MST group as opposed to the CST group. Remarkably, there was a greater frequency of complications in the CST group, including gallbladder rupture, bile leak, and mild hemorrhage which is similar to the literature (7, 12, 13). These complications highlight the possible hazards connected with the traditional method even though they were handled without major negative effects. On the other hand, the modified approach demonstrated encouraging safety outcomes; no cases of major bleeding and a lower incidence of bile leak were noted.

In a study by Arkoudis et al., the clinical success rate was 92% with the Seldinger technique for PC (7). In another study, it was 95.7% (12). Although the clinical efficacy, as measured by the remission of symptoms and inflammatory markers, was similar in both groups in our study, our results were lower compared to the literature (85-88%). This could be attributed to patient population differences, sample size, and the experience and skill of the practitioners. However, this finding implies that the modified method does not undermine the clinical results of PC. Moreover, the death rates during the hospital stay and the 3-month follow-up period were comparable across the MST

and CST groups, suggesting that the modified strategy does not pose any extra risks in terms of patient survival.

An intrinsic limitation of our study is its retrospective design, which has the potential to introduce biases and confounding factors. Furthermore, the limited sample size may restrict the applicability of our findings, and additional studies with larger groups of participants are necessary to confirm the validity of our results. Additionally, collecting data on the long-term outcomes of patients who underwent PC utilizing the improved approach beyond the first 3-month period would offer useful insights into the sustainability of these results.

Our study concludes that the MST for PC is a safe and efficient substitute for the traditional method. The updated approach eliminates the need for sequential dilatation phases, which can lower the risk of complications associated with the procedure while still achieving similar therapeutic outcomes. Further prospective studies are necessary to validate these findings and clarify the long-term advantages of the modified method in the treatment of AC.

Conflict of Interest Statement

The authors declare no conflicts of interest.

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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