의학박사 학위논문

흉부 경막외 시술을 위한 정밀하고 안전한 경막외 접근법

Accurate and secure alternative methods of epidural space access for thoracic epidural intervention

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흉부 경막외 시술을 위한
정밀하고 안전한 경막외 접근법

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이 논문을 의학박사 학위 논문으로 제출함

2021년 2월

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전공의 때부터 정말 성심성의껏 저를 가르쳐 주시고 이번 박사 논문 심사까지 맡아 주신 전인구 교수님께도 깊은 감사를 드리며 전공의부터 전임의 시절까지 저를 좋게 봐주시고 진심 어린 조언과 가르침을 주신 김영욱 교수님께도 무한한 감사의 말씀드립니다. 연구의 기초부터 계획, 어떻게 논문을 잘 쓸 수 있는지를 체계적으로 너무나 훌륭하게 지도해주신 김영국 교수님께도 진실한 감사의 인사를 드립니다. 블록을 시작할 때 아무것도 모르던 저를 포기하지 않고 열의를 다해 가르쳐 주신 이종혁 교수님께도 감사의 말씀 올리며 스승이자 동료, 친한 형님으로 앞으로도 함께 잘 지냈으면 좋겠습니다. 항상 제가 난처한 문제가 생기면 본인 일처럼 나서서 도와주고 해결해주는 박준영 선생님에게도 감사의 말씀드립니다. 전공의 시절부터 늘 도움만 받고 있고, 저의 페이스가 쳐질 때 옆에서 늘 열심히 연구하면서 페이스 메이커 역할도 해준 고맙고 친한 형님입니다. 앞으로도 함께 좋은 연구하면서 돈독한 우정을 잘 이어 나가고 싶습니다.

마지막으로 제가 서울아산병원과 인연을 맺을 수 있게끔 해주고 지금은 누구보다 든든하게 저를 지원해주는 사랑하는 저의 아내에게도 진실한 사랑과 감사의 말을 전하고, 잘 놀아주지도 못하고 얼굴도 잘 못 보여주는 아빠를 언제나 좋아해 주고 사랑해주는 태현이,

지현이 두 아들에게도 미안하고 고맙다는 말을 전하고 싶습니다. 그리고 오늘날의 제가 있게 해 주시고 늘 저의 결정을 믿고 지지해 주신 어머니와 아버지에게도 너무나 깊은 감사의 말을 전하고 싶습니다.

이 박사 논문은 많은 분의 사랑과 배려, 관심과 도움, 참여와 헌신으로 만들어졌습니다. 모든 분께 진심으로 감사의 인사를 드리며 지금의 이 박사 논문을 바탕으로 앞으로의 저의 연구가 의학의 발전에 조금이나마 도움이 될 수 있게 성실히, 꾸준히 노력하겠습니다.

2021 년 2 월 김두환

ABSTRACT

Introduction

Thoracic epidural access (TEA), including epidural block, blood patch, or catheter insertion, has been a widely used intervention to reduce chronic pain or acute postoperative pain. However, TEA has been still challenging, and may be associated with serious neurologic complications. Therefore, this study aims to find a safe, effective, and easy approach for TEA.

Methods

Three studies to find a safe, effective and easy approach for TEA were conducted. The first study was a prospective observational study to evaluate the utility of contralateral oblique (CLO) view and find the CLO view's optimal angle for TEA in the mid-thoracic region. The second study was a prospective randomized controlled study comparing CLO View with the lateral view for mid-thoracic epidural access. The third study was a prospective observational study to evaluate the accuracy of real-time ultrasound-guided thoracic epidural catheter placement (US-TECP).

Chapter I: After securing the mid-thoracic (T4–8) epidural space, fluoroscopic images were obtained. The needle tip location relative to the ventral interlaminar line (VILL), and the needle tip and laminar visualization were measured and analyzed on the CLO views at 40, 50, 60 degrees, and measured angle, and the lateral view.

Chapter II: Patients were randomly allocated to receive mid-TEA under the fluoroscopic lateral view (group L) or CLO view (group C). The primary outcome was the first attempt success rate of mid-TEA. The secondary outcomes were patient satisfaction and procedural pain intensity. Other outcomes measures included needling time, number of needle passes, number of skin punctures, final success rate, crossover trial success rate, and procedure-related complications.

Chapter III: After performing the real-time US-TECP, the fluoroscopic views were obtained. The location of epidural catheter tip and contrast dispersion were evaluated after obtaining the thoracic epidurography. The variables related to the operation such as success rate, needling time, number of needle passes, and the first attempt success rate were measured.

Results

Chapter I: A total of 30 subjects participated in this study. The needle tip was clearly visualized in all CLO views, compared with the lateral view (100% vs. 36.7%, P <0.001). The visualization of the laminar margin and the needle tip location on (or just anterior to) VILL using the CLO measured angle were significantly clearer compared with those in the CLO view at 40 and 50 degrees and the lateral view (laminar margin: 40˚, 56.7% vs. 3.3%, P <0.001; 50˚, 56.7% vs. 26.7%, P =0.012; 90˚, 56.7% vs. 26.7%, P =0.035; needle tip location: 40˚, 96.7% vs. 26.7%, P <0.001; 50˚, 96.7% vs. 63.3%, P =0.002; 90˚, 96.7% vs. 66.7%, P =0.012). There was no difference in these values between the CLO view at 60 degrees and CLO measured angle.

Chapter II: In total, 44 patients (21 patients in group L and 23 patients in group C) were included in the study. First attempt success rate was significantly higher in group C than in group L (69.6% vs. 28.6%, P=0.016). Final success rate was significantly lower in group L compared with group C (76.2% vs. 100%, P=0.044). Pain intensity scores were significantly lower in group C compared to group L, 2.2 ± 0.9 versus 3.7 ± 1.8, respectively (P = 0.002). Patient satisfaction was significantly greater in group C than in group L (6.0 [6.0 – 7.0] vs. 5.0 [4.0 – 6.0], P=0.001). During the mid-TEA, needling time and number of needles passes were significantly less in group C over group L (94.0 [84.0 – 155.0] vs. 125.0 [115.0 – 205.0], P=0.035; 1.0 (1.0 – 2.0) vs. 3.0 (1.0 – 4.0), P=0.003). There were no serious complications in both groups.

Chapter III: The thirty-eight patients participated in this study. During the real-time US-TECP, the median value of needling time was 49.0 seconds and the number of needle passes was 1.3±0.6. The first attempt success rate was 76.3%. After the assessment of thoracic epidurography, we found that the epidural catheter tips were positioned all in the epidural space and epidural catheter tip was almost located on the between T9 and T10 (84.2%). The evaluation of contrast dispersion showed that the cranial and caudal of contrast spread was 5.4±1.6 and 2.6±1.0 level of a vertebral body, respectively after injection of 4 ml of contrast medium. There were no complications related to the procedure.

Conclusion

In the mid-thoracic region, a CLO view at 60 degrees and obliquity measured based on magnetic resonance imaging (MRI) or computed tomography (CT) may be optimal angle for fluoroscopic guided TEA, can provide clearer visualization of laminar margin and needle tip, and more consistent needle tip location than the lateral view. Without available CT or MRI images, the use of CLO view at 60 degrees can increase the success rate and patient satisfaction, reduce procedural time and patient discomfort, and provide the possibility of guaranteeing the safety when performing mid-TEA. In the low-thoracic region, real-time US-TECP showed a complete success rate, suggesting that real-time ultrasound guidance may be useful for TECP with an increased success rate, reduced patient discomfort, and no radiation hazard. Therefore, the present results recommend that the fluoroscopic CLO view at 60 degrees and real-time US guidance may be primary considered for achieving the safe, effective, and easy TEA.

Key words: Catheter placement; chronic pain; contralateral oblique view; epidural access; epidural analgesia; fluoroscopy; lateral view; low-thoracic; mid-thoracic; ultrasonography

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BACKGROUND AND GENERAL INTRODUCTION

Thoracic epidural access (TEA) is necessary for therapeutic spine interventions or thoracic epidural analgesia to reduce chronic pain or acute postoperative pain.[1-3] Proper execution requires accurate identification of the target epidural space and surrounding anatomical structures.[4] The thoracic vertebrae have unique anatomical properties compare to cervical or lumbar vertebrae; The longer, steeper, and over-lapping spinous processes make the interlaminar spaces of thoracic spine narrow and difficult to access, making the epidural space access in the thoracic region technically challenging. In addition, these properties are more prominent in the mid-thoracic region (T4-8),[5, 6] thus, the mid-thoracic region is known to be the most difficult area from which to approach the epidural space.[7]

Given the anatomical difficulty of TEA, the use of fluoroscopic anteroposterior (AP) and the lateral view has been standard practice for therapeutic spine interventions.[8] However, AP and lateral fluoroscopic views cannot accurately assess the depth of the needle tip in relation to the epidural space and discriminate between true and false LOR,[9] major spinal cord injury continues to occur, even with the use of fluoroscopy.[10] Thus, more recent attention has been directed toward using a contralateral oblique (CLO) view for therapeutic spine interventions.[11, 12] However, compared to cervical or lumbar region, the researches of the CLO view in the thoracic region is lack and optimal degree of CLO view for the mid-TEA is unknown. Ultrasound-guided TEA has been also recently introduced to improve the accuracy of thoracic epidural catheter placement (TECP).[13, 14] Although ultrasound-guided TECP (US-TECP) showed the possibility of successful achievement of TECP, its evidence is weak. Besides, technical description, accuracy, and clinical performance of real-time US-TECP require further elucidation.

Therefore, this study aims to find an accurate and secure alternative approach for TEA using the fluoroscopic CLO view and real-time US guidance. Specifically, the objectives of the present thesis were followings; 1) to identify the optimal angle of CLO view in mid-thoracic region, 2) to evaluate

the clinical usefulness of the determined CLO view in mid-thoracic region, 3) to access the success rate of real-time US-TECP using fluoroscopy.

CHAPTER I

Determination of Optimal degrees for Contralateral Oblique View in Mid-Thoracic Epidural Access:

A Prospective Observational Study

INTRODUCTION

A thoracic epidural access (TEA) including epidural block, blood patch, or catheter insertion has been a widely used intervention to reduce chronic pain or acute postoperative pain after chest and upper abdominal surgery [1-3]. Accuracy in TEA is needed in order to achieve success in these procedures [15]. However, TEA is known to be relatively difficult, compared with cervical or lumbar epidural access, as the spinous process of the thoracic vertebrae is longer and steeper, the epidural space is smaller due to an acute angle, and the distance between the skin and the epidural space is longer [16]. These properties are more prominent in the mid-thoracic region (T4-8) [5, 6]. According to the evidence available, failure rates of TEA can be up to 32% [15], which increase at the mid-thoracic region [17]. Previous studies have demonstrated that the mid-thoracic region is the most difficult area from which to approach the epidural space [5, 7].

Although the use of fluoroscopy improves accuracy of TEA [18], this technique still has significant drawbacks, such as false loss of resistance (LOR) and difficulty in assessing the depth of the needle tip in lateral views in relation to the epidural space [9]. To overcome this issue, TEA using the contralateral oblique (CLO) view was introduced [19].

The CLO is the angle in which the X-ray beam runs parallel to the slope of the target lamina. It can be obtained by first identifying the target lamina to which the needle tip is related and then focusing the image intensifier away in an oblique contralateral direction from the lamina [12]. The advantages and optimal angle of CLO view in the cervical or lumbar have been systematically and specifically studied [11, 20-22]; however, the use of the CLO view in the mid-thoracic region has not yet been investigated. Therefore, this study was designed to compare needle tip and lamina visualization in the lateral fluoroscopic view with several CLO views at different angles when accessing the mid-thoracic epidural space. In addition, we investigated the optimal angles in the CLO fluoroscopic view to identify the most reliable needle tip location to access the mid-thoracic epidural space.

METHODS

Study design and participants

This prospective observational study was conducted at the Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea from February 2019 to October 2019. This study was approved by the institutional review board of the Asan Medical Center (2018-1551) and was registered at ClinicalTrials.gov (number of registration: NCT03789955) on December 31, 2018. Participants were enrolled from February 22, 2019 to November 7, 2019. Written informed consent was obtained from each participant before inclusion in this study. All patients scheduled for mid-thoracic (T4-T8) epidural block, blood patch, and catheter insertion were assessed for eligibility. Patients were included if they were aged 20–79 years and available for thoracic magnetic resonance imaging (MRI) or computed tomography (CT). Patients were excluded if they had an allergy to local anesthetics and contrast dye or steroids, infection at the insertion site, neurological or psychiatric disorders, or prior spine instrumentation. Patients who were pregnant, had coagulopathy, or had used anticoagulants or antiplatelet medication, were also excluded.

Thoracic epidural access protocol

No sedatives were administered before the intervention. Patients were placed on an operating table with a pillow to optimize prone positioning and were monitored with noninvasive blood pressure, pulse oximetry, and 3-lead electrocardiogram. Fluoroscopy (Ziehm Vision RFD, Ziehm, Nuremburg, Germany) was employed to identify the thoracic vertebrae level. An insertion site ranging from T4 to T8 was selected and sterilized. According to a previous study,[5] the needle entry point was determined to be at the junction between the midline of the pedicle paralleled to the midline of the inferior vertebral body (IVB) to the target interlaminar space and the lower border of IVB on an anteroposterior (AP) fluoroscopic view (Fig. 1-1).

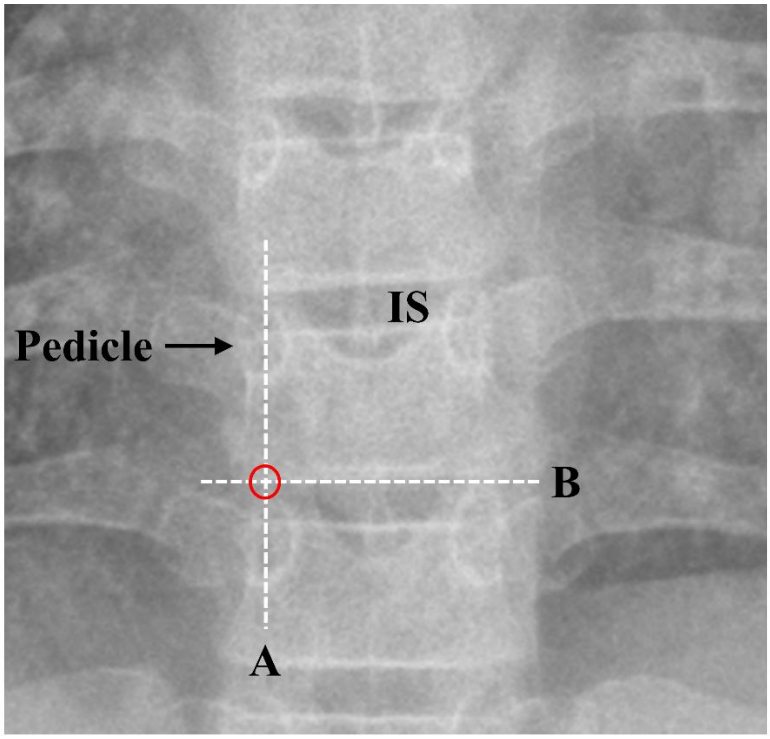

Figure 1-1. The needle entry point on an anteroposterior fluoroscopic view with the Nagaro's method. IS, target interlaminar space; A, midline of the pedicle paralleled to the midline of the inferior vertebral body (IVB); B, lower end plate of IVB. Red circle is the junction between A and B line, which indicates the needle entry point.

The AP fluoroscopic view was set to line up with the plane of the lower endplate of IVB. A 22-gauge Tuohy needle (Green Medical Supply Co., Seoul, Korea) or 18-gauge Tuohy needle (Perifix, B. Braun Melsungen AG, Melsungen, Germany) was used to access the epidural space. After local infiltration with 1% lidocaine, the Tuohy needle was advanced with an angle of approximately 10–15 degrees medially until it reached halfway through the vertebrae body. Then, fluoroscopy was used to obtain the CLO measured angle and it was subsequently advanced further until it was located in the epidural space using a LOR-to-air technique. The CLO measured angle was previously determined by measuring the angle of the superior lamina with the midsagittal plane on MRI or CT before the procedure. Picture archiving and communication system (PACS) in Asan Medical Center (PetaVision, version 3.1, Seoul, Korea) was used to measure the angle on the axial image at the cut where the lamina, pedicle, and the spinous process were well visualized. Based on the midpoint between the two pedicles, a first line was drawn from this point, to pass through the exact midline of the spinous process. A second line was drawn parallel to the ventral lamina through the middle. Subsequently, the angle between the two lines was calculated. Once LOR was achieved, six fluoroscopic views were obtained: AP, CLO at 40 degrees, 50 degrees, 60 degrees, the measured angle, and lateral views (Fig. 1-2). Correct epidural access was confirmed by the injection of contrast medium (Omnipaque 300, GE Healthcare, Little Chalfont, UK) in AP, multiple CLO views, and lateral views (Fig. 1-2). The procedure was performed by two physicians with more than 10 years of experience in TEA following identical protocols.

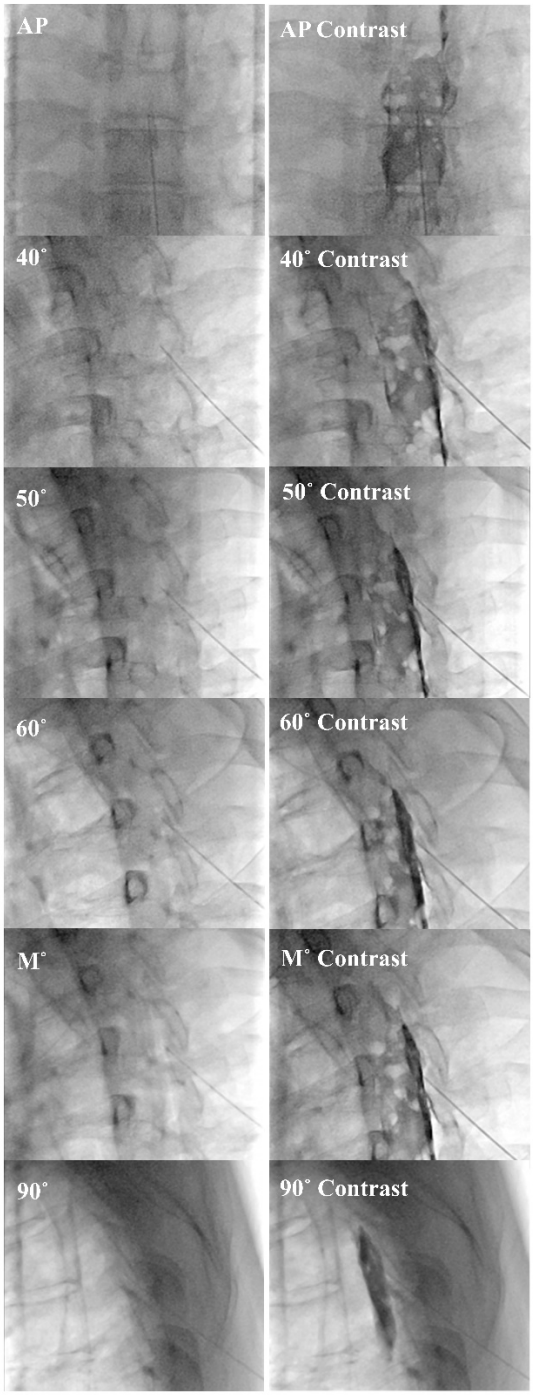

Figure 1-2. After accessing the mid-thoracic epidural space, 12 images were obtained at six different angles before and after the contrast medium injection. AP: anteroposterior view; 40°, 50°, and 60°: each angle of the contralateral oblique view; M°: measured angle of the contralateral oblique view; 90°: lateral view; AP−90°: AP, multiple angles of contralateral oblique view, and lateral view after contrast medium administration.

Fluoroscopic finding review and outcome measurement

All fluoroscopic images obtained were reviewed by three investigators who did not participate in the procedure. In the CLO and lateral views, each grade and location of the needle tip and laminar visualization were defined from prior studies with some modifications [11, 20]. Needle tip visualization was categorized as Grade 1 (clearly visualized without ambiguity), Grade 2 (poorly visualized or visualized with effort), or Grade 3 (indicated nearly not or not visualized). Laminar margin visualization was also categorized as Grade 1 (clearly visualized with complete demarcated laminar), Grade 2 (fairly visualized with incomplete demarcated laminar), Grade 3 (poorly visualized with incomplete demarcated laminar), or Grade 4 (nearly not or not visualized with incomplete demarcated lamina) (Fig. 1-3). The ventral interlaminar line (VILL) refers to an imaginary line connecting the ventral laminar margins. Location of the needle tip in the CLO and lateral views was defined as: Grade –2 (significantly posterior to VILL), Grade –1 (just posterior to VILL), Grade 0 (on VILL), Grade +1 (just anterior to VILL), Grade +2 (significantly anterior to VILL), and Grade U (undetermined grade; needle tip location was not able to be evaluated due to lack of visualization) (Fig. 1-4). A grade of visualization and location of needle tip, and laminar visualization were determined by consensus among three investigators.

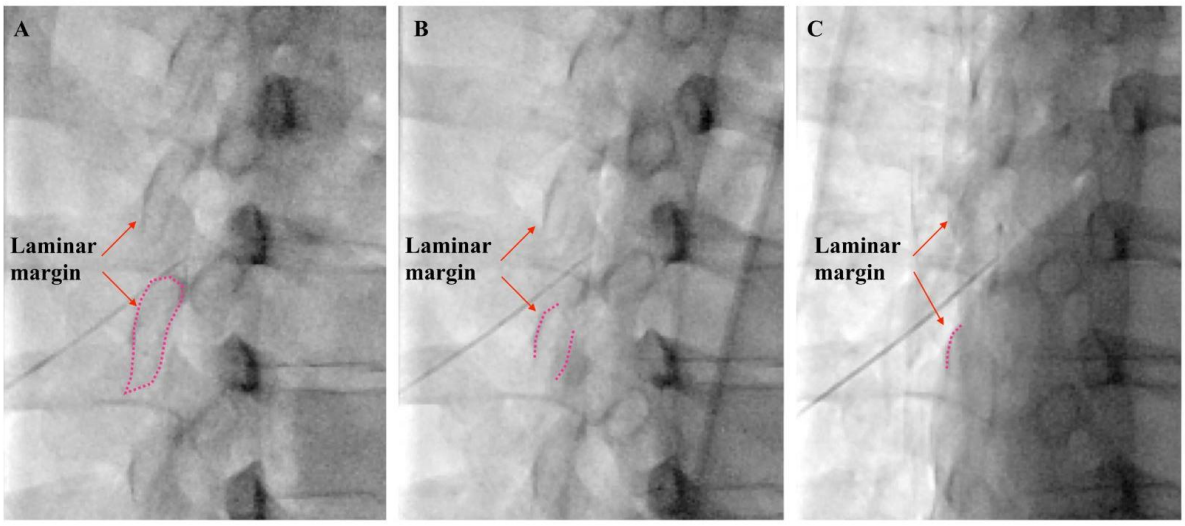

Figure 1-3. Grades of visualization of the laminar margins in the contralateral oblique view. A: Grade 1, clearly visualized with complete demarcated lamina; B: Grade 2, fairly visualized with incomplete demarcated lamina; C: Grade 3, poorly visualized with incomplete demarcated lamina.

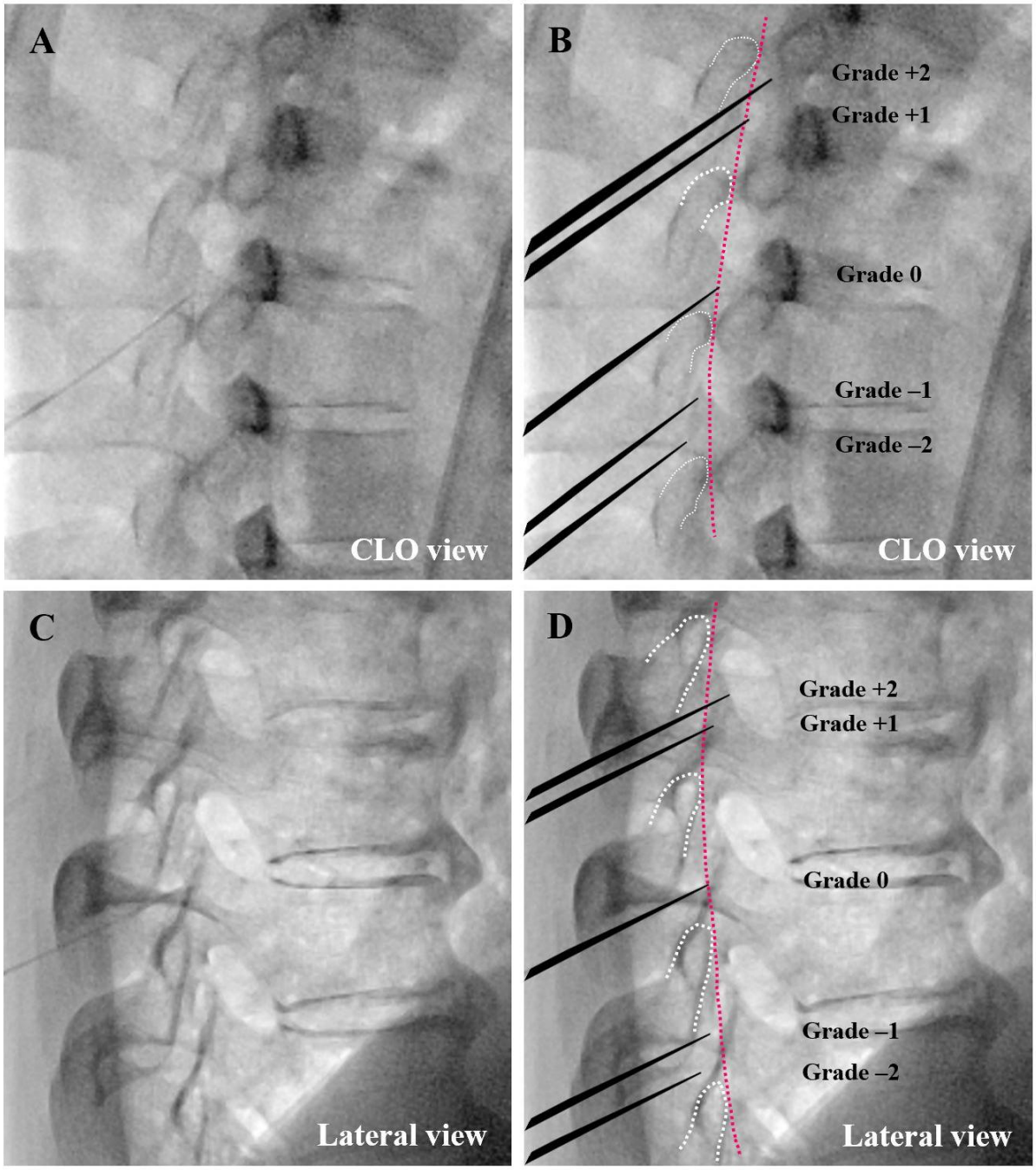

Figure 1-4. Original fluoroscopic and schematic views for describing the grade of needle tip location in the contralateral oblique view (A and B) and lateral views (C and D). White dot lines indicate the laminar margin. Red dot lines indicate the ventral interlaminar line (VILL). Grade –2, significantly posterior to VILL; Grade –1, just posterior to VILL; Grade 0, on VILL; Grade +1, just anterior to VILL; Grade +2, significantly anterior to VILL.

Statistical analysis

The sample size was based on a previous study [11] and limited to reduce radiation exposure of participants. Data are expressed as mean ± standard deviation, median (interquartile range), and number (proportion), as appropriate. The McNemar test was used to compare the needle tip size and lamina visualization, and needle tip location in the multiple CLO views and lateral view. Multiple groups were divided into Grade 1 and other grades (e.g., Grade 1 vs. Grade 2 plus Grade 3). We considered the location of the needle tip on the VILL or just anterior to the VILL to be ideal for safe and structured TEA. Hence, in the analysis of needle tip location, we compared Grade 0 plus Grade +1 and other grades (Grade –2, –1, +2, and U). Statistical significance was set at a P value of < 0.05.

RESULTS

Patient and procedural characteristics

A total of 30 patients were enrolled in this study. There were no excluded patients. Mean age was 57.2 ± 16.4 years, with 50.0% being male (Table 1-1). In our cohort, postherpetic neuralgia and intercostal neuralgia (23.3% and 20%) were the most common reasons to perform TEA. The mid-TEA was conducted at the interlaminar spaces of T4−5 (20%), T5−6 (20%), T6−7 (26.7%), and T7−8 (33.3%). The median value of CLO angle measured from T4−5 to T7−8 ranged from 54.0 degrees to 63.5 degrees. The mean and standard deviation of CLO angle measured from the whole mid-thoracic region was 58.8 ± 5.5 degrees. The CLO measured angle seemed to gradually increase, corresponding to decreasing thoracic vertebra level in the mid-thoracic region. All needle tips were successfully placed in the epidural space, which was confirmed by contrast dispersion on AP, lateral, and various oblique views.

Table 1-1. Patient characteristics

Demographics	Total patients (n=30)
Age (years)	57.2±16.4
Gender (Male), n (%),	15 (50)/ 15 (50)
Body mass index (kg/m^2)	24.1±3.8
Underlying diseases	
Chronic post-thoracotomy pain	3 (10.0)
Postherpetic neuralgia	7 (23.3)
Intercostal neuralgia	6 (20.0)
Cancer pain	5 (16.7)
Spontaneous intracranial hypotension	5 (16.7)
Compression fracture	4 (13.3)
Target level/CLO angle measured	
T4−5	6 (20.0)/ 54.0 (50.0–56.0)
T5−6	6 (20.0)/ 59.0 (55.0–62.0)
T6−7	8 (26.7)/ 58.0 (54.5–63.0)
T7−8	10 (33.3)/ 63.5 (61.0–65.0)

CLO angle measured, contralateral oblique angle measured based on imaging modalities; Data are expressed as number (%) or median (interquartile range).

Visualization of needle tip

The needle tip in all CLO views was clearly visualized without ambiguity (i.e. Grade 1) compared with that in the lateral view (100% vs. 36.7%, P<0.001, in Grade 1 vs. Grade 2 plus Grade 3, respectively) (Table 1-2). In the lateral view, sixteen (53.3%) and three (10.0%) needle tips were categorized to Grade 2 and Grade 3, respectively. The visualization of needle tips in Grade 2 and 3 were not observed in all CLO views.

Table 1-2. Comparison of needle tip visualization in various degree of contralateral oblique views compared to that in the lateral view

	CLO view, n (%)				Lateral view
	40 degree	50 degree	60 degree	Measured	90 degree
Grade 1	30 (100)*	30 (100)*	30 (100)*	30 (100)*	11 (36.7)
Grade 2	0 (0)	0 (0)	0 (0)	0 (0)	16 (53.3)
Grade 3	0 (0)	0 (0)	0 (0)	0 (0)	3 (10.0)

CLO, contralateral oblique; Measured, angle measured based on imaging modalities; Grade 1, clearly visualized without ambiguity; Grade 2, poorly visualized or visualized with effort; Grade 3, nearly not or not visualized. *P<0.001 compared with the lateral view (grade 1 vs. entire other grades).

Visualization of laminar margin

The visualization of the laminar margin using the CLO measured angle was significantly clearer (Grade 1) compared with that in the CLO view at 40 and 50 degrees and the lateral view. (40˚, 56.7% vs. 3.3%, P<0.001; 50˚, 56.7% vs. 26.7%, P=0.012; 90˚, 56.7% vs. 26.7%, P=0.035 in Grade 1) (Table 1-3). There was no difference in the visualization of the laminar margins between the CLO view at 60 degrees and CLO measured angle (63.3% vs. 56.7%, P=0.688); 23.3% of cases in the lateral view were visualized in Grade 3 and 4 but none in the CLO view at 60 degrees and CLO measured angle view.

Table 1-3. Comparison of laminar margin visualization in various degree of contralateral oblique views compared to that in the lateral view

	CLO view, n (%)				Lateral view
	40 degree	50 degree	60 degree	Measured	90 degree
Grade 1	1 (3.3)**	8 (26.7)*	19 (63.3)†	17 (56.7)	8 (26.7)*
Grade 2	20 (66.7)	21 (70.0)	11 (36.7)	13 (43.3)	15 (50.0)
Grade 3	9 (30.0)	1 (3.3)	0 (0)	0 (0)	3 (10.0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)	4 (13.3)

Measured, angle measured based on imaging modalities; Grade 1, clearly visualized with complete demarcated lamina; Grade 2, fairly visualized with incomplete demarcated lamina; Grade 3, poorly visualized with incomplete demarcated lamina; Grade 4, nearly not or not visualized with incomplete demarcated lamina. *$P<0.05$, ** $P<0.001$, and $^{\dagger}P=0.688$ compared with CLO view at measured (grade 1 vs. entire other grades).

Location of needle tip

Table 1-4 showed needle tips location in various degrees of contralateral oblique views and in the lateral view. The needle tips which were located on the VILL (Grade 0) or just anterior to the VILL (Grade +1) were significantly more frequently seen in the CLO measured angle view, compared with the CLO views at 40 and 50 degrees, and the lateral view (40˚, 96.7% vs. 26.7%, P<0.001; 50˚, 96.7% vs. 63.3%, P=0.002; 90˚, 96.7% vs. 66.7%, P=0.012 in Grade 0 and 1; Figure 1-5). No difference was noted between the CLO view at 60 degrees and CLO measured angle (96.7% vs. 96.7%, P>0.999). In the CLO view, needle tips were all located on the VILL or just anterior at the VILL and were closer to the VILL as the angle of the CLO view increased. In contrast, in the lateral view, 16.7% of needle tips were located posterior to the VILL and the needle tip locations were not evaluated in 13.3% of cases lack of visualization of the laminar margin and needle tip.

Table 1-4. Comparison of needle tips location in various degree of contralateral oblique views compared to that in the lateral view

Grade	CLO view, n (%)				Lateral view
	40 degree***	50 degree**	60 degree†	Measured	90 degree*
–2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
–1	0 (0)	0 (0)	0 (0)	0 (0)	5 (16.7)
0	0 (0)	4 (13.3)	19 (63.4)	16 (53.4)	11 (36.7)
+1	8 (26.7)	15 (50.0)	10 (33.3)	13 (43.3)	9 (30.0)
+2	22 (73.3)	11 (36.7)	1 (3.3)	1 (3.3)	1 (3.3)
U	0 (0)	0 (0)	0 (0)	0 (0)	4 (13.3)

CLO, contralateral oblique; Measured, angle measured based on imaging modalities; –2, significantly posterior to VILL; –1, just posterior to VILL; 0, on VILL; +1, just anterior to VILL; +2, significantly anterior to VILL; U, undetermined grade - needle tip location was not able to be evaluated because of nearly not visualized laminar margin and needle tip. *P<0.05, **P<0.01, ***P<0.001, and †P>0.999 compared with CLO view at measured (grade 0 and +1 vs. other grades).

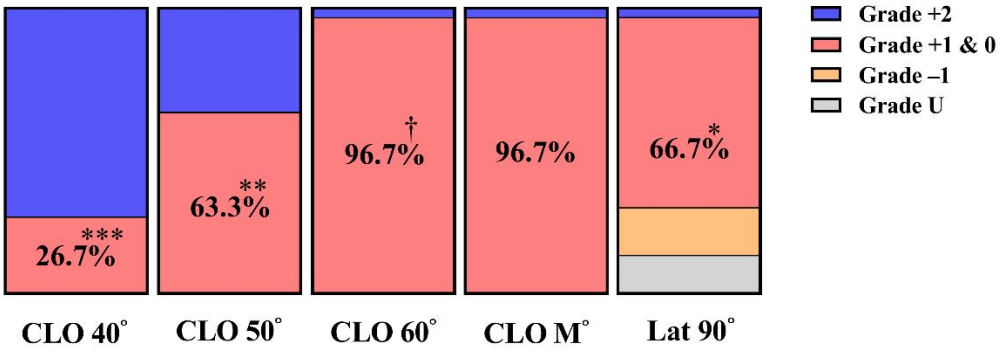

Figure 1-5. Stacked bar plots comparing the proportion of the grade of needle tip location according to various degrees of contralateral oblique views and the lateral view. CLO, contralateral oblique; M°, angle measured based on imaging modalities; Grade +2, significantly anterior to the ventral interlaminar line (VILL); Grade +1, just anterior to VILL; Grade 0, on VILL, Grade –1, just posterior to VILL; Grade U, undetermined grade (needle tip location was not able to be evaluated due to lack of visualization). *P<0.05, **P<0.01, ***P<0.001, and †P>0.999 compared with CLO view at measured (grade 0 and +1 vs. other grades).

DISCUSSION

This study demonstrated three main findings. First, the needle tip was clearly visualized at any CLO view, compared with the lateral view in the mid-thoracic region. Second, the laminar margin was significantly well visualized at the CLO view at 60 degrees and the CLO measured angle view in the mid-thoracic region. These properties could aid in visualization of the needle tip on fluoroscopic images to avoid the lamina, improving the accuracy of TEA in the mid-thoracic region. Third, in the CLO view at 60 degrees and CLO measured angle view, needle tips were all located on or just anterior to the VILL in the mid-thoracic epidural space. The ability to confirm the depth of the needle tip in relation to the epidural space could ensure safe TEA.

When approaching the mid-thoracic epidural space, successful TEA can be difficult to achieve due to the unique anatomical characteristics of the mid-thoracic region, including long and steep spinous processes and a narrow interlaminar space [5]. To improve the success rate of TEA in the mid-thoracic region, Nagaro's method of using a pedicle as a landmark on the AP and lateral fluoroscopic view was proposed [16]. However, the mid-TEA still remained technically challenging [17, 19]. The slanted and long spinous processes, the thin lamina of vertebrae and the mediastinal organs in the mid-thoracic region blunts the contrast of the interlaminar space, making its visualization difficult despite the use of fluoroscopy with any projection [16]. Moreover, AP and lateral fluoroscopic views cannot accurately assess the depth of the needle tip in relation to the epidural space and discriminate between true and false LOR [9]; therefore, explaining why major spinal cord injury continues to occur, even with the use of fluoroscopy [10].

Considering the limitations of conventional fluoroscopic views, the CLO view has been recommended because it leads to better visualization of the needle tip and lamina which provides a reliable radiographic landmark [12, 23, 24]. Through rigorous and precise analyses of the CLO view when accessing epidural space, Gill et al. suggested that each CLO view at 50 and 45 degrees were superior

to the lateral view in the cervical and lumbar epidural region respectively, for improving needle tip visualization and providing a consistent landmark when accessing the epidural space [11, 20].

In this study, our results were in line with those of previous studies of CLO views. In the CLO view at 60 degrees and measured angle view, needle tips and lamina were clearly visualized, which has several advantages. Firstly, clear needle tip visualization could help the operator recognize and correct the location of the needle tip, whereas, indistinct needle tip visualization could make it challenging to identify the location of the needle tip and the operator could inadvertently advance the needle into the epidural space causing dura puncture or cord injury. Indeed, only 36.7% of cases showed clearly visualized needle tips at the lateral view. All cases showed clearly visualized needle tips in any CLO view in the present study. Secondly, well demarcated laminar margins could increase success rate and decrease procedural time and patient discomfort as the operator could advance the needle without encountering the lamina. In TEA, the epidural needle can frequently encounter the lamina, causing discomfort and pain from periosteal contact, needle redirections, and multiple skin punctures [25]. In the present findings above, in 50% of cases the laminar margin was clearly visualized with complete demarcated laminar in the CLO view at 60 degrees and measured angle view; none were poorly or not visualized laminar margins. In contrast, 23.3% of cases were poorly or not visualized in the lateral view, which could lead to difficult TEA.

Notably, in almost all cases (96.7%) in the CLO view at 60 degrees and CLO measured view, the needle tips were located on or just anterior to the VILL, achieving successful TEA. These views provided significant consistency in the needle location at the point where the epidural space was accessed. Importantly, the epidural space could not be accessed until the needle tip reached or passed the VILL, allowing needle advancement up to just before the VILL without LOR. This consistency of the needle location could make operator allow anticipation of the locus in which the LOR could be obtained. Furthermore, this view could help discriminate between true and false LOR, and confirm successful TEA through epidurography contrast patterns seen in front of the VILL. If the needle tip was not in the epidural space, contrast spread posteriorly to VILL. Hence, these virtues of the CLO view at

60 degrees and measured view could improve clinical performance, increase success rate, reduce procedural time, and decrease patient discomfort, while guaranteeing safety when performing mid-TEA. Interestingly, in the lateral view, the needle tip locations were not evaluated in 13.3% of cases as the laminar margin and needle tip were not visualized, and 16.7% of needle tips were located posterior to the VILL. Therefore, the lateral view could not provide consistency of needle location and thus lead to difficult TEA. Hence, the CLO view at 60 degrees and measured view appeared to be superior to the lateral view for mid-TEA.

In the previous study, use of the CLO view at 50 and 45 degrees was recommended for cervical and lumbar epidural access, respectively [11, 20]. In this study, outcomes of the CLO measured view were not statistically different from that provided by CLO view at 60 degrees. The mean of CLO measured angle on the mid-thoracic region was 58.8 degrees. Therefore, we suggest the use of CLO views at 60 degrees when accessing the mid-thoracic epidural space in clinical situations where thoracic CT or MRI is not available.

This study has some limitations. Firstly, this was a pilot study with a small number of participants, therefore unable to provide conclusive results demonstrating the superiority of the CLO view over the lateral view and the optimal angle of CLO view when accessing the mid-thoracic epidural space. Secondly, delicate and detailed geometric analysis was insufficient, compared with previous studies [11]. However, the essential and fundamental findings were included in our analysis, and additional geometric analysis may not have affected the results of this study. Thirdly, this study followed the methodological protocol of the previous studies [11]. However, the subjective and ambiguous criteria of evaluation such as “just anterior” and “significantly posterior” may induce bias despite final measured values based on the consensus of an independent investigator. Further rigorous and precise study using the objective standard criteria should be done. Fourthly, we did not evaluate the angles above 60 degrees at CLO view because of its similarities to the lateral view. However, if the angles above 60 degrees at CLO view were evaluated in this study, the results that CLO view at 60 degrees was the optimal view during mid-TEA might be more logical. Finally, clinical improvements such as increased success rate,

reduced procedural time, and decreased patient discomfort were not included as primary objectives in this study; therefore, evaluation of the clinical usefulness of the CLO view and lateral view is warranted.

In comparison to the lateral view and other CLO angles, the CLO view at 60 degrees and obliquity measured based on CT or MRI can provide consistent needle tip locations and clear visualization of needle tip and lamina. This could potentially be used to identify the needle in relation to epidural space and achieve success in TEA. Without available CT or MRI images, the CLO view at 60 degrees may be considered and selected as the optimal view during mid-TEA.

Declaration

This article in press; this article has not been formally published but accepted for publication in *Pain Physician.*

CHAPTER II

Randomized Trial for Comparison of Contralateral Oblique View at 60 degrees with the Lateral View in Mid-Thoracic Epidural Access: an interim analysis

INTRODUCTION

Fluoroscopy is one of most commonly used device in therapeutic spine interventions to improve safety and accuracy in the clinical practice.[26] Fluoroscopic AP and the lateral view is mainly used to identify the needle tip position related to anatomical structures during the interventions.[27] Accurate and precise visualization of the needle tip is critical to prevent serious complications such spinal cord injury. Lateral view can display how far the needle is from the target area such as epidural space, which help recognize needle depth and ensure patient's safety.[28] However, visualization of the needle tip in the lateral view is often impaired because the lateral view is topographically inappropriate to visualize the position of the needle tip in the epidural space.[29]

Considered the limitations of fluoroscopic lateral view, the CLO view has been recommended because it leads to better visualization of the needle tip and lamina which provides a reliable and consistent radiographic landmark.[28, 30] Compared to systemically studied the optimal angle and advantage of CLO view in the cervical or lumbar region, but the utility of the CLO view in the mid-thoracic region is lack. The results of chapter 1 showed that CLO view at 60 degrees provided clearer visualization and more consistent needle tip location than the lateral view for mid-TEA. Therefore, it is speculated that CLO view at 60 degrees may be an optimal angle for mid-TEA. In addition, compared to the lateral view, it can increase the success rate and improve clinical outcomes such as reduced procedural time and decreased patient discomfort. Thus, the aim of this study was to evaluate the clinical usefulness of the CLO view at 60 degrees compared with lateral view when accessing mid-thoracic epidural space.

METHODS

Study design and patients

This prospective randomized controlled study was conducted at the Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea. All patients were enrolled from June 2020 to October 2020. The study protocol was approved by the institutional review board of the Asan Medical Center (2020-0535), and written informed consent was obtained from all participants. Before enrollment of any patients, the study protocol was registered with the Clinical Research Information Service (KCT0004926) on April 16, 2020. The methods in this study were conducted in accordance with approved guidelines. All patients scheduled for mid-thoracic epidural steroid injection, blood patch, and catheter placement were assessed for eligibility. Patients were included if they were aged 20–79 years. Patients were excluded if they had an allergy to local anesthetics, contrast medium or steroids, or infection at the insertion site, neurological or psychiatric disorders, or prior spine instrumentation. Patients who were pregnant, had coagulopathy, or had used anticoagulants or antiplatelet medication, were also excluded.

Randomization

Patients were randomly assigned to group L (mid-TEA was performed in the lateral view) or group C (mid-TEA was performed in the CLO view), according to a computer-generated randomization schedule. Random allocation was conducted via the web-based randomization software (Random Allocation Software version 1.0, Isfahan University of Medical Sciences, Isfahan, Iran) by the first investigator enrolling and assessing participants. Block randomization was utilized, with random block sizes of 4 and an allocation ratio of 1:1. Opaque and sealed envelopes labelled with sequential study numbers, concealed by the first investigator, were given to the pain physicians who conducted mid-TEA on the day of the procedure. Although the pain physicians could not be blinded to the type of procedures, all patients were blinded to those. The second investigator, who was not blinded to the allocation groups, evaluated the procedure-related outcomes in the operating room. The third

investigator, who was blinded to the allocation groups, assessed the patient's subjective outcomes such as patient satisfaction and procedural pain intensity in the postanesthetic care unit.

Study protocol – thoracic epidural access

No sedatives were administered before the intervention. All patients were placed on an operating table with a pillow to widen the target interlaminar space and were monitored with pulse oximetry, noninvasive blood pressure, and 3-lead electrocardiogram. Mid-TEA was conducted by using the fluoroscopy (Ziehm Vision RFD, Ziehm, Nuremburg, Germany). After identification of the thoracic vertebrae level, an insertion site ranging from T4 to T8 was selected and sterilized. According to a previous study,(6) the needle entry point was determined to be at the junction between the midline of the pedicle paralleled to the midline of the IVB to the target interlaminar space and the lower border of IVB on an AP view (Fig. 1-1). Before the needle insertion, the AP view was set to line up with the plane of the lower endplate of IVB. A 22-gauge Tuohy needle (Green Medical Supply Co., Seoul, Korea) or 18-gauge Tuohy needle (Perifix, B. Braun Melsungen AG, Melsungen, Germany) was used to access the epidural space. After local infiltration with 1% lidocaine, the Tuohy needle was advanced with an angle of approximately 10–15 degrees medially until it reached the pedicle level on the vertebrae body. Then, AP view turned to the lateral view (Fig. 2-1.A) or CLO view at 60 degrees (Fig. 2-1.B) in group C or L, respectively. The epidural needle was subsequently advanced just before the VILL without a loss-of-resistance (LOR) technique (Fig. 2-1.C). At this point, the needle should be advanced further cautiously until epidural space was obtained using a LOR-to-air technique. After achievement of LOR, correct epidural access was confirmed by the injection of contrast medium (Omnipaque 300, GE Healthcare, Little Chalfont, UK) in AP, CLO view at 60 degrees (group C), and lateral views (group L). Final success was defined as that correct epidural space was accessed within allowed epidural access attempts. If the epidural needle encountered the laminae and could not be advanced, the needle was withdrawn and was re-advanced with changing the angulation of the needle. Epidural access attempt was defined as achieving the epidural access via one needle pass without the needle withdrawal. If any needle withdrawal was present, the needle advancement was regarded as a new attempt. Our protocol

allowed to withdraw and re-insert the needle for a maximum of three attempts on the one skin puncture. If three attempts were failed, new needle entry point was determined; three skin punctures were maximally allowed. Failure was defined as if epidural space was not accessed despite the maximal nine attempts. In the failed case, a maximum of three attempts on only one skin puncture was allowed under the use of another group's view. Crossover trial success was defined as that mid-TEA was successfully achieved using another group's view. The procedure was performed by two pain physicians with more than 10 years of experience in TEA following identical protocols.

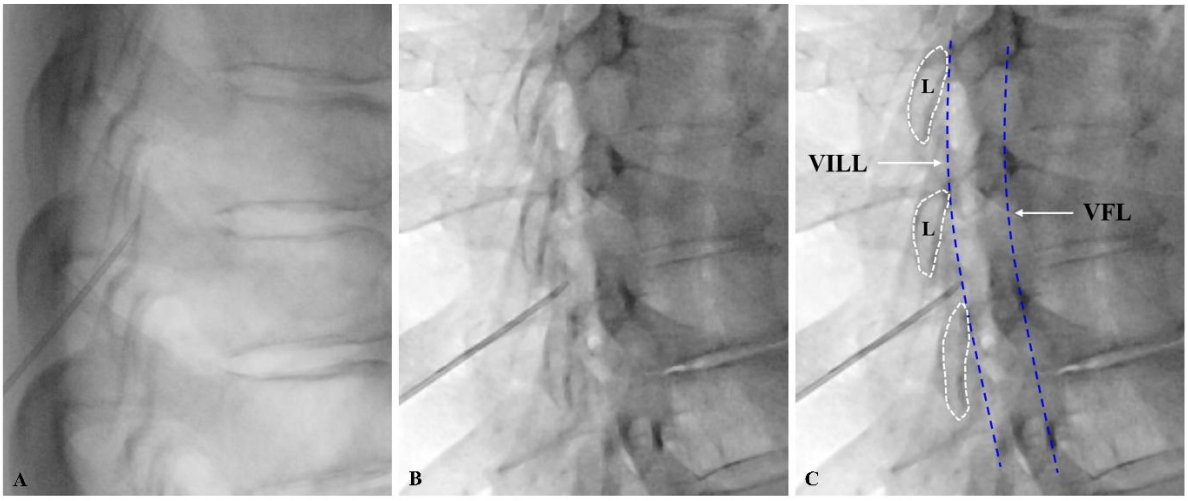

Figure 2-1. Original fluoroscopic lateral view (A), contralateral oblique (CLO) view (B), and schematic view (C) for describing the ventral interlaminar line (VILL, imaginary line connecting the ventral laminar margins) and ventral foraminal line (VFL, imaginary line along the ventral margin of foramen). L indicates laminae. White dot lines indicate the laminar margin. Blue dot lines indicate VILL and VFL. Epidural space and spinal cord are present in the area between the VILL and VFL.

Outcomes

The primary outcome was the first attempt success rate of mid-TEA using the fluoroscopic imaging. The first attempt success was defined as that epidural needle reached the epidural space at once without any needle withdrawal. Secondary outcomes were patient satisfaction and procedural pain intensity. Patient satisfaction was assessed after the procedure by global perceived effects on a 7-point scale (GPES) with some modifications; grade 1 = very dissatisfied, 2 = somewhat dissatisfied, 3 = slightly dissatisfied, 4 = neither satisfied nor dissatisfied, 5 = slightly satisfied, 6 = somewhat satisfied, and 7 = very satisfied.[31, 32] Procedural pain intensity was also evaluated when assessing patient satisfaction, using a single 11-point numeric rating scale (NRS), in which 0 = no pain and 10 = worst pain imaginable. To obtain valid NRS and GPES outcomes data, all patients were instructed on how to grade their pain using an NRS and their satisfaction using a GPES before the procedure. Other outcomes measures included following as; 1) needling time: the time to access the epidural space from skin insertion, 2) number of needle passes: first needle pass plus additional needle passes, which define as an attempt to re-insert the needle after any needle withdrawal with changing the direction, 3) number of skin punctures; first skin puncture plus additional skin punctures, which define as reinsertion at a new location with complete needle withdrawal from the skin, 4) crossover trial success rate, 5) procedure-related complications: vasovagal reaction, epidural hematoma, dura puncture, intravascular or intrathecal local anesthetic injection, cord injury, and pneumothorax, 6) cumulative total radiation dose; it was obtained from the fluoroscopic report of each procedure.[33]

Statistical analysis

Data are expressed as mean ± standard deviation, median (interquartile range), or number (proportion) as appropriate. We focused the primary outcome as the first attempt success rate of TEA, was compared using the χ^2 test. Other categorical data were compared using the χ^2 test or Fisher exact test, as appropriate. Normal distribution of continuous data was assessed using the Kolmogorov-Smirnov test. Non-normally distributed continuous data such as NRS and patient satisfaction were

compared using the Mann-Whitney U test. $P < 0.05$ was considered significant. Data were analyzed using MedCalc (version 11.3.3.0; MedCalc Software bvba, Mariakerke, Belgium) and the Statistical Package for the Social Sciences (SPSS, Version 21.0, IBM SPSS Statistics; IBM Corporation, Armonk, NY).

First attempt success rate using CLO view 60 degrees based on previous data in our institution was 80%. We assumed first attempt success rate using the conventional lateral view to be 50%. With a 2-sided significance level of 0.05 and power of 0.8, a minimum of 39 subjects per group were required. Considering a dropout rate of 5%, 42 subjects in each group were included.

This prospective study was designed to achieve the end of the study's results within 1 year since the trial began. An interim analysis was planned 6 months after the beginning of the trial to verify the sample size based on the first attempt success rate and evaluate of the occurrence of serious complications associated with the procedure.

RESULTS

These outcomes were an interim analysis's results of this prospective trial. Between June 2020 and October 2020, 48 patients were assessed for eligibility before the intervention. Two patients over 80 years were excluded, then 46 patients were randomized to the allocated groups. After randomization, one patient in each group did not receive the allocated intervention. In total, 44 patients (21 patients in group L and 23 patients in group C) were finally analyzed (Fig. 2-2).

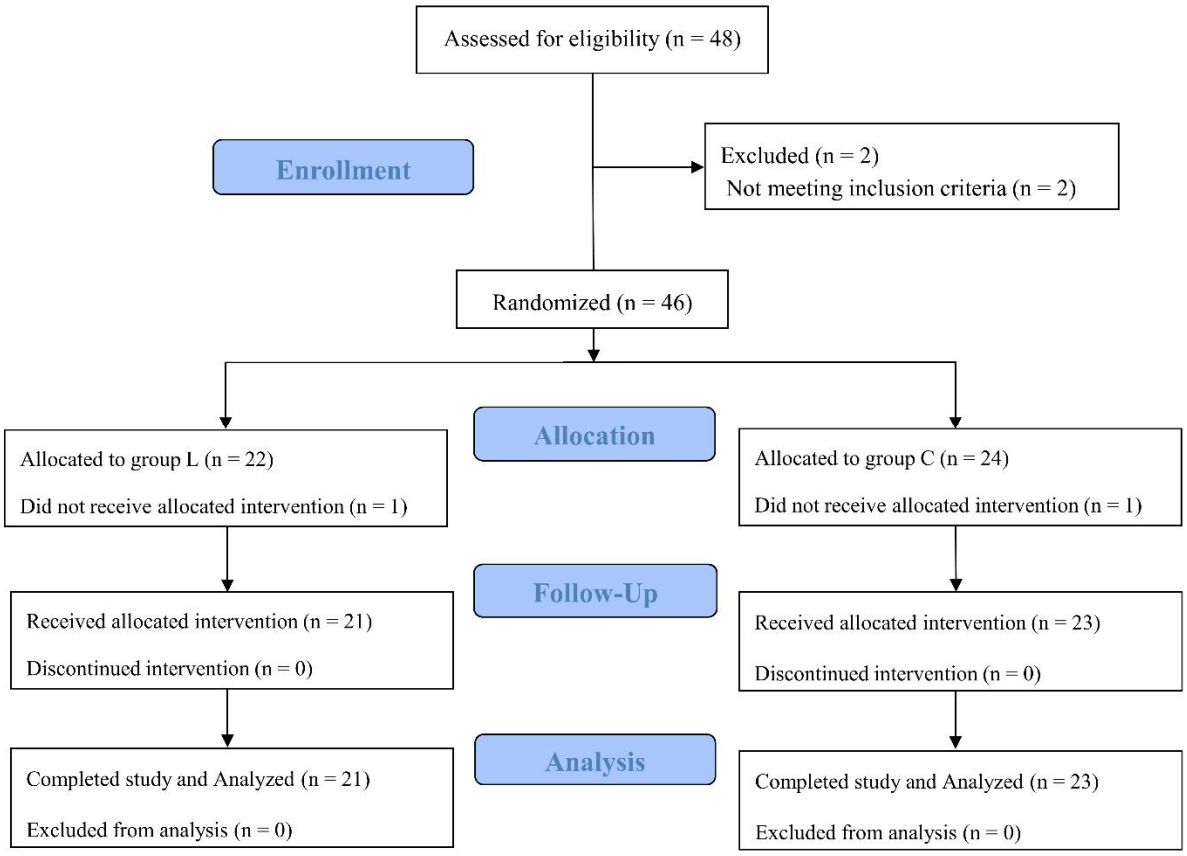

Figure 2-2. CONSORT flow diagram of patients included in the study. Group L comprised patients who received mid-TEA under the fluoroscopic lateral view. Group C comprised patients who received mid-TEA under the fluoroscopic contralateral oblique view.

Clinical characteristics of study subjects were similar for both groups (Table 2-1). Most common cause of the mid-TEA was the purpose of patient-controlled analgesia; thus, thoracic epidural catheter placement was the most common intervention, and the mid-TEA was most frequently conducted at the interlaminar spaces of T7-8.

Table 2-1. Clinical characteristics of study subjects

	Group L (n = 21)	Group C (n = 23)	P value
Age (year)	64.0 (59.0–72.0)	64.0 (58.5–72.0)	0.778
Sex, male (%)	12 (57.1)	18 (78.3)	0.239
Body mass index (kg/m^2)	22.9 ± 3.9	22.8 ± 2.7	0.869
Cause of interventions			0.275
Spontaneous intracranial hypotension	2 (9.5)	0 (0.0)	
Postherpetic neuralgia	2 (9.5)	3 (13.0)	
Chronic postsurgical pain	2 (9.5)	0 (0.0)	
Patient-controlled analgesia	15 (71.5)	20 (87)	
Type of interventions			0.317
Steroid injection	4 (19.0)	5 (21.7)	
Blood patch	2 (9.5)	0 (0.0)	
Catheter placement	15 (71.4)	18 (78.3)	
Target level			0.438
T4−5	3 (14.3)	3 (13.0)	
T5−6	0 (0.0)	2 (8.7)	
T6−7	4 (19.0)	2 (8.7)	
T7−8	14 (66.7)	16 (69.6)	
Location of needle insertion, right (%)	9 (42.9)	13 (56.5)	0.674

Data are expressed as mean (standard deviation), number (%), or median (interquartile range).

First attempt success rate was significantly higher in group C than in group L (69.6% vs. 28.6%, P=0.016; Figure 2-3). All Mid-TEA were successfully achieved in group C, and final success rate was significantly higher in group C compared with group L (100% vs. 76.2%, P=0.044; Figure 2-3). Crossover trial was conducted only in group L (n = 5, 23.8%); then, all crossover trials using the CLO view at 60 degree were successfully completed. During the mid-TEA, needling time and number of needles passes were significantly less in group C over group L (94.0 [84.0 – 155.0] vs. 125.0 [115.0 – 205.0] seconds, P=0.035; 1.0 (1.0 – 2.0) vs. 3.0 (1.0 – 4.0), P=0.003; Table 2-2). The use of CLO view resulted in decreased number of needle skin punctures (P=0.041). Cumulative total radiation dose in group C was also significantly reduced than that in group L (54.7 ± 26.4 vs. 94.4 ± 83.6 cGy x cm^2, P=0.048). One case of the vasovagal reaction occurred in group C, and there were no serious complications in both groups.

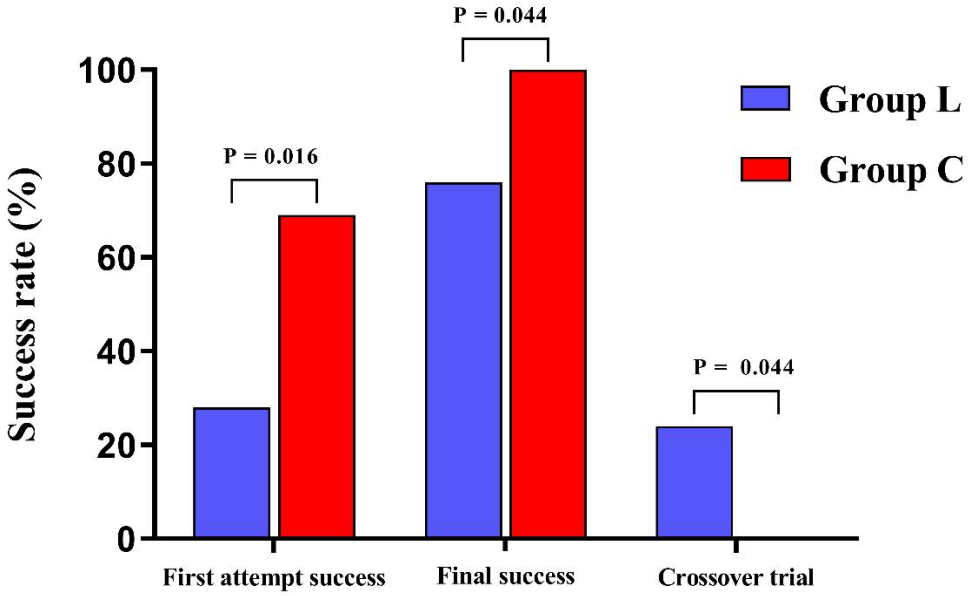

Figure 2-3. Comparison of the success rate of fist attempt success, final success, and crossover trial between the two groups. Group L comprised patients who received mid-TEA under the fluoroscopic lateral view. Group C comprised patients who received mid-TEA under the fluoroscopic contralateral oblique view.

Table 2-2. Variables during the mid-thoracic epidural access

	Group L (n = 21)	**Group C (n = 23)**	**P value**
Needling time (seconds)	125.0 (115.0 – 205.0)	94.0 (84.0 – 155.0)	0.035
Number of needle passes	3.0 (1.0 – 4.0)	1.0 (1.0 – 2.0)	0.003
Number of skin punctures			0.041
1	15 (71.4)	22 (95.7)	
2	1 (4.8)	0 (0.0)	
3	0 (0.0)	1 (4.3)	
4	5 (23.8)	0 (0.0)	
Radiation dose (cGy x cm^2)	94.4 ± 83.6	54.7 ± 26.4	0.048
Complications	0 (0.0)	1 (4.3)	0.999

Data are expressed as number (%) or median (interquartile range).
Complications include vasovagal reaction, epidural hematoma, dura puncture, intravascular or intrathecal local anesthetic injection, cord injury, and pneumothorax.

Procedural pain intensity (NRS) scores were significantly lower in group C compared to group L, 3.7 ± 1.8 versus 2.2 ± 0.9, respectively (P = 0.002; Table 3). Patient satisfaction (GPES) was significantly greater in group C than in group L (6.0 [6.0 – 7.0] vs. 5.0 [4.0 – 6.0], P=0.001).

Table 2-3. Maximal pain intensity during the procedure and patient satisfaction after the procedure

	Group L (n = 21)	**Group C (n = 23)**	**P value**
Pain intensity (NRS)	3.7 ± 1.8	2.2 ± 0.9	0.002
Patient satisfaction (GPES)	5.0 (4.0 – 6.0)	6.0 (6.0 – 7.0)	0.001

Data are expressed as median (interquartile range) or number (%). NRS, numeric rating scale; GPES, global perceived effect scale.

DISCUSSION

This is the first randomized study to evaluate the clinical utilities of the CLO view at 60 degrees compared with the lateral view in the mid-TEA. Encouraging results of this interim analysis showed that the CLO view improved first attempt and final success rate of mid-TEA. In addition, we observed that the CLO view at 60 degrees significantly reduced the needling time and number of needle passes necessary to successfully achieve epidural access. These CLO view's advantages alleviated procedural pain, increased patient satisfaction, and decreased total cumulative radiation dose during the mid-TEA.

Fluoroscopic guidance can improve the success rate of epidural block, decrease the complications related to an inadvertently directed needle,[34] and increase the incidence of correctly positioned thoracic epidural catheters for postoperative analgesia.[35] Although fluoroscopic guided TEA has several advantages, the mid-TEA remained technically challenging.[17, 19] Because the unique anatomical properties of the thoracic region aforementioned in chapter I are more prominent in the mid-thoracic region.[5, 6] Furthermore, the thin lamina of vertebrae and the mediastinal organs in the mid-thoracic region blunts the contrast of the interlaminar space, making its visualization difficult despite the use of conventional fluoroscopic views.[16] These conventional AP and lateral view cannot accurately identify the depth of the needle tip in relation to the epidural space and discriminate between true and false LOR.[9] According to our previous study of mid-TEA, needle tips and laminar margins were poorly visualized on the fluoroscopic lateral view at mid-thoracic region.

Although the use of fluoroscopic AP and the lateral view has been standard practice, more recent attention has been directed toward using a CLO view for determining needle depth during the interlaminar epidural approach.[8] The CLO view seems to be a feasible alternative to the traditional fluoroscopic view for epidural access.[28, 30] Through scientific geometric analyses of the CLO view, Gill et al. suggested that each CLO view at 50 and 45 degrees were proper in the cervical and lumbar epidural access respectively, for improving needle tip visualization and providing a consistent landmark when accessing the epidural space.[28, 30] However, compared to cervical or lumbar region, the researches of

the CLO view in the thoracic region is lack and optimal degree of CLO view for the mid-TEA is unknown. Thus, in chapter 1, CLO view at 60 degrees may be appropriate for mid-TEA. The CLO view at 60 degrees can provide clear visualization of needle tip and laminar margin in the mid-thoracic region. These properties of the CLO view can make the needle tip avoid the lamina without periosteal contacts, achieving a higher first attempt success rate (69.6%) and improving the accuracy (100%) of mid-TEA in this study. In the results of chapter 1, 63.3% of cases were poorly visualized needle tips and 23.3% of cases were poorly or not visualized laminar margin at the lateral view, which could lead to difficult TEA and be associated with a lower first attempt success rate (28.6%) in the study. When performing conventional fluoroscopic guided or landmark based TEA, epidural needle tip usually encounters the laminae. This encountering the lamina results in increased procedural pain, the number of needles passes, and procedural time, subsequently increasing patient discomfort.[25] Because CLO view at 60 degrees helped epidural needle tip advance without touch the lamina, it might lead to decreased pain intensity and increased patient satisfaction in our results.

From a safety perspective, CLO view at 60 degrees can play an important role to prevent serious neurologic complications such as cord injury. According to results of chapter 1, when achieving successful mid-TEA at the CLO view at 60 degrees, needle tips were all located at or just beyond the VILL (Figure 2-1.C), which refers to an imaginary line connecting the ventral laminar margins. The area between VILL and ventral foraminal line (VFL: imaginary line along the ventral margin of foramen) on the CLO views contains epidural space and spinal cord. Notably, the epidural space is never accessed until the needle tip reaches the VILL, allowing needle advancement up to just before the VILL without LOR. At this point, the needle tip is located in ligament flavum, which may help reduce the false positive LOR and procedural time. From this locus, the needle tip should be advanced with LOR; then, epidural space can be obtained at or just beyond the VILL as soon, making the operator anticipation of the locus in which the LOR can be accessed. This remaining cognizant of the needle depth anticipated to achieve epidural access serves as a safety measure against false negative LOR,[8] preventing an aberrant ventral

needle placement, which can cause dura puncture or cord injury. In this study, there were no complications related to inappropriate needle placement in both the CLO and lateral view.

The greatest risk with the cervicothoracic interlaminar interventions is advancing the needle into the spinal cord and a subsequent intramedullary injection.[8] This could occur through a false negative LOR and unsuitable ventral needle advancement. Thus, for the safe mid-TEA using the CLO view, there are some recommendations following as; first, the LOR portion of the procedure must be initiated near but not through the VILL; second, a contrast medium should be administered if LOR is not obtained despite the needle tip is somewhat deeply located beyond the VILL because of the need to exclude false negative LOR; third, in case of this deep needle tip location, needle tip should be identified on the fluoroscopic AP view. Because if the needle tip crossover the midline and is located contralateral side, the tip is deeply located beyond the VILL on the CLO view for the geometric reason.[29] Consequently, the physician should keep in mind that deep needle tip location could cause serious neurological complications, and perform cautiously epidural access to obtain the procedure's safety.

There are some limitations in the present study. This report is results of interim analysis of our prospective randomized controlled study. The possibility of a change of final results may be rare but present when the study is finished. Another limitation is the relatively small sample size to evaluate the safety and complications related to the procedure. Although there were no serious complications in this interim analysis, the interpretation of the CLO view's safety should be cautiously approached until evaluation for the complications with the proper sample size will be studied. In addition, the lateral view group showed high failure rate (23.8%) compared to previously reported failure rate (1−2%).[35, 36] This inconsistency may be explained by limited epidural access attempts and restricted interventional field (mid-thoracic region) in this study. Finally, the mid-TEA was most frequently conducted at the interlaminar spaces of T7-8 from T4-5 to T7-8 in this study, and thus, this uneven distribution of target interlaminar spaces may weaken the validity of our conclusions. However, we believe that this disproportion will be decreased as participants are increasing.

In conclusion, the use of CLO view at 60 degrees can increase the success rate and patient satisfaction, reduce procedural time and patient discomfort, and provide the possibility of guaranteeing the safety compared to the lateral view when performing mid-TEA. Therefore, we recommend that the CLO view at 60 degrees may be primary considered as the optimal view for achieving the effective and safe mid-TEA.

CHAPTER III

Real-Time Ultrasound-guided Epidural Access in Low-Thoracic Region: Technical Consideration and Fluoroscopic Evaluation

INTRODUCTION

Perioperative multimodal analgesia and truncal blocks, such as transversus abdominis plane and erector spinae plane block have recently been arising standard methods for perioperative analgesia,[37, 38] which may attenuate the significance of thoracic epidural analgesia (TEA) in perioperative pain management. However, according to available guidelines, TEA still should be considered as the first line approach to postoperative analgesia for major abdominal and esophageal surgery.[39, 40] Thus, TEA for open abdominal and thoracic surgery continues to be an important part of the perioperative care plan, which has been associated with significant improvement of pain control, less opioid consumption and side effects related to opioid, and enhancement of clinical outcomes.[41 42, 43]

Although TEA provides reliable perioperative pain relief, accessing the epidural space in the thoracic region remains technically challenging, and landmark palpation based thoracic epidural catheter placement (TECP) is associated with high failure rate (published rates ranging from 12% to 40%).[13, 44-46] With the recent advancements in ultrasound applications, sonographic technique and sonoanatomy for TECP have developed, which can provide preprocedural target imaging; interlaminar space, bony structures, and ultrasound-estimated epidural depth in the thoracic region.[47, 48] However, compared to several studies investigating the utility of ultrasound for lumbar epidural catheterization,[49-53] there are only two clinical studies of ultrasound-guided TEA. Although it may show the possibility of a safe, consistent, and successful ultrasound-guided TECP (US-TECP),[13, 14] technical description, accuracy, and clinical performance of US-TECP have been still insufficient.

In addition, the real-time US-TECP has been recently introduced, the interest of that is increasing because of the visualization of needle advancement and the possibility of improved success rates[14]. It seems to be a feasible alternative to traditional placement methods, but accuracy and the success rate of real-time US-TECP remains unknown, and detailed technical descriptions for the procedure is needed. Therefore, we aimed to describe the detailed technical consideration for thoracic

epidural placement under real-time ultrasound guidance, and to assess the success rate of real-time US-TECP using fluoroscopy in this study.

METHODS

Study Design and Patient Recruitment

This prospective observational study was conducted at the Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea between July 2019 and December 2019. This trial protocol was approved by the institutional review board of the Asan Medical Center (2019-0320) and was registered at ClinicalTrials.gov (number of registration: NCT03890640). Written informed consent was obtained from all participants. Adult patients (20–79 years) who scheduled upper abdominal surgery and needed patient-controlled epidural analgesia in the thoracic region were considered eligible for enrollment. Patients were excluded when they meet the following criteria: 1) allergy to local anesthetics, contrast dye or steroids; 2) infection at the insertion site; 3) neurological or psychiatric disorders; 4) prior spine instrumentation or compression fracture near the insertion site; 5) coagulopathy or use the anticoagulants or antiplatelet medication.

Real-Time Ultrasound-Guided Thoracic Epidural Catheter Placement Protocol

Real-time US-TECP was performed in the separately prepared block room preoperatively, because the insertion of thoracic epidural catheter in a preoperative block room setting can significantly reduce epidural failure rates.[54] According to previous reports of US-TECP,[13, 14] patients were generally put in a sitting position during the procedure. However, in our experience, the fixation of ultrasound probe was sometimes challenging when sitting position, thus, patients were placed on prone positioning with a pillow under upper abdomen to widen the target interlaminar space. Routine monitoring with noninvasive blood pressure, pulse oximetry, and 3-lead electrocardiogram were established prior to the procedure. Traditionally, although the interlaminar space between T6 and T8 was recommended for the target space of epidural catheterization in patients who undergoing the upper abdominal surgery,[55] interlaminar space between T9 and T12 was determined as target space for US-TECP in our center because of use of the programmed intermittent epidural bolus (PIEB) infusion as our institutional protocol for thoracic epidural patient-controlled analgesia, which could provide more extensive cephalic spread of epidural medication.[56, 57] After preprocedural scanning on bilateral interlaminar space between

T9 and T12, the interlaminar space with the best visualized epidural structures including ligament flavum, posterior dura, or anterior complex (anterior dura, posterior longitudinal ligament, vertebral body) was determined as target space. As was our standard of care, the T10–T11 interspace was most commonly chosen for real-time US-TECP. All placements were performed by two investigators who had 2 years of experience related to the procedure.

First, the 12MHz high-frequency linear ultrasound probe (NextGen LOGIQe, GE Healthcare, Madwason, WI, USA) was placed in the longitudinal plane near the scapular line of thoracolumbar junction, then the 12th rib on the target side was identified via the caudal-to-cranial scanning. Subsequently, the probe was cephalo-medially moved to find the intercostal space in line with the target interspace (Fig 3-1.A.a). In this view, round-shape rib and hyperechoic pleural line could be detected (Fig 3-1.D). Second, the probe was moved more to the medial for obtaining the paramedian sagittal transverse process view (Fig 3-1.A.b), where the square-shaped transverse processes could be seen (Fig 3-1.E). Third, the paramedian sagittal articular process view was obtained by moving the probe slightly medially from the transverse process view (Fig 3-1.A.c), which could visualize the corresponding the laminae resembling wave-like structures and superior articular process of inferior vertebrae between the laminae (Fig 3-1.F). At this point, to obtain the paramedian sagittal oblique view, the physician should medially tilt the probe (Fig 3-1.B), then, the posterior complex including ligamentum flavum and posterior dura could be seen as linear hyperechoic structures between the laminae (Fig 3-1.G). Intrathecal space and anterior complex dura could be usually seen in this view. Subsequently, cephalad end of the probe was medially turning (Fig 3-1.C), then, decreased the height of laminae of the inferior vertebral body compared to that of the paramedian sagittal oblique view could be found. This point could ensure that the pathway of the epidural needle tip was not interrupted by the laminae (Fig 3-1.H). Final location of the probe was demonstrated in the Figure 3-1.A.d.

Once the target interlaminar space was identified, the center of the interlaminar space, and both cephalad and caudal end of the probe was marked on the overlying skin. After local infiltration with 2% lidocaine at the intended needle entry site, an18-gauge Tuohy needle (Perifix, B. Braun Melsungen AG,

Melsungen, Germany) was inserted from the caudal end of the probe and was advanced in-plane view under real-time US guidance until the needle tip reached in front of the posterior complex on interlaminar space. In real practice, it was common to see only one of the ligamentum flavum or posterior dura in posterior complex as a single linear hyperechoic structure. In addition, the needle tip was not visualized at all times despite using the real-time US guidance at this depth.[58] Therefore, to guarantee the safety for the procedure, advancement of the needle under the real-time US guidance should be stopped in front of the posterior complex. Then, needle was further advanced until the space was accessed using the LOR techniques with normal saline. After thoracic epidural access, the epidural catheter was advanced through the needle such that 4 cm remained in the epidural space. Finally, the mixture (normal saline and air) of 0.5 ml was administered via the epidural catheter under real-time ultrasound monitoring, then, shining epidural catheter could be observed. If an epidural catheter was present out of the epidural space, bulging around the laminae could be checked.

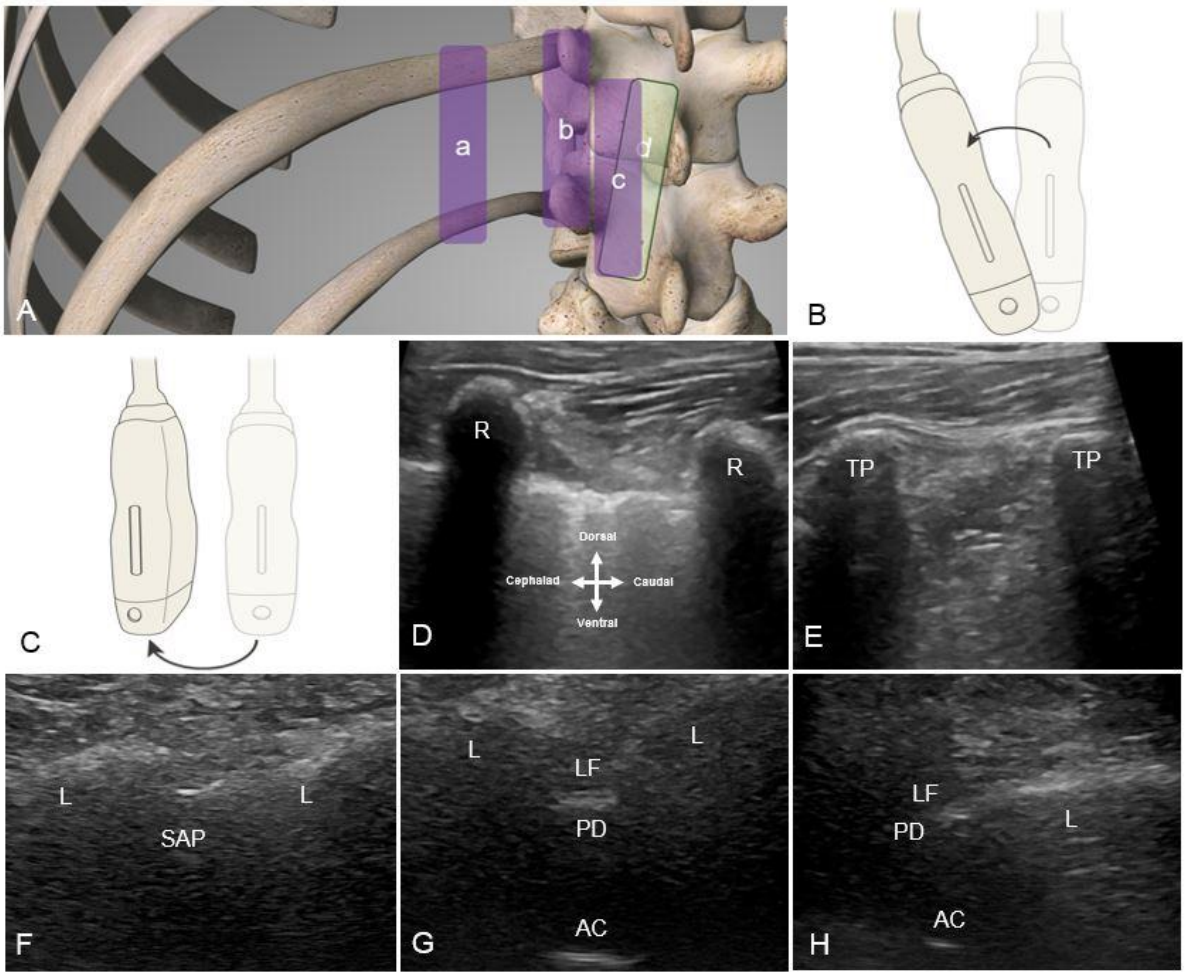

Figure 3-1. Location of the ultrasound probe corresponding to ultrasound views, and handling of ultrasound probe to obtain proper ultrasound views. **A.a**, the probe is located to find the intercostal space in line with the target interspace **A.b**, probe is more moved to the medial for the paramedian sagittal transverse process view. **A.c**, the paramedian sagittal articular process view is obtained by moving the probe slightly medially from the transverse process view. **A.d**, final location of the probe for the real-time ultrasound-guided thoracic epidural catheter placement. **B**, for obtaining the paramedian sagittal oblique view, the probe is medially tilting. **C**, for decreasing the height of laminae of the inferior vertebral body, cephalad end of the probe is medially turning. **D**, round-shape rib and hyperechoic pleural line can be detected on the intercostal space view at the probe position A.a. **E**, square-shaped transverse processes can be seen on the paramedian sagittal transverse process view at

the probe position A.b. **F**, laminae resembling wave-like structures and superior articular process of inferior vertebrae between the laminae can be seen on the paramedian sagittal articular process view at the probe position A.c. **G**, posterior complex including ligamentum flavum and posterior dura can be seen as linear hyperechoic structures between the laminae on the paramedian sagittal oblique view at the tilted probe position A.c. **H**, decreased the height of laminae of the inferior vertebral body compared to that of the paramedian sagittal oblique view can be detected when cephalad end of the probe is medially turning at the probe position A.d. R, rib; TP, transverse process; L, laminae; SAP, superior articular process; LF, ligamentum flavum; PD, posterior dura; AC, anterior complex.

Fluoroscopic findings

After real-time US-TECP, the fluoroscopic evaluation was performed to identify the position of the catheter. First, counting and establishing the epidural catheter inserted thoracic vertebrae level, then, the AP fluoroscopic view was set to line up with the plane of the lower endplate of inferior intervertebral body of target level. Because the used epidural catheter was not radiopaque, correct epidural access was confirmed by the injection of 1ml of contrast medium (Omnipaque 300, GE Healthcare, Little Chalfont, UK). Fluoroscopic real-time and continuous pulsed imaging for 3 seconds was utilized to identify the correct position of catheter tip and to verify no intravascular and subarachnoid spread of contrast.

Primary and secondary outcomes

The primary outcome measure for this study was the success rate of real-time US-TECP which could be validated by the third investigator through the interpretation of fluoroscopic images. Secondary outcomes included following as; 1) time to mark spaces; the time to obtain the best ultrasound images of target the interlaminar space and mark the skin, 2) needling time; the time to access the epidural space from skin insertion, 3) number of needle passes; first needle pass plus additional needle passes, which defined as an attempt to re-insert the needle after any needle withdrawal with changing the direction, 4) number of skin punctures; first skin puncture plus additional skin punctures, which defined as reinsertion at a new location with complete needle withdrawal from the skin, 5) first attempt success rate; successful US-TECP on only first needle pass and first skin puncture, 6) Complications; epidural hematoma, dura puncture, intravascular or intrathecal local anesthetic injection, and pneumothorax, 7) the distance between skin to epidural space, 8) fluoroscopic findings; the location of catheter tip at vertebral body level. All secondary outcomes were measured by the fourth investigator except for fluoroscopic findings. Postprocedural clinical outcomes (the occurrence of hypotension and opioid requirements in PACU, and numeric rating scale at postoperative 0 and 1 hour) were also assessed.

Statistical analysis

According to the previous studies of landmark based TECP,[15, 46, 59] its published success rate ranges between 68% and 75%. We assumed its success rate to be 73% and the success rate of real-time US-TECP to be 90%. With a one-sided significance level of 0.05 and power of 0.8, a minimum of 34 subjects were required. Considering a dropout rate of 10%, total 38 subjects were included. Data are expressed as mean ± standard deviation, median (interquartile range), and number (proportion), as appropriate. Data were analyzed using the Statistical Package for the Social Sciences (SPSS, Version 21.0, IBM SPSS Statistics; IBM Corporation, Armonk, NY).

Results

Thirty-eight patients participated in this study. Mean age was 62.5 ± 9.9 years, with 60.5% being male (Table 3-1). One patient was classified to American Society of Anesthesiologists (ASA) 3 and others were classified to ASA 1 or 2. Real-time US-TECP was conducted at the interlaminar spaces of T9-10 in 13 patients (34.2%), T10-11 in 24 patients (63.2%), and T11-12 in 1 patient (2.6%). Attempts at epidural catheter insertion were all successful.

Table 3-1. Patient Characteristics

Demographics	Total patients (n = 38)
Age (yrs)	62.5 ± 9.9
Gender (Male)	23 (60.5)
Body mass index (kg/m^2)	24.1 ± 3.5
ASA class	
1/2/3	13 (34.2)/24 (63.2)/1 (2.6)
Diagnosis	
Pancreatic cancer	12 (31.6)
Neuroendocrine tumor	6 (15.8)
Cholangiocarcinoma	8 (21.1)
Gall bladder cancer	3 (7.9)
Intraductal papillary mucinous neoplasm	3 (7.9)
Ampullary cancer	2 (5.3)
Other tumors*	4 (10.5)
Operation	
Pylorus-preserving pancreaticoduodenectomy	17 (44.7)
Pancreaticoduodenectomy	5 (13.2)
Total pancreatectomy	5 (13.2)
Hepatectomy	4 (10.5)
Distal pancreatectomy	2 (5.3)
Extended cholecystectomy with bile duct resection	3 (7.9)
Choledochal cyst excision	2 (5.3)
Target level of epidural space	
T9−10	13 (34.2)
T10−11	24 (63.2)
T11−12	1 (2.6)
Location of needle insertion (Right/Left)	24 (63.2)/14 (36.8)

Data are expressed as mean ± standard deviation, number (%), or median (interquartile range). ASA, American Society of Anesthesiologists. Others* include two choledochal cysts, liposarcoma, and gastrointestinal stromal tumor.

Table 3-2 shows outcomes of ultrasound guided epidural catheterization. Marking the overlying skin for the procedure took a mean of 49.5 ± 13.8 seconds. The median times for epidural needle placement was 49.0 (39.0–62.0) seconds. All patients underwent one skin puncture for needle insertion. The first-attempt success rate was 76.3% (29 patients), the second was 18.4% (7), and above three was 5.3% (2). The mean distance between skin to epidural space was 5. 6± 0.5 cm.

Table 3-2. Epidural catheterization outcomes

Procedural variables	Total patients (n = 38)
Needling time (seconds)	49.0 (39.0 − 65.0)
Time to mark spaces (seconds)	49.5 ± 13.8
Number of skin punctures	
1	38 (100)
≥ 2	0 (0)
Number of needle passes	
1, first attempt success	29 (76.3)
2	7 (18.4%)
≥ 3	2 (5.3%)
Skin to epidural distance (cm)	5.6 ± 0.5

Data are expressed as mean ± standard deviation, number (%), or median (interquartile range).

Table 3-3 presented fluoroscopic findings after real-time US-TECP. Based on contrast dispersion after the injection of 1 ml of contrast medium, catheter tips were all successfully placed in the epidural space, usually located between T9–10 (n=32, 84.3%), frequently presented in median epidural space (26, 68.4%).

Table 3-3. Fluoroscopic findings

Contrast dispersion after the injection of 1 ml of contrast medium	
Catheter tip in epidural space, n (%)	38 (100)
Tip location at vertebral body, n (%)	
T8−9	2 (5.2)
T9−10	32 (84.2)
T10−11	3 (7.9)
T11−12	1 (2.6)
Tip location (Right/Median/Left), n (%)	5 (13.2)/ 26 (68.4)/7 (18.4)

Data are expressed as number (%).

In the PACU, hypotension was developed in one patient (Table 3-4). Median NRS at admission to the PACU was 3.5 (1.0–4.0) and median NRS at discharge to the PACU was 2.0 (2.0−2.5). The median opioid requirement in PACU was fentanyl 50.0 (0.0–87.5) μg.

Table 3-4. Postprocedural clinical outcomes

Postprocedural variables	Total patients (n = 38)
Hypotension in PACU	1 (2.6)
NRS at postprocedural 0 hr	3.5 (1.0 – 4.0)
NRS at postprocedural 1 hr	2.0 (2.0 – 2.5)
Opioid requirement in PACU (μg)	50.0 (0.0 – 87.5)

Data are expressed as number (%) or median (interquartile range). PACU, post-anesthesia care unit; NRS, numeric rating scale.

Discussion

To the best of our knowledge, this is the first study to evaluate the accuracy of real-time US-TECP using the fluoroscopy. This study showed that real-time US-TECP was successfully achieved in all participants and provided the possibility of increased first-attempt success rate, and decreased skin punctures and number of needle passes compared to traditional TECP. In addition, the tip of the epidural catheter located between T9–10 can make contrast medium sufficiently spread over the dermatome level corresponding to the surgical incision.

Epidural catheter insertion in the thoracic region is relatively more difficult than in other regions.[35] When compared to lumbar vertebra, the longer spinous process of the thoracic vertebrae, an acute angle of the spinous process, and larger distance between the skin and the epidural space make it difficult to access the thoracic epidural space. Furthermore, the area through which the needle can approach the epidural space is relatively smaller.[16] Consequently, failure rates of TEA were up to 32%.[15] Prior reports have suggested that the cause of TEA failure varies; primary insertion failure, secondary migration, dislodgement, kinking, obstruction, and the impact of local anesthetic dose, volume, and concentration,[15, 60] with 50% of those failures likely due to primary insertion failure which is related to unique anatomical characteristics of thoracic vertebrae.[35]

A variety of techniques have been proposed to aid TECP, but these approaches generally lack sufficient accuracy or practicality.[15] Although fluoroscopic guided TECP is the gold standard method to identify the correct anatomical structures and confirm the epidural space with contrast medium,[36, 61] its use is limited for perioperative pain management because of the difficulty of using fluoroscope and the burden of radiation exposure.[62]

Ultrasound imaging can be a valuable tool to preview spine anatomy and to obtain visualization of needle advancement.[25, 52] These properties can reduce the risk of failed lumbar epidural catheterizations, as well as the number of needle insertions and redirections.[53] The clinical efficacy of ultrasound for thoracic epidural catheterization has been recently investigated, but, there are only two clinical studies of US-TECP.[13, 14] Auyong et al[13] reported benefits of preprocedural ultrasound imaging;

decreased postsurgical pain scores and the number of skin punctures compared to landmark palpation based TECP. The number of needle passes and skin punctures in our study were similar to the results of Auyong's study. Investigation of real-time US-TECP was only one study, that was conducted successfully in 15 cases of thoracic and upper abdomen surgery,[14] and provided a specific technical description for real-time US-TECP for the first time. The epidural catheters were all successfully placed in thoracic epidural space under real-time ultrasound guidance in this study. The previous study also reported that successful epidural placement was achieved in every patient.[14] However, this success rate originated from speculation based on the clinical outcomes and participants were very small (n=15). Our study showed definitely complete success rate of real-time US-TECP using the fluoroscopic imaging with relatively more participants over the previous study. We thought that real-time ultrasound guidance could induce these complete success rate of TECP.

Ultrasound-guided epidural placement has several advantages compare to landmark palpation based epidural placement. First, accurate vertebral level corresponding to surgical incision can be identified by counting the ribs on the ultrasound views.[63] Second, preprocedural ultrasound imaging can improve success rate of epidural catheterization.[53] Epidural catheter placement under real-time ultrasound guidance is one step further in the process of ultrasound-guided epidural placement, which can provide the visualization of the needle advancement with simultaneous identification of the epidural space between the target laminae. Clear needle tip visualization can advance the needle without encounter the lamina.[25] Added to these advantages of real-time US-TFCP, final identification of epidural catheter placement using the administration of air-normal saline mixture under real-time ultrasound observation can play an important role in increasing the success rate and prevent primary insertion failure.

False positive LOR is common encountered in cervical or thoracic region when accessing epidural space, which may be due to degeneration of the interspinous ligament or lack of midline fusion of ligamentum flavum.[64, 65] It can lead to improper epidural catheter placement (e.g. the catheter located in the locus between the erector spinae muscle and the laminae).[64] Real-time ultrasound guidance and

final identification can contribute to prevent the malposition of epidural catheter due to false positive LOR.

Based on the previous technical description,[14] we added detailed considerations during the real-time US-TFCP. First, if epidural space is relatively wider, posterior complex, intrathecal space, and anterior complex can be visualized on the paramedian sagittal oblique view; however, when the target thoracic vertebral level is higher (esp., above T9 level), intrathecal space and anterior complex cannot be usually visualized. At this point, it can be difficult to distinguish SAP and posterior complex because the single hyperechoic line between the laminae can be only identified. In our experience, we sometimes meet the failure of optimization of the paramedian sagittal oblique view to identifying the posterior complex, especially on the above mid-thoracic region. In this case, the epidural needle can usually encounter the SAP and cannot advance the needle. If the physician meets the failure of optimization of the paramedian sagittal oblique view and the needle contact the SAP, we recommend that the epidural needle should be withdrawn until 1 cm above the laminae, then the needle should be advanced more medially to access the epidural space. We believe that this approach can overcome these difficulties in real-time US-TFCP. Second, either air or normal saline in detecting the LOR can be used, LOR to saline is more suitable to real-time US-TFCP. Because if air spread around the laminae and erector spinae muscles, the target ultrasound view can be poor. Third, the ligamentum flavum and posterior dura may also be seen as a single linear hyperechoic structure which is referred to as the "posterior complex" or "ligamentum flavum–posterior dura complex."[66] Thus, the physician cannot discriminate whether a single hyperechoic line is ligamentum flavum or posterior dura not. Moreover, the needle tip cannot be generally visualized at the below laminae or under a depth greater than 4 cm.[14] To ensure safety of the procedure and prevent dura puncture, the needle should be advanced with LOR to saline in front of the posterior complex until the epidural space is identified.

There are limitations to the present study. First, although this was prospective observational study, small number of participants limited the power of our study and the robustness of our conclusions. However, to reduce radiation exposure of participants, sample size should be limited. Second,

unintentionally, obese patients did not include in the study. Real-time US-TECP may be difficult in the obese patients because of poorly visualized the target epidural space and needle advancement. If they participate this study, outcomes would be changed; therefore, evaluation of the clinical usefulness of the real-time US-TECP in the obese patients is warranted. Third, our procedural target sites were not included in mid-thoracic region which is known to be the most difficult area when accessing epidural space. Thus, the interpretation of our results should be cautiously approached until it is validated to the upper-mid thoracic region.

In conclusion, this study demonstrates that real-time ultrasound guidance may ensure improved success rate of TECP in the low-thoracic region. This approach can be a feasible alternative to traditional placement methods. Considered potentially reducing the number of needle redirection, reinsertions, and periosteal contact, this approach may improve procedural success while reducing patient discomfort and complications.

GENERAL CONCLUSIONS

The stepwise and systematical three studies for TEA showed the accurate and secure alternative methods of epidural space access for thoracic epidural intervention. In the mid-thoracic region, a CLO view at 60 degrees may be optimal angle for fluoroscopic guided TEA, can provide clearer visualization of laminar margin and needle tip, and more consistent needle tip location than the lateral and other CLO angle views. The use of CLO view at 60 degrees can increase the success rate and patient satisfaction, reduce procedural time and patient discomfort, and provide the possibility of guaranteeing the safety when performing mid-TEA. In the low-thoracic region, real-time US-TECP showed a complete success rate, suggesting that real-time ultrasound guidance may be useful for TECP with an increased success rate, reduced patient discomfort, and no radiation hazard. Therefore, the present results recommend that the fluoroscopic CLO view at 60 degrees in the mid-thoracic region and real-time US guidance in the low-thoracic region may be primary considered for achieving the accurate and secure TEA.

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국문요약

서론

흉부 경막 외 접근법은 경막 외 차단술, 혈액 봉합술 또는 카테터 삽입 시술 등에 필요하며 만성 통증 또는 급성 수술 후 통증을 줄이기 위해 널리 사용되는 중재술이다. 그러나 흉부 경막 외 접근법은 여전히 어려우며 심각한 신경학적 합병증을 유발할 수 있다. 따라서 이 연구는 흉부 경막 외 접근법 시 안전하고 효과적이며 쉬운 접근법을 찾는 것을 목표로 한다.

연구방법

흉부 경막 외 접근법에 대한 안전하고 효과적이며 쉬운 접근법을 찾기 위한 세 가지 연구가 수행되었다. 첫번째 연구는 반대측 경사 영상의 유용성을 평가하고 흉부 중간 영역에서 흉부 경막 외 접근법에 대한 반대측 경사 영상의 최적 각도를 찾기 위한 전향적 관찰 연구였다. 두번째 연구는 중간부 흉부 경막 외 접근 시 반대측 경사 영상과 측면 영상을 비교하는 전향적 무작위 대조 연구였다. 세번째 연구는 실시간 초음파 유도 흉부 경막 외 카테터 배치의 정확성을 평가하기 위한 전향적 관찰 연구였다.

Chapter I: 중간부 (T4–8) 흉부 경막 외 공간을 확보한 후 투시 영상을 시행한다. 배쪽 추간판 간의 연결선 (VILL)에 대한 바늘 끝 위치와 바늘 끝 및 추간판 경계의 시각화는 반대측 경사 영상 40, 50, 60 도 및 사전에 측정된 각도와 측면보기에서 측정 및 분석 되었다.

Chapter II: 환자는 측면 투시 영상 (그룹 L) 또는 반대측 경사 영상 (그룹 C)에서 중간부 흉부 경막 외 접근법을 받도록 무작위로 할당되었다. 일차결과지표는 중간부 흉부 경막 외 접근법 시 첫 시도 성공률이었다. 이차결과지표는 환자 만족도와 시술 중 통증 강도였다. 다른 측정된 변수들은 바늘 통과 시간, 바늘 통과 횟수, 피부 천자 횟수, 교차 시험 성공률 및 시술의 합병증이 포함되었다.

Chapter III: 실시간 초음파 안내 하 흉추 경막외 카테터 삽입을 수행한 후 투시 영상을 얻었다. 경막 외 조영술을 통해 경막 외 카테터 팁의 위치를 평가하였다. 첫 시도 성공률, 성공률, 바늘 통과 시간, 바늘 통과 횟수 등 시술 중의 변수들을 측정하였다.

연구결과

Chapter I: 총 30 명의 피험자가 이 연구에 참여하였다. 바늘 끝은 측면 영상과 비교하여 모든 반대측 경사 영상에서 명확하게 시각화 되었다 (100 % vs. 36.7 %, P <0.001). 사전 측정된 각도의 반대측 경사 영상에서는 40 도, 50 도 각도의 반대측 경사 영상 및 측면 영상과 비교하여 훨씬 더 선명한 VILL 바로 위 또는 바로 앞에 위치한 바늘 끝과 추간판 경계를 볼 수 있었다. (추간판 경계: 40 도, 56.7 % vs. 3.3 %, P <0.001; 50˚, 56.7 % vs. 26.7 %, P = 0.012; 90˚, 56.7 % vs. 26.7 %, P = 0.035; 바늘 끝 위치: 40˚, 96.7 % vs. 26.7 %, P <0.001; 50˚, 96.7 % vs. 63.3 %, P = 0.002; 90˚, 96.7 % vs. 66.7 %, P = 0.012). 60 도 각도의 반대측 경사 영상과 사전 측정된 각도의 반대측 경사 영상이에는 이러한 값에 차이가 없었다.

Chapter II: 총 44 명의 환자(L 군 21 명, C 군 23 명)가 연구에 포함되었다. 첫 시도 성공률은 L 군보다 C 군에서 유의하게 높았다 (69.6 % vs. 28.6 %, P = 0.016). 최종 성공률은 C 군에 비해 L 군에서 유의하게 낮았다 (76.2 % vs. 100 %, P = 0.044). 통증 강도 점수는 C 군에서 L 군과 비교하여 각각 3.7 ± 1.8 vs. 2.2 ± 0.9 로 유의하게 낮았다 (P = 0.002). 환자 만족도는 L 군보다 C 군에서 현저히 높았다 (6.0 [6.0 – 7.0] vs. 5.0 [4.0 – 6.0], P = 0.001). 중간부 흉부 경막 외 접근법 동안, 바늘 통과 시간과 바늘 통과 횟수는 L 군에서 보다 C 군에서 현저히 적었다 (94.0 [84.0 – 155.0] vs. 125.0 [115.0 – 205.0], P = 0.035; 1.0 (1.0 – 2.0) vs. 3.0 (1.0 – 4.0), P = 0.003). 두 군 모두에서 심각한 합병증은 없었다.

Chapter III: 38 명의 환자가 이 연구에 참여하였다. 실시간 초음파 안내 하 흉추 경막외 카테터 삽입술 동안 바늘 통과 시간의 중앙값은 49.0 초였고 바늘 통과 횟수는 1.3 ± 0.6 이었다. 첫 시도

성공률은 76.3 %였다. 흉부 경막 외 조영술을 평가한 후 경막 외 카테터 팁이 모두 경막 외 공간에 위치하는 것을 확인하였다. 시술과 관련된 합병증은 없었다.

결론

중간부 흉부 영역에서 60 도 각도의 반대측 경사 영상은 투시 영상 안내 하 흉부 경막 외 접근법에서 이상적인 반대측 경사 각도 일 수 있으며, 측면 영상보다 더 명확한 추간판 및 바늘 끝의 시각화와 더 일관된 바늘 끝 위치를 제공할 수 있다. 60 도 각도의 반대측 경사 영상을 사용하면 시술의 성공률과 환자 만족도를 높이고 시술 시간과 환자의 불편감을 줄일 수 있으며 중간부 흉부 경막 외 접근법 시 안전을 보장할 수 있다. 실시간 초음파 안내 하 흉추 경막외 카테터 삽입술은 완벽한 성공률을 보여주었고, 이는 실시간 초음파 안내가 시술의 성공률 증가 및 환자의 불편함 감소, 방사선 위험의 감소로 흉추 경막외 카테터 삽입술에서 유용할 수 있음을 시사한다. 따라서 안전하고 효과적이며 쉬운 흉부 경막 외 접근법을 달성하기 위해 60 도 각도의 반대측 경사 투시 영상 및 실시간 초음파 안내의 사용을 우선적으로 고려할 것을 권장한다.

핵심 단어: 경막외강 확인; 카테터 삽입; 만성 통증; 반대측 경사 영상; 경막 외 진통; 투시 조영; 측면 영상; 중간부 흉부; 초음파