Influence of needle-insertion depth on successful epidurogram and clinical outcomes in caudal epidural injections: a randomized clinical trial

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Influence of needle-insertion depth on successful epidurogram and clinical outcome in caudal epidural injections:

a randomized clinical trial

Directed by Professor Shin Hyung Kim

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<TABLE OF CONTENTS>

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Influence of needle-insertion depth on successful epidurogram and clinical outcomes in caudal epidural injections: a randomized clinical trial

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Introduction: A caudal epidural injection (CESI) is a commonly used method to improve symptoms of lumbosacral pain. We compared the achievement of successful epidurogram and patient reported clinical outcomes following a different needle insertion depth during CESI.

Materials and Methods: A total of 130 patients who underwent CESI under fluoroscopy was randomly assigned into the two groups: conventional method group (n=65) receiving the caudal injection after advancement of the needle into the sacral canal and alternative method group (n=65) receiving the injection right after penetrating the sacrococcygeal ligament. Epidural filling patterns and vascular uptake during fluoroscopy were determined to verify successful epidural injection. Procedural pain scores were investigated immediately after the procedure. Pain scores and patient global impression of symptom change were evaluated at 1 month follow-up.

Results: Assessments were completed by 127 patients (conventional method, n=64; alternative method, n=63). Incidence of intravascular injection was significantly lower in the alternative method group than in the conventional method group (3.2% vs. 20.3%, P=0.005). Procedural pain during needle insertion was significantly lower in the alternative method group (3.7±1.3 vs. 5.3±1.2, P<0.001). Epidural contrast filling patterns were similar in both groups.

One-month follow-up pain scores and patient global impression of symptom change were comparable in both groups.

Conclusion: Compared with the conventional method, the alternative method for CESI could achieve similar epidural spread and symptom improvement. The alternative technique exhibited clinical benefits of a lower rate of intravascular injection and less procedural pain.

Key words : caudal block; epidurogram; intravascular injection

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I. INTRODUCTION

Caudal epidural steroid injection (CESI) is a commonly used strategy to improve lumbosacral pain[1]. Traditionally, performing a CESI involves placing a needle through the sacral canal to deliver medications into the epidural space. It is a blind technique simply performed by palpating the sacral hiatus. However, inadvertent vascular injection is more common than with lumbar epidural injections, resulting in an increased risk of complications and ineffective injection[2,3]. Additionally, there is a potential risk of dural puncture as the end of the dural sac may extend below the S3 level[4].

With the introduction of fluoroscopy and ultrasound to guide needle placement, caudal epidural block success rates have dramatically improved[5,6]. Recently, some studies reported an alternative approach, injecting medications immediately after penetration of the sacrococcygeal ligament, in which placing needle into the sacral canal becomes unnecessary[7]. These studies demonstrated the reduced intravascular injection using the real time fluoroscopy and manual blood aspiration method. However, the detailed extent of epidural spread such as cephalad spread and nerve root involvement was not compared with the conventional approach. Furthermore, clinical benefits of the alternative CESI

technique on procedural pain and patient-reported symptom improvement after the procedure were not investigated.

In this study, we used two different needle-insertion depths (into the sacral canal versus immediately after sacrococcygeal ligament penetration) for CESI and compared epidurogram patterns and the incidence of intravascular injection using the digital subtraction angiography (DSA). Needle related pain during the procedure and patient global impression of symptom change at 1-month follow-up were investigated. Ultimately, we determined the clinical reliability of this alternative approach compared with the conventional approach for CESI.

II. MATERIALS AND METHODS

1. Study population and randomization

This randomized prospective clinical trial was approved by our institutional review board (4-2016-1030) and registered at ClinicalTrials.gov (NCT 03057197). Written informed consent was provided by each patient before study enrollment. The study was conducted at the outpatient department for pain management at Yonsei University College of Medicine, Seoul, Korea, between March 2017 and March 2018. This manuscript adheres to the applicable CONSORT guidelines for randomized controlled studies. The study included 130 patients (20–80 years of age) scheduled for CESI. Patients with general contraindications for fluoroscopy-guided injection, such as pregnancy, contrast material allergy, and coagulopathy, were excluded. Each patient was assigned to either the conventional method group or alternative method group using a computer-generated randomization protocol. The different CESI methods were then given to each patient based on group assignment (Fig. 1).

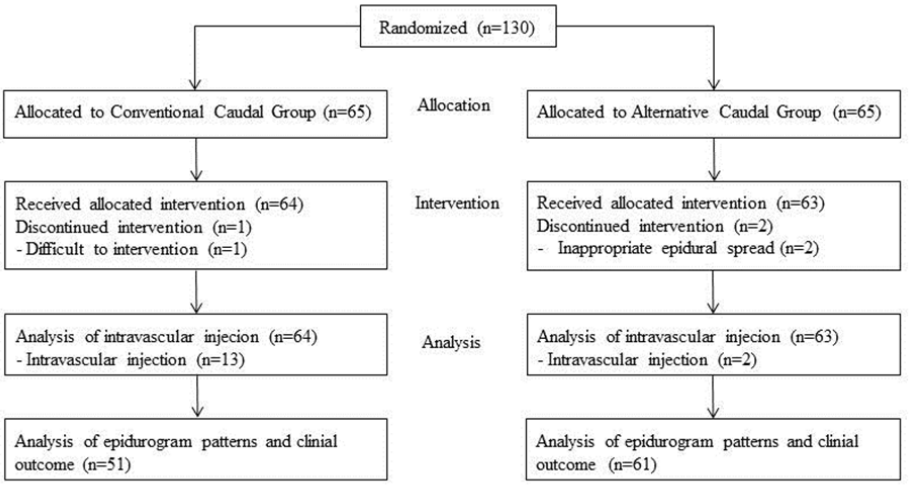

Figure 1. The CONSORT flow diagram.

2. Caudal epidural injections and outcome measures

All procedures were performed using the same C-arm fluoroscopy system (ARCADIS Varic 2013 model; Siemens Medical Solutions, Erlangen, Germany). An operator with 5 years of experience performed all procedures. The patients were placed in the prone position with a pillow beneath the lower abdomen and then covered with a sterile drape. The sacral hiatus was identified in the lateral fluoroscopy view as an abrupt drop-off at the caudal end of the S4 lamina. After infiltration of the skin at the planned needle entry point with 1% lidocaine, a spinal needle (22-G, 8-cm Quincke) was inserted into the epidural space through the sacral hiatus using intermittent fluoroscopic guidance. In the conventional method group, the needle was inserted into the sacral canal and advanced to the mid S3 level. In the alternative method group, the needle tip was inserted into the epidural space until a “pop” was felt as the sacrococcygeal ligament was penetrated; the sacral canal was unaffected (Fig. 2).

After verification of the final needle position using lateral and antero-posterior

(AP) views, the needle was attached to an extension tube, which was connected to a 5-mL syringe at the opposite end. The plunger of the syringe was withdrawn to check for blood. If this aspiration test was negative, 1 mL of contrast medium was slowly injected at 0.1 mL/sec; DSA was used to assess intravascular and sacral epidural space injection. Intravascular injection was characterized by the appearance and immediate disappearance of contrast medium in a snake-like pattern. Each distribution pattern was assigned to one of three categories: epidural only, epidural and intravascular, or intravascular only. If intravascular spread of contrast medium was observed, the needle was repositioned and lack of vascular uptake was confirmed. When no vascular flow was observed, 15 mL of injectate (0.2% lidocaine with 5 mg dexamethasone disodium phosphate and 5 mL contrast medium) was injected, then the pattern of contrast distribution was observed under fluoroscopy. Contrast-media dispersion into the epidural space and filling of nerve roots were observed in AP and lateral views.

We collected patient demographic and clinical data, including age, sex, weight, height, body mass index, pain score, duration of pain, and main diagnoses, and previous spinal surgery history. Procedural pain was investigated separately from the existing (pre-procedure pain), using a 10-point numeric rating scale from 0=no pain to 10=worst imaginable pain. We defined procedural pain as pain from the start of needle insertion until it reaches its final position. Patients rated the procedural pain immediately after the CESI was completed. At 1-month follow-up, we evaluated patient-reported pain scores and overall symptom improvement (patient global impression of change: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse). An independent observer not involved in the procedure confirmed and recorded all assessments in this study.

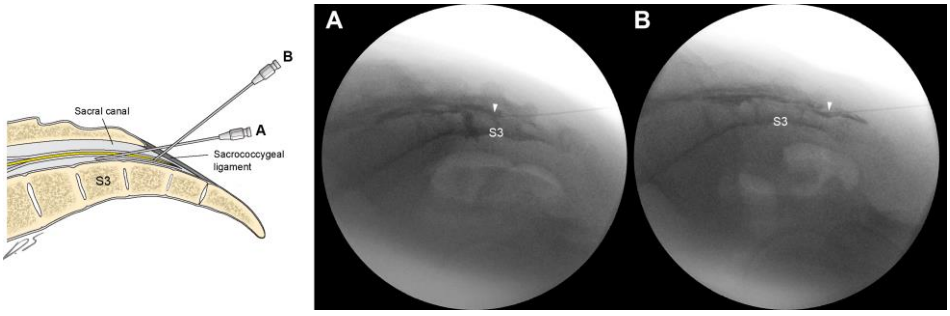

Figure 2. Schematic diagram and fluoroscopic images demonstrating needle placement of the conventional method (A) and alternative method (B) for caudal epidural injection.
S3, 3rd vertebral body of sacral spine. Arrow head indicates the tip of needle.

3. Statistical analysis

The primary endpoint of this study was the success rate of epidural spread without intravascular uptake. The results of a previous study revealed a 41.7% incidence of intravascular injection for CESI, when verified by DSA[8]. We considered a 55% decrease in rate of intravascular injection with the alternative method of CESI to be clinically relevant. Power analysis results indicated that a sample size of 65 patients was required for each group (α-error=0.05, power=80%, drop-out rate=5%). All results are expressed as mean ± standard deviation, median (interquartile range), or number of patients. The Shapiro-Wilk test was used to determine whether data were normally distributed. Student's t-test, Chi-square test, or Mann-Whitney U test was used where appropriate for between-group comparisons of demographic and clinical data. The Statistical Package for the Social Sciences 23 (SPSS Inc, Chicago, IL, USA) was used for all analyses. Results with a P-value < 0.05 were considered to be statistically significant.

III. RESULTS

We enrolled and randomized 130 patients. Three patients were excluded from the study population for the final analysis. One patient in the conventional method group was converted to the alternative method group because of difficulty approaching the sacral canal. Two patients from the alternative method group were converted to the conventional method group because the contrast medium was mostly observed in the coccygeal level, thus, failed to ascend to the cephalad epidural space. Therefore, data from 64 patients in the conventional method group and 63 patients in the alternative method group were analyzed. In 13 conventional method group patients and 2 alternative method group patients, intravascular uptake was observed, and needle repositioning or a second attempt for the epidural injection was subsequently necessary during the procedure. These patients were excluded in the analysis of epidurogram patterns and the clinical outcomes at 1-month follow-up (Fig. 1).

Patient characteristics and baseline clinical data, including pre-procedure pain scores, are presented in Table 1. The rate of successful epidural spread was significantly higher in the alternative method group than in the conventional method group (96.8 % vs. 79.7%, P=0.005). The incidence of intravascular injection was significantly lower in the alternative method group (3.2% vs. 20.3%, P=0.005) (Table 2). Procedural pain during needle insertion was significantly lower in the alternative method group (3.7±1.3 vs. 5.3±1.2, P<0.001). The epidural and nerve root filling patterns are presented in Table 3. Most patients (93%) exhibited ventral filling extending up to the L5-S1 level. Ventral filling and nerve root filling were not significantly different between the two groups. While pain scores in both groups were reduced at 1-month follow-up, there was no statistically significant difference in post-procedure pain relief between the two groups (1.7 ± 1.3 vs. 1.7 ± 1.6, P=0.913) (Fig. 3). The median value of PGIC similarly was 3 (minimally improved) in both group

(P=0.889) (Table 4). There were two cases of facial edema, which was possibly a corticosteroid side effect. No severe episodes such as dural puncture were reported.

Table 1. Patient characteristics and baseline clinical data.

	Conventional (n=65)	Alternative (n=65)	p-value
Gender(female/male)	40/25	35/30	0.375
Age, years	65.6 ± 10.5	65.1 ± 11.4	0.810
Body mass index, kg/m^2	24.3 ± 2.7	24.8 ± 3.5	0.363
Baseline pain scores, NRS	6.8 ± 1.6	6.7 ± 1.8	0.643
Pain duration, months	5.5 ± 4.2	4.6 ± 3.4	0.207
Lumbar spine surgery history	45 (69.2%)	46 (70.7%)	0.848
Diagnosis			
Spinal stenosis	29 (44.6%)	32 (49.2%)	0.725
Herniated lumbar disc	15 (23.0%)	9 (13.8%)	0.258
Post spinal surgery syndrome	16 (24.6%)	11 (16.9%)	0.387
Radiculopathy of other origin	5 (7.6%)	13 (20.0%)	0.073

Values are expressed as mean ± standard deviation, number, or number (%) of patients.

NRS, numeric rating scale (0 to 10)

Table 2. Incidence of intravascular injections.

	Conventional (n=64)	Alternative (n=61)	p-value
Epidural only	51/64 (79.7%)	61/63 (96.8%)	0.004
Intravascular	13/64 (20.3%)	2/63 (3.2%)	0.005
Epidural and intravascular	12/13 (92.3%)	2/2 (100%)	
Intravascular only	1/13 (7.7%)	0 (0 %)	

Values are expressed as number (%) of patients.

Table 3. Analysis of epidurogram patterns.

Type of spread	Conventional (n=51)	Alternative (n=59)	p-value
Ventral spread			
L5-S1 level	48/51 (94.1%)	54/59 (91.5%)	0.722
L4-5 level	15/51 (29.4%)	14/59 (23.7%)	0.523
Nerve root spread			
S1 root	27/51 (52.9%)	32/61 (52.4%)	1.000
L5 root	4/51 (7.8%)	3/61 (4.9%)	0.702

Data are presented as number of cases with spreading/total number of cases in the group (% of cases with spreading).

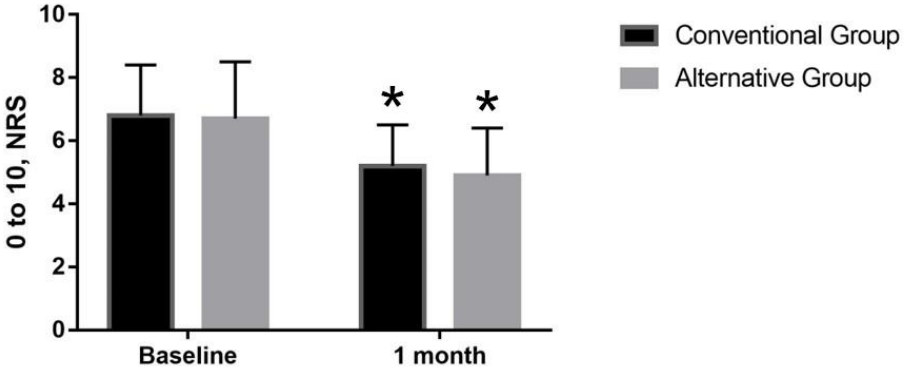

Figure 3. Changes in pain scores during the study period.
Values are expressed as mean ± standard deviation. NRS, numeric rating scale. *, P value < 0.05 vs. baseline in each group. There was no significant difference in pain scores between the two groups at 1 month after injection (P=0.333).

Table 4. Patient global impression of change at 1 month follow-up.

PGIC ratings	Conventional (*n*=51)	Alternative (*n*=61)
1. Very much improved	0 (0%)	0 (0%)
2. Much improved	13 (25.5%)	17 (27.9%)
3. Minimally improved	32 (62.7%)	34 (55.7%)
4. No change	6 (11.8%)	10 (16.4%)
5. Minimally worse	0 (0%)	0 (0%)
6. Much worse	0 (0%)	0 (0%)
7. Very much worse	0 (0%)	0 (0%)

Values are expressed as number of patients (%). PGIC, patient global impression of change. Mann–Whitney U test showed no significant difference in PGIC ratings between the two groups at P=0.889.

IV. DISCUSSION

In the present study, compared with the conventional method, the alternative method for CESI could achieve similar epidural spread and symptom improvement. The alternative technique exhibited clinical benefits of a lower rate of intravascular injection and less procedural pain.

In caudal epidural injections, intravascular injection increases the likelihood of complications and reduces the effectiveness of the procedure[2,3]. Our results showed that during CESI, the incidence of intravascular injection was significantly lower with the alternative method than with the conventional method. There are two possible explanations for this difference. In the alternative technique, as the sacral canal is preserved from needling, the bony contact with the needle is less likely. When the needle touches bone, it may penetrate or injure vessels near the bone surface. Shin et al. reported that when the needle contacts bone between the posterior and anterior sacral foramina during S1 transforaminal epidural steroid injections, an intravascular injection rate increases, with an odds ratio of 2.624[9]. The second explanation involves the kyphotic nature of the sacrum and the needle insertion angle. In the conventional technique, the needle is inserted at a shallow angle to the sacral canal where in many cases it comes in contact with the anterior wall of the sacral spine. The sacral venous plexus is located along the anterior wall of the sacral canal and usually terminates at S4 but may extend inferiorly, particularly in older patients[10,11].

There are few researches regarding procedural pain during caudal epidural injections. Previous studies reported post-injection pain as one of the adverse effects of caudal blocks. Ogoke reported that pain may persist at the sacral hiatus site of entry, but it usually resolves within 2 to 6 months and is associated with ecchymosis at the injection site[12]. Another previous study reported injection-site soreness in 18% of patients after caudal epidural injection[3]. In our

study, compared with the conventional method, the alternative method was associated with lower procedural pain. This finding may be attributed to the fact that the pain-sensitive structures, such as sacral nerves, fat tissue, and bone, are secured from needling in the alternative approach.

In the present study, contrast agent spread to the coccygeal level in 2 of 65 patients in the alternative method group instead of ascending to lumbosacral level. These patients excessively complained of pain during the procedure and were subsequently injected using the conventional method. The injectate failed to travel in the cephalad direction and stagnated at the coccygeal level outside the sacral canal possibly because of anatomic variation, such as a very small sacral canal diameter[13]. Conversely, one patient had a narrow sacral canal that was difficult to access by the conventional technique. When the alternative method was used, instead, the injection was successful. Certain anatomic features and variations of the sacral hiatus may lead to difficult needle insertion into the caudal epidural space. A previous study reported that an AP diameter < 3.7 mm at the sacral hiatus apex was associated with difficulty inserting a needle into the caudal epidural space using the blind technique[14]. Nikooseresht and colleagues[15] reported that the average AP diameter of the sacral hiatus apex in patients with failed caudal epidural needle insertion was 1.61±0.1 mm, which was significantly less than the diameter in patients with successful insertion (4.7 ± 1.7 mm). On the other hand, the extent of epidural spread confirmed by fluoroscopy during CESI may be associated with the clinical outcome after procedure[16,17]. There was no difference in ventral spread or nerve root filling between the two groups in the current study. Moreover, pain relief was mostly achieved at 1- month follow-up in both groups. Collectively, this study demonstrated that the alternative method may be a useful option when the conventional approach is difficult in clinical practice.

There are some limitations in this study. First, the operator was not blinded to the injection method, although an independent observer not involved in the

procedure recorded and confirmed the results. Second, this study used a real world clinical practice model in which attending physician decided the treatment option for lumbosacral pain. Thus, we could not control for potential confounders such as medication type, which could affect clinical outcomes. Third, we did not assess psychological factors which may have affected procedural pain and post-procedure clinical outcomes.

V. CONCLUSION

In conclusion, this study confirmed that successful epidural spread can be achieved during CESI if the needle passes through the sacrococcygeal ligament but does not advance into the sacral canal. Moreover, this alternative technique was associated with a lower incidence of intravascular uptake and less procedural pain. Therefore, this study supports the use of ultrasound guided CESI with the alternative approach. Although needle placement within the sacral canal may anatomically guarantee drug delivery into epidural space, the alternative approach would be beneficial for selected patients in whom technical difficulty or excessive sensitivity to procedural pain is expected during CESI.

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ABSTRACT(IN KOREAN)

미추 경막외 신경차단술 시행 시 바늘 삽입 깊이가 경막외강 조영 및 임상 예후에 미치는 영향

<지도교수 김신형>

연세대학교 대학원 의학과

박 상 준

미추 경막외 신경차단술은 요천추부 통증의 증상 호전을 위해 흔히 사용되는 방법이다. 본 연구에서는 미추 경막외 신경차단술 시행 시 바늘의 깊이에 따라 경막외강 조영의 성공여부 및 임상 예후를 비교하였다.

미추 경막외 신경차단술을 시행 받는 130명의 환자를 무작위로 천추강 내로 바늘을 진입시키는 기존의 방법을 사용한 환자군 (n=65)과 바늘이 천미인대를 통과한 직후에 약물을 주입하는 대체 방법을 사용한 환자군 (n=65)으로 나누었다.

경막외강 주입을 확인하기 위해 디지털 감산 혈관 조영술 (digital subtraction angiography)을 이용하여 혈관 내 주입여부 및 경막외강 조영 양상을 분석하였다. 시술 관련 통증을 시술 직후에 확인하였으며 통증점수 및 증상호전 여부를 시술 1개월 이후 확인하였다.

127명의 환자가 평가를 완료하였다. 혈관 내 주입율은 대체 방법을 사용한 환자 군에서 기존의 방법을 사용한 환자 군 보다 현저히 낮았다 (3.3% vs. 20.3%, P =0.005). 바늘 자입시 시술 관련 통증은

기존의 방법을 사용한 환자 군에서 더 높았다 (5.3 ± 1.2 vs. 3.7 ± 1.3, P<0.001). 두 군간에 경막외강 조영 양상에는 차이가 없었다. 1개월 후 확인한 통증 점수 및 증상 호전 여부 또한 두 군간에 차이가 없었다.

대체 방법을 통한 미추 경막외 신경차단술은 기존의 방법과 유사한 임상적 효능을 보이고 성공적인 경막외 약물 주입이 가능했다. 이에 더불어 시술 관련 통증을 줄이고, 혈관 내 주입율을 낮추는 임상적으로 의미 있는 결과를 확인할 수 있었다.

핵심되는 말: 미추 경막외 신경차단술, 경막외강 조영술, 혈관 내 주입