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Technical Notes & Surgical Techniques

Ventral epidural steroid injection with catheter techniques for radicular pain patients: A prospective observational study

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ABSTRACT

Aim

Using the controllable caudal catheter (CCC) is the other option for ventral epidural steroid injection. This study determined the pain reduction result by CCC in leg pain patients who were poor surgical candidates.

Material and methods: Sixty nine cases were met inclusion criteria. Visual Analog Scale score and Roland Morris Disability Questionnaire of two groups were determined at 2 weeks, 1 month, 3 months and 6 months. Mixed linear regression model was applied to compare Visual Analog Scale score and Roland Morris Disability Questionnaire between two groups.

Results: Overall mean Roland Morris Disability for CCC and Transforaminal selective nerve root block (TF-SNRB) are 0.68 (95% CI: 0.58, 0.78) and 0.50 (95% CI: 0.42, 0.59), respectively. Overall mean Visual Analog Scale score for CCC and TF-SNRB are 3.77 (95% CI: 3.04, 4.51) and 3.65 (3.04, 4.26), respectively. Comparing between two groups, the coefficient of Roland Morris Disability and Visual Analog Scale score were −0.173 (95% CI: −0.314, −0.031) and −0.123 (95% CI: −1.148, 0.901), respectively.

Conclusion: The pain reduction result by CCC was comparable with TF-SNRB in early follow-up. They are also useful for patients who are not candidates for surgery.

1. Introduction

Epidural steroid injection (ESI) is the most common minimally invasive management technique for chronic radicular pain [7,8,24]. By using a local anesthetic agent and steroid as injectates, several studies have disclosed a number of benefits in palliative back pain management [9,11,14,24]. Both diagnosis and treatment for nerve irritation causing leg and lower back pain in the lumbar spine can be achieved by ESI and has been accepted worldwide [24]. However, many studies have reported inconsistent effectiveness of palliative outcomes [1,2,14,18–20,24]. There are a variety of techniques for ESI, including caudal, transforaminal (TF) and interlaminar approaches. The approaches which are reported to have a satisfactory outcome should target the ventral epidural space and nerve roots directly. For this reason, the transforaminal selective nerve root block (TF-SNRB) route is often preferred, in which the injectates can be spread ventrally to the thecal sac [4–6,10]. Nevertheless, there is another technique using a special device, a controllable caudal catheter (CCC), which is inserted caudally. Under fluoroscopic guidance, the CCC is inserted via the sacrococcygeal ligament between the sacral cornua. In addition, a ventral approach is feasible to achieve with CCC. Finally, this catheter will always stay ventral to the thecal sac, and can reach the L1–L2 level on either the right or left side. The tip of the catheter is flexible and can be rotated by the controllable hand piece. The aim of the present study was to compare the analgesic effectiveness of ESI technique between CCC and TF-SNRB in radicular pain patients who were poor surgical candidates.

2. Materials and methods

This study (the protocol number is ID 03-56-35) was approved by the institutional review board of Ramathibodi Hospital, Bangkok, Thailand. Written informed consent in Thai was obtained from all subjects before the study. Leg and/or low-back pain patients who were poor surgical candidates were recruited consecutively. All procedures, as shown in Fig. 1, were performed by the first author only. Inclusion criteria included: ambiguous findings between imaging and neurological examination of lumbar radiculopathy; elderly with one or more severe underlying diseases and high risks for operation under anesthesiologist's evaluation; lumbar radiculopathy; radicular pain with

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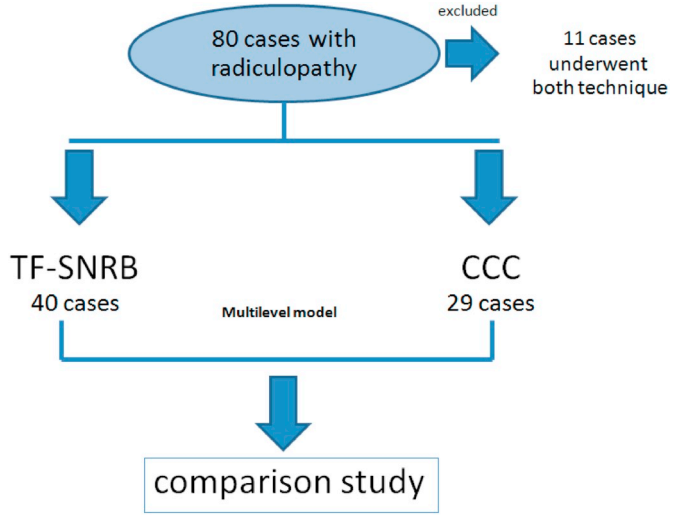

Fig. 1. Diagram illustrating the method of the present study, comparing transforaminal selective nerve root block (TF-SNRB) and controllable caudal catheter (CCC).

previous back surgery; and elderly who denied for surgery. Exclusion criteria were a definite indication for back surgery, and incomplete or lost medical records. The duration of the study was May 2013–May 2014. The sample size was estimated based on primary objective which is comparison of RM score between controllable caudal catheter (CCC) and transforaminal selective nerve root block (TF-SNRB). The sample size equation for comparison two independent means is shown as the followings:

$$n = 2 \times \left[\frac{(Z_{a/2} + Z_{\beta})\sigma}{(\mu_1 - \mu_2)} \right]^2$$

Based on the information from previous study, the mean and standard deviation of RM score in TF-SNRB group was 10.9 and 4.7, respectively [23]. If the CCC is efficacious, it should be able to decrease RM score at least 5 compared with TF-SNRB. The ratio, type I and type II errors were set as 1:1, 0.5 and 0.20, respectively. The sample size can be estimated as the followings.

$$n = 2 \times \left[\frac{(1.96 + 0.84) \times 4.7}{5} \right]^2 = 13.85$$

Finally, the estimated sample size was about 28–30 cases as a recruitment plan.

TF-SNRB was performed following a neurological examination and after informed consent was given. A 20 G × 20 cm Chiba® biopsy needle (DCHN-20-20.0) was inserted under fluoroscopic guidance at the desired level, 10 cm laterally from the midline. About 2–5 cc of Iopamiro 300® (300 mg iodine/cc) was used as a contrast media. A total of 2 cc of Diprospan® (containing 4 mg betamethasone sodium phosphate and 10 mg betamethasone dipropionate) was used.

In performing CCC, a tip-controllable (St. Reed®) catheter was used, with an external diameter of 2 mm and a length of 30 cm, as shown in Figs. 2 and 3. The device, shown in Fig. 4, was inserted caudally after a trocar needle was placed through the sacrococcygeal ligament between the sacral cornua. After insertion, the catheter was placed in the ventral epidural space, which could be confirmed under fluoroscopy. This catheter was able to reach the L1–L2 level. The contrast media or injectates could be injected via the injection port in the caudal part of the device without guided wire removal. Under fluoroscopic guidance, the tip of the catheter could be controlled and reach the desired lumbar spinal level on either the right or left side with only one puncture. Finally, both TF-SNRB and CCC group were received totally 2 cc of Diprospan® (containing 4 mg betamethasone sodium phosphate and 10 mg betamethasone dipropionate) for each case.

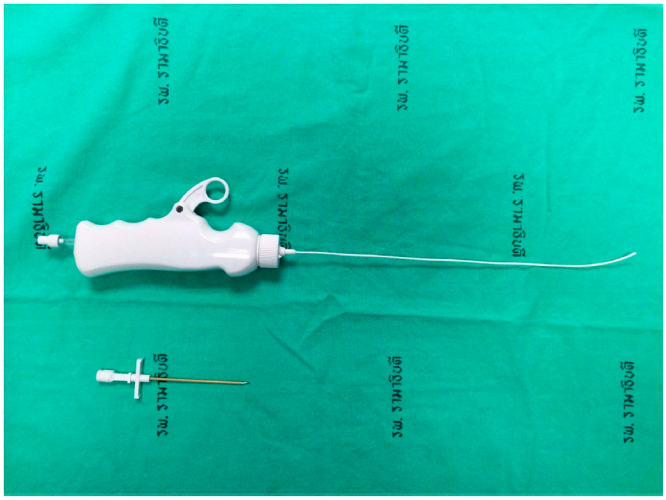

Fig. 2. Illustration showing the controllable caudal catheter (CCC).

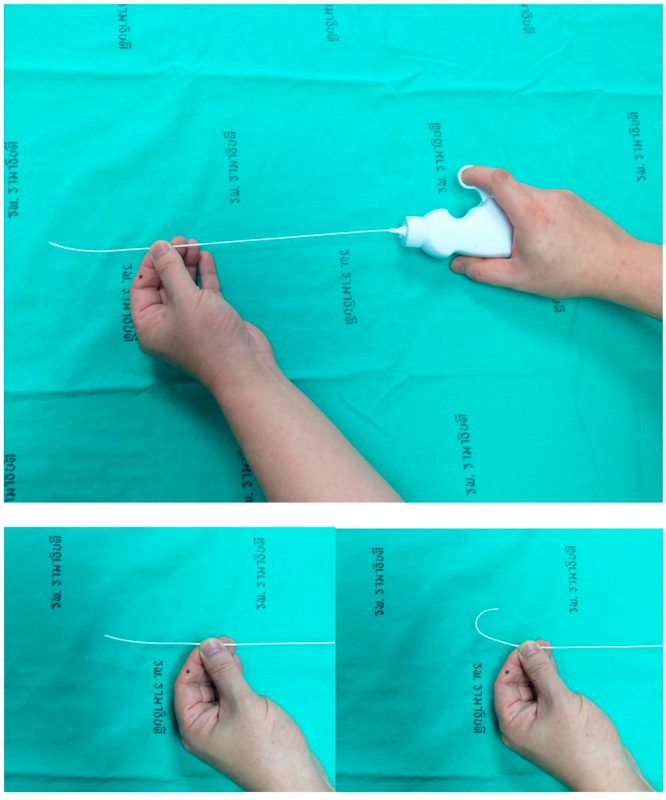

Fig. 3. Illustrations showing the flexible tip of the catheter and hand piece.

After interventions, the Visual Analog Scale (VAS) spine score and Roland Morris Disability Questionnaire (RM) of the two groups were recorded and determined at 2 weeks, 1 month, 3 months and 6 months. Concerning alterations of motor power and sensory, it means that the patient was asked whether there was some variation of the motor or sensory after the intervention. Generally, the motor power should not be different but back pain should be improved after intervention. Initially, there were 80 cases; but 11 cases were underwent both TF-SNRB and CCC during study period. Eventually, these cases were excluded to avoid bias. Moreover, we applied the mixed linear model to deal with these parallel data. There were 40 cases underwent TF-SNRB alone and twenty nine cases with CCC as shown in Table 1.

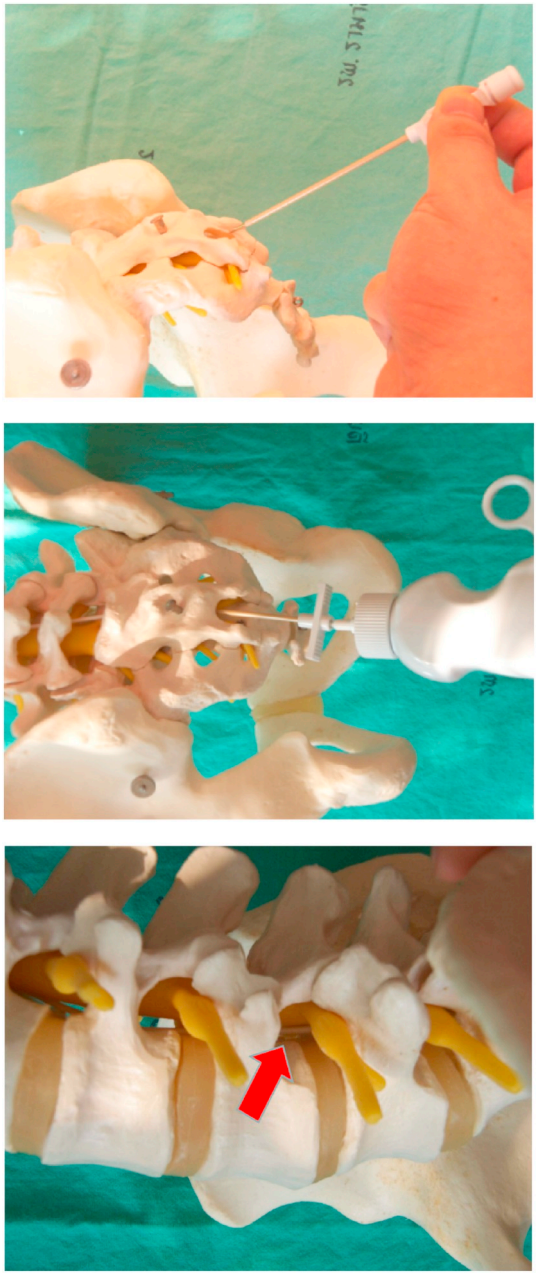

Fig. 4. Illustrations showing the catheter insertion; the red arrow indicates the catheter placement. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

2.1. Statistical analysis

Continuous variables were described as mean (SD) if data have normally distributed otherwise were described by median (range). Categorical variables were described as numbers and percentages. The Chi– squared test (or Fisher's exact test) was used for comparison categorical variables between groups. Student *t*-test (or Mann-Whitney test) was used for comparison continuous variables between groups. For continuous outcomes (RM and VAS), mixed linear regression analysis was used to assess the intervention effect by adjusted with confounding factors (such as age and diagnosis). For dichotomous outcomes (sensory and motor), logistic regression analysis was used to determine the intervention effect by adjusted with confounding factors (such as age and diagnosis). A p-value 0.05 was considered statistically significant. All analyses were performed using STATA version 14.0 (Stata Corporation, College Station, TX, USA).

2.2. Procedure in detail

2.2.1. Transforaminal selective nerve root block (TF-SNRB)

The actual technique of TF injection is as the followings. First, the subject was placed in the prone position after sterile preparation, draping, and local anesthesia under fluoroscopic guidance, it is practically applied nearby the segmental nerve root in the foramen. A straight 22-gauge Quinke needle was gently inserted on oblique view to the safe-triangle. The needle-tip should be inserted and placed in the "safe triangle". It is at the inferior to the pedicle and superior lateral to the exiting nerve root. A tangential base that corresponds to the exiting nerve root and the lateral border of the vertebral body is identified. Both anteroposterior and lateral fluoroscopic guidance confirmed appropriate needle-tip placement. After that, 1–2 cc. of contrast medium was injected to confirm the position at each level under fluoroscopic guidance. Then, a sufficient flow of contrast media was documented under fluoroscopic guidance. No blood or CSF was aspirated. And also the absence of intravascular injection should be confirmed. Finally, the injectate will be following injected.

2.2.2. Controllable caudal catheter (CCC) insertion

The following is a step of CCC procedure. First, to prepare the patient, the risks and benefits of the procedure must be discussed with the patient and family. And also, the informed consent is obtained. Risks include infection, side effect of medication, nerves or blood vessels injury, bruising, bleeding, worsening of pain, paralysis and bowel/bladder incontinence. The urodynamic evaluation before the procedure is necessary in patient with history of urinary incontinence. A complete blood count is assessed for any undiagnosed infections. In addition, history of bleeding or abnormal coagulation and platelet function are also concerned. These investigations must be completed before the procedure established. The procedure must be sterile and carried out using an aseptic technique in the operating room. The patient is placed in the prone position. To correct the lumbar lordosis, pillows are placed under the chest and abdomen. The patient comfort is also concerned. After sterile preparation and draping, the sacral hiatus is identified under fluoroscopic guidance. Then, a local anesthesia is given above the sacral hiatus in midline position. The skin is nicked with surgical scalpel blade No. 11 at the sacral hiatus opening. The 15-guage epidural needle is punctured and inserted through the nick at a 45-degree angle under fluoroscopic guidance. When the needle is through the hiatus, the angle of the needle is declined for horizontal level to approximately 10–15 degrees and advanced. After it is in position, 2–4 cc. of contrast media is injected to confirm a proper needle placement. The appropriate position should be below the level of the S3 foramen on anteroposterior (AP) view under fluoroscopic guidance. In this present study, Iopamiro 300 mg/cc solution is used for epidurographic injection. It is very important to confirm by a negative aspiration for blood or cerebrospinal fluid prior injection of the contrast media or medication. Accidental subarachnoid injections or vessel injury can lead to the following complications. Then, take out the stylet and needle leaving the introducer in the hiatus. At that point, insert CCC through the introducer by bending the CCC-tip downward as figured. This could increase the chance of ventral placement. During the advancement of CCC under fluoroscopic guidance, continuous bending the tip downward is recommended to ensure the CCC-placement ventrally. Under continuous fluoroscopic guidance in lateral view, advance and bending the CCC-tip toward the ventral epidural space and steer to the target level. Check a lateral view to confirm that the CCC-tip is in the ventral epidural space. It is needed to repeat or redirect the CCC-tip if the ventral epidural space could not be achieved. When the catheter is already placed ventrally and reached the desired level, slowly inject the contrast media to confirm the level and the ventral placement. During advancing CCC, the patient may complain of discomfort. To reduce this pain or

discomfort, 2–4 cc. of local anesthesia could be injected. At the target level under AP view, 3–5 cc. of injectate will be following injected and then the catheter is slowly flushed with 2–3 cc. of preservative-free normal saline. After that, CCC and introducer are removed. The nick at the skin is closed and the patient needs to be observed to document the clinical condition prior discharged. The first clinic follow-up is within 14–15 days.

3. Results

Among 80 consecutively recruited cases, 40 cases were recruited to undergo TF-SNRB, 29 consecutive cases underwent CCC alone, and 11 cases were underwent both TF-SNRB and CCC during study period. These eleven cases were excluded. Forty-six (63.89%) of 80 patients are females. The mean age was 57.65 years and mean BMI was 25.19. The major diagnosis was degenerative disc disease (DDD) at L4–5 (about 22.2%). The characteristic between two groups were shown in Table 1. Fourteen cases were excluded to avoid bias. Regarding RM, the overall mean RM for CCC and TF-SNRB are 0.68 (95% CI: 0.58, 0.78) and 0.50 (95% CI: 0.42, 0.59), respectively. The mean and standard deviation (SD) for RM between two groups according to follow period are presented in Table 2. The different of RM adjusted by age and diagnosis between two methods yields the coefficient of −0.173 (95% CI −0.314, −0.031) with a statistical significance of $p = 0.017$. This can be interpreted that the CCC is about 0.173 units higher in RM than the TF-SNRB method. The results are presented in Table 3. Regarding the VAS, the overall mean VAS for CCC and TF-SNRB are 3.77 and 3.65, respectively. The mean and SD for VAS between two groups according to follow up period are presented in Table 2. Comparing between CCC and TF-SNRB, the coefficient was −0.123 (95% CI −1.148, −0.901) with a statistical significance of $p = 0.813$ after adjusted with confounding factors, as shown in Table 3. This means that the VAS in CCC method has 1.148 units lower than TF-SNRB method. The motor power and sensory were not changed comparing before and after procedures in both group as shown in Tables 4 and 5.

4. Discussion

Radicular pain leads to significant disability and cost of treatment [8,9,25]. ESI for nonsurgical treatment candidates with radicular pain typically utilizes steroidal anesthetic drugs [1,4,14,16,21,24]. It is very useful both for diagnosis and treatment in radicular pain patients. ESI is the most frequently performed procedure for palliative treatment with dramatic pain relief using a minimally invasive technique [1]. The approach which is reported to have the most satisfactory outcome is by injection at the ventral epidural space and nerve roots directly. For this reason, the TF-SNRB route is widely used, and the injectates could be spread ventrally to the thecal sac but it is inconsistent, as shown in Fig. 5. There is no any consensus to perform the TF procedure. Some complications with spinal cord injury after TF injection have been reported [12]. However, there is another technique using a special device, the CCC, which is inserted caudally. This catheter was invented based on a Racz catheter concept, but the tip of the catheter can be controlled and flexible enough to reach the desired lumbar spinal levels on either the right or left side with only one puncture, as shown in Fig. 6. To our knowledge, there is no data comparing this device to any other kind of ESI approach. In the present study, the CCC device was easy to use, but there could be some difficulty at the initial step when inserting the catheter if it is desired to place the catheter ventrally. However, it is feasible to insert the catheter safely directly into the epidural space via the sacrococcygeal ligament between the sacral cornua. Because the end of the thecal sac is at S1–S2, epidural space insertion via a caudal approach is preferable and safe. As a result, the RM and VAS scores for radicular pain improvement in the CCC group were greater than in the TF-SNRB group, with statistical significance although this could be the minimum clinically important change [3]. The clinically important change in RM score should be more than 5 points as Roland recommends avoiding the minimum clinically important change [3]. However, radicular pain was markedly improved within the first 2 weeks for the CCC group and after 1 month for the TF-SNRB group. The lessons learned in the present study include: 1) the feasibility and safety of using CCC to alleviate radicular pain was confirmed particularly for the patient who was poor surgical candidates; 2) CCC is easy to use, and by placing the catheter at the ventral epidural space the desired lumbar spinal level can be reached in one puncture; 3) in cases where there is stenosis of the lumbar spinal foramen, such as lumbar spinal scoliosis or achondroplastic dwarfism, CCC might be advantageous for performing ESI because the stenosis or deviation of the foramen will cause the obscurity under fluoroscopy in TF-SNRB; 4) the volume of the contrast media used in CCC might be greater than for TF-SNRB, as about 2–3 cc of sterilized saline flushing was needed in the CCC group so it requires more further investigation for the increased amount of contrast medium that is necessary in CCC group regarding the outcomes or responsiveness; and 5) it might be difficult or impossible to use in CCC cases where there is no opening between the sacral cornua. A limitations of this present study which should be taken into account when interpreting our results were: a) the small, non-probability sample size and included lack homogeneity in both approaches to epidural injection, as well as in injection frequency and only 11 cases had undergone both TF and CCC. The reasons included; i) 3 cases with severe L5-S1 stenosis and inadequate to drive injectate ventrally in the epidural space toward the exiting nerve root after TF; ii)

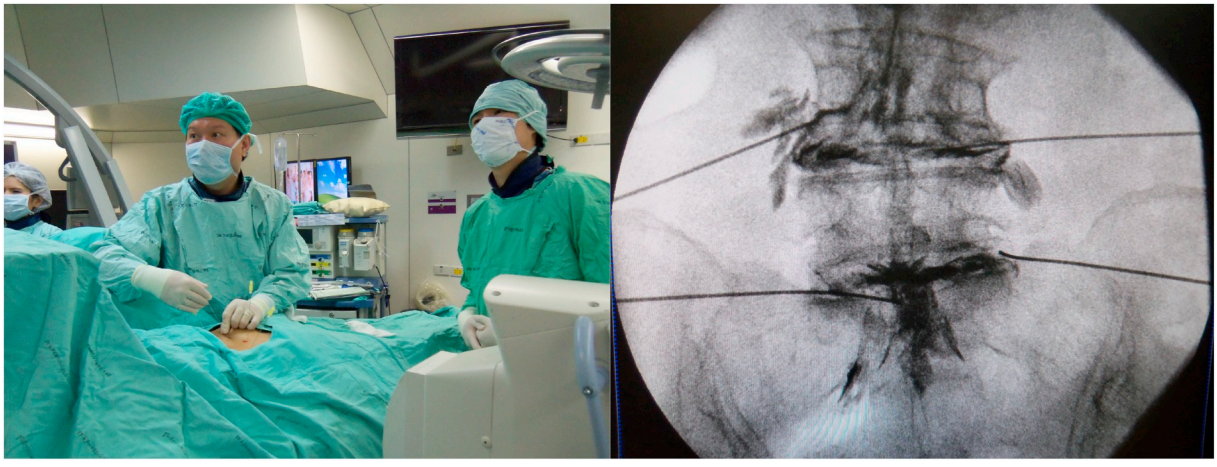

Fig. 5. Illustration of TF-SNRB technique.

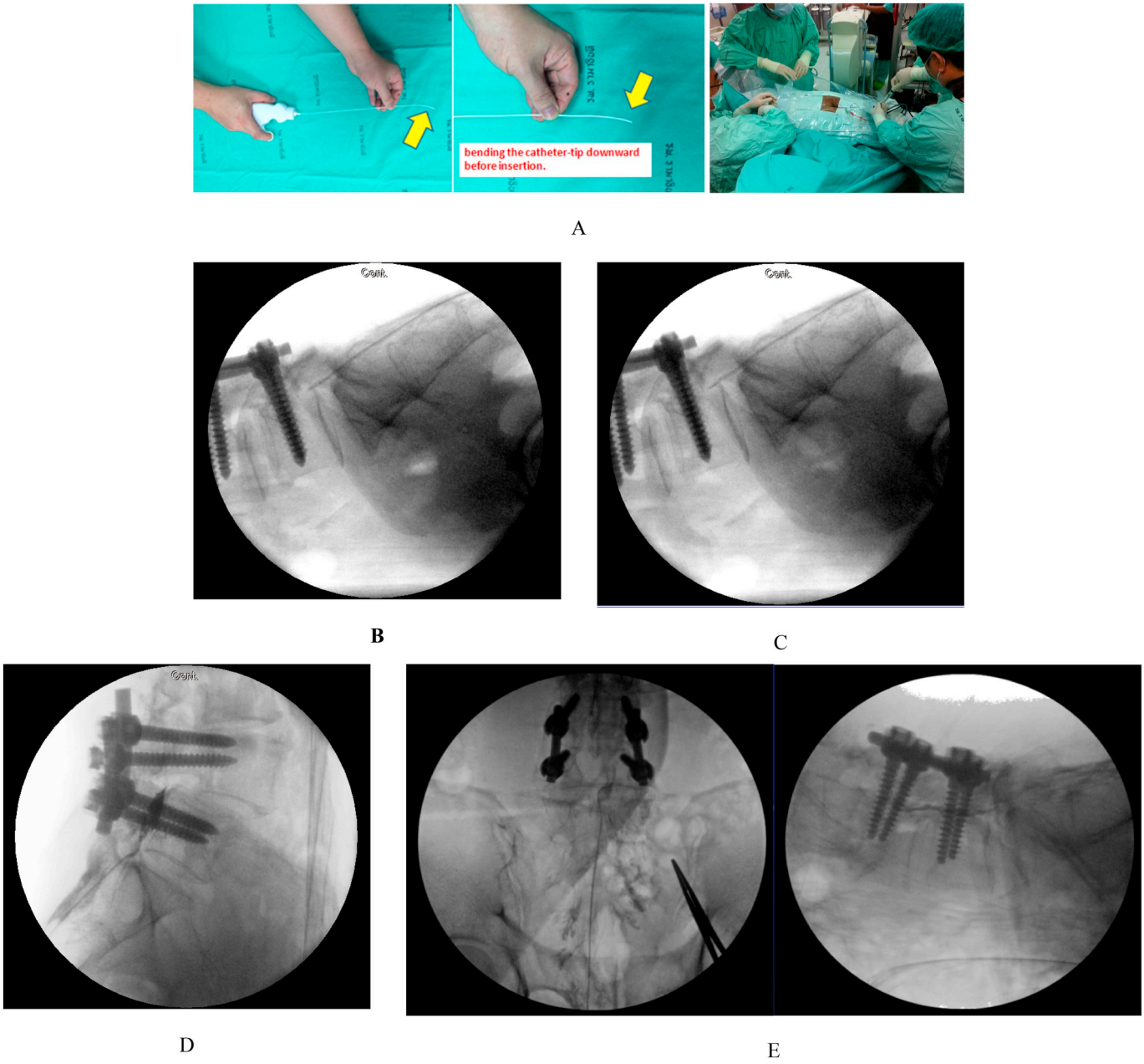

Fig. 6. Illustrations showing that the catheter was inserted caudally and placing ventrally of the thecal sac with downward-bending tip; A. The confirmation of catheter placement ventrally under fluoroscopic guidance is revealed; B and C. The injectate in the ventral epidural space is identified, compared with TF-SNRB; D and E.

7 cases with recurrent back and leg pain after TF and agreeable to try CCC after informed consent; iii) 1 case of achondroplastic dwarfism with inability to place contrast media into the ventral epidural space after TF; b) due to financial constraints, we disclosed that there was no financial support and the 50 controllable caudal catheters were free of charge so the study was underpowered. The size, and homogeneity of the two groups in this present study limit the generalizability of this study; c) however, we can recruit only 69 patients, therefore, the power of test remains 70%. This is the reason why we cannot detect difference in our study d) there is no protocol and/or any technical pitfalls inherent of the CCC to assess or allow reviewing which the investigations are further needed; d) we assumed that both TF and CCC group resulted in ventral epidural spread and related to Manchikanti et al. study [17]. In addition, the ability to drive the injectate anteriorly or ventrally of the thecal sac has led to the use of TF and CCC injection. Some studies stated about the delivery of the injectate into the anterior epidural space led to a good clinical outcome [15]. Lastly, we would like to share our lessons learned about the clinical outcome of TF and CCC technique. Additionally, the optional approach such as CCC that might be safer and could present identical or superior results is most desirable and present in this study because the complications from TF injections are reported and questioned [13,22].

5. Conclusion

Using the CCC device to deliver steroids ventrally, close to the inflamed lumbar nerve roots, under local anesthesia seems to present lower risk than transforaminal needle puncture. As a result, we speculate the lumbar radicular pain reduction in the CCC group were comparable with TF-SNRB in terms of VAS and RM scores. The safety and effectiveness of utilization of this device still need to be assessed in a further long-term follow-up study.

Declaration of Competing Interest

The 50 tip-controllable (St. Reed®) catheters were supplied with free of charge by Seawon Meditech Co., Ltd., Siheung, Gyeonggi-do, South Korea. Otherwise, no any financial support was received. The authors declare that there is no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.inat.2019.100511.

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