⬡ Brief Technical Report

Identification of the Epidural Space Using Pressure Measurement With the Compuflo Injection Pump – A Pilot Study

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Background and Objectives: While epidural anesthesia (EA) is frequently used, success rate varies and complications associated with incorrect needle placement can occur. Different methods of objective identification of the epidural space (ES) have been suggested, without receiving widespread popularity. This prospective pilot study evaluated continuous pressure measurement during low speed injection with a computerized injection pump to objectively identify the ES.

Methods: While EA was performed using a conventional loss of resistance technique in 20 consecutive patients, the injection pump technology was used to obtain pressure readings from the supraspinous ligament, the ligamentum flavum, and the ES. In the next 20 patients, the epidural space was solely identified with the computerized injection pump.

Results: Pressure reading obtained during the first part of the study revealed significant differences between the ES vs. the supraspinous ligament, and the ES vs. the ligamentum flavum (8 mm Hg, 95% confidence interval [CI] 6-11 *vs* 79 mm Hg, 95% CI 74-83 and 92 mm Hg, 95% CI 83-102, respectively) ($P < .001$). In the second part of the study, the injection pump allowed for successful identification of the ES and performance of EA in all 20 patients.

Conclusions: This investigation demonstrates that a computerized injection pump can be used to identify the epidural space and can serve as a base for further comparative research to determine whether this technology can increase the success rate of EA or lower the incidence of side effects. *Reg Anesth Pain Med 2008;33:346-352.*

Key Words: Labor analgesia, Success rate, Epidural anesthesia, Epidural space pressure.

The current techniques for identification of the epidural space (ES) rely on the subjective perception of the operator of loss of resistance (LOR) to saline or air.[1] Several objective methods for identification of the ES such as ultrasound,[2] nerve stimulation,[3] and acoustic signals[4] have been suggested, without gaining widespread popularity in the anesthesia community. Rocco et al. demonstrated in 1989 that manometry can be used for epidural space identification.[5] His method also offered the advantage that the operator could concentrate with both hands on needle advancement while an assistant monitored pressures on the manometer.[6] Consequently, several authors have used pressure measurements transduced from the tip of the epidural syringe to identify the ES. While some investigations only measured pressure at certain time points,[7] Lechner et al.[4] used continuous infusion of normal saline by an infusion pump to generate an acoustic signal and a continuous pressure reading

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while performing epidural anesthesia (EA). However, the infusion pump used was incapable of measuring or controlling pressure itself, and a separate monitoring device was necessary to display the pressures registered. A computerized injection pump has been equipped with a proprietary algorithm and a continuous digital and analog pressure display (Compuflo, Milestone Scientific, Livingston, NJ). After all physical parameters of the equipment used are programmed into this algorithm, the pump is capable of measuring and displaying pressures obtained at the injection site continuously, while injecting at rates between 0 to 2 mL/sec. In addition, the infusion pump is also capable of controlling pressures at the injection site by adjusting infusion rate according to a preset maximum value (pressure-controlled infusion). This prospective pilot study was designed to evaluate the feasibility of this technology to perform EA and serve as a basis for future comparative research.

Methods

With institutional review board approval, a total of 49 consecutive American Society of Anesthesiologists Class I to Class III patients, ages 18 to 41 scheduled for early labor EA in the absence of contraindications, were approached for enrollment. Out of the initial 49 patients, 4 patients refused EA and 5 chose not to participate in this investigation. After written informed consent, a total of 40 patients were successfully enrolled. This prospective pilot study was designed in 2 following parts, with 20 patients each.

Part 1: Validation by Pressure Measurement at 3 Points

After attaching American Society of Anesthesiologists standard monitors, patients were placed in a sitting position. Following preparation in the usual fashion, an epidural Tuohy needle (B. Braun Medical, Bethlehem, PA) was introduced at the level of L3-4. A 3-way stopcock (Abbott Laboratories, Chicago, IL) was connected to the end of the epidural needle with the in-line port of the stopcock attached to a 10 mL saline-filled LOR syringe. A 120 cm arterial pressure tubing (Abbott Laboratories, Chicago, IL) connected the side port to another 10 mL normal saline syringe, loaded into the injection pump. The stopcock was then opened toward the in-line LOR syringe allowing performance of EA in the conventional fashion. The stopcock was turned into "open" to the injection pump and "close" to the LOR syringe for 5 seconds at the following points: (1) initially after introducing the Tuohy needle to the depth of the supraspinous ligament (SSL) (supraspinous ligamentar pressure); (2) after reaching the ligamentum flavum (LF) (ligamentum flavum pressure); and (3) after encountering a LOR (epidural space). Determination of these structures relied on the subjective clinical experience of the operator. The Compuflo device was set to deliver normal saline at a rate of 0.07 mL/sec during these measurements. Pressures were recorded after 1, 2, 3, 4, and 5 seconds. After the final pressure reading, the stopcock was disconnected from the Tuohy needle and an epidural catheter (EC) was inserted. EA was initiated in the following fashion. After a 3 mL epidural test dose consisting of lidocaine (15 mg/mL) with epinephrine (5 μg/mL) was given to rule out intrathecal or intravascular catheter position, patients received 12 mL of 0.2% ropivacaine followed by an infusion of 0.2% ropivacaine at 10 mL/h via the EC. Patients were evaluated for loss of sensation to ice 30 minutes after receiving the first bolus dose of 0.2% ropivacaine. In all cases, EA was performed by the same operator and all measurements were performed in the absence of labor contractions.

Part 2: Epidural Space Identification Using Continuous Pressure Measurement

In the second part of our study, ES identification was performed as follows by the same single operator as in part 1: With all patients in a sitting position and in the absence of labor contractions, a Tuohy epidural needle was introduced to a depth of 2 cm and then directly connected to the computerized injection pump via the arterial line extension tubing. The device was set to deliver normal saline at a rate of 0.07 mL/sec with a maximum pressure limited to 250 mm Hg. The Tuohy needle was then advanced and pressures were recorded continuously. Based on the pressure values obtained in the first part of our study, a sudden drop in the pressure readings to $<$20 mm Hg lasting for at least 5 seconds (LOR) was considered as definite ES identification. If both of these criteria were not fulfilled, the result was considered as "false" LOR, and the epidural needle was further advanced and/or repositioned until a true LOR was obtained. Although it took the injection pump only 1 second in part 1 of our investigation to indicate a significant pressure difference between LF and ES, the 5-second criterion was arbitrarily chosen to allow for a large margin of safety.

The time from insertion of the epidural needle into the skin until reaching the ES was recorded and after disconnecting the extension tubing from the Tuohy needle, EA was performed in the same fashion as in part 1.

Demographic data, times, and injection volumes are reported as mean ± SD and pressures as mean and 95% confidence interval (CI). Analyses of the results were performed with statistical software (SigmaStat, SPSS, Chicago, IL). Pressures were tested with analysis of variance for repeated measurements. If significant differences were detected, a Student-Newman-Keuls test was applied. A Lilliefors test for normality was applied to evaluate "pressure drops" when reaching the ES for normal distribution.

Results

Study Part 1

EA was performed successfully in the first 20 participants. Mean age was 28 ± 7 years and average body mass index was 29 ± 8. Pressures after 1 second were significantly higher in the SSL (79 mm Hg, CI 74-83, $P < .001$) and in the LF (92 mm Hg, CI 83-102, $P < .001$) than in the ES (8 mm Hg, CI 6-11) and remained significantly higher at all measurement times (Fig 1). EA was successful in all patients as indicated by bilateral sensory levels between T8 and T10 and sufficient analgesia during labor and delivery.

Study Part 2

In the second 20 patients, mean age was 26 ± 8 years and average body mass index was 30 ± 8. The ES was identified by a significant drop in the pressure readings displayed by the injection pump below 20 mm Hg in all cases and epidural anesthesia was performed successfully without any complications, such as accidental subarachnoid dura puncture. Mean time needed for epidural needle placement (time from insertion of the needle through the skin until a true LOR was obtained) was 147 ± 38 seconds and mean volume injected was 2.6 ± 2.3 mL. The maximum amount injected was 8.5 mL in 1 patient who required 2 needle redirections. The "pressure drops," defined as differences between pressure readings immediately prior to entering the ES and in the ES, followed a normal distribution pattern as expressed by a skewness of −0.04 and a kurtosis of 3.3 (Fig 2). EA was successful in all patients with bilateral sensory levels between T8 and T12 and sufficient analgesia during labor and delivery.

During the identification of the epidural space, 2 patterns of injection pressure levels were encountered:

(1) Straightforward identification of the ES. In the majority of patients (n = 17), we observed the following pattern. After insertion of the Tuohy needle into the tissue, the pressure displayed by the injection pump quickly reached the preset maximum pressure value (250 mm Hg). Consequently, the injection pump reduced the infusion rate to avoid higher pressure. Once the pressure dropped below 20 mm Hg and the epidural space was identified, the infusion rate returned to the chosen speed (0.07 mL/sec). The total volume infused in the case presented was less than 1 mL (Fig 3).

(2) Bone encounter and false LOR. In 3 patients the operator encountered contact with bone after insertion and advancement of the Tuohy needle. The computerized injection pump displayed pressures at the maximum level of 250 mm Hg. The operator briefly stopped the injection pump and withdrew the Tuohy needle, which resulted in a brief drop of the pressure reading to approximately 30 mm Hg (Fig 4). After repositioning of the Tuohy needle, the injection pump was started again and

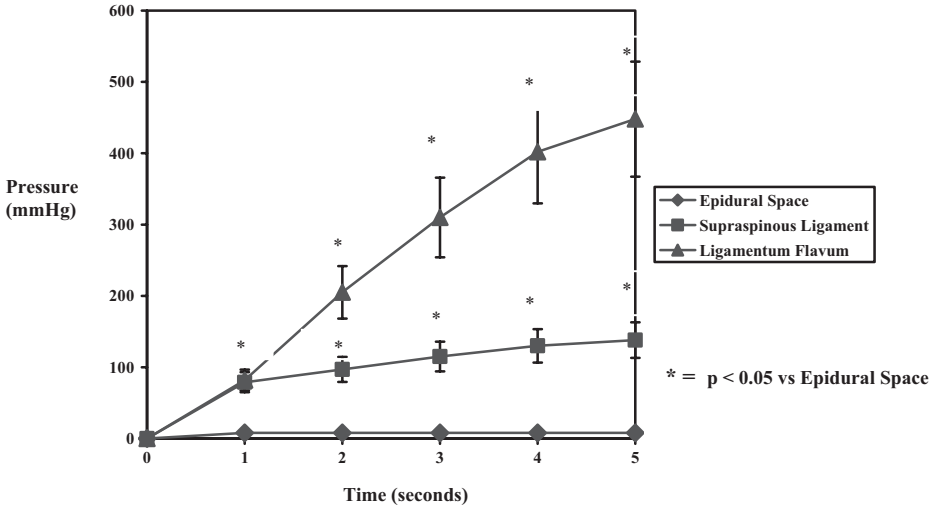

Fig 1. Pressure readings obtained in part 1 of the study (n = 20). Pressures at 1 second were 79 mm Hg (95% confidence interval [CI]74-83) in the supraspinous ligament, 92 mm Hg (95% CI 83-102) in the ligamentum flavum, and 8 mm Hg (95% CI 6-11) in the epidural space. Error bars represent SD. * $P < .05$ versus epidural space.

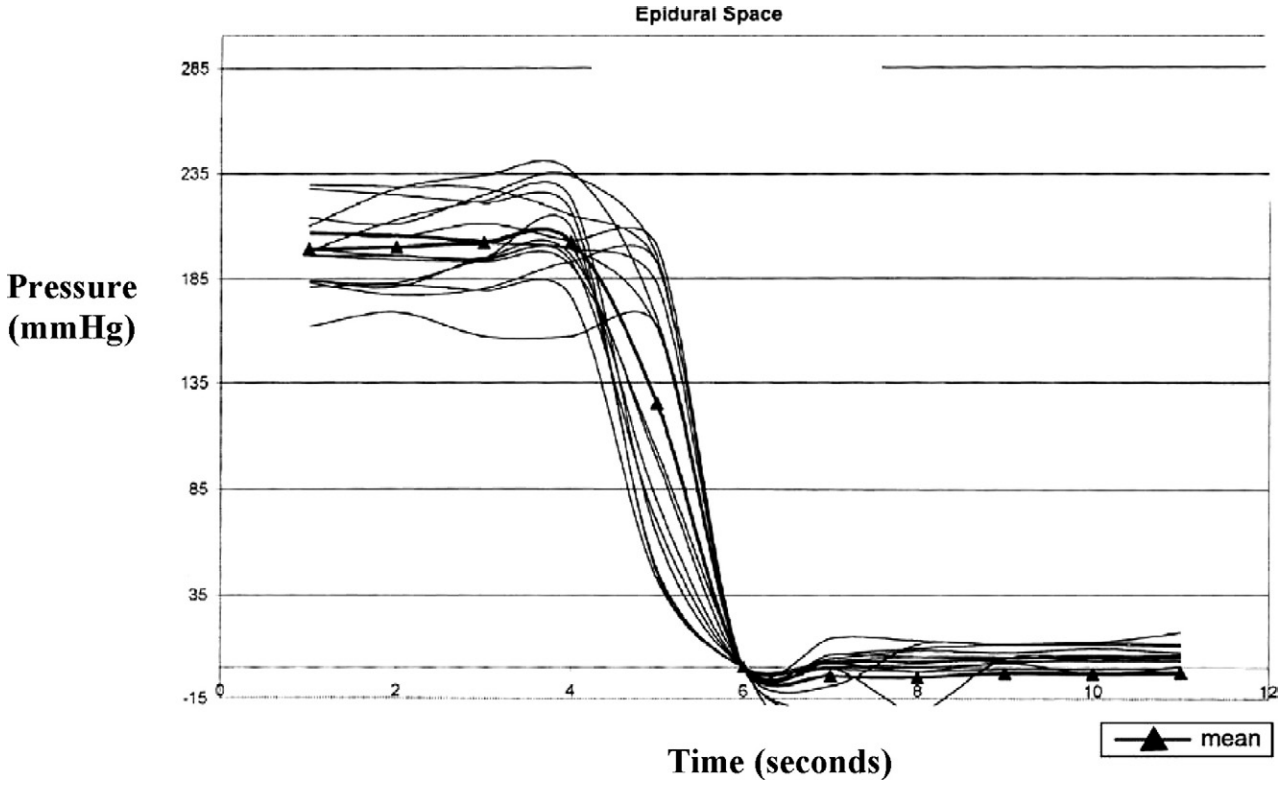

Fig 2. Distribution of "drop in pressure" curves for patients in part 2 of the study (n = 20), when the epidural space was reached. A Lilliefors test for normality suggested no evidence against normality as expressed by a skewness of −0.04 and a kurtosis of 3.3.

further advancement resulted in a LOR. While this drop in pressure was significant it did not reach levels lower than 20 mm Hg and did not stay constant for 5 seconds. Therefore, we interpreted this pattern as a "false" LOR. The Tuohy needle was consequently further advanced until a true LOR occurred and the ES was correctly identified. In the case presented, the total volume of normal saline injected was 8.5 mL.

Discussion

While a similar device is currently used in dentistry (CompuDent System; Milestone Scientific, Livingston, NJ) for controlled delivery of local anesthetics, this is the first investigation to evaluate this technology for EA. Because data regarding the performance of the computerized injection pump for this indication were not available, we first identified the pressure range at different set points during performance of EA. After establishing these values, we demonstrated that continuous pressure measurement with the injection pump can be used to identify the ES and to perform EA.

Forty years after Bromage popularized epidural anesthesia for labor,[8] large studies continue to show relatively high epidural failure rates. Pan et al. reported an overall failure rate of 12% in a review of 19,259 deliveries,[9] and Eappen et al. observed 13.1% in a retrospective review of 4,240 patients.[10] However, approximately 50% of reported failure rates in these investigations were attributable to either intravascular EC placement or unilateral block, and it is questionable whether any objective method of ES identification would have prevented these misplacements. While Evron et al. demonstrated that failure rates can be as low as 3% to 4% when lidocaine is used instead of normal saline or in combination with air for ES identification with the LOR technique,[11] all operators in their investigation had at least 5 years of experience in obstetric anesthesia. We speculate that an objective and sophisticated enough method for identification of the ES might allow reduction of the remaining failure rates even further and might also be valuable for less experienced operators or under difficult circumstances such as the performance of EA in the thoracic spine or in pediatric patients. In this regard it seems of importance that the injection pump technology used in our investigation has the capability to actually measure and display pressures continuously while injecting. Therefore, the operator constantly receives information regarding the den-

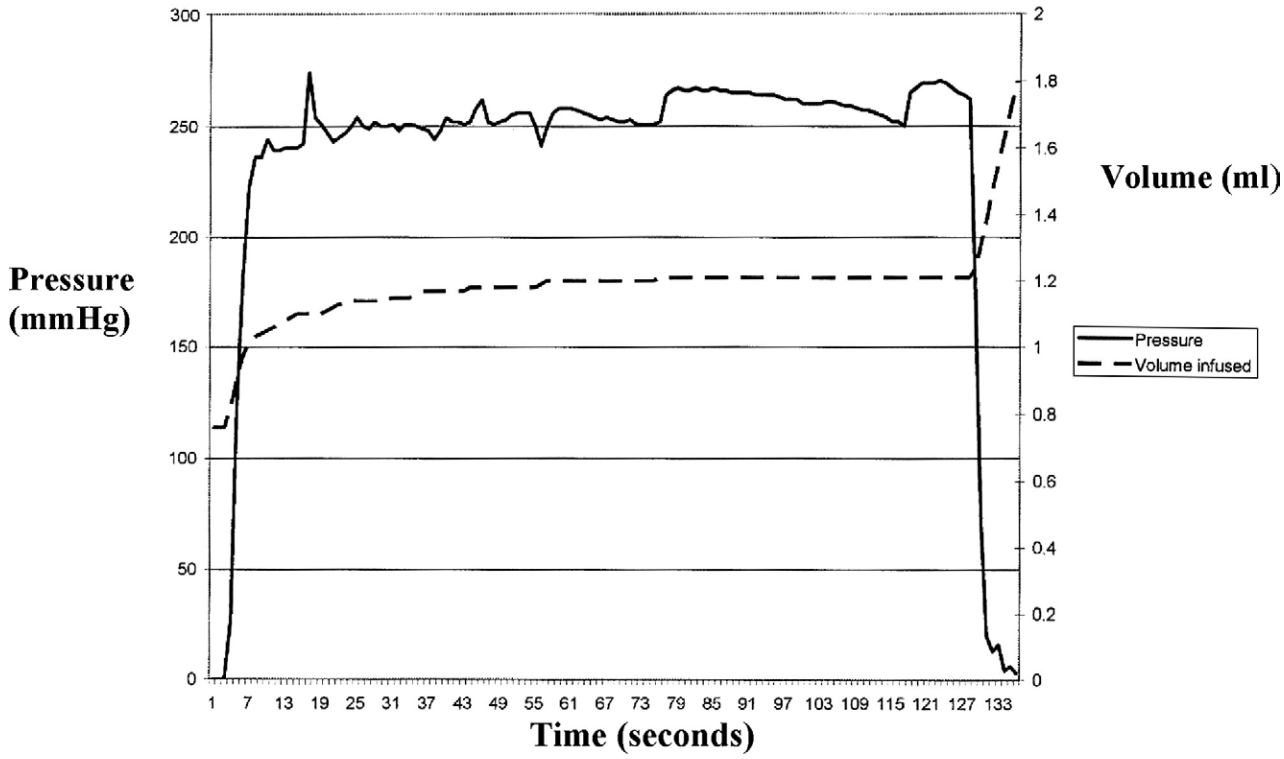

Fig 3. Typical pressure display during identification of the epidural space with Compuflo (Milestone Scientific, Livingston, NJ) in part 2 of the study.

sity or compliance of the tissue or the space in which the needle tip is inserted. This feature might be a distinct advantage over the pure pressure measurement at certain time points used in other investigations,[7] because areas of low pressure can occur in regions other than the epidural space. Consequently, not only did we require a pressure measurement below 20 mm Hg for epidural space identification, but this reading needed to be constant for at least 5 seconds while the pump continued to infuse, indicating our expectation of compliance of an open space, such as the ES. A potential area of concern with this technology is the fact that the injected volume of normal saline during a more complicated case of ES identification reached 8.5 mL. However, because the injection pump operates in a pressure-controlled mode, this amount could have been significantly reduced by choosing a lower preset pressure maximum such as 100 mm Hg. This feature of the presented technology also appears to be a significant advantage when compared with the continuous pressure readings generated by a fixed infusion rate as described by Lechner et al.[4]

A potential flaw of our study design could be that we relied on the subjective clinical judgment of the operator to derive our reference pressures in part 1 of our investigation. While the operator had more than 15 years of clinical experience in obstetric anesthesia, we cannot guarantee that the pressure readings from the SSL in some cases did not represent the intraspinous ligament instead. However, we are fairly confident that the operator's experience was sufficient to clearly identify the LF and the correct identification of the ES was demonstrated by the successful performance of EA. In addition, similar studies have also relied on the clinical judgment of the operator to determine these structures.[4]

Another shortcoming of our investigation is the fact that only healthy young patients were studied. Because it has been demonstrated that pressures in the ES are significantly higher in patients who have undergone back surgery,[12] no conclusions can be drawn as to whether the injection pump technology allows performing EA in such cases, or in patients with other spinal abnormalities. In addition, variations of epidural space pressure associated with morbid obesity may influence the ability to detect low ES pressures. While there is certainly a potential risk that the injection pump technology could increase the incidence of accidental dural puncture in these patient populations, we believe that the information regarding tissue and space compliances made available to the operator by this technology may be beneficial especially under extreme circumstances.

The provider's level of experience has been iden-

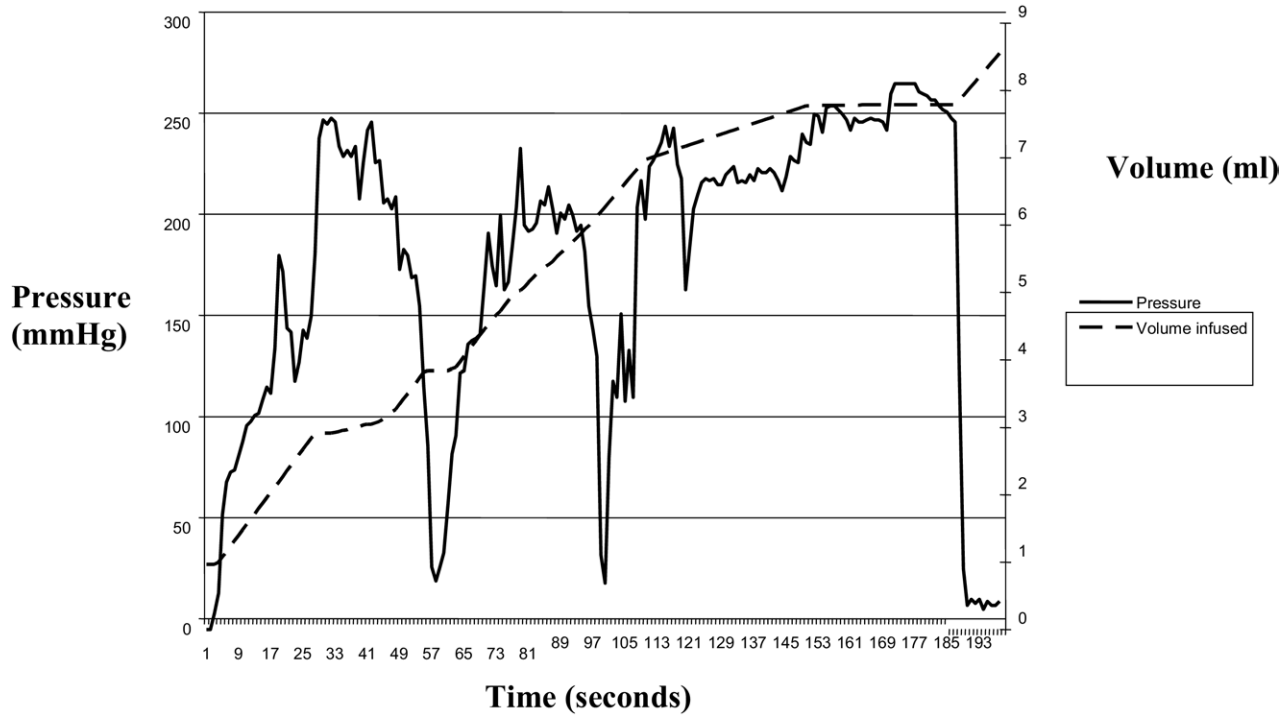

Fig 4. Bone encounter and consequent withdrawal and repositioning of the Tuohy needle (first dip). False loss of resistance (second dip) prior to final identification of the epidural space.

tified as 1 independent predictor for neuraxial block success rate.[13] Therefore, identification of the ES using continuous pressure measurement might be of special value in a resident teaching program. It enables the teacher to confirm proper Tuohy needle position instead of having to rely on the subjective feedback from the student.

Similar to the initial reports of Rocco et al.,[5,6] another potential advantage of performing EA with the computerized injection pump technology is the operator's ability to advance the epidural needle continuously with both hands while observing the graphical and digital display until the ES is reached. Compared with the widespread technique[14] in which the operator advances the Tuohy needle in small increments and then tests for LOR, this method may allow for more sensitive ES identification and may consequently lower the incidence of accidental dural puncture.

However, because we did not compare this new method to the conventional technique, no conclusions can be drawn whether identification of the ES with pressure measurements provided by the computerized injection pump technology can improve EA success rate or reduce the incidence of complications. The encouraging results of this pilot study should serve as foundation for further comparative research in order to evaluate whether this technology can actually increase EA success rate, or reduce unwanted complications such as accidental dural puncture.

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