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ORIGINAL ARTICLE

Experimental validation of the CompuFlo® epidural controlled system to identify the epidural space and its clinical use in difficult obstetric cases

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ABSTRACT
Background: This prospective study was designed to validate the CompuFlo® device and to assess its use in difficult epidural placement.
Methods: In the first part of the study, 30 parturients requesting labor epidural analgesia were recruited. The block was performed by an expert anesthesiologist, with the Tuohy needle connected to the CompuFlo® device to evaluate the agreement between the anesthesiologist's reported sensation and the variation of pressure recorded by the CompuFlo®. In the second part of the study, 56 consecutive parturients, for whom at least two complete needle reinsertions were made by trainees during epidural placement for labor analgesia, were enrolled. CompuFlo® was used as a rescue tool for the subsequent attempt.
Results: In all cases epidural analgesia was successful and no complications were noted. There was a good correlation between the operator's feelings and the delta of pressure recorded by the CompuFlo®, for both identification of the ligamentum flavum and of the epidural space (Rho = 0.79; tau = 0.67). In the second part of the study, all the difficult blocks performed with the CompuFlo® were successful after a single attempt. The pressure curves of false loss-of-resistance were significantly different from the true loss-of-resistance ($P < 0.0001$)
Discussion: CompuFlo® was validated as a tool to identify the epidural space. It may also assist trainees in successful epidural placement in difficult cases.

Keywords: Epidural technique; Labor analgesia; Loss-of-resistance device

Introduction

Epidural block is widely used in obstetrics, either alone or as the epidural component of a combined spinal-epidural (CSE) technique. In a loss-of-resistance (LOR) technique, tactile feedback from the needle and surface landmarks are traditionally used to guide the epidural needle into the epidural space. However, despite its popularity, epidural block may be associated with a significant failure rate.[1] To aid identification of the position of the tip of the epidural needle, some devices have been proposed to replace the subjective and tactile nature of LOR with objective visual or auditory end-points.

Almost 30 years ago, Rocco et al. reported that manometry can be used for identification of the epidural space.[2] Jacob et al. used a stethoscope to amplify the sound heard when the needle passes though the ligamentum flavum when using the LOR to air technique.[3] While Samhan et al. used a pressurised bag of normal saline connected to a Tuohy needle and observed fluid dripping in the fluid chamber of the intravenous (IV) set when the epidural needle entered the epidural space,[4] Lechner et al. used continuous infusion of normal saline from an infusion pump to generate an acoustic signal and a continuous pressure reading while performing epidural insertion;[5,6] however, the infusion pump was unable to measure or control the pressure itself.

More recently the CompuFlo® Instrument (Milestone Scientific, Inc. Livingston, New Jersey, USA) has been introduced.[7] This is a computer-controlled drug-delivery system that can precisely measure the pressure of human tissues in real-time at the orifice of a needle. It uses an algorithm to determine the pressure at the tip of the needle via a continuous fluid path, and is capable of distinguishing different tissue types by

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continuously providing real-time "exit-pressure" data at the needle tip when in situ. Measured pressure constitutes part of a feedback loop that regulates the electromechanical motor, which controls flow-rate and hence the fluid dispensed by the system. Audible signals and visual graphics of exit-pressure are provided to enable the operator to focus on the injection site. Preliminary reports indicate that this computerised injection pump can be safely used to identify the epidural space.[8]

This prospective study was designed to validate such an instrument and to assess whether it is suitable for difficult epidural placement. In the first part of the study, the inter-rater correlation between an expert anesthesiologist using LOR; and the CompuFlo® Epidural Computer-Controlled System, for identification of the epidural space in a pregnant patient, was compared. The primary endpoint was successful concordance of identification of the ligamentum flavum and of the epidural space during a standard epidural procedure.

In the second part of the study the utility of CompuFlo® in difficult epidural placement was examined. The primary endpoint was successful epidural placement, after previous unsuccessful epidural insertion without the device.

Methods

The study (Trial Registration: 03165708) received formal approval from the Institutional Ethics Committee of Lazio 1 (Roma, Italy). Written informed consent was obtained from all participants. Between April 2017 and May 2017, healthy women with an ASA physical status I or II, between the ages of 20 and 45 years and more than 38 weeks' singleton gestation who requested labor epidural analgesia were enrolled. Epidural block was performed in the lateral position using a 16-gauge Tuohy needle at the L3–L4 or L4–L5 interspace.

Part 1. Validation of the pressure measurements

For this part of the study 30 patients were enrolled. All epidural insertions were performed by a senior anesthesiologist (operator) and all the CompuFlo® settings and measurements were made by an independent investigator.

For instrument validation the experiment was blinded. The CompuFlo® tubing was connected to the Tuohy needle and a standard LOR syringe via a three-way stopcock (Fig. 1). This permitted the operator to perform epidural placement in the usual fashion while being unaware of the CompuFlo® flow rate adjustments and pressure recordings. After local anesthesia of the skin and subcutaneous insertion of the Tuohy needle, an independent investigator zeroed the CompuFlo® measurement in order to show the change (delta) of pressure encountered by the needle during its advancement. The CompuFlo® device was set to deliver normal saline at a rate of 0.05 mL/s with a maximum pressure limited to 200 mmHg. All audible feedbacks were silenced and the device was turned away from the operator in order to make them unaware of the CompuFlo® information.

As soon as resistance was felt during the needle advancement, the operator told the investigator, who flagged this on the screen of the CompuFlo® device. If no sensation was felt the operator said "none". When the resistance or "crunch" (believed to indicate initial penetration of the needle in the ligamentum flavum) was felt, and when LOR was felt as the needle point emerged from the ligamentum flavum into the epidural space, the operator told the investigator, who again flagged this on the CompuFlo® device. The operator then stopped the procedure for at least 10 s, since a sustained drop in pressure for more than 5 s was deemed consistent with entry into the epidural space.[8] The infusion pump was stopped and the CompuFlo® device measured the epidural pressure. After this final epidural pressure reading, the stopcock was disconnected and an epidural catheter was inserted in the usual manner.

All the data were recorded and downloaded. The correlation between the operator's reported sensation and the variation of pressure given by the CompuFlo® was analysed. Variable numbers were treated as ordinals and analysed by Spearman's Rho and Kendall's Tau tests. Differences in pressure drop were compared using the unpaired Student's t-test. For this part of the study, the power analysis required a sample size of 26 observations to set 80% test power and a 95% significance level.

Part 2. Clinical use in difficult epidural placement

In the second part of the study, 56 consecutive parturients, in whom at least two needle complete re-insertions (new skin punctures) had been made during the epidural procedure for labor analgesia, were recruited. The CompuFlo® was used for the subsequent attempt, as a rescue tool in the same interspace. All epidural blocks were performed by supervised trainees.

Methods and device settings were the same as described above, but the CompuFlo® was attached via the tubing directly to the Tuohy needle (Fig. 1) and the physician could see the readings and hear the audio. During advancement of the Tuohy needle pressures were displayed and recorded continuously; a sudden drop in pressure (typically greater than 50% of the maximum pressure) on the visual display, accompanied by a distinct fall in the tone of the audio output, resulting in the formation of a low and stable pressure plateau sustained for more than 5 s, was considered consistent with entry into the epidural space. If these criteria were not fulfilled, such as with a small increase of delta pressure followed by a slight transient drop, the result was considered as "false LOR", and the epidural needle was further advanced and/or repositioned until a true LOR was obtained.

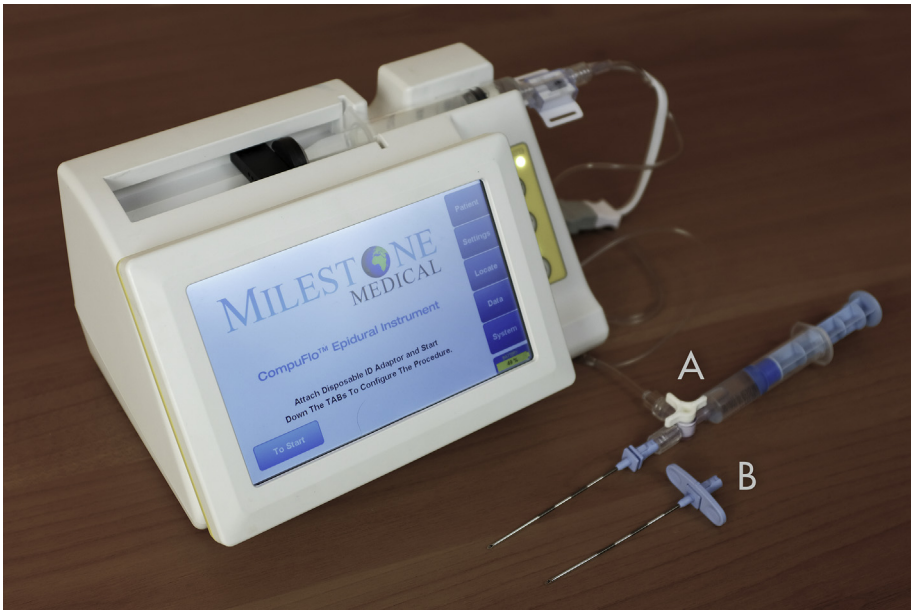

Fig. 1 CompuFlo® set up for (A) Experimental validation (first part of the study) and for (B) Clinical use by trainees (second part of the study). (A) For the validation of the instrument, a three-way stopcock was attached to a standard epidural syringe to let the expert operator perform the epidural block in the usual fashion, independently and unaware of the CompuFlo® flow rate adjustments and pressure recordings. (B) For the second part of the study the CompuFlo® device was attached via the tubing directly to the Tuohy needle, in this case the physician being able to see the CompuFlo® readings and hear the audio

The primary goal was the ability of the CompuFlo® device to differentiate true and false LOR. The number of epidural attempts before and after use of the CompuFlo® and the successful epidural analgesia rate were recorded. After the epidural catheter placement, all patients received our routine epidural loading dose (20 mL levobupivacaine 0.0625% plus sufentanil 10 μg) followed by a patient-initiated epidural bolus, as described elsewhere.[9] The efficacy of epidural block was evaluated using a 100 mm Visual Analogue Scale (VAS) for pain (0 = no pain; 100 = worst pain ever), which was assessed at the apex of a painful contraction. Analgesia was considered successful if the parturient reported a VAS equal to or less than 10, twenty minutes after administration of the epidural loading dose. Routine follow-up for post-anesthetic complications was performed.

Differences in pressure drop were compared using the Student's t-test. A sample size of 50 observations was required to set 80% test power and a 95% significance level.

Results

Study part 1

Three patients were excluded due to tubing disconnection, leaving 27 patients for data analysis. The mean (standard deviation (SD)) age of participants was 29.3 (5.9) years; the mean (SD) body mass index (BMI) 25.5 (1.5) and the mean (SD) gestation 39.3 (0.9) weeks. Seventeen (63%) parturients were nulliparas and 10 (37%) were multiparas. In all cases the epidural block was performed successfully, without complication. There was a good correlation between the operator's perceptions and the delta pressure recorded by the CompuFlo® device, for both identification of the ligamentum flavum and of the epidural space (Spearman's Rho index = 0.79 and Kendal's tau = 0.67).

Fig. 2 shows the pressure curves registered by the CompuFlo® when the epidural needle was deemed to be within the ligamentum flava and thereafter in the epidural space, compared to those insertions with a false LOR. The pressure reduction associated with the identification of the epidural space was significantly greater than that recorded when there was false LOR (96% vs 37%, P=0.05). The mean pressure measured within the epidural space was 17.5 mmHg (SD 6.65, 95% CI 14.90 to 20.01).

Study part 2

All women enrolled in this part of the study had their data analysed. Their mean (SD) age was 28.7 (4.9) years; mean (SD) BMI 32.4 (4.7) and mean (SD) weeks' gestation 38.6 (1.6). There were 48 (80%) nulliparas and 11 (20%) multiparas. Epidural cannulations performed after use of the CompuFlo® device were successful after a single attempt in all cases. The pressure curves of false LOR were significantly different from those associated with the true LOR (P <0.0001, Fig. 3).

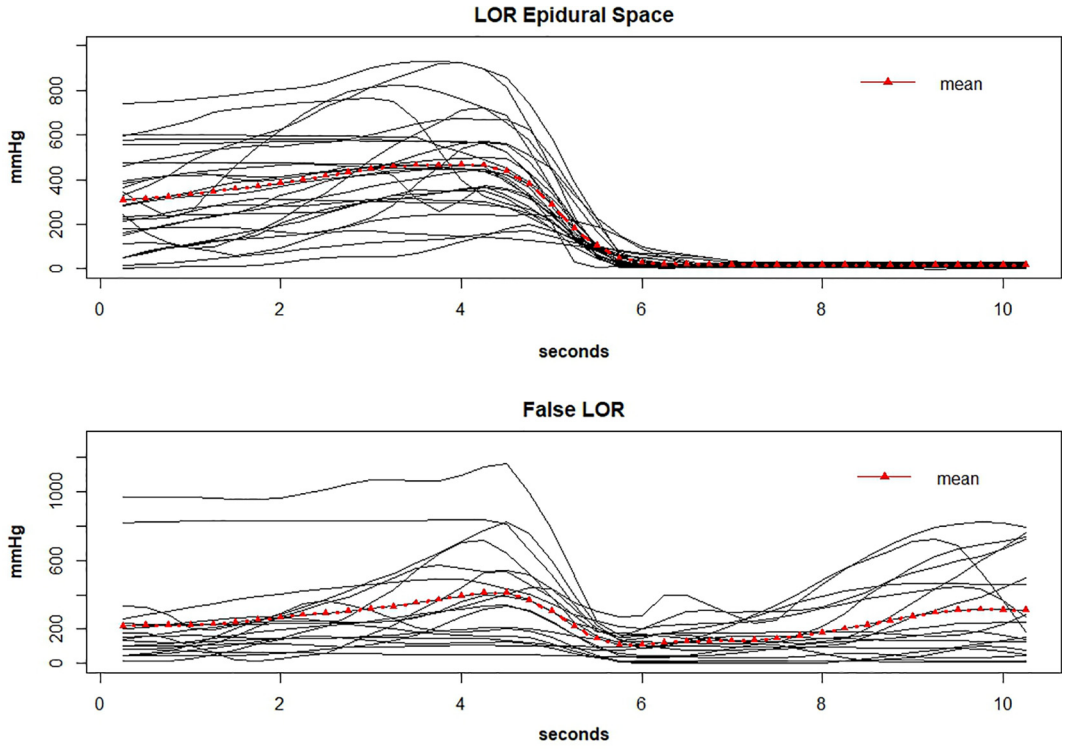

Fig. 2 Distribution of "drop in pressure" curves when the epidural space was reached and when the epidural needle encountered a false resistance. In such cases, after the initial drop there was an increase of pressure (study part 1). LOR: loss-of-resistance

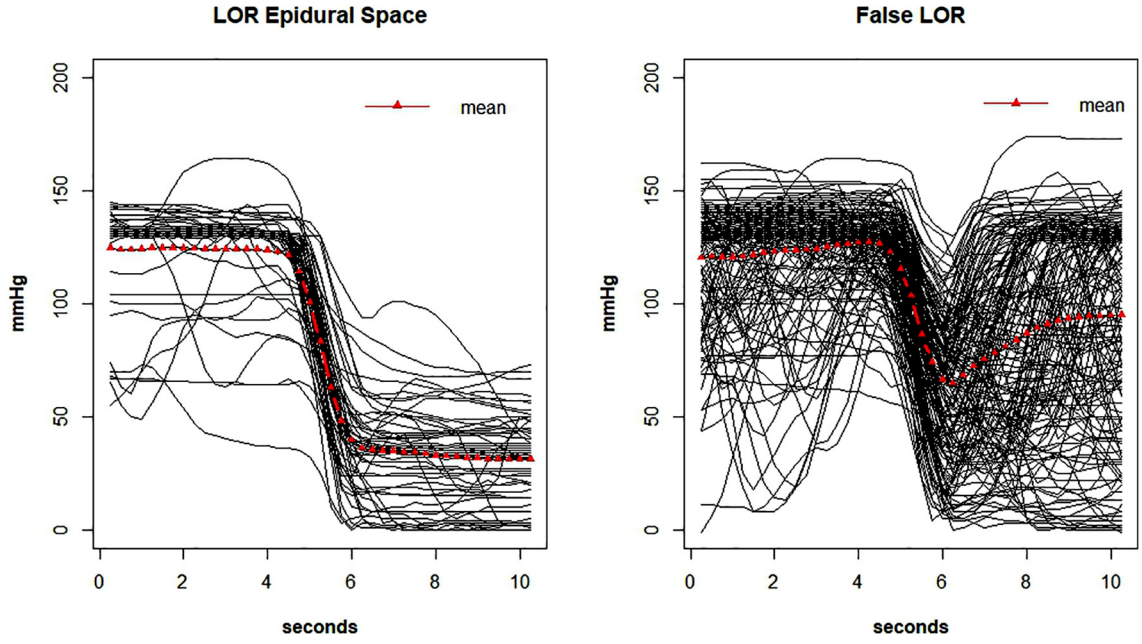

Fig. 3 Distribution of "drop in pressure" curves when the epidural space was reached and when the epidural needle encountered a false resistance in difficult cases (study part 2). LOR: loss-of-resistance

Discussion

When a new technique becomes available it should be compared to the current "gold standard". In the first part of the study a good correlation was demonstrated between the gold standard comparator (the operator's tactile sensations of inserting the needle into the ligamentum flavum and the LOR as the needle entered the

epidural space) and the delta of pressure recorded by the CompuFlo® device. Using the CompuFlo®, entry into the epidural space usually results in a sudden fall in pressure on the visual display, as well as a distinct fall in the tone of the audio output.[8] Since the first part of the study was blinded, the correlation between the operator and the acoustic signal and visual display could not be performed, but we consider the results are more valuable due to the blinded experimental conditions. An increase, followed by a brisk drop in pressure for at least 5 s seen on the CompuFlo® screen, consistently indicated successful positioning of the needle in the epidural space and corresponded to the operator's perceptions. The epidural pressures measured were consistent with the values previously reported in pregnant patients.[10,11] A correlation between the operator's judgement and the CompuFlo® recordings with a false LOR was demonstrated.

In clinical practice, the epidural needle is frequently introduced in the lumbar area to a depth of approximately 2–3 cm, to avoid accidental entry into the epidural space. The needle may, however, be inserted into the supraspinous or interspinous ligaments, the paraspinous muscles or subcutaneous tissue before a LOR technique with a syringe is attempted, and this may give rise to a false LOR. The CompuFlo® recordings indicated the instrument could differentiate between false and true LOR during both parts of the study. This may be useful for trainees, who typically insert the epidural needle a few centimeters in the lumbar area, superficial to the ligamenta flava, and who may be unfamiliar with the typical sensations associated with passage of the epidural needle through different tissue planes. Our trainees were able to use the CompuFlo® device successfully in all their difficult cases. In a preliminary report of a chronic pain management study, a 100% success rate was reported for the spread of dye during fluoroscopy among 219 subjects in whom the CompuFlo® was used. This was equal to the success rate obtained with the standard LOR insertion technique.[12]

We demonstrated the same success rate in patients deemed to be difficult due to two previous attempts at insertion and hypothesise that use of touch (for the needle), hearing (auditory signal) and visualisation (graph) may make the epidural insertion process simpler and more reliable. Jacob et al., using a stethoscope connected by a sterile tubing to the Tuohy needle, reported that auditory identification of the space occurred fractionally earlier than the tactile LOR to air.[3] Auditory reaction time is faster than visual,[13] and it has been reported that there is an increasing multisensory alert system with visual, auditory and tactile integration.[14] A further advantage of the CompuFlo® device is that the epidural procedure may be documented, since data are printable and could be included in the patient's chart.

In all our cases epidural drug administration was effective and no complications occurred. However, the CompuFlo® may have the same disadvantages associated with a traditional LOR technique; it is not known whether a decrease in pressure might be difficult to interpret in the case of, for example, obese patients, those with previous spinal surgery, or in the event of accidental dural tap. Our study has some limitations. Due to the nature of the protocol in the second part of the study, we cannot exclude bias in classifying the difficulty of the needle insertion by the trainee operator. In addition, we used the CompuFlo® as a rescue tool and further studies, with a different design, should be performed in the future to make a direct comparison between insertion using the CompuFlo® device and the traditional technique, using a larger series of patients and in different settings.

In conclusion, we validated the CompuFlo® device as a means of adequately identifying the ligamentum flavum and the epidural space. Our preliminary findings suggest that it could assist the physician in training when performing epidural insertion.

Funding

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Conflicts of interest

At the time of the performance of the study (in May 2017) and at the time of analysing the data and writing the preliminary draft of the study (in July 2017), GC had no conflicts of interest. From September 2017, GC joined the Scientific Advisory Board of Milestone Inc.

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