

Epidural Space Identification Using Continuous Real-Time Pressure Sensing Technology (CompuFlo®): A Report of 600 Consecutive Cases

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Abstract

Introduction. The aim of this open, prospective, single operator study was to report the clinical experience with the CompuFlo® Epidural Instrument. *Method.* Epidural block was performed with the CompuFlo® Epidural Instrument in all consecutive patients undergoing an epidural or thoracic block under the author's care over a two years period. The epidural needle was considered to have reached the epidural space when an increase in pressure (accompanied by an increase of the pitch of the audible tone) was followed by a sudden and sustained drop in pressure of more than 5 seconds accompanied by a sudden decrease of the pitch of the audible tone, resulting in the formation of a low and stable pressure plateau on the instrument's visual display. The following outcomes were evaluated: incidence of accidental dural puncture, success of anesthesia, procedure time, volume of saline used for the epidural procedure, number of epidural attempts to reach the epidural space, number of needle redirections, and the operator's agreement with his tactile sensation of loss of resistance and the CompuFlo® pattern. *Results.* A total of 600 cases were studied. All the epidural blocks were successful and no accidental dural punctures were noted. Epidural space was correctly identified on the first attempt in 91% of cases, in 95% of cases the operator judged as a perfect correlation between his tactile sensations and the CompuFlo® recordings. *Conclusion.* The major finding of this paper is the very high success rate of the epidural blocks, no matter in what clinical setting (obstetrical, surgical or blood patch intervention) or at which vertebral level (thoracic or epidural) were done. Most importantly, the reporting of zero incidence of any accidental dural puncture.

Keywords

Epidural, Technique

1. Introduction

The most currently used technique for identification of the epidural space relies on the subjective perception of the operator of loss of resistance (LOR). This depends on sudden loss of resistance to the injection of saline or air as the tip of the epidural needle traverses the ligamentum flavum and enters the epidural space.

Recently the continuous real-time pressure sensing technology (CompuFlo® Epidural Instrument, Milestone Scientific Inc. Livingston, NJ, USA) was introduced to measure the pressure of human tissues in real-time at the orifice of a needle [1] [2] [3].

This technology is capable of distinguishing different tissue types by providing continuously real-time “exit-pressure” data from the needle tip when placed in-situ using an algorithm to determine the pressure at the tip of the needle via a continuous fluid path [4]. This system is unique in that pressure becomes a feedback loop and controller to the system, thus regulating the electro-mechanical motor which controls flow-rate and the fluid dispensed by the system.

An audible feedback and visual graphic of exit-pressure is provided to direct the procedure. This way the physician has an objective, quantitative method to identify the epidural space since the entry of the needle into the epidural space may be seen through the graphic display which shows a typical and reliable pattern, and, at the same time, it may be also confirmed by the clear changes of the audible tone.

The CompuFlo® Epidural Instrument has previously been demonstrated to be able to successfully identify the epidural space with high sensitivity [1] [2] [3].

The aim of this open, prospective, single-operator study was to report the clinical experience with the CompuFlo® Epidural Instrument over a two years period.

2. Methods

Ethical Committee approval and written informed consent from each participant was obtained.

This prospective, open study was conducted by a single operator at Clinica Alemana University of Desarrollo, Chile, from March 2017 to July 2019 and included all consecutive patients undergoing epidural or thoracic block under the author’s care.

Lumbar epidural block was performed using a 18G Tuohy needle at the L2-L3 interspace and thoracic epidural block was performed using a 16G Tuohy needle at the T8-T11 level.

All the blocks were performed with the CompuFlo® Epidural Computer Controlled Anesthesia System. The instrument requires an epidural disposable kit, which includes a 20 mL syringe, 48 inch tubing set, a pressure sensor and an ID adapter that is assembled on the sterile field immediately before the block.

After disinfection, draping and skin local anesthesia, the epidural Tuohy needle

was introduced subcutaneously and connected by the extension tubing to the pressure transducer and to the CompuFlo® instrument, in order to register the delta of pressure encountered by the needle during its advancement. The CompuFlo® instrument was set to deliver normal saline at a rate of 0.05 mL/s with a maximum pressure limited to 200 mmHg. The system was calibrated and zeroed at the level of the skin to allow for accurate pressure readings at the needle tip. The Tuohy needle was then slowly advanced and pressures were 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 pitch of the audio output, resulting in the formation of a low and stable pressure plateau sustained for more than 5 seconds, was considered consistent with the entry into the epidural space [1] [2] [3].

If these criteria were not fulfilled, the epidural needle was further advanced and/or repositioned until a true loss of resistance was obtained. After the entry into the epidural space, the infusion pump was stopped and the CompuFlo® measured the actual epidural pressure (mmHg). After this final epidural pressure reading, the tubing was disconnected, and an epidural catheter was inserted in the usual manner.

The following outcomes were evaluated:

Procedure time assessed as the time from the start of the procedure with CompuFlo® to the entry of the epidural needle into the epidural space (seconds).

Volume of saline used for the epidural procedure (mL).

Operator's agreement with his tactile sensation of loss of resistance and the CompuFlo® pattern of sudden drop of pressure followed by a plateau indicating the epidural space (1 = agreement; 0 = no agreement).

The number of epidural attempts to reach the epidural space. An attempt was defined as a needle completely withdrawn and reinsertion from the skin at the same or at a different interspace.

The number of needle redirections. A needle redirection was defined as a needle partial withdrawn and/or change of direction within the tissues of the chosen interspace in case of bone contact or due to operator's uncertainty of needle location within the tissues.

The following criteria were used to differentiate a true-loss of resistance (True-LOR) versus the identification of a false-loss of resistance (False-LOR) using the CompuFlo® Epidural Instrument [4]: a true-LOR (identification of the epidural space) was defined as an increase in pressure followed by a sudden and sustained (>5 seconds) drop in pressure (typically greater than 50% of the maximum pressure), resulting in the formation of a "low and stable pressure plateau" for at least 5 seconds.

A false-LOR was defined as an increase of pressure followed by a drop-in pressure (typically less than 50% of the maximum pressure) that is either not sustained or inconclusive of representing a "low and stable pressure plateau". If the pressure rapidly increased after a drop of pressure this was identified as a false-loss of resistance and the operator was elected to continue to advance the

needle.

Epidural block was considered to be successful if, in case of labor analgesia, the parturient had adequate analgesia (VAPS < 20/100) within 30 minutes from the epidural injection or if, in case of surgery, the patient had no intraoperative pain nor required intraoperative additional analgesic medications or required conversion to general anesthesia, or, in case of blood patch, if the patient had the resolution of headache within the first day (and in this latter case the patients were followed up for two weeks after the blood patch).

Any occurrence of accidental dural puncture was noted.

All the data were recorded and presented as descriptive statistics. Unpaired T-test, ANOVA and linear regression analysis were used where appropriate.

3. Results

A total of 600 consecutive cases performed using the CompuFlo® Epidural instrument were studied. Patients' characteristics and results are reported in **Table 1**.

All the epidural blocks were successful and no accidental dural punctures were noted.

The majority of epidural blocks were performed in lateral position (97%) for elective cesarean section (81.5%). The mean time to perform the procedure was less than 1 minute and the mean consumption of saline solution to perform the block was less than 1 mL.

Figure 1 reported the box plot of the time needed to identify the epidural space in different settings.

According to the linear regression analysis the procedural time was strongly correlated to the number of epidural attempts and needle redirections ($P < 2 \times 10^{-16}$; $r^2 = 0.692$) but not with BMI or with the clinical setting. In particular, every new attempt increased the procedural time of 59.7 seconds ($< 2 \times 10^{-16}$).

Overall, epidural space was correctly identified on the first attempt in 91% of cases, and, on the average, in one quarter of cases the needle was properly redirected, due to bone contact or identification of false or pseudo loss of resistances. In 95% of cases, the operator judged as perfect the correlation between his tactile sensations of inserting the needle in the ligamentum flavum and thereafter the loss of resistance due to the entry of the needle in the epidural space and the delta of pressure recorded by the CompuFlo® Epidural instrument.

4. Discussion

Previous studies have reported the ability and reliability of the CompuFlo® instrument to detect the epidural space and thereafter to obtain the analgesic success of the epidural block [1] [2] [3]. This instrument is also reported to be very useful in helping the anesthesiologist correctly differentiate the false from true losses of resistances encountered as an epidural needle advances during the epidural procedure [5] and in being used as a teaching simulation tool [6].

Table 1. Results.

	Mean	n	%	SD	95% CI	
Age (years)	36			6.25	35.59	36.59
BMI	28.49			4.31	28.14	28.83
Gender						
Male		2	0.3%			
Female		598	99.7%			
Position						
Lateral		583	97%			
Sitting		17	3%			
Procedure						
Cesarean section		489	81.5%			
Labor analgesia		2	0.33%			
Gynecological surgery		7	1.2%			
Blood patch		9	1.5%			
Thoracic block		29	5%			
Procedural time (sec)	50.33			47.03	46.54	54.11
Total volume used (ml)	0.71			0.78	0.65	0.77
Epidural space pressure (mmHg)	16.48			8.00	15.82	17.12
Attempts						
1		548	91.3%			
2		42	7%			
>2		10	1.7%			
Needle redirection						
0		390	65%			
1		151	25.2%			
>1		59	9.8%			
False positive LOR						
0		333	55.5%			
1		186	31%			
2		81	13.5%			
Epidural block efficacy						
Effective		600	100%			
Ineffective		0	0%			
Operator agreement						
No		28	5%			
Yes		571	95%			
Accidental dural puncture		0	0%			

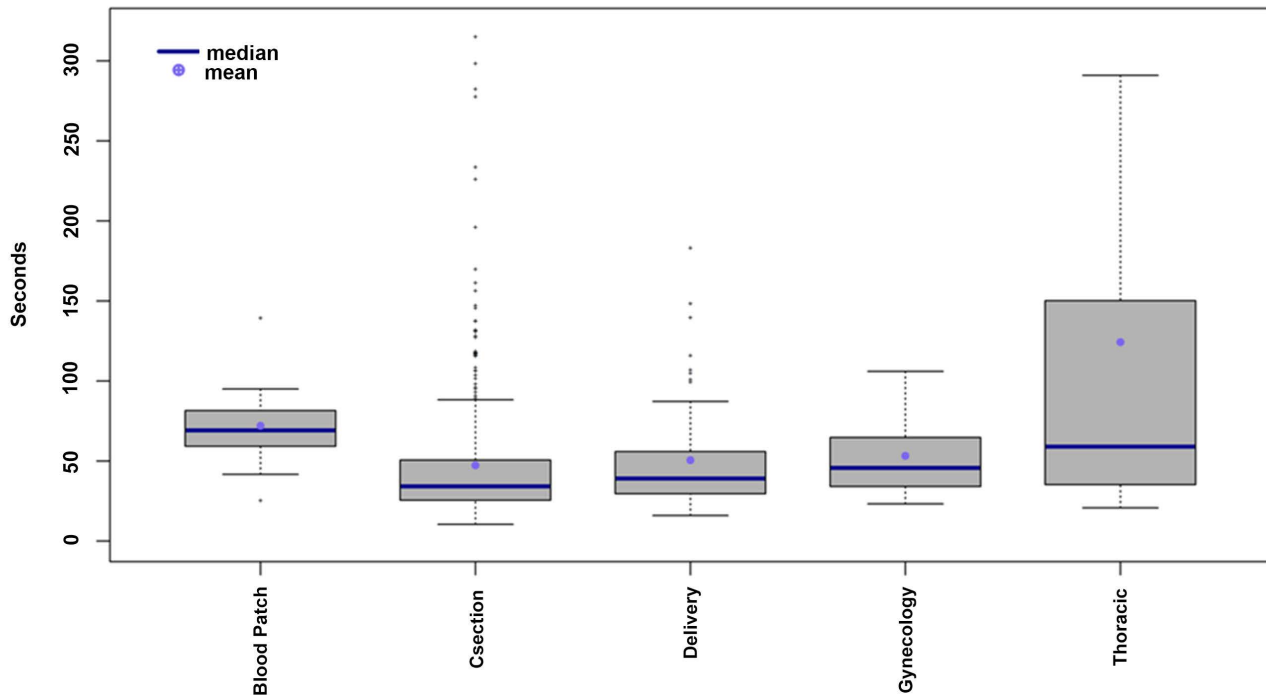


Figure 1. Box plot of the time needed to identify the epidural space in the different settings.

This study adds valuable information to those provided by previous comparative and/or double-blinded studies since it reports a large, consecutive number of procedures, performed by a single operator, documenting for the first time clinical experience with the CompuFlo® Epidural instrument over a period of two years. The major finding of this paper is the very high success rate of the epidural blocks, no matter in what clinical setting (obstetrical, surgical or blood patch intervention) or at which vertebral level (thoracic or epidural) were done, and, most importantly, the absence of any accidental dural puncture. The operator's personal accidental dural puncture rate during the two-years immediately preceding CompuFlo® use was of 0.41% (4/980). This difference deserves comments. The operator is a senior anesthesiologist with 35 years of clinical practice, and a low rate of accidental dural puncture. Nevertheless, this has been further reduced using the CompuFlo® Epidural Instrument. While this study is not a controlled, randomized trial, and therefore a statistical comparison cannot be made with historical controls, a large number of patients scale provides a sufficient sample to make a comparison [6].

Due to the expert nature of the operator, on the average, the length of time to perform the procedure was faster than that previously reported by others with the same instrument [2].

One possible concern with this study is that the epidural blocks were performed by the same single operator and therefore the results cannot be generalized. However this possible limitation can be counterbalanced by a large number of patients involved. In addition, studies where multiple operators are involved may suffer from the inter-operator variability bias.

5. Conclusion

In conclusion, this study reported 100% success rate and 0% accidental dural puncture rate in a large sample of consecutive epidural blocks performed with the CompuFlo® Epidural Instrument. This suggests that CompuFlo®'s objective epidural space identification technology may be a routine, practical alternative to a variety of traditional techniques performed in neuro-axial regional anesthesia.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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