Scientific Research Publishing

Open Journal of Anesthesiology, 2020, 10, 171-178
https://www.scirp.org/journal/ojanes
ISSN Online: 2164-5558
ISSN Print: 2164-5531

Confirmation of Epidural Catheter Location by Epidural Pressure Waveform Recordings by the Compuflo® Cath-Checker System

Giorgio Capogna[1*], Michela Camorcia[2], Cristiana Berritta[2], Mark Hochman[3], Matteo Velardo[1]

[1]EESOA Maternal Neonatal Simulation Center, Roma, Italy
[2]Città di Roma Hospital, Roma, Italy
[3]Milestone Inc, Livingston, USA
Email: *capogna.eesoa@gmail.com

How to cite this paper: Capogna, G., Camorcia, M., Berritta, C., Hochman, M. and Velardo, M. (2020) Confirmation of Epidural Catheter Location by Epidural Pressure Waveform Recordings by the Compuflo® Cath-Checker System. *Open Journal of Anesthesiology*, **10**, 171-178.
https://doi.org/10.4236/ojanes.2020.105015

Received: April 11, 2020
Accepted: May 8, 2020
Published: May 11, 2020

Abstract

Background: Pulsatile waveforms originating from the spinal cord and transmitted through the dura in synchrony with heart rate have been used to confirm the epidural location of the catheter. Lumbar epidural space identification using the CompuFlo® instrument has been reported and validated. The aim of this preliminary study was to evaluate the new CompuFlo instrument which allows the identification of pulsatile waveform recordings. **Methods:** We tested 30 epidural catheters previously successfully used for post cesarean analgesia and about to be removed. All patients were given 5 mL 2% lidocaine to test the catheter before its removal. After priming with 5 mL saline, the catheter was connected to CompuFlo® to record the occurrence of pulsatile waveforms and/or their disappearance during its removal. **Results:** Pulsatile waveforms were observed in all the catheters properly located in the epidural space and disappeared when the catheter was extracted from the epidural space. No waveforms were recorded in 2 cases in which no sensory block occurred after the test dose (catheter dislodgement). The pressure waveform analysis through the epidural catheter had a sensitivity of 100%, a positive predictive value of 100%, a specificity of 100% and a negative predictive value of 100%. **Conclusions:** In this preliminary trial pulsatile pressure waveform recording with CompuFlo® CathCheck™ System through the epidural catheter resulted in high sensitivity and positive predictive value.

Keywords

Neuraxial Blocks, Epidural, Acute Pain, Clinical Pain, Obstetrics

1. Introduction

The position of the epidural catheter tip is an important factor in determining whether satisfactory epidural analgesia will be achieved, and the best confirmation of the correct positioning of an epidural catheter is the evidence of satisfactory analgesia (or anesthesia) and/or the evidence of sensory block after an adequate dose and volume of the anesthetic solution.

Computer Tomography [1], fluoroscopy [2] and epidural stimulation test [3] may be used to confirm the correct placement of an epidural catheter but these techniques have not been adopted widely most likely since some of them require exposure to radiation (CT, fluoroscopy) or because may be technically difficult (epidural stimulation test) or cumbersome to perform in a perioperative or obstetric setting and in all cases add an additional expense to the treatment.

Transducing and plotting the pressure measured in the epidural space produces a unique and reproducible waveform, which reflects heart rate and peripheral cardio-vascular pulse waves. These waveforms are thought to originate from the spinal cord and are transmitted through the dura to the epidural space [4].

The presence of pulsatile waveforms have been well documented in cervical [5], thoracic [6] [7] [8] [9] [10] and lumbar epidural space, [8] [11] and high sensitivity to reliably identify the epidural space and correct epidural positioning of needle and catheter has been reported in many studies [12].

However the detection of pulsatile waveforms has not recognized as a routine method to confirm the epidural catheter location in the epidural space, most likely due to complexity of the preparation which includes a pressurized 500 ml saline bag, a pressure transducer kit to be leveled with the heart, a rigid extension tubing (pressure monitoring line) and an invasive blood pressure portable monitor. Additionally, the lack of current standardization of materials and of a required technique introduces variability to the detection of a waveform.

The CompuFlo® Epidural Instrument, a well-established and validated computerized instrument to detect the lumbar epidural space [13] [14], has been recently integrated with a pulse-wave view (CathCheck™ System, CCS, Milestone Scientific, Inc.) which detects and displays the pulsatile waveform found in the epidural space.

This instrument system combines both objective pressure measurements and the detection of a pulsatile pressure waveform in a single system device. Utilizing a high resolution in-line pressure sensor the system is capable of detecting both the objective pressure in-situ as well as the presence of a pulsatile waveform when present.

This prospective, open trial is the first study that investigates the capability of CompuFlo® CathCheck™System to detect the presence of pulsatile waveform confirming the correct placement of an epidural catheter.

2. Methods

The study (Clinical Trials.gov Registration: NCT04205773) received formal ap-

proval from the Institutional Ethics Committee of Lazio 1 (Roma, Italy). The patients agreed to the referral, and written informed consent was obtained from all participants. Patients were enrolled from November 1st 2019 to November 30th 2019.

We enrolled in this study (inclusion criteria) 30 consecutive healthy patients who underwent elective cesarean section under CSE anesthesia and who had programmed epidural analgesia (PIEB) for their post cesarean analgesia.

All the patients had a closed ended multiport 16 G epidural catheter (Smiths Medical, USA) (which is our standard routine equipment for epidural CSE Anesthesia) which was previously successfully used for post-operative epidural analgesia and about to be removed.

For the purpose of this preliminary study, we used the CompuFlo® CathCheck System™, a new computer-controlled drug delivery system that provides objective pressure measurements and the detection of a pulsatile pressure waveform in a single system.

After removing the epidural filter and after a negative aspiration test, all the patients were given 5 mL 2% lidocaine to test the catheter before its removal. Immediately after the test dose, the catheter was primed with 5 mL saline, and connected to the CompuFlo® CathCheck™ instrument to record the occurrence of pulsatile waveforms and/or their disappearance during its removal.

All the measurements were performed immediately after priming the epidural catheter and during its removal until the disappearance of the pulsatile waveforms. All the epidural catheters were marked at the skin level and the distance between the skin at the time of measurements was recorded. All the patients were tested with a pin prick tests for the occurrence of L2-3 sensory block after the test dose in order to further confirm the correct placement of the epidural catheter.

All the results were recorded and data were analyzed for the specificity and sensitivity. The cut-off value for the length of epidural catheter withdrawal associated with its exit from epidural space was analyzed with the one-sample t-test.

The power analysis was set to detect a 99% specificity and sensitivity, and required a sample of 30 observations to set 80% test power and 95% significance level.

3. Results

The mean (SD) patient's age was 32.5 (7.7) years, the mean weight was 77.5 (2.8) Kg and the mean height was 166.3 (8.9) cm.

Pulsatile waveforms were observed in all the catheters properly located in the epidural space (confirmed by the occurrence of L2-3 sensory block after the test dose) (28/28) and disappeared when the catheter was extracted from the epidural space (28/28).

In **Figure 1** is depicted the typical waveform associated with the correct location of the catheter in the epidural space and its disappearance when the

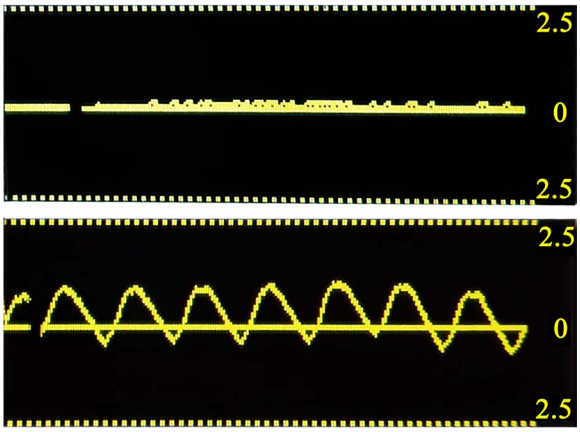

Figure 1. The typical waveform associated with the correct location of the catheter in the epidural space (below) and its disappearance when the catheter is withdrawn (above).

catheter is withdrawn.

The mean length of epidural catheter withdrawal associated with its exit from epidural space was 3.56 cm (CI 95% 3.12 - 4.01) and this can be considered as the cut-off value ($P = 1.27^{e-15}$; t = 16,494).

No waveforms were recorded in the 2 cases in which no sensory block occurred after the test dose (catheter dislodgement).

The pressure waveform analysis through the epidural catheter had a sensitivity of 100%, a positive predictive value of 100%, a specificity of 100% and a negative predictive value of 100%.

4. Discussion

In this preliminary trial, pulsatile pressure waveform recording with CompuFlo® through the epidural catheter resulted in high sensitivity and positive predictive value.

All previous studies have used a commercially available monitor for invasive pressure to observe epidural waves. Ghia and co-workers [15] were the first to describe a crude set-up using the end of the epidural catheter connected to a disposable pressure transducer, followed by a 5-mL normal saline bolus injection to ensure the patency of the epidural catheter, and an epidural pressure waveform was displayed and recorded on an invasive blood pressure monitor on a scale of 0 to 30 mm Hg, at a speed of 12.5 mm/second. The epidural pressure waveforms obtained by transducing the epidural catheter was used as a surrogate for the accurate location of the epidural catheter. The study demonstrated a strong correlation between the epidural pressure waveform and the occurrence of the correct epidural catheter placement as assessed by CT-scan. Unfortunately, sensitivity and specificity and predictive value of the EPWF could not be calculated due to the small sample size. In addition, the sample was mixed by gender and by epidural block level (cervical, thoracic and lumbar).

Gong *et al.* [8] in a large single-center, prospective cohort study of 3326 patients undergoing thoracic, abdominal, and lower limb surgery were able to

demonstrate that the specificity and sensitivity of epidural pressure waveform was higher than the traditional loss of resistance technique (LORT), and it also provided higher satisfaction with anesthesia when compared with the LORT (62.8% vs 45.6%; $P < 0.05$). Epidural pressure waveform also performed better than LORT in risk of anesthesia failure (0.4% vs 1.1%; $P < 0.05$) and catheter replacement-related complications (0% vs 0.6%; $P < 0.05$).

Leurcharusmee *et al.* [9] used a set-up similar to that described by Ghia and co-workers in 2001. Recording system consisted of an epidural needle and a sterile extension tubing, connected to a pressure transducer (leveled with the heart), which was attached to the needle. The epidural waveform was recorded on a portable monitor using a 0- to 30-mm Hg scale. The pulsatile pressure waveform correlated well with a successful outcome of anesthesia.

Concerning pregnant women, Sebbag *et al.* [16] were not able to observe any epidural pressure waveforms in a preliminary, very small sample of laboring women, and they attributed their findings to anatomical and physiological differences in the lumbar epidural space of parturients. However, they did not prime the epidural catheter with saline before measurements. Different results were obtained by Al-Aamri *et al.* [11] who used an invasive blood pressure transducer leveled with the heart, in both sitting and lateral decubitus positions in laboring women. They found that a needle positioned in the epidural space displayed a pulsatile waveform in 96% of cases. They attribute the success of their results to the fact that they injected 5 ml of saline through the epidural needle before connecting the extension tubing, in keeping with the recommendation by de Medicis *et al.* [7] However although de Medicis *et al.* [7] suggested a priming volume of 5 mL, such a volume yielded positive waveforms in only 90% of their subjects. Thus, the rate of false negative waveforms could perhaps be decreased with a higher injected volume of saline and the use of a higher resolution scale for the detection of the pulsewave. This hypothesis was confirmed by our study. By using a total 10 mL volume for priming (5 mL lidocaine test dose and immediately after 5 mL saline) in combination with a proprietary software that amplifies the pressure signal we were indeed able to demonstrate a very high sensitivity and positive predictive value for the occurrence of epidural waveforms, confirming the importance of first the priming of the epidural catheter with an appropriate volume of saline and secondly using a system that is optimized to detect the pressure pulse waveforms.

All previous studies so far have used commercially available blood pressure invasive equipment with limited signal sensing. By using such an instrument, there is no means to detect the pulsatile waveform in combination with the detection of an objective pressure value to determine the patency of the catheter used. Invasive pressure systems cannot determine an objective pressure value in response to injection of a bolus of drug and determining the response to that bolus on a visual screen. Moreover, the level of pressure transducer has to be adjusted to the heart level. Until now, in clinical practice, the steps required for

confirmatory waveform analysis (saline injection through the epidural needle, connection of the extension tubing, identification of the waveform and disconnection of the extension tubing) can be accomplished in a variable length of time, depending if the transducer kit is available and prepared in advance and may be problematic in obstetric and postoperative settings. In addition, the use of invasive blood pressure monitor and transducer may be considered "off-label" for this kind of equipment which is not optimized for this application.

The CompuFlo® Epidural with CathCheck™ provides the operator with an optimized system to monitor the pressures produced from injecting a fluid to flush a catheter. All previous studies employed commercially available in-line blood pressure transducers with monitoring of scales between ± 20 mm/Hg to ± 30 mm/Hg, making the signal sometimes difficult to detect. CathCheck™ System has overcome this deficiency by optimizing the detection of a low-level pulsatile waveform by employing greater sensibility and scales ranging from ±1.25 mm/Hg to ±20 mm/Hg. In addition, the CathCheck™ System requiring standardized disposables designed for the system thus avoiding the variability introduced when using different setups with varying components.

Secondly, this same system can allow an operator to observe the objective pressure values over period of time to determine if proper absorption of the drug is occurring. Thirdly, it simultaneously displays the presence or the absence of a pulsatile pressure waveform which is reflective of the cardio-vascular system's effect on the target site. Such as that which is noted in the epidural space. In the absence of the pulsatile waveform it can be understood that the catheter may have migrated out of position from the target site after placement.

This study design however has some limitations. We studied only epidural catheters previously successfully used for post-cesarean analgesia and about to be removed and therefore our findings are, for the time, being applicable only to this clinical condition. We did not investigate laboring women nor whether the EPWF may be able to detect subarachnoid, intravascular, or subdural catheter misplacement. Single cases of the appearance of a signal synchronous with arterial pulsation have been reported when the needle or catheter was inadvertently placed intrathecally or in an artery [12]. However, whether similar or other types of waveform could be demonstrated by unintentional placement of epidural catheter outside the epidural space has not been studied yet.

CompuFlo®, utilizing a high resolution pressure in-line sensor system, is capable of detecting both the pressure in-situ as well as the presence of a pulsatile waveform when present with a high grade of sensitivity. This specific feature will allow the development of future studies to also investigate whether the dwell time of the epidural catheter, the type of the tip of the catheter, patients' position, the presence of active labor contractions and the priming volume of the epidural catheter may affect the sensitivity and positive predictive value of the EPWF.

In conclusion, in this preliminary trial pulsatile pressure waveform recording

with CompuFlo® Epidural Instrument integrated with a pulsewave view (CathCheck System™) through the epidural catheter resulted in high sensitivity and positive predictive value. This adds further value to the CompuFlo® Epidural instrument which, in addition to accurately identifying the epidural space, has also now proved capable of identifying the correct positioning of the epidural catheter.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

[1] Motamed, C., Farhat, F., Rémérand, F., Stéphanazzi, J., Laplanche, A. and Jayr, C. (2011) An Analysis of Postoperative Epidural Analgesia Failure by Computed Tomography Epidurography. *Anesthesia & Analgesia*, **103**, 1026-1032. https://doi.org/10.1213/01.ane.0000237291.30499.32

[2] Yeager, M.P., Parra, M.C. and Sites, B.D. (2017) Imaging Guidance for Thoracic Epidural Catheter Placement. *Anesthesia & Analgesia*, **125**, 704-705. https://doi.org/10.1213/ANE.0000000000002219

[3] Tsui, B.C.H., Gupta, S. and Finucane, B. (1999) Determination of Epidural Catheter Placement Using Nerve Stimulation in Obstetric Patients. *Regional Anesthesia and Pain Management*, **24**, 17-23. https://doi.org/10.1097/00115550-199924010-00005

[4] Nakamura, K., Urayama, K. and Hoshino, Y. (1997) Lumbar Cerebrospinal Fluid Pulse Wave Rising from Pulsations of Both the Spinal Cord and the Brain in Humans. *Spinal Cord*, **35**, 735-739. https://doi.org/10.1038/sj.sc.3100548

[5] Hong, J.H. and Jung, S.W. (2018) Analysis of Epidural Waveform for Cervical Epidural Steroid Injections Confirmed with Fluoroscopy. *Medicine*, **97**, e0202. https://doi.org/10.1097/MD.0000000000010202

[6] Lennox, P.H., Umedaly, H.S., Grant, R.P., White, S., Fizmaurice, B.G. and Evans, K.G. (2006) A Pulsatile Pressure Waveform Is a Sensitive Marker for Confirming the Location of the Thoracic Epidural Space. *Journal of Cardiothoracic and Vascular Anesthesia*, **20**, 659-663. https://doi.org/10.1053/j.jvca.2006.02.022

[7] deMedicis, E., Pelletier, J., Martin, R., Loignon, M.J., Tetrault, J.P. and Laroche, L. (2007) Technical Report: Optimal Quantity of Saline for Epidural Pressure Waveform Analysis. *Canadian Journal of Anesthesia*, **54**, 818-821. https://doi.org/10.1007/BF03021709

[8] Gong, Y., Shi, H., Wu, J., *et al.* (2014) Pressure Waveform-Guided Epidural Catheter Placement in Comparison to the Loss-of-Resistance Conventional Method. *Journal of Clinical Anesthesia*, **26**, 395-401.

https://doi.org/10.1016/j.jclinane.2014.01.015

[9] Leurcharusmee, P., Arnuntasupakul, V., Chora De La Garza, D., *et al.* (2015) Reliability of Waveform Analysis as an Adjunct to Loss of Resistance for Thoracic Epidural Block. *Regional Anesthesia and Pain Management*, **40**, 694-697. https://doi.org/10.1097/AAP.0000000000000313

[10] Arnuntasupakul, V., Van Zundert, T.C., Vijitpavan, A., *et al.* (2016) A Randomized Comparison between Conventional and Waveform-Confirmed Loss of Resistance for Thoracic Epidural Blocks. *Regional Anesthesia and Pain Management*, **41**, 368-373. https://doi.org/10.1097/AAP.0000000000000369

[11] Al-Aamri, I., Derzi, S.H., Moore, A., *et al.* (2017) Reliability of Pressure Waveform Analysis to Determine Correct Epidural Needle Placement in Labouring Women. *Anaesthesia*, **72**, 840-844. https://doi.org/10.1111/anae.13872

[12] Hilber, N.D., Rijs, K., Klimek, M., *et al.* (2019) Systematic Review of the Diagnostic Accuracy of Epidural Wave form Analysis to Identify the Epidural Space in Surgical and Labor Patients. *Minerva Anestesiologica*, **85**, 393-400. https://doi.org/10.23736/S0375-9393.18.13089-6

[13] Capogna, G., Camorcia, M., Coccoluto, A., Micaglio, M. and Velardo, M. (2018) Experimental Validation of the Compuflo® Epidural Controlled System to Identify the Epidural Space and Its Clinical Use in Difficult Obstetric Cases. *International Journal of Obstetric Anesthesia*, **36**, 28-33. https://doi.org/10.1016/j.ijoa.2018.04.008

[14] Gebhard, R.E., Moelter-Bertram, T., Dobeki, D., *et al.* (2019) Objective Epidural Space Identification Using Continuous Real-Time Pressure Sensing Technology: A Randomized Controlled Comparison with Fluoroscopy and Traditional Loss of Resistance. *Anesthesia & Analgesia*, **129**, 1319-1327. https://doi.org/10.1213/ANE.0000000000003873

[15] Ghia, J.N., Arora, S.K., Castillo, M. and Mukherji, S.K. (2001) Confirmation of Location of Epidural Catheters by Epidural Pressure Waveform and Computed Tomography Cathetergram. *Regional Anesthesia and Pain Management*, **26**, 337-341. https://doi.org/10.1097/00115550-200107000-00011

[16] Sebbag, I., Qasem, F., Armstrong, K., Jones, P.M. and Singh, S. (2016) Waveform Analysis for Lumbar Epidural Needle Placement in Labour. *Anaesthesia*, **71**, 984-985. https://doi.org/10.1111/anae.13540