Technical report: optimal quantity of saline for epidural pressure waveform analysis

[Compte-rendu technique : quantité optimale de solution saline pour l'analyse d'une forme d'onde de la pression périodurale]

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Purpose: Epidural waveform analysis (EPWA) is a simple test to confirm the optimal placement of an epidural catheter. It relies on the transmission of the thecal pressure waveform through the epidural catheter. Little is known about the optimal volume of catheter injectate needed to optimize the EPWA test.

Methods: In a randomized controlled trial we compared three different catheters: stimulating, open-ended hole [S1]; stimulating, three-hole [S3]; non-stimulating three-hole [NS3] in 60 patients in an unblinded pilot study. After catheter insertion using a loss of resistance to air technique, we recorded the dose response curve of EPWA and the presence of epidural pressure wave transmitted through the catheter to repeated injections of 2.5 mL saline boluses in the catheter to a total volume of 10 mL. All patients were followed by the acute pain service to confirm adequacy of postoperative epidural analgesia.

Results: The S3 catheters were significantly more responsive (able to transmit a pulsatile waveform) compared to the S1 [$P = 0.003$ (S3) and $P = 0.012$ (NS3)] at low injectate volume, while there was no differences between the S3 catheters in their ability to transmit a waveform for EPWA ($P = 0.25$). There was no increase in responsiveness after 2.5 mL injected for S3 catheters and 5 mL for the S1 catheter. Three patients had soft catheters that did not transmit an epidural pulsative waveform.

Conclusions: For EPWAs, S3 epidural catheters are superior to S1 catheters for determining pulsative waveform transmission at low injectate volume. The optimal initial quantity of saline for EPWA is 5 mL regardless of the catheter type used.

Objectif: L'analyse d'une forme d'onde périodurale (EPWA – Epidural waveform analysis) est un test simple utilisé pour confirmer le positionnement optimal d'un cathéter périodural. Ce test s'appuie sur la transmission de l'onde de pression thécale à travers le cathéter périodural. Nous ne disposons que de très peu de connaissances concernant le volume optimal de la dose injectée dans le cathéter afin d'optimiser le test EPWA.

Méthode : Dans le cadre d'une étude randomisée contrôlée, nous avons comparé trois cathéters différents : stimulant, à embouchure ouverte [S1] ; stimulant, à trois ouvertures [S3] ; non-stimulant, à trois ouvertures [NS3]. Soixante patients ont participé à cette étude pilote ouverte. Après l'insertion du cathéter à l'aide d'une technique de perte de résistance à l'air, nous avons enregistré la courbe de dose réponse d'EPWA ainsi que la présence d'une onde de pression périodurale transmise par le cathéter lors d'injections répétées de bolus salins de 2,5 mL dans le cathéter, pour atteindre un volume total de 10 mL. Tous les patients ont été suivis par le service de douleur aiguë afin de confirmer que l'analgésie périodurale postopératoire était adéquate.

Résultats : Les cathéters S3 ont été significativement plus aptes à transmettre une forme d'onde pulsatile, par rapport aux S1 [$P = 0,003$ (S3) et $P = 0,012$ (NS3)] lorsque le volume injecté était bas, alors qu'aucune différence n'a été observée entre les cathéters S3 dans leur capacité à transmettre une forme d'onde pour l'EPWA ($P = 0,25$). Il n'y a eu aucune augmentation de la transmissibilité lorsque plus de 2,5 mL ont été injectés dans les cathéters S3 et 5 mL dans les cathéters S1. Trois patients ont eu des cathéters souples qui n'ont pas transmis de forme d'onde pulsatile périodurale.

Conclusion : Pour les tests d'EPWA, les cathéters périoduraux S3 sont supérieurs aux cathéters S1 afin de déterminer la transmission d'une forme d'onde pulsatile à un bas volume injecté. La quantité initiale optimale de solution saline pour l'EPWA est 5 mL, quel que soit le cathéter utilisé.

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SUBOPTIMAL placement of epidural catheters within the epidural space may be responsible for a significant proportion of failures of postoperative epidural analgesia.¹ Epidural waveform analysis (EPWA) is a new method for confirming correct epidural placement.² The only specialized equipment required for EPWA is a pressure transducer connected to the epidural catheter or needle. The epidural space is confirmed by the transmission of the wave pressure of the pulsating dura mater. In a recent study, the positive predictive value of EPWA was 100%.³ Epidural catheters need to be primed with liquid in order to improve pulse wave transmission. The dose-response of priming volume *vs* pulsative waveform transmission for EPWA for different types of epidural catheters has never been described.

The principal aim of this study was to determine the optimal volume of injectate to transmit a pulsatile epidural waveform. A secondary objective was to test for differences in the responsiveness of commercially available epidural catheters when using EPWA.

Methods

After Institutional Review Board approval of the study protocol, and obtaining signed informed consent, 60 patients who were scheduled for elective major surgery warranting postoperative epidural analgesia were enrolled. Surgical procedures included major abdominal, urological, thoracic and aortic surgeries. Excluded were patients with any contraindication to epidural techniques.

In the operating room, prior to surgery, routine monitors were attached and a peripheral intravenous catheter was secured. With the patient either sitting or in the lateral decubitus position, the epidural space was identified using a loss of resistance to air, with minimal air injection. The epidural catheter was either a Portex 20G® (Smith Medicals MD, Inc., St Paul, MN, USA) [stiff, non-stimulating, three-hole (NS3)], a Portex Duraflex 19G® (Smith Medicals MD, Inc., St Paul, MN, USA) [soft, stimulating, three-hole (S3)], or an Arrow Flex Tip Plus® 19G (Arrow International, Inc., Reading, PA, USA) [soft, stimulating, single open-ended hole (S1)], according to a previously determined randomization schedule. If the catheter could not be threaded, another catheter, at the choice of the attending anesthesiologist, was inserted. After the epidural catheter was inserted 5 cm into the epidural space and secured, the patient was placed supine. The epidural catheter was connected to a pressure transducer positioned at the mid-axillary level of the patient. Measures of the pressure transduced by the epidural catheter were recorded at baseline and after four suc-

cessive boluses of 2.5 mL of 0.9% normal saline (NS) administered through the catheter. All values were recorded following passive exhalation approximately ten seconds after the bolus. The test was considered positive for epidural catheter placement in the epidural space when positive pressure waveform deflections were seen on the monitor screen in synchrony with cardiac contractions (either by electrocardiogram or pulse oximetry). No minimal value was set for the positive waveform deflections. The injections were done in sequence, after each pressure reading, so the whole testing procedure did not last more than five minutes. If EPWA confirmed correct catheter placement, the attending anesthesiologist was permitted to inject the epidural test dose and proceed with the case. If EPWA was negative after 10 mL of 0.9% NS, an alternative confirmation technique was used: if positive, the case was allowed to proceed; if negative, the epidural catheter was reinserted and the patient was excluded from the study. All patients were evaluated postoperatively by the acute pain service team to ensure adequate epidural analgesia (visual analogue score < 4/10). In the absence of adequate epidural analgesia, patients were excluded from the study.

Randomization was done using a random numbers table. An arbitrary sample size of 20 patients per group was chosen for this pilot study. Since the data are not distributed normally, and repeated measures were involved, a Friedman's test was used to analyze the changes of EPWA between volumes of injectate. Two by two comparisons were analyzed with the Mann-Whitney U test. A *P* value < 0.05 was considered statistically significant.

Results

Of 62 patients who were screened and met study inclusion criteria, two declined participation, leaving 60 subjects who were subsequently randomized. Two catheters in the S1 group and one in the group S3 could not be threaded initially, but the epidural space was eventually catheterized in all three subjects with the stiffer NS3 catheters. Results from the patients were assigned to the effective indwelling catheter group. One catheter in the NS3 group was in an epidural vein, with positive EPWA results. This patient was excluded from the study. All other epidural catheters provided adequate postoperative analgesia.

Patient characteristics and the distribution of epidural techniques were similar amongst the three groups (Table). There was no increase in EPWA responsiveness above 2.5 mL 0.9% NS injected through the S3 catheters, and above 5.0 mL for the S1 catheters. The responsiveness of the S3 were equivalent (*P* = 0.25),

TABLE Patient demographics and epidural technique

Catheter type	S1	S3	NS2
Patients (n)	19	18	22
Age (yr - mean/range)	61 (43-80)	58.9 (36-75)	61.8 (36-88)
Sex (male/female)	12/7	10/8	11/11
Body mass index (kg·m ⁻² mean/range)	26.2 (20-37.1)	27.3 (21.9-34.5)	24.5 (16.5-37.3)
Epidural level (thoracic/lumbar) (n)	18/1	16/2	20/2
Epidural approach (median/paramedian) (n)	19/0	17/1	20/2
Patient position (sitting/lateral decubitus) (n)	17/2	16/2	21/1

There were no significant differences between groups. S1 = stimulating, single open-ended hole epidural catheter (Arrow Flex Tip Plus® 19G); S3 = stimulating, three-hole epidural catheter (Portex Duraflex 19G®); NS3 = non-stimulating, three-hole catheter (Portex 20G®).

but superior to that of the S1 catheter ($P = 0.003$ for S3 *vs* S1, and $P = 0.012$ for NS3 *vs* S1, Figure). At 0 and 2.5 mL injected, the S1 catheter was less effective in transmitting a pulsative waveform compared to the S3 and NS3 catheters ($P < 0.001$ and 0.003 respectively), but there were no differences between groups at 5 mL ($P = 0.055$) and above.

Two patients in group S1 and one patient in group S3 had negative EPWA tests following 10 mL of NS injectate despite having adequate postoperative epidural analgesia.

Discussion

We hypothesized that the volume of NS injected into the epidural space and also the specific catheter design would influence the sensitivity of the EPWA test to confirm correct epidural placement. Our study shows that an initial bolus of 5 mL NS is optimal, independent of the catheter used. These results indicate that multi-orifice catheters produce a superior epidural waveform transmission at low injectate volumes, with no difference between soft and stiff catheters, as compared with a single endhole catheter. However there was no difference in waveform transmission between multi-orifice and single-hole catheters at a priming volume of 5 mL or more. A power analysis indicated a requirement of at least 100 patients, 50 receiving single-hole catheters and 50 receiving multi-orifice catheters, to show that multi-orifice catheters are superior to endhole catheters at a priming volume of 5 mL or more assuming the responsiveness of the respective catheters was identical to our initial findings.

FIGURE S1 = stimulating, single open-ended hole epidural catheter (Arrow Flex Tip Plus®, 19G); S3 = stimulating, three-hole epidural catheter (Portex Duraflex 19G®); NS3 = non-stimulating, three-hole catheter (Portex 20G®). S1 *vs* S3, $P = 0.003$; S1 *vs* NS3, $P = 0.012$; S3 *vs* NS3, $P = 0.25$. Set bolus values: 0 mL, S1 *vs* S3 and NS3, $P < 0.001$; 2.5 mL, S1 *vs* S3 and NS3, $P = 0.003$; 5 mL, S1 *vs* S3 and NS3, $P = 0.055$; > 5 mL, S1 *vs* S3 and NS3, $P = \text{NS}$. S3 *vs* NS3, $P = \text{NS}$ at all bolus values. S1 catheters: $P = \text{NS}$ for 7.5 mL and 10 mL *vs* 5.0 mL. S3 and NS3 catheters: $P = \text{NS}$ for 5.0, 7.5 and 10 mL *vs* 2.5 mL.

In a previous study,³ we observed a sensitivity (responsiveness) of 80% after priming an S1 catheter with 5 mL of saline (218 patients). This finding was similar to the results of Lennox *et al.*⁴ at 2.5 mL injected, we observed an S1 sensitivity of 53% compared to 55.6% after 3 mL injected in their study. The catheter size, 19G (S3) *vs* 20G (NS3) did not influence the EPWA sensitivity ($P = 0.25$). We obtained a sensitivity of 82% for the NS3 after 2.5 mL injected *vs* 88.9% after 3 mL injected in the Lennox study.

One patient had a false positive EPWA, the first in over 311 prospectively evaluated subjects in two previous randomized controlled trials^{3,4} and the results of the current investigation. As per study design, aspiration and test doses were not performed prior to data recording. This characterizes one limitation of the epidural waveform analysis technique, as a catheter inserted into an epidural vein or into the intrathecal space will also transmit an epidural pressure waveform. EPWA testing does not eliminate the need for catheter aspiration and a test-dose in order to exclude the possibility of intravascular or intrathecal catheter insertion. In our previous study of 218 patients, only eight (3.7%) had an improperly placed epidural catheter: the specificity of EPWA was 100% (the negative predictive value was 17%).³ One further limitation of the technique is that three patients in the soft stimulating catheter group had a negative EPWA after 10 mL saline was injected; all three subjects had a positive Tsui test.

Three soft catheters could not be threaded in the epidural space. Prior epidural expansion with fluids may improve the success of catheter advancement into the epidural space, but because of concern that prior epidural fluid administration may alter the EPWA/fluid dose response curve, this technique was not allowed in the current study. Further studies would be required to quantify the influence of prior fluid injection in the epidural space on the EPWA test.

Our study has several limitations, including the lack of blinding procedures. However, as we were evaluating transmitted pulse pressure waveforms, blinding would have minimal influence on the accuracy of recorded measures. Secondly, there were modest variations in the time intervals as which recordings were made following injection. This is because airway pressures are transmitted through the thoracic epidural space.⁵ As we always recorded data at the end of a passive expiration, some measurements occurred longer than ten seconds of elapsed time post-bolus. In the lumbar epidural space, the pressure plateaus about 30 sec after the injection of fluids, but the presence of the epidural wave pressure is detectable immediately after the bolus.⁶ Hence, the variable intervals at which the values were recorded may have influenced, to a certain degree, the recorded values of the mean epidural pressure and the epidural differential wave pressure, but not the presence or absence of pulsatile waveform. All epidural spaces were identified with a loss of resistance to air technique: we cannot eliminate the possible effect of a small amount of air entering the epidural space affecting our results. Finally, we assumed that multiple discrete boluses of 2.5 mL are equivalent to a single larger bolus. A recent study examining serial magnetic resonance imaging studies of the lumbar spine in young patients showed that lumbar cerebrospinal fluid volume after epidural injections of 10 mL was minimal five minutes post-injection, and had not returned to baseline until 30 min after injection.⁷ In our protocol, recordings were done at intervals less than one minute between injections, and the whole experiment lasted only about five minutes per subject. Based on the findings of Higuchi *et al.*,⁷ we believe that our assumption of additive saline boluses is valid.

In conclusion, in this randomized controlled trial, we found that the optimal quantity of saline to for EPWA is 5 mL independent of the epidural catheter used. Three-hole epidural catheters are superior to S1 catheters for EPWA at this low injectate volume. Larger clinical trials are warranted to further define the sensitivity, specificity and positive/negative predictive values of the EPWA using multi-orifice catheters.

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