A Randomised Controlled Trial using the Epidrum for Labour Epidurals

Abstract
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The aim of our study was to determine if using the Epidrum to site epidurals improves success and reduces morbidity. Three hundred parturients requesting epidural analgesia for labour were enrolled. 150 subjects had their epidural sited using Epidrum and 150 using standard technique. We recorded subject demographics, operator experience, number of attempts, Accidental Dural Puncture rate, rate of failure to site epidural catheter, rate of failure of analgesia, Post Dural Puncture Headache and Epidural Blood Patch rate. Failure rate in Epidrum group was 9/150 (6%) vs 0 (0%) in the Control group (P=0.003). There were four (2.66%) accidental dural punctures in the Epidrum group and none in the Control group (P=0.003). There were four (2.66%) accidental dural punctures in the Epidrum group and none in the Control group (P=0.003). There were four (2.66%) accidental dural punctures in the Epidrum group and none in the Control group (P=0.003). There were four (2.66%) accidental dural punctures in the Epidrum group and none in the Control group (P=0.003).

Methods
After ethical approval and written informed consent, 300 parturients requesting epidural analgesia for labour, were enrolled in our study. Patients younger than 18 or those unable to give informed consent were excluded. The 300 subjects were randomised into two groups using computer generated numbers. One group (Epidrum group) received epidural analgesia using the Epidrum and the other group (Control group) received epidural analgesia using standardised LORS technique. All epidurals were performed by seven trainee anaesthetists rotating through the hospital during the period of the study. The experience of our operators in anaesthesia ranged from 1.5 to 8 years. All the trainee anaesthetists who participated in the study were trained in using the Epidrum device (via a simulated LOR device provided by Exmoor Innovations Ltd.) prior to using it on patients. All epidurals were carried out with subjects in the sitting position, using the Tuohy needle and the saline LORS technique. The epidural catheter was advanced 4 cm into the epidural space in all subjects. A standardised test dose and maintenance infusion was used in all subjects. If the trainee failed to site the epidural after three attempts in the Epidrum group and failure of analgesia, PDPH and EBP. All comparisons were made with a level of significance of 0.05.

Results
We recorded the following variables in the labour ward: subject demographics, anaesthetic experience of the operator in years, dural puncture, number of attempts taken to site epidural, failure (defined as being unable to site the epidural catheter after three attempts) to site epidural requiring a second operator, and failure of epidural analgesia (defined as failure to obtain a sensory block after initial local anaesthetic loading dose, resulting in the epidural catheter being removed within 48 hours) on any of the subjects; need for second operator, accidental dural puncture, failure of analgesia, PDPH and EBP. All comparisons were made with a level of significance of 0.05. There were no significant differences between the two groups for age, height, weight, BMI, parity or anaesthetic experience (Table 1). There were no significant differences between techniques except for failure to site the epidural requiring a second operator. In 9 out of 150 epidurals (6%) in the Epidrum group a second anaesthetist was required to site it, compared to none in the Control group (P=0.003) (Table 2). There were four accidental dural punctures in the Epidrum group and none in the Control group (P=0.003). Two of these subjects suffered from a PDPH as a result. One subject was managed conservatively and the other received an epidural blood patch. In the Epidrum group two out of 150 epidurals were re-sited, versus three out of 150 epidurals in the control group (P=0.003).

Discussion
Our pilot study showed that use of Epidrum to site epidurals was equivalent to LORS, except for failure to site the initial epidural where LORS was superior. It is the first study using the Epidrum to look specifically at morbidity as a primary outcome. It is also the largest study so far comparing Epidrum to standard LORS techniques. The principle aim of our pilot study was to estimate population rates of adverse events in each group. Therefore the number of participants (150 per group) was insufficient to power any definitive tests, but not so small as to observe sufficient numbers of events to adequately estimate the rates, given the time and resources available. We note that 150 individuals is a low number compared to the 1000 patients who contribute annual data to the SAGE database. Simple calculation shows that to detect an observed rate of 1 adverse event in 250 patients per year (as in our study) with 90% power, 1804 patients per year would be needed. This is equivalent to 1804 epidurals per year. We note that the rate of adverse events ranges are broad (0.2% to 3.6% for ADP, 0.1% to 2.9% for PDPH), but centred around a 1-2% rate. Powering a study to detect even a 1 or 2 percentage point shift between groups would require a sample with at least twice as many participants and a much larger labour ward. For the above reasons we measured Pearson’s chi-squared test was used. A Fishers exact test was used to compare the data in variables were the expected frequency was less than 5 in greater than 25% of the subjects; no second operator, accidental dural puncture, failure of analgesia, PDPH and EBP. All comparisons were made with a level of significance of 0.05.
LOR technique. The small number of investigators in the study (n=7) may have provided an opportunity for individual bias to skew the results in favour of one technique over another. As such, it would seem prudent when designing a future randomised controlled trial to engage anaesthetic operators of a similar experience, preferably novice as in the pilot study we found experienced operators were less enamoured with the new device.

Our results differ somewhat from two previous studies carried out comparing the Epidrum to standard LOR techniques. Both these studies found the Epidrum to be superior to conventional LOR techniques, however they focused more on the time taken to carry out the procedure and ease of use, while our study looked primarily at morbidity and clinical endpoints. While our results did not show the Epidrum to offer any real advantage to LORS for sitting epidurals, it may have a useful role to play in the teaching of the epidural procedure. It is often difficult for an anaesthetist teaching a trainee to determine whether there is a true loss of resistance simply by observing the procedure. If used correctly the Epidrum provides a very obvious visual signal that the epidural space has been reached, thus removing operator and observer subjectivity. In conclusion, the results of our pilot study do not suggest that using Epidrum compared to the standard LORS technique improves success or reduces morbidity associated with labour epidurals. All comparisons are from within our study.

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References