A Factorial Trial of Ultrasound and Manometry to Improve the Success of Thoracic Epidural Placement

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ABSTRACT

In a variety of thoracic and abdominal surgeries, thoracic epidural (TE) placement is associated with better pain relief, less opioid consumption, and decreases in adverse perioperative cardiac events. Unfortunately, TE catheter placement is challenging and is not always successful. The epidural space in the thoracic region is especially difficult to access due to the steep and inferior angulation of most of the spinous processes. The primary objective of this study is to investigate the use of ultrasound (US) and manometry (MAN) to increase the success rate of TE placement. The use of US for lumbar epidural catheter placement is well established and is thought to assist in identifying an optimal skin entry point, depth to lamina and ligamentum flavum, and needle trajectory. The use of sterile MAN tubing to demonstrate a falling and oscillating fluid column has been described as a confirmatory test in the placement of lumbar epidurals. This study will determine if the efficacy of TE placement is improved if placement is performed with the use of either US, or MAN, or both techniques combined, compared with a standard landmark-based placement technique alone. This study utilized a randomized, controlled, single center trial with a factorial design to assess the primary endpoint of TE placement success as measured by diminished sensation to pinprick or ice in two or more adjacent dermatomes after 1.5% lidocaine catheter injection. Data acquisition was completed for 220 of 480 subjects. Exclusions were applied to 12 of the subjects. Preliminary analysis was performed; however, the data set was low powered. No difference between groups was found in TE placement success rates, X2 (9, N= 206) = 9.57, p= .39. Validity cannot be assumed within this analysis; a thorough review of all 480 subjects remains needed to assess TE placement success rates between study groups.

OBJECTIVE

To determine if ultrasound assistance to preview anatomical depths before TE needle insertion and manometry to confirm TE space location will increase the success of TE placement.

INTRODUCTION

The majority of TEs are placed with a landmark-based technique wherein the prominences of the vertebrae are used to estimate the interlaminar space, the needle is then advanced into the epidural space and confirmed by a “loss of resistance (LOR)”. These techniques are performed blindly by the operator. Unsurprising this approach is associated with a significant number of unsuccessful attempts, long procedure times, and TE failure rates as high as 32%.[1-3] Higher numbers of attempts also lead to an increased risk for complications.[4] The high failure rate of this procedure highlights the need for more studies on ways to improve the techniques for TE access.

US measurement of the epidural space depth before catheter placement decreased the rate of lumbar epidural catheter replacements and number of epidural attempts.[5] US assisted access to the TE space has not been studied. The anatomy of the thoracic vertebrae permits the use of ultrasound to identify the thoracic transverse processes, allowing for measures of epidural space depth which can be used to guide TE needle placement. The manometry technique for identifying the correct epidural space involves using a stopcock connected to IV tubing filled with normal saline. When LOR is detected, it can be confirmed by connecting the prefilled tubing to the Tuohy needle and opening the stopcock to air. If the Tuohy needle tip is in the epidural space, the saline column will fall, then exhibit pulsatility linked with heartbeat and respiration. The identification of the epidural space by respiratory and heartbeat fluctuations in the air-fluid level has been previous described.[6-7] We hypothesize that the simple, rapid, and inexpensive technique of extension tubing manometry will offer benefits for confirmation of TE placement.

STUDY DESIGN

Hypothesis: The hypothesis is that US assistance to preview anatomical depths before needle insertion and MAN to confirm TE space location will increase the primary success of TE placement.

Primary Objective: to evaluate the success of TE placement in the following groups
1) Landmark-based placement (Standard)
2) Landmark-based placement with manometry confirmation (Manometry)
3) Ultrasound assisted placement (Ultrasound)
4) Ultrasound assisted placement with manometry confirmation (Manometry + Ultrasound)

Successful TE placement was measured by diminished sensation to pinprick or cold in two or more adjacent dermatomes 15 minutes after the injection of 5 mL of 1.5% lidocaine with 1:200,000 epinephrine into an epidural catheter.

Secondary Objective: to evaluate group differences in total procedure time, total number of attempts to place epidural, and occurrence of adverse events.

Design: Randomized controlled, single center trial using a factorial design. Post-consent, 480 subjects were randomly assigned to one of four possible strategies: Standard, Manometry, Ultrasound, or Manometry + Ultrasound.

Study Population: Inclusion criteria was adults ≥ 18 years old to ≤ 80 years old, surgical patients clinically indicated for T4-10 thoracic epidural placement, and American Society of Anesthesiologists (ASA) physical status 1 to 4. Exclusion criteria was non-English speaking, pregnancy, decisionally impaired, or incarcerated.

Demographics

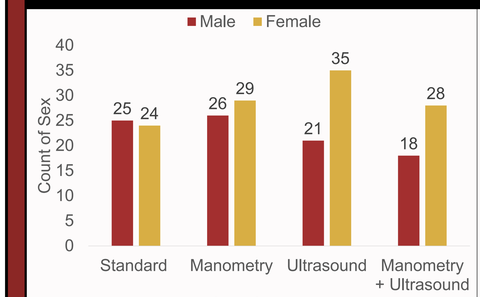

Figure 1: Sex of participants by group.

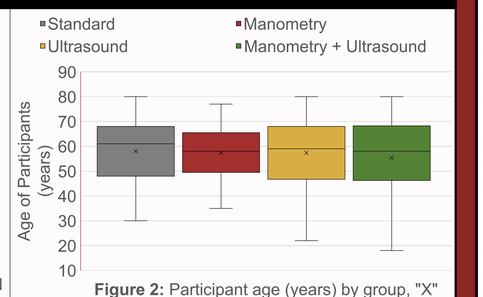

Figure 2: Participant age (years) by group, "X" indicates average.

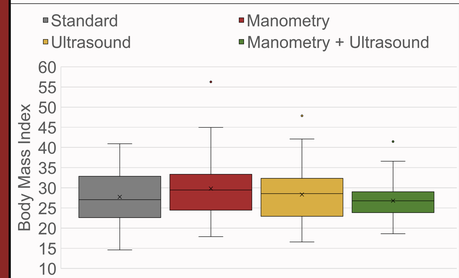

Figure 3: Participant Body Mass Index by group, "X" indicates average.

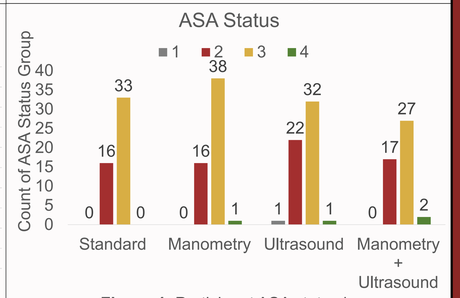

Figure 4: Participant ASA status by group.

Objective Outcomes

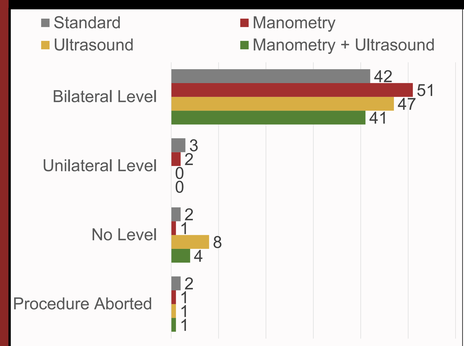

Figure 5: Count of TE placement leading to diminished sensation by group.

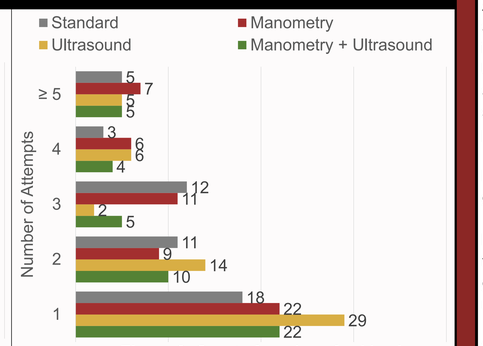

Figure 6: Count of number of epidural placement attempts by group.

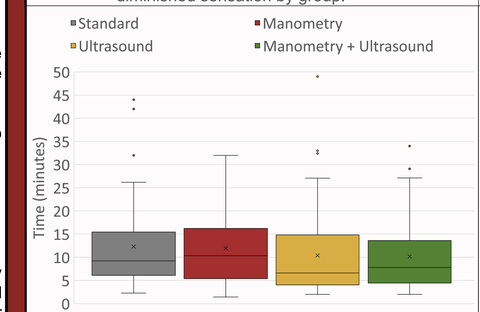

Figure 7: Total procedure time in minutes by group, "X" indicates average.

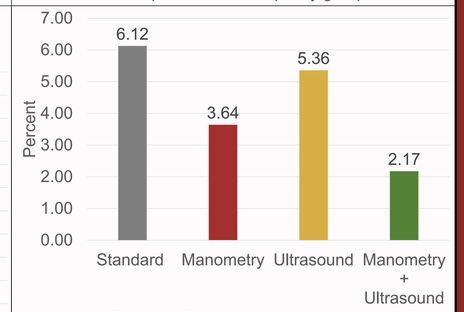

Figure 8: Prevalence of adverse events by group.

RESULTS

Data acquisition and input was completed for 220 of 480 subjects. Exclusions were applied to 12 subjects. Final subject sample size was 206 and 49, 55, 56, and 46 subjects were in groups Standard, Manometry, Ultrasound, and Manometry + Ultrasound, respectively. Data was assessed utilizing non-parametric tests as normalcy was not achieved. All data were assessed with an alpha value of p< .05.

Demographic data for sex (Figure 1) and ASA status (Figure 4) was evaluated with Chi-square test. Comparing the total number of male and female participants per group, we found X^2 (3, N =206) =2.6, p= .39. Chi-square test for the categorical variable of ASA status was minimally skewed by the absences of subjects in some groups for ASA status 1 and 4. To perform this analysis, counts of 0 were converted to a count of 1. Results were X^2 (9, N =206) =2.78, p= .97. Kruskal-Wallis test for age (Figure 2) found an H statistic of 0.35 (3, N= 206), p= 0.95 and for BMI (Figure 3) found an H statistic of 4.3 (3, N= 206), p= 0.23. There were no significant differences found in sex, age, BMI, or ASA status between groups.

To evaluate primary endpoint of a successful TE placement (Figure 5), dermatome values reported with an upper and lower range on each side of the body were converted into discrete categories relating to level of diminished sensation achieved: “Bilateral Level”, “Unilateral Level”, “No Level”, or “Procedure Aborted”. Chi-square test of categorical variables was utilized for analysis. The test was minimally skewed by the absences of subjects in “Unilateral Level” for two groups. To perform this analysis, counts of 0 were converted to a count of 1. Results were X^2 (9, N= 206) = 9.57, p= .39. No statistical difference among groups was found in possible outcomes. Additionally, no statistical differences were found in total number of attempts to place epidural (Figure 6) (X^2 (12, N= 206) = 13.45, p= .34), total procedure time (Figure 7) (H statistic of 5.8 (3, N= 206), p= 0.12), or occurrence of adverse events (Figure 8) (X^2 (3, N= 206) = 1.09, p= .79).

DISSCUSSION

The results reported here should be considered with caution. Over half of the subject data remains to be input for analysis. Initial calculations determined that 110 subjects per group are required to have an 80% chance of detecting a significance at the 5% level of an increase in success rate: assumption of 76% success in the control group (Standard) to 90% in an intervention group. Control group success rate was estimated based on a 24% failure rate found in the literature. The current data set results in only 41-51% of the participation in each group predicted to produce 80% power and thus, the resulting analysis is low powered. We cannot assume validity in our analysis that there is no difference in epidural placement success rates, number of attempts, total procedure time, or adverse event rates between groups.

A few interesting trends were observed. First, adverse event rates were lower in all interventional groups and the lowest in the Manometry + Ultrasound group (2.17%) supporting utility of the combined technique in risk reduction. Secondly, single attempt rates were highest in the Ultrasound (51%) and Manometry + Ultrasound (48%) groups and lowest in the Standard (37%) control. This may be due to the US preview allowing the identification of a superior access points. Lastly, the interquartile range for procedure time was smallest in the Manometry + Ultrasound group potentially indicating the combined technique leads to more procedural efficiency. Analysis of the full data set will determine if these trends become significant.

In the analyzed data set, no significant differences were found within sex, age, BMI, or ASA status between groups. Demographics were well matched and unlikely to contribute to group differences in outcomes.

Full TE success rates, defined as a bilateral level of decreased sensation in 2 or more dermatomes from the TE placement, were between 85-93% throughout all groups. This means that failure rates were no greater than 15% within any group. If this finding maintains in the full dataset, the study risks staying underpowered.

Currently, it is unclear as to whether the addition of ultrasound preview, manometry confirmation or both techniques combined provide a benefit in TE placement success over standard landmark-based techniques.

ACKNOWLEDGEMENTS

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REFERENCES

1. Chin, K.J., et al., Ultrasound imaging facilitates spinal anesthesia in adults with difficult surface anatomic landmarks. Anesthesiology, 2011. 115(1): p. 94-101.
2. Vallejo, M.C., et al., Ultrasound decreases the failed labor epidural rate in resident trainees. Int J Obstet Anesth, 2010. 19(4): p. 373-8.
3. Grau, T., et al., Ultrasound imaging improves learning curves in obstetric epidural anesthesia: a preliminary study. Can J Anaesth, 2003. 50(10): p. 1047-50.
4. Narouze, Samer MD, PhD*; Benzon, Honorio T. MD†; Provenzano, David A. MD‡; Buvanendran, Asokumar MD§; De Andres, José MD, PhD||; Deer, Timothy R. MD#; Rauck, Richard MD**; Huntoon, Marc A. MD††. Interventional Spine and Pain Procedures in Subjects on Antiplatelet and Anticoagulant Medications: Guidelines From the American Society of Regional Anesthesia and Pain Medicine, the European Society of Regional Anaesthesia and Pain Therapy, the American Academy of Pain Medicine, the International Neuromodulation Society, the North American Neuromodulation Society, and the World Institute of Pain. Regional Anesthesia & Pain Medicine.May/June 2015 - Volume 40 - Issue 3 - p 182–212
5. De Q.H. Tran, MD, FRCPC, Tom C.R.V. Van Zundert, MD, PhD, EDRA, Julian Aliste, MD, Phatthanaphol Engsusophon, MD, and Roderick J. Finlayson, MD, FRCPC. Primary Failure of Thoracic Epidural Analgesia in Training Centers The Invisible Elephant? Reg Anesth Pain Med 2016;41: 309–313.
6. Mustafa K, Miliken R. A simple device for the identification of the epidural space. Anesthesiology. 1982; 57: 330-332
7. Cohen S, Amar D, Nagashima H: Extradural block in obstetric patients: review of experience with gravity administration. Anaesthesiol Scand 1998;35: 676-9