Paravertebral analgesia in transapical transcatheter aortic valve replacement

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INTRODUCTION

Transapical transcatheter aortic valve replacement (TA-TAVR) through mini-thoracotomy is an alternative approach to aortic valve replacement that has been used successfully in patients with symptomatic severe aortic stenosis. Patients who qualify for TA-TAVR are considered to be high-risk or inappropriate candidates for traditional aortic valve replacement surgery, frequently possessing poor peripheral arterial access excluding them from trans-femoral TAVR. In Europe, TA-TAVRs comprise about 16% of TAVR cases (1). Importantly, TA-TAVR patients have had higher rates of morbidity and mortality than TF-TAVR patients.
The reason for this observation may be related to both the characteristics of the cohort selected for TA-TAVR as well as the procedure itself (2, 3). Importantly, the rate of chronic obstructive pulmonary disease in TA-TAVR patients ranges between 20-40% (2, 4, 5). Poor respiratory function has been shown to be a predictor of mortality in TA-TAVR patients (6). A recent single institution review found that much of the additional morbidity in TA-TAVR cases may be related to pulmonary complications such as post-operative pneumonia, and that epidural analgesia was associated with a decrease in both morbidity and mortality (7). However, epidural anesthesia in patients with severe aortic stenosis can result in problematic vasodilation and is not recommended in patients on clopidogrel therapy. Accordingly, single injection or “single shot” paravertebral analgesia has been safely used since the initiation of the TA-TAVR program at Maine Medical Center (8).

In this study it was hypothesized that paravertebral blockade in this population would be associated primarily with decreased opioid requirements and more frequent extubation in the operating room. Secondarily it was hypothesized that paravertebral blockade would be associated with a decrease in new onset atrial fibrillation rates, shorter intensive care unit (ICU) stay, and a decrease in 30 day mortality.

METHODS

After institutional review board approval, demographic, procedural and post-procedural outcome data was retrospectively obtained via electronic chart review on 61 patients who underwent TA-TAVR. Patients scheduled for TA-TAVR were evaluated and consented for left sided thoracic paravertebral blockade. Of the 61 total patients, 48 received a left sided single shot paravertebral blockade. All patients received general anesthesia with endotracheal intubation for their TA-TAVR procedure.

All nerve blockades were performed in a designated room outside of the operating suite, prior to placement of invasive monitors. Sedation with midazolam and fentanyl was administered as needed for each blockade. 13 patients receiving a TA-TAVR did not receive a paravertebral block either because they had their surgery prior to the initiation of the block protocol, or because they had a contraindication to paravertebral blockade according to the American Society of Regional Anesthesia guidelines related to anti-coagulation. One patient had the blockade aborted as a result of a small subcutaneous hematoma produced with the initial infiltration of local anesthetic. Anesthesiologists primarily employed a landmark technique to access the paravertebral space rather than an ultrasound guided technique. Patients received a single, two or three level left sided thoracic paravertebral blockade. The number of blockade levels was chosen at the discretion of the attending anesthesiologist. Additional levels were added to ensure block success if a patient was found to have poor anatomic landmarks or the block was considered technically difficult.

Patients were placed in a sitting position, with arms rested on a pillow, head and neck flexed, and shoulders relaxed with standard ASA (American Society of Anesthesiologists) non-invasive monitors applied. The superior aspects of the spinous processes were marked at T3-T5 levels. Entry sites were marked 2.5 cm lateral to the spinous process marks on the left side. Skin was prepared with a 2% chlorhexidine gluconate solution and aseptic technique was maintained throughout the procedure. Lidocaine (1%) was used to anesthetize the skin over the entry sites. A 20-gauge Tuohy needle was attached to extension tubing and a syringe filled with local anesthetic mixture.
The Tuohy needle was then inserted perpendicular to the skin until it came in contact with the transverse process. Then the needle was redirected caudad or cephalad and advanced until a loss of resistance was detected. The needle was aspirated, if no blood, air, or spinal fluid was encountered then 0.2% ropivacaine with clonidine was injected at each level. Single level blockades were performed using a total of 20ml 0.2% ropivacaine with 100mcg clonidine. Two level and three level blockades were performed using a total of 30ml 0.2% ropivacaine with 100mcg clonidine divided equally between levels. Blockade success was generally confirmed with dermatomal ice or pinprick testing.

Intra-operatively, all patients received general anesthesia with endotracheal intubation. Radial arterial lines were placed prior to induction of general anesthesia. Pulmonary arterial catheters were also placed for hemodynamic monitoring following induction. Transesophageal echocardiography (TEE) was performed by Cardiology.

With regard to peri-operative anticoagulation management the following practice was employed. Pre-operatively, patients’ anticoagulation regimens varied based on their pre-existing comorbidities, however warfarin was generally withheld 5 days prior to surgery and patients were bridged on IV heparin infusions until midnight the night before surgery. Clopidogrel was withheld 5 days prior to surgery. Aspirin was continued throughout the perioperative period. Intraoperatively unfractionated heparin was bolused targeting an activated clotting time greater than 250s. Clopidogrel was started on postoperative day zero. Postoperatively, clopidogrel was continued for at least 6 months, and aspirin was continued indefinitely.

Patient medical records were reviewed to collect preoperative demographic and comorbidity data in addition to the following information: 1) peri-operative fentanyl dose administered by the anesthesiologist, 2) timing of extubation, 3) new onset atrial fibrillation, 4) length of ICU stay and 5) 30-day mortality rate. Analyzing the incidence of new onset post-operative atrial fibrillation in our patient population, 16 patients who received a paravertebral blockade and 5 patients who did not had pre-existing atrial fibrillation and therefore were excluded from analysis.

**Statistical analysis.** Due to the small sample size in this study, group comparisons were performed using Fisher’s exact test for categorical variables e.g. extubation in the operating room vs. extubation in the ICU. Continuous variables including fentanyl dosage and time spent in the ICU were compared between groups using an unpaired T-test. Variables exhibiting a p-value < 0.05 were considered statistically significant. As previously mentioned, in the analysis of the incidence of new onset atrial fibrillation, 16 of 48 patients in the paravertebral group and 5 of 13 patients in the non-paravertebral group were excluded due to pre-existing atrial fibrillation.

**RESULTS**

A total of 61 TA-TAVR cases were analyzed (Table 1). Thirteen patients did not receive a paravertebral blockade. The mean age of all study participants was over 80 years old. Of the patients receiving a paravertebral blockade, no adverse outcomes occurred related to block placement. The mean perioperative opioid administration was slightly less in patients receiving a paravertebral blockade. Patients with paravertebral blockades also appeared to be extubated more frequently in the operating room. The incidence of new onset post-operative atrial fibrillation was significantly less in patients who received a paravertebral blockade. Of patients receiving a paravertebral block-
ade for their TA-TAVR, 40 of 48 (83.3%) were successfully extubated in the operating room. This is in contrast to the patients who did not receive a paravertebral blockade in which 6 of 13 (46.2%) were successfully extubated in the operating room. There was a non-statistically significant trend towards decrease length of ICU stay among those TA-TAVR patients with paravertebral analgesia (58.3 hrs vs 75.8 hrs, p value 0.35). There were no deaths in the 30-day post-operative period in either group (Table 2).

**DISCUSSION**

To the authors’ knowledge, this is the first published case series of the use of paravertebral blocks in TA-TAVR patients. This preliminary experience suggests that paravertebral analgesia may have a valuable role in caring for TA-TAVR patients. Importantly, this analysis demonstrates both the safety and practicality of using paravertebral blockades in this patient population. There were no complications in 48 patients related to paravertebral blockades and importantly, these blockades were performed in a time efficient manner in a busy clinical practice. Additionally, this analysis supports that paravertebral blockades are associated with a slightly lower intra-operative opioid administration and a higher rate of extubation in the operating room. With regard to post-operative outcomes, a lower frequency of new onset atrial fibrillation was observed in patients who received paravertebral analgesia as well. While there

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<th>Table 1 - Patient Demographics.</th>
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CI = Confidence Interval; LV = Left Ventricle; PVB = Paravertebral Block; SE = Standard Error; SD = Standard Deviation; NYHA = New York Heart Association.

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<th>Table 2 - Outcomes in Patients With or Without Paravertebral Blocks</th>
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<td><strong>PVB n = 48</strong></td>
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<td>Incidence of New Post-Op A-fib*</td>
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<td>Mean Fentanyl Dose (mcg)</td>
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PVB = Paravertebral Block; OR = Operating Room.  
*16 of 48 patients with PVB and 5 of 13 patients without PVB excluded due to pre-existing atrial fibrillation.
was a trend towards a decreased length of stay in the intensive care unit, this was not statistically significant. There were no mortalities within 30 days in either group. Thoracic surgery in general is associated with a decline in post-operative pulmonary function as a result of pain, diaphragmatic dysfunction, impaired chest wall compliance and atelectasis. This effect is likely more pronounced in elderly patients and those patients with pre-existing pulmonary disease. In the TAVR population, reduced pulmonary function is an important factor in predicting poor outcomes (5-10).

Pain is a powerful stimulator of catecholamine release which may contribute to cardiac irritability, postoperative agitation, and pulmonary complications (11, 12). Transapical access in TAVR is a risk factor for new onset atrial fibrillation, which occurs in about one-third of patients undergoing TAVR (13). The use of epidurals in both thoracic and cardiac surgery has been associated with improved post-operative pulmonary function and cardiovascular outcomes including atrial fibrillation (7, 9, 14-18). It is therefore not surprising that the use of epidurals in patients undergoing TA-TAVRS has been associated with a decrease respiratory complications, new onset atrial fibrillation and mortality (7, 19, 20).

Paravertebral nerve blockades have been documented to be at least as effective as epidural anesthesia, and superior to parenteral opioids in relieving post-thoracotomy pain (9, 21-24). Unlike epidural anesthesia, which impacts the sympathetic chain bilaterally, paravertebral blocks generally produce a unilateral sympathectomy. This theoretically reduces the risk of hypotension associated with block use and is substantiated by studies that have demonstrated lower fluid and vasopressor requirements with the use of paravertebral catheters when compared to epidurals (22, 25, 26). Significant concerns also exist about the use of epidural analgesia in the setting of systemic anticoagulation and the use of anti-platelet agents (27, 28). Single shot paravertebral blockade with long acting local agents largely circumvents these concerns. This initial small retrospective review has unavoidable limitations. The control group size is small in comparison to the intervention group. This small control group of patients who did not receive paravertebral blockades may be too small to be representative, and lack of randomization clearly limits the wider clinical applicability of our observations. This pilot study also does not include post-operative pain scores or post-operative opiate administration. Visual analogue scales for pain assessment were recorded by nursing staff at variable time points, were frequently confounded by the use of sedation on intubated patients and by pain at unrelated non-operative sites such as lower back pain. A formal analysis of the post-operative visual analogue scale was therefore not possible. Similarly, variable time to extubation prevented analysis of post-operative opiate administration. We acknowledge that the rate of atrial fibrillation in our control group is above published levels in recent literature (12). The number of blockade levels varied between 1 and 3 and the volume of local given also varied which would quality of the blockade. Finally, plasma clonidine levels following epidural administration have been shown to approximate plasma levels after intravenous administration (29). Systemic absorption of clonidine may contribute to hypotension, and could influence the post-operative course of cardiac surgery patients and may have confounded our observations (29-31). Finally, the goal for every patient in this cohort was an on-table extubation in the setting of adequate oxygenation, ventilation, hemodynamic stability and neurologic function. Though some avoidable inter-operator subjectivity may exist
in regards to readiness for extubation, the observed statistical difference favoring intraoperative extubation would appear clinically relevant.

CONCLUSION

This is the first reported experience of paravertebral analgesia in TA-TAVR. Despite the obvious and unavoidable limitations of this retrospective review, our initial experience and patient outcomes using paravertebral blockade in TA-TAVR appears akin to published experience with epidural catheters.

The pilot outcome data from this case series suggests that addressing peri-operative sympathetic stimulation with neuraxial anesthesia may have a measurable benefit garnered beyond what is achieved with an opioid-based approach.

The lack of complications at a minimum demonstrates the technique can be done safely in this high-risk patient cohort. These preliminary observations should be confirmed using a more formal prospective, randomized, potentially multi-institutional investigation.

REFERENCES

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Paravertebral block for TA-TAVR


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