A Prospective Randomized Study of Paravertebral Blockade in Patients Undergoing Robotic Mitral Valve Repair

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<u>Objective</u>: The aim of this study was to evaluate the addition of paravertebral blockade to general anesthesia in patients undergoing robotic mitral valve repair.

Design: A randomized, prospective trial.

<u>Setting</u>: A single tertiary referral academic medical center. <u>Participants</u>: 60 patients undergoing robotic mitral valve surgery.

<u>Interventions</u>: Patients were randomized to receive 4-level paravertebral blockade with 0.5% bupivicaine before induction of general anesthesia. All patients were given a fentanyl patient-controlled analgesia upon arrival to the intensive care unit, and visual analog scale pain scores were queried for 24 hours. On postoperative day 2, patients were given an anesthesia satisfaction survey.

<u>Measurements and Main Results</u>: After obtaining institutional review board approval, surgical and anesthetic data were recorded perioperatively and compared between groups. Compared to general anesthesia alone, patients receiving paravertebral blockade and general anesthesia reported significantly less postoperative pain and required

PARAVERTEBRAL BLOCKADE (PVB) HAS BECOME an increasingly popular alternative to thoracic epidural as an adjuvant to general anesthesia (GA).¹⁻⁵ It is easy to learn, associated with less risk of failed block.^{6,7} and has been shown to offer equally efficacious postoperative pain relief in thoracic⁸⁻¹⁴ and cardiac surgery.^{15,16} PVB can be performed routinely in under 10 minutes.¹⁷ It is associated with less dural puncture,³ improved postoperative pulmonary function,¹⁸ and less risk of spinal cord injury from epidural hematoma compared with neuraxial techniques, which have limited the use of the latter in cardiac procedures involving full heparinization.¹⁹ Single-dose injection has been shown to be effective for as much as 23 hours.²⁰ PVB has been integrated into anesthetic protocol for minimally invasive cardiac surgery.²¹ A retrospective review of its use in robotic mitral valve repair has shown an association with immediate extubation in the operating room, good postoperative analgesia and decreased intensive care unit (ICU) and hospital lengths of stay (LOS) with no adverse events.²² A prospective study of cardiac patients is warranted.

The purpose of this study was to determine whether the addition of PVB to GA reduced postoperative pain as well as both intraoperative and postoperative narcotic requirements in patients undergoing minimally invasive cardiac surgery. With

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fewer narcotics intraoperatively and postoperatively. Patients receiving paravertebral blockade also reported significantly higher satisfaction with anesthesia. Successful extubation in the operating room at the conclusion of surgery was 90% and similar in both groups. Hospital length of stay also was similar. No adverse reactions were reported.

<u>Conclusions</u>: The addition of paravertebral blockade to general anesthesia appears safe and can reduce postoperative pain and narcotic usage in patients undergoing minimally invasive cardiac surgery. These findings were similar to previous studies of patients undergoing thoracic procedures. Paravertebral blockade alone likely does not reduce hospital length of stay. This may be more closely related to early extubation, which is possible with or without paravertebral blockade.

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an increased focus on early extubation, rapid recovery and patient satisfaction, the authors also were interested in determining the role of PVB in immediate extubation, LOS, and overall patient satisfaction.

METHODS

After obtaining institutional review board approval, eligible patients undergoing totally endoscopic robotic mitral valve repair at a single institution between January 29, 2013 and February 11, 2014 were randomized to receive PVB and GA (referred to as PVB group) or GA alone (referred to as GA group) using a random number generator. The authors estimated that for a type-1 error risk of 0.05, they would need 50 patients to complete the entire study protocol to achieve adequate power, although the exact number of enrolled patients to reach this number was unknown. Based on retrospective review of the authors' institutional experience, they estimated that 80% of enrolled patients in the PVB group and 65% in the GA group would complete the entire study protocol.

Patients with at least moderately severe (3+) mitral regurgitation or symptomatic moderate (2+) regurgitation were offered surgery in accordance with the American College of Cardiology and American Heart Association guidelines. When indicated, patients also underwent hybrid procedures involving postoperative coronary stenting or other concurrent procedures including patent foramen ovale closure, atrial septal defect closure, or atrial myxoma excision. Surgical exclusion criteria included severe pectus deformities, severe mitral annular calcification or severe aortic atherosclerotic disease, which would prevent safe peripheral arterial cannulation and retrograde perfusion. Patients were excluded from either arm of this study if they refused consent or had absolute contraindications to PVB such as infection at the injection site.^{3,23} Patients with known coagulopathy or those unable to stop their prescribed

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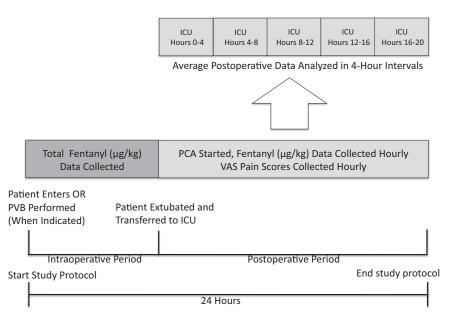


Fig 1. Timeline of study protocol, beginning upon entering the operating room and ending after 24 hours. Intensive care unit time divided into four-hour intervals for data analysis. PVB, paravertebral blockade; ICU, intensive care unit; OR, operating room; PCA, Patient-controlled analgesia; VAS, visual analog scale.

anticoagulation before surgery in accordance with the American Society of Regional Anesthesia and Pain Medicine guidelines also were excluded.²⁴

The study protocol began upon entering the operating room (Fig 1). The surgical and ICU teams were blinded to the type of anesthesia, but the patient and the anesthesiologist were not. The same anesthesiologist who performed the PVB when applicable also provided general anesthesia for the case. PVB was performed using aseptic technique in the operating room in the sitting position prior to induction of anesthesia. Patients were given 4 right-sided injections from T3-T6 using a blind technique.¹ Each transverse process was identified using landmarks and a 22-gauge 10-cm Chiba spinal needle (Havel's Incorporated, Cincinnati, OH) was inserted 2 cm lateral to the spinous process in a purely anterior direction to minimize the risk of neuraxial trauma. A total of 30 mL of 0.5% bupivicaine without epinephrine was injected over 4 levels, up to a maximum of 3 mg/kg. GA then was induced using midazolam, fentanyl, vecuronium, and etomidate. Sevoflurane, fentanyl, and vecuronium were used for maintenance and titrated using Bispectral Index monitoring (Covidien, Mansfield, MA) to a value between 40 and 60. Lung isolation was achieved by placement of a leftsided double-lumen endotracheal tube. Patients were monitored with transesophageal echocardiography (TEE), bilateral radial arterial catheters and a central venous catheter via the right internal jugular vein. A second introducer was placed in the right internal jugular vein through which a coronary sinus catheter was placed under TEE guidance.

A full description of the surgical technique at the authors' institution has been published in detail.²⁵ A totally endoscopic approach was achieved by placement of ports into the right chest in between the fourth and sixth intercostal space. The endoscope was placed in the fourth midclavicular intercostal space via a 12-mm access soft port. Two 7-mm instrument

ports were placed above and below the access port and an atrial retractor was positioned in the 4th or 5th intercostal space at the sternal border. Cardiopulmonary bypass was achieved by placement of a long femoral venous cannula and a femoral arterial cannula via cutdown. Aortic cross-clamping was accomplished by an endoballoon clamp. Positioning was confirmed under TEE guidance and without the use of fluoroscopy. At the completion of the procedure, the femoral cannulation and chest incision sites were infiltrated with 10 mL of 0.25% bupivicaine in both groups. Patients underwent a trial of pressure-support ventilation during closure and were extubated when standard extubation criteria were met after neuromuscular reversal. Time from incision closure to extubation was limited to 10 minutes. Patients recovered in the ICU and started on fentanyl patient-controlled analgesia (PCA) once extubated, with settings of 10 µg demand dosing, a 10-minute lockout interval, and a clinician rescue dose of 25 µg and without a basal infusion. Pain assessment was completed by the ICU nurses every hour per protocol using the visual analog scale (VAS) pain score ranging from 0 (no pain) to 10 (worst possible pain). The study protocol ended 24 hours after patient arrival to the operating room. On postoperative day 2, patients were asked whether or not they were satisfied with their postoperative pain control and to score their overall satisfaction from 0 (least satisfied) to 10 (most satisfied).

Statistical analyses were performed using the Statistical Package for the Social Sciences 20 (IBM Corp, Armonk, NY). The primary outcomes measured in this study were the post-operative requirement for fentanyl (expressed in µg fentanyl per kg body weight) and the postoperative VAS pain scores, which were both recorded hourly. These values were averaged over 4-hour intervals starting upon arrival to the recovery room and analyzed using repeated measures ANOVA. The 2 groups also were compared at each 4-hour interval using rank analysis for

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