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Analgesic Effect of Iliohypogastric/Ilioinguinal Nerve Block in Transcatheter Aortic Valve Replacement Transfemoral (TAVR-TF): A Randomized Clinical Trial

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ABSTRACT

Background: An increasingly common minimally invasive treatment for aortic valve dysfunction is transcatheter aortic valve replacement. Our study aimed to compare the efficacy and safety of ilioinguinal/iliohypogastric (IH/II) nerve block and local infiltration intraoperatively. Sufficient pain control is essential for improving recovery and lowering complications following transcatheter aortic valve replacement (TAVR) in such a frail group of patients.
Methods: In this prospective, double-blinded, randomized controlled study, 60 patients scheduled for TAVR were divided into two groups. Group A received blind local infiltration with 20 ml of lidocaine 1%, while Group B received a US-guided IH/II nerve block with 20 ml of bupivacaine 25%. The primary outcome, intraoperative pain scores, was assessed using the Numerical Rating Scale (NRS) at predefined procedural time points. Hemodynamics, oxygen saturation, level of consciousness, and required analgesia were recorded at 5 time points as secondary outcomes.
Results: The block group experienced significantly lower NRS levels than the Local Group during puncture (1.1±0.8 vs. 3.1±0.8, $p < 0.001$), balloon insufflation (0.6±0.8 vs. 2.8±0.7, $p<0.001$), and sheath removal (1.5±1.4 vs. 3.5±0.5, $p < 0.001$). Patients in the block group also required considerably fewer analgesics (16.3% vs. 53.3%, $p = 0.003$). MAP and heart rate decreased considerably ($p < 0.05$) in the Block Group during sheath removal, balloon insufflation, and piercing. SpO_2 values were significantly higher in the Block Group during puncture and balloon insufflation ($p < 0.01$).
Conclusion: An IH/II nerve block offered superior analgesia and hemodynamic stability in TAVR-TF patients compared to local infiltration, resulting in considerably lower pain scores and analgesic use. This method provides better pain control for TAVR operations.

Introduction

Transcatheter aortic valve replacement (TAVR) has become a well-established and increasingly popular treatment option for patients with severe aortic stenosis who are deemed high-risk or unsuitable for surgical aortic valve replacement. Continuous developments in valve technology, delivery systems, and procedural approaches have led to better outcomes, fewer complications, and shorter hospital stays [1-3].

When TAVR programs first started, most facilities followed GA approaches. The main benefit of GA is that a transesophageal echocardiography (TOE) probe can be left in place throughout the entire procedure, which helps to reduce the amount of dye used during radiological

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imaging, position the prosthesis, assess residual aortic regurgitation, and enable early diagnosis of problems [4-5].

Furthermore, GA eliminates the patient's anxiety, discomfort, and mobility issues throughout the operation. However, general anesthesia is associated with inherent risks, including hemodynamic instability and the need for ventilation and intubation. Consequently, monitored anesthesia care (MAC) has emerged as a popular alternative, offering potential benefits in selected patients [6].

While conscious sedation speeds up recovery, it requires good locoregional analgesia to manage pain from crucial procedural steps such as femoral artery puncture, balloon valvuloplasty, and sheath manipulation [7]. Inadequate analgesia can cause patient discomfort, involuntary movement, and sympathetic activation, resulting in hemodynamic instability, which may affect procedural safety and success. The reduced sympathetic response during balloon insufflation may also be influenced by valve type and deployment characteristics, which vary between balloon-expandable and self-expandable systems [8]. Thus, continuous communication between the cardiologist, the anesthesiologist & the vascular surgeon is important for optimizing perioperative care in TAVR patients [9].

But the improvement of CT sizing preoperatively and the advances in 3D transthoracic echo (TTE) decrease the need for TOE [1]. The current standard for local analgesia in transfemoral TAVR (TF-TAVR) is subcutaneous local anesthetic infiltration at the vascular access site. However, ultrasound-guided ilioinguinal/iliohypogastric (IH/II) nerve block has emerged as a promising regional approach for more extensive inguinal somatic blockade [7]. A few earlier randomized experiments by Hasak et al. and Rashed et al. found that the IH/II block could reduce pain and narcotic usage when compared to local infiltration [7,10].

Therefore, this prospective, randomized, double-blind controlled trial aims to assess the analgesic efficacy and hemodynamic impact of ultrasound-guided IH/II nerve block vs. typical local anesthetic infiltration in patients undergoing TF-TAVR under dexmedetomidine-based sedation. We expected that the nerve block would give better pain relief, reduce the need for rescue analgesics, and improve hemodynamic stability throughout the surgery.

Methods

Study design and setting

This prospective, randomized, double-blind, controlled trial was conducted at the Cardiothoracic Academy, Ain Shams University Hospitals, from November 2023 to September 2024. The study protocol was approved by the Institutional Research Ethics Committee of the Faculty of Medicine (include approval number if available) and prospectively registered at ClinicalTrials.gov (NCT06362915). Written informed consent was obtained from all participants.

Study population

Patients scheduled for elective transfemoral TAVR (TF-TAVR) with sedation were evaluated for eligibility. Inclusion criteria were age >18 years; severe aortic stenosis deemed suitable for TF-TAVR by the institutional Heart Team; and American Society of Anesthesiologists (ASA) physical status II-IV. Exclusion criteria included patient refusal, known allergy to local anesthetics, coagulopathy (INR >1.5 or platelet count <50,000/μL), local skin infection at the puncture/block site, chronic opioid or analgesic use (defined as regular use for >3 months), and severe cognitive impairment.

Randomization and blinding

Using G*Power software (version 3.1) with an α error of 5% and power of 80% and based on a large effect size (dz = 0.8) from prior data (Hasak et al., 2019), a sample size of 60 patients (30 per group) was calculated. Patients were randomly allocated in a 1:1 ratio to either the local infiltration group (Group A) or the nerve block group (Group B) using computer-generated random numbers. The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes opened by a non-involved anesthesiologist just prior to the procedure. All patients, attending cardiologists, procedural staff, and outcome assessors (collecting pain scores and hemodynamic data) were blinded to group assignment. The anesthesiologist performing the analgesic technique (infiltration or block) was not involved in subsequent patient assessment or data collection.

Intervention

All patients received standard monitoring (electrocardiogram, pulse oximetry, and noninvasive blood pressure) on arrival to the catheter lab. Invasive arterial pressure monitoring via the left radial artery and central venous access were established under local anesthesia and ultrasound guidance prior to the main intervention.

Sedation protocol

For both groups, procedural sedation was initiated and maintained with a dexmedetomidine intravenous infusion, starting at 0.1 μg/kg/h and titrated to a target rate of 0.3–0.5 μg/kg/h to achieve a Richmond Agitation-Sedation Scale (RASS) score between -1 (drowsy) and 0 (alert and calm) under continuous monitoring for the heart rate and blood pressure. No loading dose was administered [11]. Then the patients were divided into two groups: 1) Group A (Local Infiltration): Prior to femoral artery puncture, the operating anesthesiologist performed a blind subcutaneous infiltration at the planned vascular access site using 20 mL of 1% lidocaine. 2) Group B (Nerve Block): Prior to femoral artery puncture, the operating anesthesiologist performed an ultrasound-guided IH/II nerve block on the procedural side. Using a linear high-frequency ultrasound probe, the nerves were identified in the plane between the internal oblique and transversus abdominis muscles.

Under aseptic conditions, 20 mL of 0.25% bupivacaine was injected with real-time visualization to ensure adequate spread.

Outcomes

Primary outcome: Intraoperative pain intensity was measured using the 11-point Numerical Rating Scale (NRS; 0=no pain, 10=worst imaginable pain) [12] at three crucial procedural timepoints: 1) femoral artery puncture, 2) balloon valvuloplasty/insufflation, and 3) sheath removal/vascular access closure.

Secondary outcomes: 1) Hemodynamic parameters (Heart Rate [HR] and Mean Arterial Pressure [MAP]) recorded at baseline, 5 minutes after sedation induction, and at the three procedural time points mentioned above 2) Oxygen saturation (SpO_2); 3) Level of consciousness assessed by the Glasgow Coma Scale (GCS); 4) Need for rescue analgesia (defined as an NRS score of ≥4 at any timepoint). The blinded attending anesthesiologist chose between intravenous fentanyl (0.5-1 µg/kg bolus) and propofol (0.5 mg/kg bolus) for rescue analgesia. The total number of rescue dosages was recorded.

Data collection and statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 28.0 (IBM Corp., Chicago, IL, USA). Data were coded, tabulated, and analyzed accordingly. Quantitative variables were tested for normality using the Shapiro–Wilk test and were expressed as mean ± standard deviation (SD). Comparisons between the two groups were performed using the independent samples t-test.

Qualitative variables were presented as numbers and percentages and compared using the chi-square test or Fisher's exact test, as appropriate. A P value < 0.05 was considered statistically significant.

Results

A total of 72 patients were assessed for eligibility. Twelve patients were excluded due to not meeting the inclusion criteria (n=9) and declining to participate (n=3). The remaining 60 patients were randomly allocated into two equal groups: 30 patients were assigned to the block group and 30 patients to the local infiltration group. All randomized participants received the allocated interventions and were included in the final analysis, with no losses to follow-up (Figure 1).

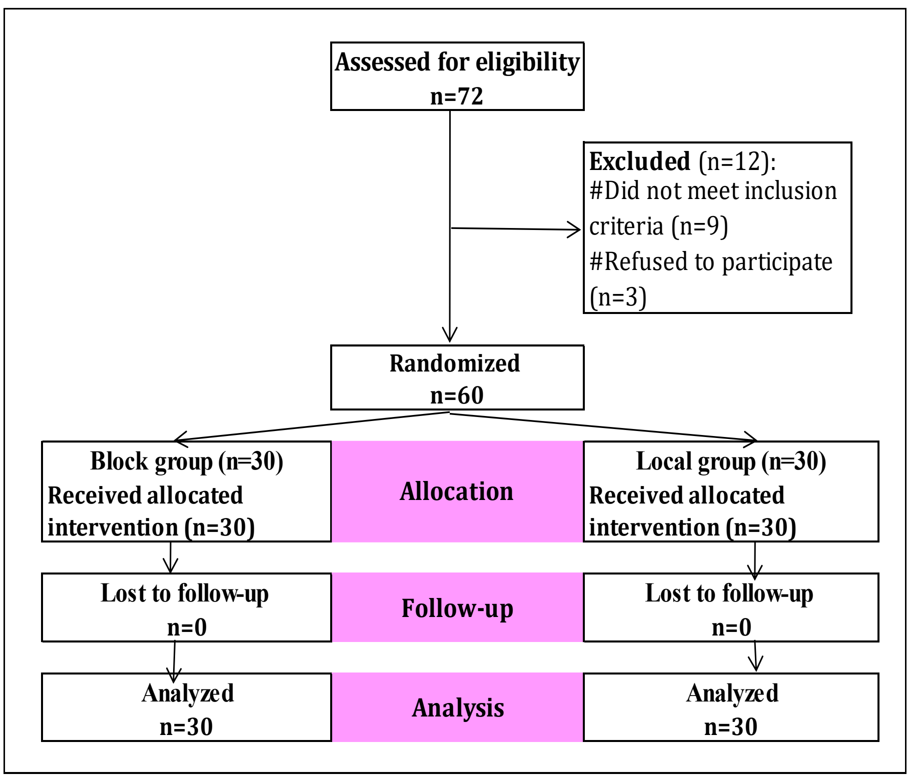

Figure 1- The CONSORT flow diagram of the studied cases.

The baseline demographic and procedural features were similar between the two study groups. There were no statistically significant variations in age, gender distribution, BMI, ASA physical status, or operation time (Table 1).

Pain intensity, according to the Numerical Rating Scale (NRS), was significantly lower in the nerve block group at all predetermined procedural time points. During femoral artery puncture, balloon insufflation, and sheath removal with skin closure, NRS values were considerably lower in the nerve block group compared to the local infiltration group ($p < 0.001$) (Table 2).

There were significantly fewer patients in the nerve block group who required rescue analgesia than in the local infiltration group (16.3% vs. 53.3%, $p = 0.003$). In addition, the nerve block group received significantly fewer analgesic dosages ($p < 0.001$). These findings show that the IH/II nerve block provides superior analgesia during transfemoral TAVR procedures ((Table 2), (Figure 2)).

There were no statistically significant changes between the two groups in heart rate, mean arterial pressure, oxygen saturation, or Glasgow Coma Scale (GCS) values at baseline or during induction (5 minutes). During femoral puncture, balloon insufflation, and sheath removal with skin closure, the nerve block group had a considerably lower heart rate than the local infiltration group ($p < 0.01$).

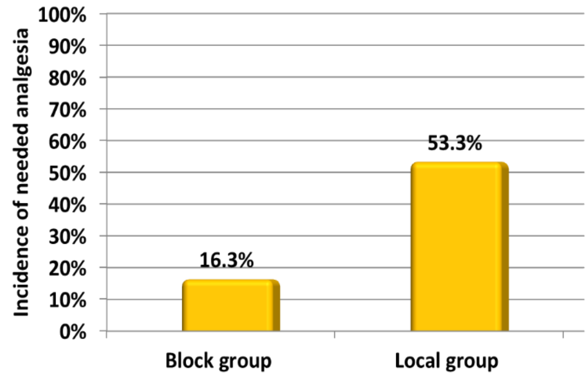

Figure 2- Comparison regarding the incidence of needed analgesia.

Similarly, the nerve block group showed a significant reduction in mean arterial pressure at the same time points ($p < 0.05$).

The nerve block group had significantly higher oxygen saturation during piercing, balloon insufflation, and sheath removal ($p < 0.01$), but there were no differences at baseline or during induction.

Regarding consciousness, GCS levels were comparable between groups at baseline and induction. However, the local infiltration group had significantly lower GCS scores during puncture, balloon insufflation, and sheath removal, indicating that deeper sedation was required versus the nerve block group (Table 3).

Table 1- Comparison regarding demographic characteristics.

Variables		Block group (total=30)	Local group (total=30)	P value
Age (years)		66.3±6.3	67.6±4.8	^0.347
Sex	Male	18 (60.0%)	16 (53.3%)	#0.602
	Female	12 (40.0%)	14 (46.7%)	
BMI (kg/m^2)		27.8±3.2	27.1±2.4	^0.324
ASA	II	14 (46.7%)	14 (46.7%)	§0.708
	III	12 (40.0%)	14 (46.7%)	
	IV	4 (13.3%)	2 (6.7%)	
Operation duration (min)		126.9±8.6	128.9±10.3	^0.416

BMI: Body mass index; ASA: American Society of Anesthesiologists; Data presented as Mean±SD or number (%); ^Independent t-test; #Chi-square test. §Fisher's exact test.

Table 2- Comparison regarding pain score (NRS) and analgesic requirements.

Events	Block group (Total=30)	Local group (Total=30)	P value	Relative effect	
				Mean±SE/ Relative risk	95% CI
Pain score (NRS)					
Puncture	0.8±1.1	3.1±0.8	^<0.001*	-2.4±0.2	-2.9–-1.9
Balloon insufflation	0.6±0.8	2.8±0.7	^<0.001*	-2.3±0.2	-2.6–-1.9
Sheath removal & skin closure	1.5±1.4	3.5±0.5	^<0.001*	-2.0±0.3	-2.6–-1.4
Analgesic requirement					
Needed analgesia	5 (16.3%) Total = 5	16 (53.3%) Total = 16	#0.003*	0.31	0.13–0.74
Number of doses	1.0±0.0	2.0±0.8	^<0.001*	-1.0±0.2	-1.4–-0.6

Data presented as Mean±SD or number (%); ^Independent t-test; #Chi-square test; *Significant; Relative effect: Effect in block group relative to that in local group; SE: standard error; CI: Confidence interval.

Table 3- Comparison regarding heart rate, mean arterial pressure, SPO_2, and GCS.

Events	Block group (Total=30)	Local group (Total=30)	^P value	Relative effect	
				Mean±SE	95% CI
Heart rate (beat/min)					
Baseline	67.9±5.8	66.4±5.8	0.317	1.5±1.5	-1.5–4.5
Induction (5 min)	68.8±5.8	66.8±5.4	0.173	2.0±1.4	-0.9–4.9
Puncture	73.4±7.1	79.4±6.6	0.001*	-5.9±1.8	-9.5–-2.4
Balloon insufflation	71.4±7.2	77.2±6.6	0.002*	-5.8±1.8	-9.4–-2.2
Sheath removal & skin closure	75.8±7.2	81.9±6.5	0.001*	-6.1±1.8	-9.6–-2.6
Mean arterial pressure (beat/min)					
Baseline	86.8±7.8	84.7±7.7	0.299	2.1±2.0	-1.9–6.1
Induction (5 min)	89.2±9.4	88.3±10.9	0.742	0.9±2.6	-4.4–6.1
Puncture	94.2±9.0	101.5±8.9	0.003*	-7.3±2.3	-11.9–-2.7
Balloon insufflation	92.8±10.6	99.5±8.1	0.008*	-6.7±2.4	-11.6–-1.8
Sheath removal & skin closure	97.9±10.2	103.2±9.0	0.035*	-5.3±2.5	-10.3–-0.4
SPO_2 (%)					
Baseline	97.8±0.8	98.0±0.9	0.542	-0.1±0.2	-0.6–0.3
Induction (5 min)	97.7±0.7	97.8±0.8	0.499	-0.1±0.2	-0.5–0.3
Puncture	97.7±0.7	96.1±2.4	0.001*	1.6±0.5	0.7–2.5
Balloon insufflation	97.8±0.8	96.5±2.3	0.004*	1.4±0.4	0.5–2.3
Sheath removal & skin closure	97.0±1.2	95.1±2.2	<0.001*	1.8±0.5	0.9–2.8
GCS					
Baseline	15.0±0.0	15.0±0.0	NA	NA	NA
Induction (5 min)	15.0±0.0	15.0±0.0	NA	NA	NA
Puncture	15.0±0.0	14.5±0.7	<0.001*	0.5±0.1	0.3–0.8
Balloon insufflation	15.0±0.0	14.6±0.8	0.012*	0.4±0.1	0.1–0.7
Sheath removal & skin closure	14.8±0.4	14.0±0.9	<0.001*	0.8±0.2	0.4–1.2

Data presented as Mean±SD; NA: Not applicable; ^Independent t-test; *Significant; Relative effect: Effect in block group relative to that in local group; SE: standard error; CI: Confidence interval.

Discussion

The results of this prospective, randomized, double-blind trial show that an ultrasound-guided IH/II nerve block provides better peri-procedural analgesia and hemodynamic stability than conventional local infiltration in patients undergoing transfemoral transcatheter aortic valve replacement (TF-TAVR) under dexmedetomidine sedation. Patients who had the nerve block had significantly lower pain scores at all important procedural stages—arterial puncture, balloon insufflation, and sheath removal—and required far less rescue analgesia. Furthermore, the nerve block group had more favorable hemodynamic profiles, including lower heart rate and mean arterial pressure during stressful stimuli, as well as greater oxygen saturation and level of consciousness. This study adds to the growing evidence supporting regional techniques in TAVR anesthesia protocols, which vary widely in clinical practice [13].

Our findings immediately verify and expand on the seminal randomized experiment by Hasak et al. (2019), who suggested the IH/II block for TAVR and showed lower pain and opiate usage compared to local infiltration [7]. The consistency of these findings across different centers adds to the regional technique's validity. Rashed et al. (2023) discovered significantly lower pain levels and analgesic needs in patients receiving an ilioinguinal block compared to local infiltration during TAVR under propofol-based sedation [10]. Our study supports these findings while also contributing by demonstrating these advantages within a dexmedetomidine-based sedation protocol—an agent preferred for its minimal respiratory depression, analgesic-sparing properties, and potential for improved hemodynamic stability in cardiac procedures [11]. This suggests that the benefits of the nerve block are consistent across different sedative techniques. The mechanism for this superior analgesia is anatomically based; the IH/II block provides a more reliable and extensive somatic blockade of the inguinal region (T12-L1 dermatomes), effectively covering the site of large-bore femoral access and manipulation, which is frequently insufficiently covered by superficial local infiltration alone [7,14].

The block group demonstrated improved hemodynamic stability, which is a clinically meaningful secondary result. The reduced sympathetic response to nociceptive stimuli—as demonstrated by lower heart rate and blood pressure during puncture and balloon inflation—is consistent with the notion that successful regional anesthesia reduces stress-induced catecholamine release [1,15]. This is especially useful in the frail, cardiologically compromised TAVR patient, where hemodynamic instability can cause myocardial ischemia or arrhythmias. Our findings during balloon insufflation suggest that effective regional analgesia may mitigate procedural stress, potentially reducing myocardial injury markers, as seen in studies omitting balloon valvuloplasty [16]. Furthermore, our finding of better-maintained oxygen saturation and GCS scores in the block group adds to the procedural safety profile of a well-conducted nerve block, implying less sedation-related respiratory depression and a more cooperative, comfortable patient—a key principle of the "awake TAVR" philosophy [17].

Several limitations to this study should be addressed. First, the study was conducted at a single high-volume tertiary facility, which may limit the findings' applicability to various practice settings. Second, while the double-blind approach is advantageous, the inherent physical distinctions between completing an ultrasound-guided block and a subcutaneous infiltration prevent the operator from being blinded; nonetheless, all outcome assessors and data analysts were. Third, our follow-up was confined to the intraoperative period; longer-term studies could measure the influence on post-operative pain, opioid use on the ward, and patient satisfaction. Finally, the block was executed by professional anesthesiologists; thus, its effectiveness in less experienced hands may vary, emphasizing the importance of good training.

Conclusion

In conclusion, this randomized study's findings support the superiority of IH/II nerve blocks over the standard local infiltration in TF-TAVR operations. This approach provides better pain control, minimizes the need for rescue analgesics, and promotes greater hemodynamic and respiratory stability. Given the growing justification for TAVR in younger, lower-risk patients where expedited recovery is critical, implementing this regional anesthetic approach should be strongly investigated to improve the safety, comfort, and efficiency of the peri-procedural pathway.

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