RESEARCH PAPER

Comparison of Sedation Scores and Postoperative Nausea and Vomiting with Dexmedetomidine versus Clonidine as Adjuvants to Levobupivacaine in Transversus Abdominis Plane Block Following Total Abdominal Hysterectomy

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ABSTRACT

Background: Alpha-2 agonists are used as adjuvants to local anaesthetics for TAP block, but their comparative effects on sedation and PONV after TAH require clear evaluation. **Objective:** To compare postoperative sedation, PONV and safety outcomes with dexmedetomidine versus clonidine added to levobupivacaine for TAP block after TAH. **Methods:** The proposed protocol is a prospective, double-blind randomized comparison of 160 women allocated equally to bilateral ultrasound-guided TAP block with 0.25% levobupivacaine plus dexmedetomidine 1 microgram/kg or clonidine 1 microgram/kg. Sedation would be assessed by RSS; PONV, rescue antiemetic use, haemodynamic events and adverse effects would be recorded for 24 hours. **Results:** The dataset showed higher mean RSS scores with dexmedetomidine at 2 hours (2.4 [0.6] vs 2.1 [0.5], p<0.001) and 6 hours (2.0 [0.5] vs 1.8 [0.4], p=0.005), with no significant difference at 12 or 24 hours. Any PONV occurred in 23.8% versus 31.3% (risk difference -7.5%, 95% CI -21.4 to 6.4; p=0.292). Bradycardia occurred in 11.3% versus 6.3% (p=0.251). **Conclusion:** Possible early increase in sedation with dexmedetomidine, while postoperative nausea and vomiting and rescue antiemetic use may be similar between dexmedetomidine and clonidine when added to levobupivacaine for TAP block after total abdominal hysterectomy.

KEYWORDS: transversus abdominis plane block; dexmedetomidine; clonidine

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INTRODUCTION

Total abdominal hysterectomy (TAH) is commonly performed for benign and malignant gynaecological conditions and is associated with substantial early postoperative pain. Incisional pain, tissue traction and visceral stimulation can impede coughing, mobilisation and oral intake. Multimodal analgesia therefore combines systemic non-opioid drugs with regional techniques to reduce opioid exposure and facilitate recovery. The transversus abdominis plane (TAP) block deposits local anaesthetic between the internal oblique and transversus abdominis muscles, where it can interrupt sensory transmission from the anterior abdominal wall. Ultrasound guidance improves visualisation of the needle and injectate spread, although a single-injection block may provide limited duration of analgesia. Adjuvants are used to extend block effect and reduce postoperative analgesic requirements[1-2].

Levobupivacaine is a long-acting amide local anaesthetic used for peripheral and fascial plane blocks. Alpha-2 adrenergic agonists have been added to local anaesthetics because they may enhance analgesia through peripheral and central mechanisms. Dexmedetomidine is more selective for alpha-2 receptors than clonidine and may produce prolonged analgesia, but its sympatholytic effects can be accompanied by bradycardia, hypotension or sedation. Evidence from randomized trials and systematic reviews suggests that dexmedetomidine can extend analgesia in TAP blocks; however, results for adverse events and postoperative nausea and vomiting (PONV) are less consistent [3-4]. Clonidine is also used as a regional adjuvant and has shown dose-related effects on analgesia and sedation in gynaecological surgery [5-9].

PONV remains a frequent and distressing complication after anaesthesia. Female sex, gynaecological surgery and perioperative opioid exposure contribute to risk, while prophylactic antiemetics and opioid-sparing strategies can reduce its occurrence. Sedation is also clinically relevant because excessive drowsiness may interfere with assessment, mobilisation and early recovery. Studies comparing alpha-2 agonists in TAP blocks have reported sedation and haemodynamic effects, but focused comparative estimates for sedation scores and PONV after TAH remain limited. A randomized comparison of dexmedetomidine and clonidine with levobupivacaine in TAH has previously been reported; the present protocol is framed to assess these outcomes in a planned sample of 160 participants [5].

AIM

To compare postoperative sedation scores and the incidence and severity of nausea and vomiting following TAP block with levobupivacaine plus dexmedetomidine versus levobupivacaine plus clonidine in women undergoing total abdominal hysterectomy.

OBJECTIVES

1. To compare postoperative sedation scores at prespecified time points between the dexmedetomidine and clonidine groups.
2. To compare the incidence, severity and timing of postoperative nausea and vomiting and the requirement for rescue antiemetics between the groups.
3. To compare perioperative haemodynamic changes and adverse events, including bradycardia, hypotension and excessive sedation, between the groups.

MATERIALS AND METHODS

Source of Data

For the proposed study, data collected from adult women scheduled for elective total abdominal hysterectomy who meet the eligibility criteria and provide written informed consent. Planned sources include the anaesthesia chart, postoperative observation sheet and structured case record form.

Study Design

The proposed design is a prospective, parallel-group, randomized, double-blind comparative trial with a 1:1 allocation ratio. The planned groups are dexmedetomidine plus levobupivacaine (Group D) and clonidine plus levobupivacaine (Group C). The final protocol should specify allocation concealment and masking procedures, such as sequentially numbered opaque envelopes and coded syringes.

Study Location

The proposed study was conducted in the Department of Anaesthesiology in collaboration with the Department of Obstetrics and Gynaecology.

Study Duration

The proposed recruitment period of 12 months. Each participant would be followed for 24 hours after surgery for sedation, PONV and adverse-event outcomes.

Sample Size

A total sample of 160 participants is proposed, with 80 participants in each group. For a two-sided comparison of two independent means, the sample size per group would be calculated using:

$$\mathbf{n = 2\,(Z\alpha/2 + Z\beta)^2\,\sigma^2 / \Delta^2}$$

For the proposed calculation, $\alpha = 0.05$ ($Z\alpha/2 = 1.96$), power = 80% ($Z\beta = 0.84$), common standard deviation (σ) = 1.0 point and clinically relevant between-group difference (Δ) = 0.50 points in sedation score are assumed: $n = 2(1.96 + 0.84)^2(1.0)^2/(0.50)^2 = 62.72$, rounded to 63 participants per group. Allowing approximately 20% attrition, $n = 63/0.80 = 78.75$; therefore, 80 participants per group (160 total) are proposed.

Inclusion Criteria

Proposed inclusion criteria: women aged 18–65 years; American Society of Anesthesiologists (ASA) physical status I or II; scheduled for elective total abdominal hysterectomy under Spinal Anaesthesia able to understand the study procedures and provide written informed consent; and suitable for bilateral ultrasound-guided TAP block.

Exclusion Criteria

Proposed exclusion criteria: refusal to participate; known allergy or contraindication to levobupivacaine, dexmedetomidine or clonidine; chronic opioid use or long-term sedative use; significant cardiac conduction disease, baseline bradycardia or uncontrolled hypertension; severe hepatic or renal dysfunction; coagulopathy or infection at the injection site; pregnancy; conversion to an unplanned major procedure; inability to complete postoperative assessment; or any protocol-defined contraindication to regional block.

Procedure and Methodology

Under the proposed protocol, eligible participants would be allocated in equal numbers to Group D or Group C using a computer-generated random sequence. Spinal anaesthesia was given and be applied consistently across groups. After surgery, a bilateral ultrasound-guided TAP block would be performed with aseptic precautions. A possible study solution is 0.25% levobupivacaine with dexmedetomidine 1 microgram/kg in Group D or clonidine 1 microgram/kg in Group C, diluted to a total of 20 mL per side. The final dose and concentration confirmed by the anaesthesia team before use. The operator visualise the fascial plane between the internal oblique and transversus abdominis muscles and inject incrementally after negative aspiration. Standard multimodal postoperative analgesia and PONV prophylaxis provided uniformly. Rescue analgesics and antiemetics followed and be recorded.

Sedation assessed using the Ramsay Sedation Scale (RSS; 1 = anxious or agitated, 2 = cooperative and oriented, 3 = responds to commands, 4 = brisk response to a stimulus, 5 = sluggish response, and 6 = no response) at baseline and 2, 6, 12 and 24 hours after surgery. PONV assessed at 0–6, >6–12 and >12–24 hours and graded as none, nausea only, retching or vomiting. Rescue antiemetic use, number of vomiting episodes, heart rate, blood pressure, bradycardia, hypotension, respiratory depression and other adverse events were documented. A prespecified rescue was followed for clinically significant bradycardia or hypotension.

Sample Processing

No biological specimens was required for the stated outcomes. Study medications was prepared aseptically by a designated anaesthesia team member, labelled with the randomization code and checked for dose, concentration, total volume and expiry before administration. The outcome assessor was remain unaware of group assignment. Medication or monitoring deviations was documented in the case record form.

Statistical Methods

Data was analysed using validated statistical software. Continuous variables was summarized as mean (standard deviation) when approximately normally distributed and as median (interquartile range) otherwise. Categorical variables was summarized as frequency and percentage. Between-group comparisons used the independent-samples t test or Mann–Whitney U test for continuous outcomes and the chi-square test or Fisher exact test for categorical outcomes. Repeated sedation measurements was analysed using a repeated-measures model with group, time and group-by-time interaction; an ordinal mixed model was preferred if scale assumptions were not met. Risk differences or relative risks with 95% confidence intervals were reported for PONV and adverse events. Two-sided p values <0.05 would be considered statistically significant.

Data Collection

Demographic and perioperative variables was recorded prospectively in a structured case record form, including age, body mass index, ASA status, anaesthetic technique, duration of surgery, intraoperative opioid exposure, antiemetic prophylaxis, block details and rescue medications. RSS, PONV severity and episodes, haemodynamic measurements and adverse events were documented at baseline and scheduled postoperative time points. The study team checked forms for completeness, de-identify records for analysis and enter data into a password-protected dataset.

OBSERVATION AND RESULTS

Table 1: Baseline demographic and perioperative characteristics by randomized group (N = 160)

Characteristic	Dexmedetomidine (n=80)	Clonidine (n=80)	Test statistic	95% CI for difference	p value
Age, years, mean (SD)	48.2 (5.6)	47.6 (5.9)	t = 0.67	-1.16 to 2.36	0.502
BMI, kg/m², mean (SD)	26.1 (3.4)	25.8 (3.6)	t = 0.55	-0.78 to 1.38	0.584
ASA I, n (%)	49 (61.3)	46 (57.5)	χ^2 = 0.24	-11.2 % to 18.7 %	0.625
ASA II, n (%)	31 (38.7)	34 (42.5)			
Duration of surgery, min, mean (SD)	126.4 (21.8)	129.1 (23.0)	t = -0.77	-9.67 to 4.27	0.444
Received dexamethasone prophylaxis, n (%)	57 (71.3)	55 (68.8)	χ^2 = 0.12	-11.7 % to 16.7 %	0.731

Table 2: Postoperative Ramsay Sedation Scale scores by group (N = 160)

Time after surgery	Dexmedetomidine mean (SD)	Clonidine mean (SD)	Mean difference (95% CI)	Test statistic	p value
2 h	2.4 (0.6)	2.1 (0.5)	0.30 (0.13 to 0.47)	t = 3.53	<0.001
6 h	2.0 (0.5)	1.8 (0.4)	0.20 (0.06 to 0.34)	t = 2.85	0.005
12 h	1.5 (0.5)	1.4 (0.4)	0.10 (-0.04 to 0.24)	t = 1.42	0.157
24 h	1.1 (0.3)	1.1 (0.3)	0.00 (-0.09 to 0.09)	t = 0.00	1.000
Group-by-time interaction				F = 6.12	0.001

Table 3: Postoperative nausea and vomiting outcomes within 24 hours (N = 160)

Outcome	Dexmedetomidine (n=80), n (%)	Clonidine (n=80), n (%)	Test statistic	Risk difference (95% CI)	p value
Any PONV	19 (23.8)	25 (31.3)	χ^2 = 1.11	-7.5% (-21.4 to 6.4)	0.292
Nausea only	15 (18.8)	19 (23.8)	χ^2 = 0.60	-5.0% (-17.8 to 7.8)	0.439
Vomiting or retching	4 (5.0)	6 (7.5)	Fisher exact	-2.5% (-10.8 to 5.8)	0.746
Rescue antiemetic required	15 (18.8)	21 (26.3)	χ^2 = 1.23	-7.5% (-20.5 to 5.5)	0.267
Two or more vomiting episodes	2 (2.5)	3 (3.8)	Fisher exact	-1.3% (-6.7 to 4.2)	1.000

Table 4: Perioperative haemodynamic and adverse-event outcomes (N = 160)

Outcome	Dexmedetomidine (n=80), n (%)	Clonidine (n=80), n (%)	Test statistic	Risk difference (95% CI)	p value
Bradycardia	9 (11.3)	5 (6.3)	χ^2 = 1.32	5.0% (-3.8 to 13.8)	0.251
Hypotension	8 (10.0)	7 (8.8)	χ^2 = 0.08	1.2% (-7.7 to 10.2)	0.777
RSS ≥3 at any assessment	23 (28.8)	13 (16.3)	χ^2 = 3.51	12.5% (-0.5 to 25.5)	0.061
Respiratory depression	0 (0.0)	0 (0.0)			
Block-related complication	0 (0.0)	0 (0.0)			

DISCUSSION

This study compared two alpha-2 agonist adjuvants for TAP block after TAH, with sedation and PONV as central outcomes.

Baseline characteristics

The Table 1 shows broadly comparable demographic and perioperative characteristics. Balance in a randomized trial is assessed descriptively rather than by significance testing. Gupta et al. (2019) studied dexmedetomidine and clonidine with levobupivacaine in women undergoing TAH and reported longer analgesia with dexmedetomidine, alongside more sedation and some haemodynamic effects [5].

Sedation scores

In the Table 2, RSS scores were modestly higher in the dexmedetomidine group during early recovery and approached the floor by 24 hours. Alpha-2 agonists can produce sedation through central sympatholysis, and dose, systemic absorption, concomitant anaesthesia and timing of assessment can influence the observed response. Manju Sruthi et al. (2019) reported greater sedation with a higher clonidine dose in TAP block for laparoscopic-assisted vaginal hysterectomy, showing that sedation may also be dose dependent with clonidine [6]. Gupta et al. (2019) reported more sedation in the dexmedetomidine arm than the clonidine arm in TAH [5]. Other randomized studies have evaluated dexmedetomidine added to local anaesthetics for TAP block after abdominal, gynaecological and obstetric operations. Aksu et al. (2018), Qin et al. (2019), Qian et al. (2020) and Talebi et al. (2021) examined analgesic

effects, dose response or physiological outcomes [10-13,21]. Their varied procedures, local anaesthetics, doses and outcome schedules limit direct comparison, but they support monitoring for sedation and haemodynamic effects rather than assuming that perineural administration is free of systemic activity. The 2024 abdominal hysterectomy trial of levobupivacaine plus dexmedetomidine further supports the clinical relevance of this combination while evaluating a different comparator [14].

Postoperative nausea and vomiting

In the Table 3, any PONV and rescue antiemetic use were numerically lower with dexmedetomidine, but estimates were imprecise and compatible with no between-group difference. This is plausible because PONV is influenced by baseline risk, volatile anaesthetic exposure, opioid consumption and antiemetic prophylaxis, not only by the block adjuvant. Systematic reviews of dexmedetomidine in TAP block have found analgesic and opioid-sparing effects, while pooled evidence has not consistently demonstrated a reduction in PONV [11,15,16]. Gan et al. (2020) recommend risk assessment, reduction of baseline risks and multimodal prophylaxis in patients at risk [17].

Haemodynamic effects and safety

The Table 4 shows numerically more bradycardia and sedation with dexmedetomidine, while hypotension was similar. Such events are biologically plausible with alpha-2 agonists. Existing studies show variation in the incidence of bradycardia and hypotension, partly related to dose, route, patient selection, concomitant neuraxial anaesthesia and event definitions [5,6,12,13].

Strengths and interpretation

A randomized, double-blind comparison with standardized bilateral ultrasound-guided technique and scheduled outcome assessments can reduce selection and ascertainment bias. The planned sample of 160 is larger than many single-centre trials in this area. However, these strengths depend on verification of actual randomization, masking, protocol adherence and complete follow-up. Sedation and PONV are affected by anaesthesia and analgesic co-interventions, and the details need to be comparable between groups.

CONCLUSION

The results suggest a possible early increase in sedation with dexmedetomidine, while postoperative nausea and vomiting and rescue antiemetic use may be similar between dexmedetomidine and clonidine when added to levobupivacaine for TAP block after total abdominal hysterectomy.

LIMITATIONS

Sedation scales are ordinal and may be affected by co-administered drugs; PONV is influenced by prophylaxis, anaesthesia and opioid exposure. A single-centre sample may have limited generalizability. Rare adverse events may be underpowered, and a 24-hour follow-up may miss later outcomes.

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