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Meta-analysis of pudendal nerve block for post-hemorrhoidectomy analgesic efficacy and safety evaluation

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Li, J[1]; Wu, HQ[2]; Zhang, JT[3]; Liu, SJ[4].

Corresponding author:
Jun Li

mzys1986@163.com

Author Affiliation:
Department of Anesthesiology, Zigong Fourth People's Hospital
Zigong Fourth People's Hospital.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2023 and was last updated on 28 July 2023.

INTRODUCTION

Review question / Objective To systematically evaluate the analgesic efficacy and safety of the pudendal nerve block in the application of hemorrhoidectomy.

Condition being studied The study aims to assess the efficacy and safety of pudendal nerve block as an anesthesia method for postoperative pain management in patients undergoing hemorrhoidectomy. The focus is on evaluating pain relief and safety outcomes based on a meta-analysis of clinical randomized controlled trials (RCTs) and employing the GRADE system for evidence-based medicine.

METHODS

Participant or population Patients aged over 18 years, of any gender, who have undergone open or closed hemorrhoidectomy.

Intervention The observation group receives pudendal nerve block in addition to the anesthesia used in the control group.

Comparator The control group receives only one type of anesthesia such as general anesthesia, spinal anesthesia, or local anesthesia, without pudendal nerve block.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria (1) Study population: Patients aged over 18 years, of any gender, who have undergone open or closed hemorrhoidectomy. (2) Intervention: The observation group receives pudendal nerve block in addition to the anesthesia used in the control group, while the control group receives only one type of anesthesia such as general anesthesia, spinal anesthesia, or local anesthesia, without pudendal nerve block. (3) Study design: RCTs, with no language restrictions. (4) Outcome measures: Postoperative pain scores at 6 hours, postoperative pain scores at 12 hours,

postoperative pain scores at 24 hours, postoperative pain scores at 48 hours, operation time, incidence of complications, proportion of hospital stays less than 1 day, incidence of urinary retention, satisfaction rate. Pain scores are measured using the Visual Analog Scale (VAS).

Information sources China National Knowledge Infrastructure (CNKI), VIP Database, Wanfang Database, Chinese Biomedical Literature Database, PubMed, Embase, and The Cochrane Library.

Main outcome(s) Postoperative pain scores at 6 hours, postoperative pain scores at 12 hours, postoperative pain scores at 24 hours, postoperative pain scores at 48 hours, operation time, incidence of complications, proportion of hospital stays less than 1 day, incidence of urinary retention, satisfaction rate. Pain scores are measured using the Visual Analog Scale (VAS).

Quality assessment / Risk of bias analysis The included RCTs were assessed for quality using the risk of bias assessment tool recommended in the Cochrane Handbook for Systematic Reviews of Interventions 5.3. This assessment tool evaluated the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other biases. Each domain was rated as low risk, unclear risk, or high risk. Two authors independently assessed the risk of bias in the included studies and cross-checked the results. In case of any disagreements, they resolved them through discussion or sought assistance from a third researcher.

Strategy of data synthesis For continuous variables and dichotomous variables in the study, the mean difference (MD) and risk ratio (RR) were calculated as effect measures to determine their pooled values and 95% confidence intervals (CI). Heterogeneity analysis among the included study results was performed using the chi-square test, and the magnitude of heterogeneity was quantitatively assessed using the I2 statistic: if there was no statistically significant heterogeneity among the study results ($P > 0.10$, $I2 \leq 50\%$), a fixed-effects model was used for meta-analysis. Conversely, after excluding obvious clinical heterogeneity effects, a random-effects model was used for meta-analysis. Subgroup analysis or sensitivity analysis was conducted for studies with significant clinical heterogeneity, or descriptive analysis was performed. Sensitivity analysis involved conducting meta-analysis after excluding one study at a time to assess the impact of that particular study on the pooled effect and to evaluate its influence on the outcome measure. When the number of included studies for a specific outcome measure was ≥ 10, publication bias was assessed using a funnel plot.

Subgroup analysis Subgroup analysis was conducted for studies with obvious heterogeneity.

Sensitivity analysis Sensitivity analysis was repeated each time after a single study was removed to evaluate the impact of the study on the combined effect and evaluate the impact of the study on this indicator.

Country(ies) involved China.

Keywords pudendal nerve; hemorrhoids; pain; meta-analysis.

Contributions of each author
Author 1 - Jun Li.
Author 2 - Hai-Qiong Wu.
Author 3 - Jun-Tao Zhang.
Author 4 - Shi-Jian Liu.