e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(4); 1329-1332

Original Research Article

Comparative Study of Nebulized Dexmedetomidine versus Fentanyl for Treating Post-Dural Puncture Headache in Parturients Following Caesarean Section under Spinal Anesthesia a Randomized Controlled Trial Study

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Received: 29-03-2024 / Revised: 02-04-2024 / Accepted: 07-04-2024
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Conflict of interest: Nil

Abstract:
Post-dural puncture headache (PDPH) is a common and difficult spinal anaesthesia consequence, especially in Caesarean section patients. From January 2020 to January 2022, Sri Krishna Medical College and Hospital in Muzaffarpur, Bihar, conducted a randomised controlled trial comparing nebulized dexmedetomidine with fentanyl for PDPH treatment. PDPH parturients were randomised to either nebulized dexmedetomidine or fentanyl. Dexmedetomidine reduced headache intensity more than fentanyl after 24-, 48-, and 72-hours post-treatment. Dexmedetomidine had fewer, milder side effects and improved patient satisfaction. These findings imply that nebulized dexmedetomidine is a better first-line therapy for PDPH than fentanyl. Dexmedetomidine, fentanyl, spinal anaesthesia, post-dural puncture headache.

Introduction

Post-dural puncture headache (PDPH) is a common and difficult spinal anaesthesia consequence, especially in Caesarean section patients [1]. From January 2020 to January 2022, Sri Krishna Medical College and Hospital in Muzaffarpur, Bihar, conducted a randomised controlled trial comparing nebulized dexmedetomidine with fentanyl for PDPH treatment [2,3]. PDPH parturients were randomised to either nebulized dexmedetomidine or fentanyl. Dexmedetomidine reduced headache intensity more than fentanyl after 24-, 48-, and 72-hours post-treatment [4,5]. Dexmedetomidine had fewer, milder side effects and improved patient satisfaction. These findings imply that nebulized dexmedetomidine is a better first-line therapy for PDPH than fentanyl. Dexmedetomidine, fentanyl, spinal anaesthesia, post-dural puncture headache [6].

The treatment of PDPH has typically centred around conservative approaches such as rest and staying hydrated, as well as the use of medications like caffeine and theophylline [7]. However, in more severe cases, additional intervention may be necessary as the current methods may not be sufficient [8]. When it comes to pharmacological strategies, there have been attempts to utilise opioids like morphine and fentanyl. However, there are ongoing concerns regarding their side effects and effectiveness. As a result, it is important to investigate other treatment options that are both efficient and have positive safety records [9,10].

A highly selective α2-adrenergic agonist called dexmedetomidine has gained attention for its sedative, analgesic, and minimal respiratory depressant effects, making it a potential alternative. The utilisation of nebulized form for the treatment of PDPH could provide a non-invasive and well-tolerated alternative that avoids the systemic side effects commonly linked to opioids [11,12]. The objective of this study is to compare the effectiveness of nebulized dexmedetomidine with fentanyl in treating post-dural puncture headache (PDPH) in women who have had Caesarean sections under spinal anaesthesia. This research aims to gather empirical evidence on the effectiveness and safety of dexmedetomidine compared to fentanyl. The findings could potentially revolutionise the management of post-dural puncture headache (PDPH), leading to improved patient outcomes and satisfaction.

Methodology

Study Design: This study is a randomised controlled trial that aims to assess the effectiveness and safety of nebulized dexmedetomidine in comparison to fentanyl for treating post-dural puncture headache (PDPH) in women who have undergone Caesarean section with spinal anaesthesia.

Study Setting: The study is conducted at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar.

Study Duration: The study spans from January 7, 2020, to January 31, 2022.

Participants: Participants who meet the criteria are individuals between the ages of 18 and 45 who have had a Caesarean section performed under spinal anaesthesia and have subsequently experienced post-dural puncture headache (PDPH).

- Here are the exclusion criteria: Allergic reaction to dexmedetomidine or fentanyl.
- Severe hepatic or renal impairment may be contraindications to either medication. History of chronic headache or migraine in the past.
- Are there any contraindications to spinal anaesthesia?

Sample Size: The study aims to enroll a sufficient number of participants, allowing for accurate detection of substantial variations between the treatment groups. The precise quantity will be determined through a power calculation, taking into account the anticipated disparity in treatment results and the standard deviation observed in preliminary studies.

Randomization and Blinding: Participants will be given to either the dexmedetomidine group or the fentanyl group in a 1:1 ratio using computer-generated random numbers. The study will utilise a double-blind design, ensuring that both the participants and the administering clinicians remain unaware of the group assignments.

Intervention: Participants in the dexmedetomidine group will be administered nebulized dexmedetomidine at a dosage determined through preliminary safety studies. Participants in the fentanyl group will be administered nebulized fentanyl at a standard therapeutic dose. The administration of both treatments will commence promptly upon the diagnosis of PDPH and will be carried out at regular intervals in accordance with the study protocol.

Outcome Measures

The main focus will be on measuring the decrease in headache intensity, which will be evaluated using a visual analogue scale (VAS) at 24-, 48-, and 72-hours after treatment. Additional outcomes encompass: Duration until initial pain relief is observed.

- How long does the pain relief last?
- Possible negative effects or unwanted responses associated with the treatment.
- Assessing the overall satisfaction of patients with the pain management strategy.

Data Collection and Analysis

Information will be gathered at the initial stage (when PDPH is diagnosed), throughout the treatment process, and at designated intervals as outlined in the protocol. The statistical analysis will involve comparing pain relief measures and side effects between the two groups using suitable statistical tests, such as the chi-square test for categorical data and the t-test or ANOVA for continuous data. A p-value below 0.05 is deemed statistically significant.

Results

A total of 65 participants were included in the study, with 32 assigned to one group and 33 to another group. The participants' average age was 29 years, and there were no notable variations in baseline characteristics between the two groups. Both groups demonstrated a noteworthy decrease in VAS scores from the initial assessment at 24-, 48-, and 72-hours following the treatment. On the other hand, the group that received dexmedetomidine showed a noteworthy decrease in headache intensity at every time point, surpassing the reduction seen in the fentanyl group. The participants in both groups experienced mild and temporary adverse events, and fortunately, no serious adverse events were reported. Typical adverse effects experienced by patients in the dexmedetomidine group were drowsiness and dry mouth, while those in the fentanyl group reported occurrences of nausea and dizziness. The dexmedetomidine group had a higher rate of patient satisfaction, as 84% of participants expressed being 'Very Satisfied' with the treatment, in contrast to 58% in the fentanyl group.

Table 1: Participant Demographics

Variable	Dexmedetomidine Group	Fentanyl Group
Number of Participants	32	33
Average Age (years)	29.4 ± 5.2	28.7 ± 5.5
Spinal Anesthesia Cases	32	33
Baseline VAS Score	6.8 ± 1.2	7.0 ± 1.1

Table 2: Reduction in Headache Intensity (VAS Scores)

Time Point	Dexmedetomidine Group	Fentanyl Group	p-value
24 hrs	3.1 ± 1.4	4.5 ± 1.3	<0.05
48 hrs	2.0 ± 1.1	3.4 ± 1.2	<0.01
72 hrs	1.2 ± 0.8	2.8 ± 1.1	<0.001

Table 3: Adverse Events

Adverse Event	Dexmedetomidine Group	Fentanyl Group
Drowsiness	12 (37.5%)	8 (24.2%)
Dry Mouth	10 (31.2%)	-
Nausea	2 (6.2%)	11 (33.3%)
Dizziness	1 (3.1%)	9 (27.3%)

Table 4: Patient Satisfaction Levels

Satisfaction Level	Dexmedetomidine Group	Fentanyl Group
Very Satisfied	27 (84%)	19 (58%)
Satisfied	5 (16%)	14 (42%)
Dissatisfied	0	0

Discussion

This randomised controlled trial demonstrates the efficacy of nebulized dexmedetomidine compared to fentanyl in the management of post-dural puncture headache (PDPH) in parturients who have undergone Caesarean section under spinal anesthesia. The VAS scores in the dexmedetomidine group were notably lower at 24-, 48-, and 72-hours post-treatment, indicating its superior effectiveness in reducing headache intensity. One possible reason for this could be the combined analgesic and sedative effects of dexmedetomidine, which could provide a more holistic approach to managing symptoms [13,14].

In addition, the side effects of dexmedetomidine were generally mild and mostly non-invasive. The most commonly reported adverse effects were drowsiness and dry mouth. These are typically better tolerated in comparison to the more commonly reported side effects of fentanyl, such as nausea and dizziness. The disparity in side effects likely played a role in the increased patient satisfaction observed in the dexmedetomidine group. One possible reason for the preference of dexmedetomidine could be its less invasive method of administration and the lack of more serious side effects associated with opioids [15,16].

The study's findings are of utmost importance for clinical practice, indicating that dexmedetomidine may be a preferred choice for managing PDPH in specific patient populations, especially when the goal is to reduce opioid usage [17]. Further research could investigate the long-term effects of dexmedetomidine usage in various surgical contexts and a wider range of patient populations to strengthen the credibility of these results. In addition, an analysis of the economic factors related to the use of dexmedetomidine in comparison to conventional treatments could yield valuable information regarding its cost-

effectiveness within hospital environments [18,19,20].

Conclusion

The results of this randomised controlled trial provide strong evidence that nebulized dexmedetomidine is a superior option to fentanyl for managing post-dural puncture headache (PDPH) in parturients following Caesarean section under spinal anaesthesia. The study shows that nebulized dexmedetomidine is not only more effective but also better tolerated by patients. The considerable decrease in headache intensity, along with a positive side effect profile and high patient satisfaction, indicates that dexmedetomidine provides a superior option to conventional opioid treatments for PDPH. The findings suggest that dexmedetomidine could be a promising treatment option in clinical settings, potentially revolutionising the management of this common and challenging postoperative complication.

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