Original Article

Efficacy of ShotBlocker device versus vapocoolant spray for spinal needle pain relief during spinal anaesthesia in elective caesarean section - A randomised controlled trial

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ABSTRACT

Background and Aims: Apprehension of pain due to a spinal needle is often a cause of anxiety and refusal. ShotBlocker provides non-painful physical stimulation, inhibiting pain perception. The vapocoolant spray contains ethyl chloride vapours, rapidly raising the skin temperature and hampering the transmission of noxious stimuli. The present study compared the effectiveness of the ShotBlocker device and the vapocoolant spray in reducing spinal needle-associated pain in primigravida women undergoing elective lower-segment caesarean section (LSCS). **Methods:** We enroled 144 primigravida women undergoing elective LSCS and were randomised to Group SB (the ShotBlocker device was firmly pressed over the skin, and the spinal needle was inserted through its slit), Group V (the vapocoolant spray was applied at the puncture site before spinal needle insertion), and Group C (received local infiltration before spinal anaesthesia (SA)). The groups were compared for needle-associated pain and patient satisfaction using a 10-point visual analogue scale (VAS) and a 3-point Likert scale. **Results:** The mean (standard deviation) [95% confidence interval (CI)] VAS scores of Group SB 3.85 (0.74) [3.64, 4.07] and Group V 3.04 (0.74) [2.83, 3.26] were significantly lower than that of Group C 5.19 (0.92) [3.28, 3.62]). On the Likert scale, the maximum number of patients in the vapocoolant group (64.6%) responded satisfactorily, while in the control group, the majority (62.5%) of participants responded dissatisfied ($P < 0.001$). **Conclusion:** Both the ShotBlocker and vapocoolant spray reduce needle puncture-associated pain before SA in primigravida patients undergoing elective LSCS. However, the vapocoolant spray is more beneficial in reducing spinal needle-associated pain than the ShotBlocker device.

Keywords: Caesarean section, ethyl chloride, lidocaine, ShotBlocker, spinal anaesthesia, vapocoolant spray

INTRODUCTION

Spinal anaesthesia (SA) is a well-proven technique of choice for parturients undergoing lower-segment caesarean section (LSCS). The fear and apprehension of needle pain at the site of administration, being wakeful during surgery, apprehension of paralysis, and persistent back pain are a few of the common concerns observed about SA. Refusal of SA due to fear of pain at the site of puncture or 'needle phobia' has an incidence as high as 10%–15%.[1]

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One potential solution is the ShotBlocker device (Bionix LLC, Maumee, Ohio, USA). This drug-free, flexible, U-shaped plastic device has blunted contact points on one side, which is placed directly on the skin, with a slit in the centre for needle insertion.[1] By firmly pressing this device onto the skin, these blunt contact points provide non-painful physical stimulation and inhibit the pain perception caused by needle insertion, aligning with the 'gate control' theory of pain.

Another method to decrease pain during a spinal injection is the vapocoolant spray (Ethyl chloride IP, Eclat Pharma, and Aerosols PVT. LTD., Palghar, Maharashtra). This spray contains 100% w/v ethyl chloride; its vapours create a sudden diminution in the skin temperature, interrupting ion channel activation and impeding pain reception.[2,3]

The ShotBlocker device and the vapocoolant spray are non-invasive, readily available methods to minimise needle pain. Therefore, we conducted the present study with the primary objective of comparing these two methods for pain relief during spinal-needle puncture in primigravida patients who had no prior experience of exposure to SA and were undergoing elective LSCS.

METHODS

This open-labelled, and randomised comparative trial was conducted at our tertiary care centre after approval from the institutional ethical committee (vide approval number V1-PGTSC-11A/P22, dated 28 January 2022) and trial registration in the Clinical Trials Registry-India (CTRI/2022/03/041100; https://ctri.nic.in/). The study was conducted from December 2021 to December 2022. Written informed consent was taken from all the patients before inclusion in the study for participation and use of the patient data for research and educational purposes, and a total of 144 participants were enroled. This manuscript follows Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. The study was carried out in accordance with the Declaration of Helsinki (2013) and good clinical practice.

The inclusion criteria were American Society of Anesthesiologists physical status II full-term primigravida scheduled for elective LSCS under SA, with no haemodynamic instability, not in active labour, no communication barriers, no psychiatric disorders, no allergy to ethyl chloride, no technically challenging spinal block due to anatomical factors, no previous experience of SA or lumbar puncture, no ongoing analgesic use, and no neurological disease.

The patients were randomly assigned into three groups based on computer-generated randomisation: Group SB, Group V, and Group C. For allocation concealment, a sequentially numbered, opaque, sealed envelope technique was used.

Upon arrival in the operation theatre, monitors (electrocardiogram, non-invasive blood pressure, and pulse oximeter) were connected, and baseline parameters were recorded. Two wide-bore intravenous (IV) cannulas were secured, and preloading with 10 mL/kg body weight of IV crystalloid was done.

The ShotBlocker device was applied in Group SB before the lumbar puncture. After preparing and draping the area, the ShotBlocker device (sterilised with 2% glutaraldehyde solution and cleaned with normal saline solution) was placed on the skin at the puncture site and pressed firmly with the non-dominant hand for 10 s. The spinal needle was then inserted through the slit of the ShotBlocker. As soon as the dura was punctured, the device was released, and the drug was injected intrathecally. In Group V, after prepping the area, the vapocoolant spray was applied at the puncture site for 10 s from a 10–20 cm distance. The spinal needle was inserted after allowing the spray to dry and cleaning the site with spirit. In Group C, after aseptic preparation, a 27-G hypodermic needle was used for local infiltration (1 mL of 2% lignocaine) in the desired intervertebral space before the spinal needle insertion.

In all the groups, lumbar puncture was performed using a 25-G Quincke spinal needle under aseptic precautions, with the patient in the sitting position, targeting the L3–L4 or L4–L5 intervertebral space. The procedure was carried out by a senior anaesthesiologist with more than five years of experience. A mixture of 10 mg hyperbaric bupivacaine with 10 μg fentanyl (total volume: 2.2 mL) was injected intrathecally after confirming the flow of cerebrospinal fluid.

Patients requiring more than two spinal attempts were excluded from the study. The first spinal attempt was considered a single-shot spinal injection without changing the direction of the spinal needle. The second spinal attempt was considered when the spinal needle hit the bone, prompting a change in its direction from the previous attempt. A failed spinal attempt was

defined as the inability to puncture the dura or obtain the free flow of cerebrospinal fluid. Immediately after the spinal block, patients were positioned supine and assessed for the adequacy of the block. The primary outcome measure was needle-associated pain, whereas the secondary outcome measures were the number of spinal attempts, overall patient satisfaction, and any adverse reactions. The needle-associated pain was evaluated using a 10-point visual analogue scale (VAS). In addition, patient satisfaction was assessed using a 3-point Likert scale (wherein a score of 1, 2, and 3 was given to dissatisfied, neutral, and satisfied responses, respectively) immediately after giving SA. The patients were observed for 24 hours postoperatively to note any adverse reactions.

The sample size was calculated based on variation in the VAS score of the ShotBlocker group and assuming the null hypothesis of equality of variation with other groups by using the formula, where σ =0.289, the standard deviation (SD) of the VAS score for the three groups under the assumption of equality, d = 25% of the mean (=1.5) of VAS, the difference considered to be clinically significant.[4] Type I error α = 5%, corresponding to a 95% confidence interval (CI) and type II error β =10%, for detecting results with 90% power of the study. Hence, the required sample size was n = 48 for each group (144 in total for three groups).

Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) statistics software version 21.0 (Armonk, NY: International Business Machines Corp, USA) statistical software. The values were represented as number (%) and mean (standard deviation) (95% confidence interval (CI)). The independent Student's *t*-test was used to compare variables with a normal distribution (age, body mass index), and the Kruskall–Wallis test was applied to evaluate non-normally distributed data (needle-associated pain). The Mann–Whitney U test was used for between-group comparison. Significance between categorical data was assessed using Fisher's exact test or the χ^2 test. The upper limit of type-I error level for statistical significance (*P* value) was regarded as 5% (*P* value < 0.05).

RESULTS

We assessed 152 patients for enrolment, of whom 144 met the study inclusion criteria [Figure 1]. All three group participants were comparable based on demographic and baseline parameters [Table 1].

Table 1: Demographic data of the study groups

Characteristics	Group SB (*n*=48)	Group V (*n*=48)	Group C (*n*=48)
Age (in years)	25.08 (3.25)	25.88 (2.61)	26.23 (2.38)
Weight (in kg)	73.04 (14.12)	73.01 (14.09)	72.55 (13.75)
Height (in cm)	150.54 (6.02)	150.34 (6.01)	151.0 (6.82)

Data represented as mean (standard deviation) or numbers. Group SB=ShotBlocker, Group V=Vapocoolant spray, Group C=control, *n*=number of patients

The spinal needle-associated pain (VAS score) was reported to be lesser among Group V and Group SB participants than in Group C (which reported the highest VAS score) ($P < 0.001$) [Table 2]. However, between groups V and SB, the VAS scores were noted to be the lowest among group V participants ($P < 0.001$).

Upon comparing the level of patient satisfaction among the study groups (3-point Likert scale), satisfied patient response was significantly more prevalent in group V than in group SB (64.6% vs 33.3%). A neutral response was given by most patients (58.3%) in group SB. Notably, group C had most patients express dissatisfaction (62.5%), and none of the participants responded satisfactorily. These differences were also statistically significant ($P < 0.001$) [Figure 2].

A higher proportion of participants in groups SB and C required two attempts for lumbar puncture compared to Group V; however, this finding had no statistical significance. No significant adverse reactions were observed in any of the groups. Only mild redness at the site of the ShotBlocker application was noted in group SB [Table 2].

DISCUSSION

Vapocoolant spray for needle puncture pain during SA in elective LSCS in primigravida women had the least needle-associated pain and higher levels of satisfaction. They required fewer spinal attempts when compared to those who received a ShotBlocker device or in the control group.

While skin infiltration with local anaesthetics is a common practice before spinal puncture to minimise needle pain, it is an invasive procedure. Various non-invasive techniques, such as a eutectic mixture of local anaesthetics (EMLA) creams and local anaesthetic application using needle-free drug delivery systems, have been used.[5,6] Despite comparable effectiveness with the vapocoolant spray, the delayed onset (30-60 min) of EMLA renders it unsuitable for emergency procedures.[2,6,7] The needle-free drug injection systems

Table 2: Comparison of the groups based on visual analogue scale (VAS) scores, numbers of attempts of lumbar puncture, and adverse reactions

	Group SB (*n*=48)	Group V (*n*=48)	Group C (*n*=48)	*P*
VAS scores	3.85 (0.74) [3.64–4.07]	3.04 (0.74) [2.83–3.26]	5.19 (0.92) [3.28–3.62]	<0.001
Number of attempts (single/two)	37/11	42/6	38/10	0.384
Adverse reaction (mild redness)	29/48	0/48	0/48	<0.001

Data expressed as mean (standard deviation) [95% confidence interval] or numbers. *Mann–Whitney *U* test for between-group comparison (Group SB vs Group V: *Z*=4.650, *P*<0.001; Group SB vs Group C: *Z*=6.179, *P*<0.001; Group V vs Group C: *Z*=7.894, *P*<0.001). Group SB=ShotBlocker, Group V=Vapocoolant spray, Group C=control, *n*=number of patients

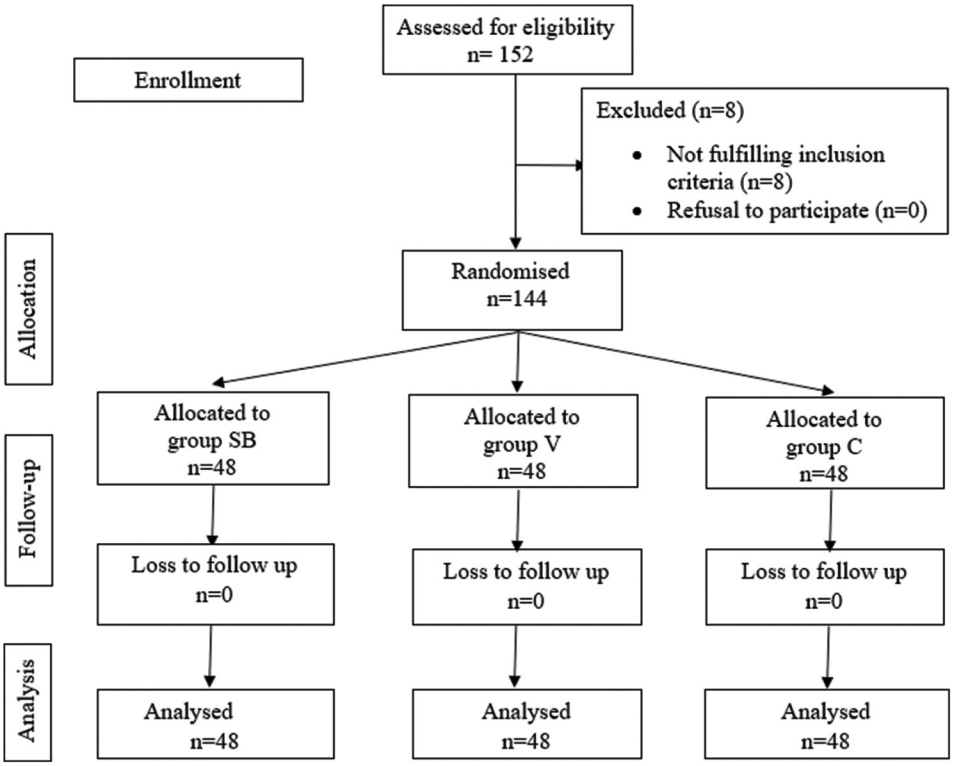

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram

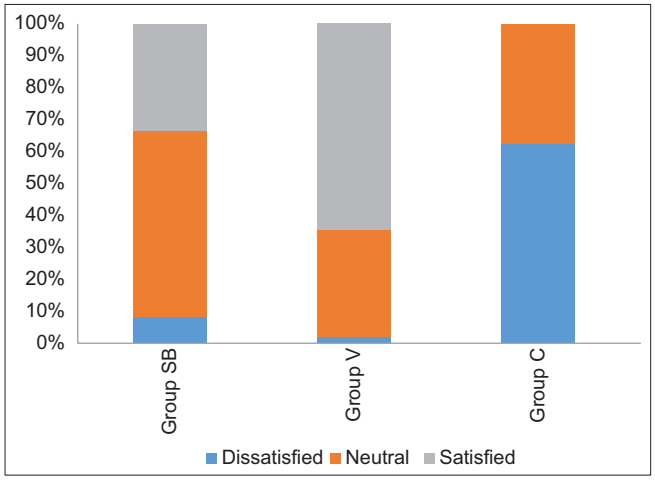

Figure 2: Comparison of the groups based on patient satisfaction based on 3-point Likert scale (*P* < 0.001)

are not cost-effective.[8] The ShotBlocker device has proved to be efficacious in reducing pain due to intramuscular injections.[9,10] Contrary to our study, Inangil and Cansiz found the ShotBlocker comparable to the control group during dermal puncture with a spinal needle.[4] This inconsistency can be attributed to the distinctions in the study population; Inangil and Cansiz included participants of both genders, whereas our study exclusively enroled pregnant females.

There is a gap in the existing literature regarding the direct comparison between the ShotBlocker device and the vapocoolant spray for alleviating needle puncture pain in the context of SA. Nevertheless, several studies have compared these two methods for reducing pain associated with intramuscular injections.[10-12] In our study, the vapocoolant spray demonstrated lower VAS scores and better patient satisfaction than the ShotBlocker device. Both methods were deemed safe, with the ShotBlocker device causing transient mild

redness, possibly due to its firm compression against the skin. The vapocoolant spray lacks adverse effects; however, the possibility of allergic reactions and the inflammable nature of ethyl chloride are potential risks. While the vapocoolant spray is relatively easy to use, the ShotBlocker device is technically challenging as sustained pressure has to be applied with a non-dominant hand. The vapocoolant spray is more economical in terms of cost.

While the vapocoolant spray seems more effective than the ShotBlocker device, further studies and systemic analyses should be conducted comparing these two and various others for alleviating pain associated with spinal needle insertion. The current evidence does not definitively identify an effective method for this purpose. It is important to note that apart from pain due to dermal puncture, other factors contributing to needle phobias can be anxiety and fear associated with SA. Therefore, an avenue for future research can explore the potential benefits of combining techniques of anxiolysis with methods aimed at allaying needle puncture pain.

The strength of our study lies in it being the first, to the very best of our knowledge, to compare the ShotBlocker and vapocoolant devices for mitigating spinal needle-associated pain. However, the limitations include a single-centre setting, a relatively small sample size, and a lack of blinding.

CONCLUSION

Both the ShotBlocker and vapocoolant device can be used to allay needle puncture-associated pain during the performance of SA in primigravida patients undergoing LSCS. However, the use of the vapocoolant spray before spinal needle insertion provides better analgesia and more patient satisfaction in comparison to applying the ShotBlocker device.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Conflicts of interest

There are no conflicts of interest.

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