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Original Research Paper

ASSESSING THE EFFICACY OF VAPOCOOLANT SPRAY TO SHOT-BLOCKER DEVICE FOR SPINAL NEEDLE PAIN RELIEF DURING SPINAL ANESTHESIA DURING ELECTIVE CESAREAN SECTIONS

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ABSTRACT

Background: Pain apprehension owing to the insertion of a spinal needle is usually a reason for refusal and anxiety. Shot Blocker helps in non-painful physical stimulation and inhibits pain perception. Vapocoolant spray has ethyl alcohol vapors as a constituent which rapidly increase the skin temperature and hamper the transmission of noxious stimulus.

Aim: The present study aimed to comparatively assess the efficacy of vapocoolant spray as a shot-blocker device for spinal needle pain relief during spinal anesthesia during elective cesarean sections (LSCS).

Methods: The present study assessed 288 primigravida females undergoing elective LSCS (lower segment cesarean section) and were randomly divided into Shot Blocker group I where the device was pressed firmly over the skin and via its slit, spinal needle was inserted, Group II (vapocoolant spray) applied at puncture site before inserting the spinal needle, and Group III given local infiltration before spinal anesthesia. These groups were compared for patient satisfaction and needle-associated pain using a 3-point Likert scale and a 10-point VAS (visual analog scale).

Results: The mean VAS scores were 3.83±0.72 and 3.02±0.72 in Groups I and II respectively which were significantly lower compared to Group III where it was 5.17±3.64 with $p<0.05$. On the Likert scale, a maximum number of subjects in the vapocoolant group responded satisfactorily to 65% of subjects,

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whereas, in the control group, the majority of subjects reported as dissatisfied with 62% subjects with $p<0.001$.

Conclusions: The present study concludes that both vapocoolant spray and Shot Blocker reduce the pain associated with needle puncture before spinal anesthesia in primigravida subjects undergoing elective LSCS. However, the use of vapocoolant spray is more productive in reducing the pain associated with spinal needle puncture compared to the Shot Block device.

Keywords: Cesarean section, ethyl chloride, Shot Block, spinal anesthesia, vapocoolant spray

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INTRODUCTION

SA or spinal anesthesia is a well-known and proven technique for subjects undergoing LSCS (lower segment cesarean section). The apprehension and fear associated with needle pain at the site of needle insertion, persistent back pain, apprehension of paralysis, and being wakeful during the surgery comprise of few common fears and concerns associated with spinal anesthesia. There is a high incidence of nearly 10% to 15% for refusal of spinal anesthesia owing to the fear of pain, needle phobia, and pain at the puncture site.[1]

One vital solution is the use of a Shot Blocker device which is a U-shaped plastic device that is flexible, drug-free, and has blunted contact point on one side which is directly placed on the skin with a slit in the center that facilitates the insertion of the needle. After pressing the device firmly on the skin, blunt contact points provide non-painful physical stimulation and prevent pain perception precepted by needle insertion consistent with the gate control theory of pain.[2]

Other methods of pain control have also been used to reduce pain during spinal anesthesia including the vapocoolant spray containing ethyl alcohol. This vapocoolant spray contains 100% ethyl chloride, the vapors of which create a sudden diminution in the temperature of the skin which interrupts the activation of ion channels and impedes the perception of the pain.[3]

Both the vapocoolant spray and Shot Blocker device are non-invasive methods of reducing pain and are easily available methods that reduce needle pain.[4] Hence, the present study aimed to assess the efficacy of vapocoolant spray as shotblocker device for spinal needle pain relief during spinal anesthesia during elective cesarean sections (LSCS).

MATERIALS AND METHODS

The present randomized comparative clinical study was aimed to comparatively assess the efficacy of vapocoolant spray to shotblocker device for spinal needle pain relief during spinal anesthesia during elective cesarean sections (LSCS). The study subjects were from the Department of Obstetrics and Gynecology of the Institute. Verbal and written informed consent were taken from all the subjects before study participation.

The study included 288 female subjects who were full-term primigravida, were in ASA (American Society of Anesthesiologists) physical status II, were scheduled for elective LSCS under spinal anesthesia, no neurological disease, no ongoing analgesic use, no previous experience with lumbar puncture or spinal anesthesia, no technically challenging spinal block due to anatomic factors, no allergy to ethyl chloride, no psychiatric disorders, no communication barriers, not in active labor, and no hemodynamic instability.

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These subjects were randomly divided into three groups where Group I subjects were given a ShotBlock device, Group II subjects with vapocoolant spray, and Group III subjects were controls. After taking subjects to the surgery room, monitors were connected to assess various parameters at baseline including a pulse oximeter, non-invasive blood pressure monitor, and electrocardiogram. Also, two wide-bore IV (intravenous) cannulas were secured and preloading was done with 10mL/kg body weight of IV crystalloids.

In Group I, the ShotBlock device was applied before the lumbar puncture. After preparation and draping of the surgical area, the ShotBlock device was sterilized with 2% glutaraldehyde solution followed by cleaning with normal saline solution was placed on the skin at the site of the puncture was firmly pressed using a non-dominant hand for 10 seconds. Via slit on the device, a spinal needle was inserted in the ShotBlocker group. After puncturing the dura, the device was released and the drug was injected intrathecally. In Group II, vapocoolant, after preparation of the area, the vapocoolant spray was applied at the site of the puncture for 10 seconds from a distance of 10-20 cm. A spinal needle was inserted after drying the vapocoolant spray and cleaning the site. In Group III, the control group, following aseptic preparation, the 27-gauge hypodermic needle was used for infiltration with 2% lignocaine in 1mL dose in needed intervertebral space before inserting the spinal needle.

In all three groups, lumbar puncture was done with a 25-gauge spinal needle under strict aseptic conditions and kept subjects in a sitting state that targeted L3-L4 or L4-L5 intervertebral space. The procedure was done by a senior anesthesiologist having more than five years of experience. A mixture having 10μg fentanyl with 10mg hyperbaric bupivacaine in a total volume of 2.2 ml dose was intrathecally injected following the confirmation of cerebrospinal fluid flow.

Subjects that needed more than two attempts with spinal were the exclusion criteria for the study. A first spinal attempt was considered as a single-shot spinal injection with no change in the spinal needle direction. The second attempt was taken when the spinal needle hit the bone warranting a change in direction from the last attempt. A failed spinal attempt was taken as the inability to puncture the dura or to get free flow of CSF (cerebrospinal fluid). Immediately following the spinal block, subjects were placed in the supine position and were evaluated for block adequacy.

The primary outcomes assessed were pain associated with needle puncture and the secondary outcomes assessed were any adverse effects, overall patient satisfaction, and number of spinal attempts. Needle-associated pain was assessed on VAS (Visual analog score on a scale of 1-10 and patient satisfaction was assessed on a 3-point Likert scale where scores of 1, 2, and 3 were given to dissatisfied, neutral, and satisfied responses respectively immediately following spinal anesthesia. Subjects were assessed for 24 hours postoperatively to see any adverse effects.

The data gathered were analyzed statistically using SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) for assessment of descriptive measures, one-way ANOVA (analysis of variance), Kruskal–Wallis test, Fisher exact test, and chi-square test. The results were expressed as mean and standard deviation and frequency and percentages. The p-value of <0.05 was considered statistically significant.

RESULTS

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The present randomized comparative clinical study was aimed to comparatively assess the efficacy of vapocoolant spray to shotblocker device for spinal needle pain relief during spinal anesthesia during elective cesarean sections (LSCS). The study included 288 female subjects who were full-term primigravida. These subjects were randomly divided into three groups where Group I subjects were given a ShotBlock device, Group II subjects with vapocoolant spray, and Group III subjects were controls. The mean age of the study subjects was 25.06±3.23, 25.86±2.59, and 26.21±2.36 years respectively in Groups I, II, and III which was statistically comparable. Mean height was also statistically comparable in three groups with 73.02±14.14, 73.03±14.07, and 72.53±13.73 cm. A similar statistically non -non-significant difference was seen for mean weight with 150.52±6.04, 150.32±6.03, and 151.02±6.84 kg in Groups I, II, and III respectively (Table 1).

On assessing the VAS (visual analog scale scores in the three study groups, it was seen that mean VAS scores were highest in Group III, control subjects where mean VAS scores were 5.17±0.94 followed by 3.83±0.72 in Group I with ShotBlock device, and were least in Group II with vapocoolant spray where it was 3.83±0.72. The difference in the three groups was statistically significant with the highest and lowest mean VAS scores in control and vapocoolant groups with $p<0.001$ (Table 2).

Patient satisfaction was assessed in three study groups using a 3-point Likert scale, and it was seen that significantly higher subjects responded as satisfied with vapocoolant spray in Group II compared to Group I with shotblock device with 65% and 33% subjects respectively. In the ShotBlock device group, the majority of the subjects gave a neutral response with 58% subjects. It was also seen that in Group III control subjects, most of the subjects showed dissatisfaction with 62% subjects. No subject responded satisfactorily in Group III (controls). These inter-group differences were statistically significant with a p-value of <0.001.

For several attempts, a single attempt was successful in 74, 84, and 76 subjects respectively from Groups I, II, and III. However, two attempts for lumbar puncture were needed in 22, 12, and 20 subjects from Groups I, II, and III respectively. However, the intergroup difference for the number of attempts was statistically non-significant with $p=0.382$. Adverse events were not seen in any subject from the vapocoolant and control groups. However, mild redness at the site of the lumbar puncture of the needle was seen in 58 subjects from the ShotBlock device (Group I) showing statistically significant results with $p<0.001$ (Table 2).

DISCUSSION

The present study assessed 288 female subjects that were full-term primigravida. These subjects were randomly divided into three groups where Group I subjects were given a ShotBlock device, Group II subjects with vapocoolant spray, and Group III subjects were controls. The mean age of the study subjects was 25.06±3.23, 25.86±2.59, and 26.21±2.36 years respectively in Groups I, II, and III which was statistically comparable. Mean height was also statistically comparable in three groups with 73.02±14.14, 73.03±14.07, and 72.53±13.73 cm. A similar statistically non -non-significant difference was seen for mean weight with 150.52±6.04, 150.32±6.03, and 151.02±6.84 kg in Groups I, II, and III respectively. These findings were similar to the studies of Drago LA et al[5] in 2009 and Bilge S et al[6] in 2019 where authors assessed subjects with demographic data comparable to the present study.

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It was seen that on assessing the VAS (visual analog scale scores in the three study groups, it was seen that mean VAS scores were highest in Group III, control subjects where mean VAS scores were 5.17±0.94 followed by 3.83±0.72 in Group I with ShotBlock device, and were least in Group II with vapocoolant spray where it was 3.83±0.72. The difference in the three groups was statistically significant with the highest and lowest mean VAS scores in control and vapocoolant groups with $p<0.001$. These results were consistent with the findings of Calgar S et al[7] in 2017 and Çelik N et al[8] in 2015 where authors reported that similar to the present study, in their respective studies, VAS scores were highest in controls and were lowest with vapocoolant spray in their respective studies

The study results showed that patient satisfaction was assessed in three study groups using a 3-point Likert scale, and it was seen that significantly higher subjects responded as satisfied in vapocoolant spray Group II compared to Group I with shotblock device with 65% and 33% subjects respectively. In the ShotBlock device group, the majority of the subjects gave a neutral response with 58% subjects. It was also seen that in Group III control subjects, most of the subjects showed dissatisfaction with 62% subjects. No subject responded satisfactorily in Group III (controls). These inter-group differences were statistically significant with a p-value of <0.001. These findings were in agreement with the results of Çelik N et al[9] in 2011 and Park SW et al[10] in 2015 where results for patient satisfaction reported by the authors were in line with the results of the present study.

Concerning the number of attempts, a single attempt was successful in 74, 84, and 76 subjects respectively from Groups I, II, and III. However, two attempts for lumbar puncture were needed in 22, 12, and 20 subjects from Groups I, II, and III respectively. However, the intergroup difference for the number of attempts was statistically non-significant with $p=0.382$. Adverse events were not seen in any subject from the vapocoolant and control groups. However, mild redness at the site of the lumbar puncture of the needle was seen in 58 subjects from the ShotBlock device (Group I) showing statistically significant results with $p<0.001$. These results correlated with the findings of Shipton EA et al[11] in 2012 and Doi K et al[12] in 2022 where adverse outcomes and number of attempts comparable to the present study were reported by the authors in their studies.

CONCLUSION

Within its limitations, the present study concludes that both vapocoolant spray and Shot Blocker reduce the pain associated with needle puncture before spinal anesthesia in primigravida subjects undergoing elective LSCS. However, the use of vapocoolant spray is more efficacious in reducing the pain associated with spinal needle puncture compared to the Shot Block device. Further, longitudinal studies with larger sample sizes and longer monitoring will be needed to attain a definitive conclusion.

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TABLES

S. No	Characteristics	Group I (n=96)	Group II (n=96)	Group III (n=96)
1.	**Mean age (years)**	25.06±3.23	25.86±2.59	26.21±2.36
2.	**Mean height (cm)**	73.02±14.14	73.03±14.07	72.53±13.73
3.	**Mean weight (kg)**	150.52±6.04	150.32±6.03	151.02±6.84

Table 1: Demographic characteristics of study subjects

S. No	Parameters	Group I (n=96)	Group II (n=96)	Group III (n=96)	p-value
1.	**Number of attempts**				
a)	Single	74	84	76	0.382
b)	Two	22	12	20	

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2.	**VAS scores (mean)**	3.83±0.72	3.02±0.72	5.17±0.94	**<0.001**
3.	**Adverse events**	58	0	0	**<0.001**

Table 2: Adverse events, mean VAS scores, and number of attempts comparison in three study groups