

Randomized Trial



The Effect of ShotBlocker on Pain and Patient Satisfaction for Spinal Anesthesia: A Randomized Trial

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Background: During spinal anesthesia, patients may experience pain and discomfort associated with dermal puncture. It may also cause involuntary movement, which often disturbs the patient's posture thus affecting the success of spinal anesthesia. Different methods have been studied to cope with needle-related pain. "ShotBlocker" is a flexible, plastic, U-shaped device, which has several blunt points. It is suggested that blunt points provide a nonnoxious physical stimulation and inhibit the transmission of injection pain.

Objectives: The purpose of this study was to examine the effectiveness of the ShotBlocker for dermal puncture pain during spinal anesthesia.

Study Design: Prospective randomized trial.

Setting: University hospital, operating room.

Methods: Ninety-four patients aged 18 to 65 years with physical status American Society of Anesthesiologists (ASA) I or II scheduled for elective surgery under spinal anesthesia were randomly assigned to either a ShotBlocker (n = 47) or control group (n = 47). In the ShotBlocker group, lumbar punctures were performed with the application of ShotBlocker. Needle-associated pain score and patient satisfaction were assessed by the patient, immediately after completion of the spinal anesthesia using a 10-cm Visual Analog Scale (VAS) and a 5-point Likert scale for satisfaction. Patients were also closely observed for symptoms of discomfort such as spontaneous vocalization and involuntary movement.

Results: A total of 88 patients completed the study. There was no significant difference in VAS scores, patient satisfaction, or procedure time between groups ($P > 0.05$). Spontaneous vocalization did not occur in both groups. However, incidence of unintentional movement during dermal puncture was higher in the control group (6.8% vs. 31.8%; $P < 0.05$).

Limitations: Study was conducted in a single-center with a relatively small population of patients. Only the attending anesthetist collecting data was blinded to the procedure. Patients older than age 65 years were also excluded from the study, thus our results cannot be generalized.

Conclusions: ShotBlocker did not show any advantage on VAS scores but decreased the incidence of unintentional movement during dermal puncture.

Key words: Spinal anesthesia, pain, ShotBlocker, needle, pin-prick pain, dermal puncture, neuraxial block, regional, needle phobia, lumbar puncture

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Spinal anesthesia is often preferred as a quick, reliable, and low-cost method for surgical procedures located on the lower extremities, lower body wall, and perineum. However, some patients

refuse spinal anesthesia owing to needle phobia (1). The main reason for the needle phobia is the pain associated with the needle, and it is still a problem for anesthesia practice. It affects nearly 10% of the population (2). In

a study, the reason for rejection of regional anesthesia due to needle phobia was 28% in obstetric patients (3). Needle phobia and pain may also complicate the procedure, affect the quality of spinal anesthesia, and induce syncope (2,4,5).

For optimal conditions and patient comfort during spinal anesthesia, different methods have been studied, such as local anesthetic infiltration, application of lidocaine patch, EMLA (eutectic mixture of local anesthetics) cream-patch, vapocoolant spray, and local anesthetic application with needle-free drug delivery systems (1,5,6). The use of topical local anesthetic methods is limited in clinical practice, as they need a long time for satisfactory effect (7). Use of local anesthetic infiltration with needle-free injection devices just before the procedure is also time-consuming and could interrupt the process and aseptic conditions if lower or upper intervertebral space is needed for needle reinsertion.

ShotBlocker (Bionix, Toledo, OH) is a flexible, plastic, U-shaped device, which has several short, rounded contact points on one side and a slit extending from the center for administering the injection (Fig. 1). As it is pressed against the skin, blunt points provide a nonnoxious physical stimulation and inhibit the transmission of injection pain according to the Gate Control Theory of pain (1,7). This device does not require wait time and need for preliminary preparation. We hypothesized that the use of the ShotBlocker for spinal an-

esthesia would decrease pain, prevent any involuntary movement during dermal puncture with spinal needle, and increase patient satisfaction.

METHODS

This was a prospective, randomized, controlled trial that investigated the effect of ShotBlocker for needle-related pain during spinal anesthesia. The study has been approved by the ethics committee of Medipol University (protocol 10840098-604.01.01-E.11890/190, May 16, 2017), registered with ClinicalTrials with identifier NCT03554122, and conducted between July and October 2018. Written informed consent was obtained from all patients. Ninety-four adult patients aged 18 to 65 years with physical status American Society of Anesthesiologists (ASA) I or II scheduled for elective surgery under spinal anesthesia were randomly assigned by computer-generated numbers to 1 of 2 groups.

Patients with intellectual disabilities that prevented completion of a Visual Analog Scale (VAS), receiving central or peripheral acting analgesics or sedatives, pregnant women, or patients with history of back surgery and back pain preventing adequate positioning, and any clinical contradictions to neuraxial blockade were excluded from the study.

In the preoperative period, all patients were informed of using VAS and received 10 to 15 mL/kg of intravenous crystalloid for 20 minutes before entering the operating room. Standard monitoring included 3-lead electrocardiogram, pulse oximetry, and noninvasive blood pressure measurements (Datex Ohmeda S/5 Patient Anesthesia Monitor, GE Healthcare, Helsinki, Finland). Before the procedure, sterilization of ShotBlocker device was controlled with indicator on the package. Each patient was positioned sitting for spinal puncture. After skin cleansing and application of sterile drapes under strict aseptic precautions, lumbar puncture was done at L3–L4 or L4–L5 intervertebral space using a 25-gauge spinal Quincke needle (Egemen 25-gauge, 90-mm Quincke Bevel Spinal Needle, Izmir, Turkey) without introducer by midline approach. General anesthesia was initiated when the spinal block was unsuccessful.

In the first group, lumbar punctures were performed with ShotBlocker. ShotBlocker was first put on the skin at the puncture site and pressed firmly with a nondominant hand. The slit of ShotBlocker was facing up to facilitate releasing after dermal puncture. Then the spinal needle was inserted to the skin from the slit of ShotBlocker targeting the route for subarachnoid

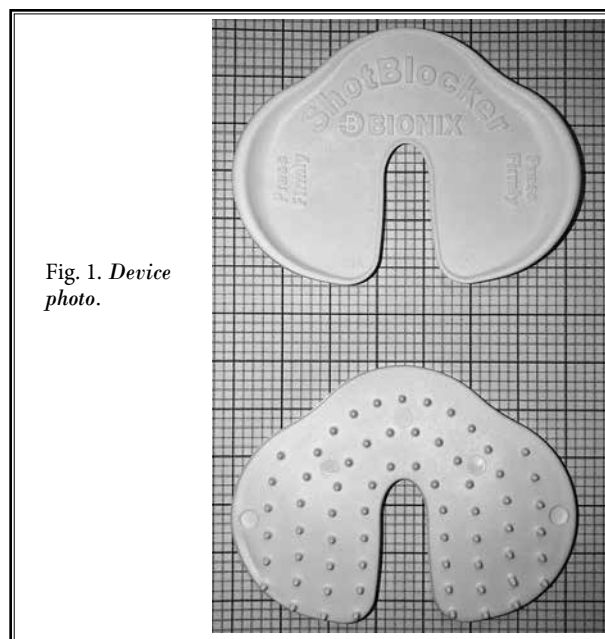


Fig. 1. Device photo.

space. After advancing the spinal needle through the skin, cutaneous tissue, and supraspinous ligament, the operator was allowed to release ShotBlocker, and spinal needle advanced until it reached the subarachnoid space. After achieving backflow of cerebrospinal fluid from the spinal needle hub, 2 to 3 mL 0.5% heavy bupivacaine was slowly injected, then the spinal needle was removed. Patients were informed before all steps of the procedure, especially during dermal puncture, and were closely observed by the attending anesthesiologist blinded to interventions for symptoms of discomfort, such as spontaneous vocalization and involuntary movement (8). In case of paresthesia during intrathecal injection, the spinal needle was removed, and alternative intervertebral space was used.

The quality of the surface landmarks was graded with ease of palpation and determination of neuraxial midline and interspinous gaps with a 4-point scale: easy, moderate, difficult, or impossible (9,10).

Needle-associated pain score and patient satisfaction were assessed by the patient, immediately after spinal anesthesia using a 10-cm VAS and 5-point Likert scale for satisfaction (1: very dissatisfied, 2: dissatisfied, 3: neutral, 4: satisfied, 5: very satisfied) (10). Demographic data and data including number of needle insertions and number of redirections and total procedural time were recorded by an independent observer. The number of redirections was defined as any change in insertion angle without complete withdrawal from skin. The number of needle insertion was defined as complete withdrawal and reinsertion. Total procedural time was defined as the time after handling the needle until subarachnoid injection. Adverse effects such as paresthesia, procedural complications such as bradycardia and hypotension, and block success were also recorded. Patients with multiple needle insertion attempts were excluded from statistical analysis.

Statistical analyses were performed with Statistical Package for Social Sciences Version 15 (SPSS Inc, Chicago, IL). A power analysis was performed with an assumption of a 30% decrease in the VAS score in the ShotBlocker group, and the required sample size was calculated as 44 patients for each group to detect an

existing difference with a power of 80% at a 0.05 level of significance. Continuous variables were expressed as mean \pm standard deviation (SD). Categorical data were presented as numbers and percentages.

Independent Student t-test was used to compare variables with normal distribution (age, body mass index), and the Mann-Whitney U test was applied for the evaluation of nonnormally distributed data (procedure time). Significance between categorical data were assessed either with the Fisher exact test or the χ^2 test. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 94 patients enrolled. Six patients were excluded for statistical analysis. A second needle insertion was required in 3 patients in the control group and 2 patients in the ShotBlocker group. Severe hypotension occurred after spinal anesthesia in 1 patient in the ShotBlocker group (Fig. 2). The patients' demographic data and clinical characteristics were similar in both groups (Table 1). General anesthesia was initiated for 1 patient in the control group due to incomplete block. There was no significant difference in VAS scores, patient satisfaction, or procedure time between groups (P

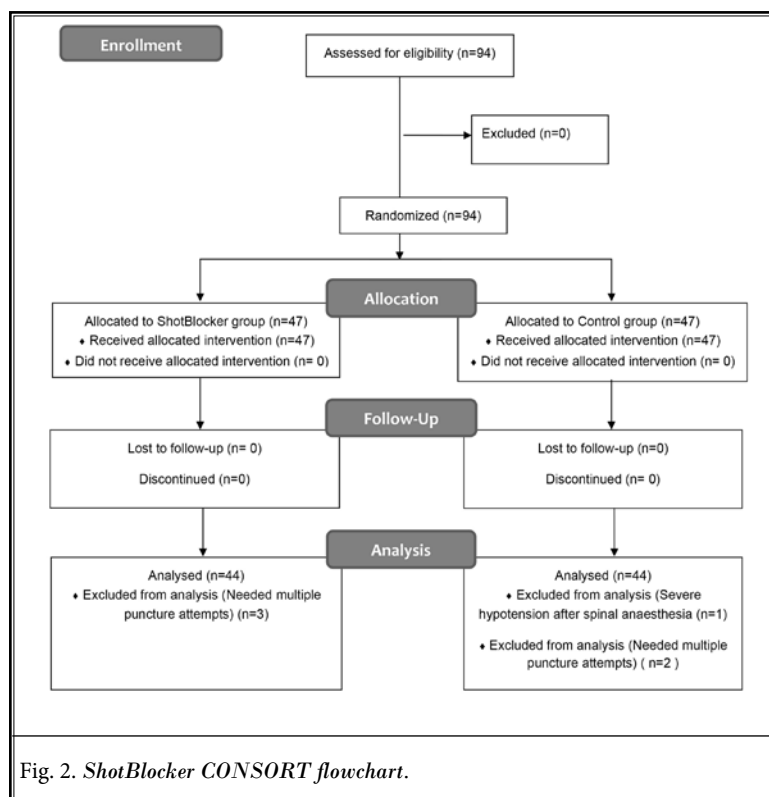


Fig. 2. ShotBlocker CONSORT flowchart.

Table 1. Demographic Data and Clinical Characteristics of the Patients

	ShotBlocker (n = 44)	Control (n = 44)	P value
Age	44.00 ± 17.13	37.34 ± 15.90	0.06
Gender (Female / Male)	6 / 38	4 / 40	0.50
ASA (I / II)	23 / 21	22 / 22	0.83
Body mass index, kg/m ²	26.86 ± 4.42	25.97 ± 4.66	0.36
Used Intervertebral Space L3-4 / L4-5	9 / 35	12 / 32	0.45
Quality of Anatomic Landmarks			0.80
Easy	17 (38.6%)	19 (43.2%)	
Moderate	23 (52.3%)	20 (45.5%)	
Difficult	4 (9.1%)	5 (11.4%)	
Impossible	0	0	

Data presented as mean ± SD. SD, Standard deviation or numbers (%)

> 0.05). Spontaneous vocalization did not occur in both groups. However, incidence of unintentional movement was higher in the control group during dermal puncture (Table 2).

DISCUSSION

When inserting spinal needles during spinal anesthesia, patients may experience pain during dermal and dural puncture, inadvertent needle impingement on periosteum, and any contact to cauda equine or nerve roots. Pain associated with this procedure may cause involuntary movement, which often disturbs the patient's posture and may affect the success of spinal anesthesia.

Some practitioners use routine local anesthetic infiltration before spinal anesthesia for designated intervertebral space. Injection of subcutaneous local anesthetic blocks pain transmission from the free nerve endings located in epidermis and dermis, however, subcutaneous and deeper injection of local anesthetics also causes pressure, discomfort, and pain (1,8,11). Many anesthetists are unsure that infiltration of local anesthetics has any advantage over a puncture without infiltration anesthesia (1,12). When spinal needle cannot be advanced from the designated intervertebral space, a lower or upper intervertebral space is usually used. In this situation, another dose of local anesthetic infiltration would be needed. There are also studies stating that infiltration of the skin and deep layers with 2 mL of 2% lidocaine has no benefit and consumes extra time (1,11).

In our clinical practice, we rarely use subcutaneous

Table 2. Results

	ShotBlocker (n = 44)	Control (n = 44)	P value
Needle redirection attempts (0 / 1 / 2)	37 / 6 / 1	36 / 8 / 0	0.52
Procedure time (seconds)	26.90 ± 20.74	30.81 ± 22.89	0.51
VAS scores	1.50 ± 0.72	1.60 ± 0.50	0.46
Unintentional Movement	3 (6.8%)	14 (31.8%)	< 0.05
Patient Satisfaction	4.70 ± 0.50	4.77 ± 0.52	0.53

Data presented as mean ± SD. SD, Standard deviation or numbers (%)

local anesthetic infiltration for spinal anesthesia procedure, especially when using Quincke spinal needles smaller in diameter than 25 gauge. However, during dermal puncture by the spinal needle patients complain of pain and involuntary movement is frequent despite warning the patient just before the puncture (8). This event often disturbs the patient's posture and may affect the success of spinal anesthesia.

EMLA patch and commercially available topical anesthetics are known to be effective to reduce needle-related pain for epidural or spinal needle insertion in adults (13,14). It is easily applied, and as an advantage when they cover a larger area, failures can easily be sustained without interruption from a lower or upper intervertebral space. The patch is commercially available as an adhesive dressing, which contains 1g of 5% local anesthetic emulsion in a matrix. It is easy to administrate and more suitable for patients waiting for surgery. It should be applied at least 90 to 120 minutes before the procedure (15). The long time to action and costs limits their clinical use, especially in busy day operating rooms (16). Koscielniak-Nielsen et al (1) compared the effects of EMLA patch and lidocaine infiltration and showed that puncture pain scores were significantly lower in the EMLA group when compared with placebo patch + infiltration and placebo patch groups with median VAS scores of 0.75, 1.75, and 1.80, respectively. However, median duration of patch application was 120 minutes (ranging 45–450 min), which is relatively long. Second, the authors did not standardized needle type, size, and the use of introducer. They also showed that lidocaine infiltration did not reduce VAS scores when compared with placebo patch. However, they used adrenaline as an adjunct to 2% lidocaine, and lower pH of solution may be responsible for these results as they stated.

Administration of vapocoolant spray with ethyl chloride is also found to be effective for needle-related pain for spinal anesthesia. A sudden decrease in skin

temperature by this cooling effect inhibits ion channel activation. Firdaus et al (6) compared vapocoolant spray and EMLA cream for reducing pain during spinal anesthesia and found no difference in pain scores and patient movement. They also stated that the majority of patients had movement regardless of pain during spinal injections, which may be related to many factors, such as anxiety and fear (6). In our study, VAS scores of patients who experienced unintentional movement during dermal puncture were higher (1.44 ± 0.59 vs. 1.98 ± 0.58 ; $P < 0.05$). These results can be explained by the fact that pain assessment can be affected by negative expectations or anxiety (17,18).

Needle-free drug delivery systems are generally based on the principle of using a spring plunger to create pressure, pushing a stream of liquid medication through a microscopic orifice. After skin contact, 0.1 to 0.5 mL can be injected to the skin with a depth of 5 to 8 mm (5,19). However, up to 1 mL of drug can be delivered with different types of needle-free drug delivery systems using compressed gas cartridges. It is alternative to infiltration anesthesia, and the analgesic effect occurs within 2 to 3 minutes (20). Gozdemir et al (5) compared pain during infiltration anesthesia with 27-gauge needle and a needle-free injection system (INJEX) for epidural needle insertion. They found that there was a significant difference in VAS during infiltration anesthesia between INJEX (0 [0-3]) and 27-gauge needle group (2 [0-4]), however, no difference was found in VAS during epidural needle insertion between groups (5).

Local anesthetic infiltration with needle-free injection devices may help pain associated with spinal needle-related pain but it consumes extra time and can interrupt the process and skin disinfection when trying upper or lower intervertebral space after an unsuccessful attempt. Skin disinfection is needed before and after performing needle-free injection systems. Costs also prevent a more widespread use of this technology (19).

ShotBlocker was designed especially for intramuscular and subcutaneous injections, such as vaccination, so it may be a little difficult to use during spinal anesthesia. Requirement for pressing the device firmly with one hand could make the procedure difficult. The technical difficulty of spinal blockade was evaluated

with parameters such as procedure time, number of needle insertions, and redirection. However, there was no significant difference between groups in our study.

In literature, the majority of studies with ShotBlocker were conducted in children receiving vaccination and results are conflicting. Some authors revealed that ShotBlocker did not affect pain scores (7,21). Drago et al (7) evaluated ShotBlocker with children aged 2 months to 17 years. Although parents and nurses rated children's pain lower, there was no significant difference in children's self-reported pain using the Wong-Baker Faces Pain Rating Scale (7). Cobb and Cohen (21) evaluated ShotBlocker with children aged 4 to 12 years.

They reported inverse correlations between children's age and all ratings of pain and anxiety. Their results revealed no significant differences on pain and anxiety (21). However, confounding factors in children's expression of pain should also be considered.

The authors referred to the Gate Control Theory (22) for the immediate effects of the ShotBlocker for intramuscular injection pain (7,17,23,24). ShotBlocker could inhibit the transmission of action potentials from small-diameter fibers by activating inhibitory interneurons in the dorsal spinal roots with a tactile stimulation with multiple blunt points. However, in our study VAS scores for both groups were similar, but unintentional movement during dermal puncture was significantly lower in the ShotBlocker group.

CONCLUSIONS

This study was conducted in a single-center with a relatively small population of patients. Patients older than age 65 years were excluded from the study because paramedian approach would be needed. Also, a placebo group was not included. The flat side of ShotBlocker could be used as a placebo intervention. Finally, only the attending anesthetist who observed the patient was blinded to the study as it was impossible to blind the patient and anesthetist. Despite these limitations, to our knowledge, this is the first study conducted with ShotBlocker for spinal needle-related pain.

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