Original Contribution

Efficacy of ShotBlocker in reducing pediatric pain associated with intramuscular injections☆

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Abstract

Objective: The aim of the study was to determine the efficacy of ShotBlocker (Bionix, Toledo, Ohio) in reducing pediatric pain with intramuscular (IM) injections.

Methods: A prospective randomized controlled trial was conducted in children aged 2 months to 17 years who required an IM injection. Children were randomized to the no-intervention group or the ShotBlocker group. Demographic data and the number of IM injections were recorded. Perceived pain scores were obtained from nurses and caregivers using a 6-point Likert-type scale. Baker Wong Faces scale was used in children 36 months or older. Difficulty using the device was also rated by nurses on a 6-point scale.

Results: One hundred sixty-five children were enrolled with 80 in the no-intervention arm and 85 in the ShotBlocker arm. The mean age of children was 45 months and 56% were male. Perceived pain scores by nurses were higher for the no-intervention group (2.6 vs 1.8, P < .001) as well as by caregivers (2.6 vs 2.1, P = .04). Children aged 36 months and older (n = 64) did not report a difference in pain scores (1.5 vs 1.3, P = .6); however, in a subgroup of children 72 months or older, pain scores trended higher in the no-intervention group (1.3 vs 0.5, P = .051). Nurse-perceived difficulty of ShotBlocker use was low 1.39 (±1.1).

Conclusions: Nurses and caregivers noted lower pain scores in children assigned to the ShotBlocker group. These differences were not as evident when children rated their own pain.

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1. Introduction

Intramuscular (IM) injections are a common painful part of routine health care and pediatric emergency department
(ED) visits. Current recommended immunization schedules require children to receive up to 20 separate injections before reaching 2 years of age, depending on the combination of vaccines used [1]. In 2001, the American Academy of Pediatrics and the American Pain Society jointly released a policy statement addressing pediatric pain. This statement acknowledged that children’s pain is often inadequately controlled and provided recommendations for minimizing pediatric procedural pain. Proposed reasons for pediatric oligoanalgesia include a general misunderstanding of pediatric pain, time constraints in a busy ED or office, health care provider lack of knowledge of children’s developmental stages and pain awareness, and concerns about using prophylactic or therapeutic pharmacologic treatments in children [2].

The ramifications of insufficient pain control in children extend beyond the immediate painful encounter. Pediatric and parental anxiety regarding painful procedures has been demonstrated to detract from other aspects of the health care visit. In 2007, an evidenced-based review of pain reduction during pediatric immunizations noted that children and parents have substantial concerns about the pain associated with injections. Children’s anxiety about injections often detracted from other important aspects of the visit such as anticipatory guidance and health care instructions, and parental anxiety adversely affected compliance with their children’s medical care [1].

Interventions would ideally be inexpensive, noninvasive, and rapidly applied to improve pediatric pain control. One device that is not yet approved by the Food and Drug Administration but is undergoing testing is the ShotBlocker (Bionix, Toledo, Ohio), a drug-free plastic device that is pressed against the skin during injection. It requires no advance preparation or wait time and has no known side effects. The ShotBlocker has a number of short blunt contact points on the underside that are placed directly on the skin before injection with a central hole for administering the injection (Fig. 1A and B). These points do not puncture the skin and provide the stimulus for the gate theory, a pain pathway postulated by Melzack and Wall [3,4]. They theorized that both large- and small-diameter peripheral nerve fibers carry pain and pressure stimuli to the central nervous system where a gate mechanism modulates the pain signal [3,4]. The proposed mechanism of action of the ShotBlocker is that the application of pressure to the skin excites the smaller-diameter, faster fibers. This stimulation closes the gates to the central nervous system, temporarily blocking the slower pain signals of the injection. In theory, this simple, noninvasive device should decrease the pain associated with IM injections. To our knowledge, this device has not yet been formally tested in a large sample of pediatric patients. We hypothesized that the use of the ShotBlocker as compared to standard of care (no intervention) would decrease pediatric pain as measured by validated pediatric pain scales.

2. Materials and methods

The objective of this prospective randomized controlled trial was to measure the efficacy of the ShotBlocker in a convenience sample of children receiving IM injections as part of their medical care. This study was approved by the Cooper University Hospital institutional review board, and informed written consent was required of all caregivers. Subject assent was additionally required of children aged 12 to 17 years.

2.1. Study setting and population

Subject screening and enrollment were performed in an outpatient pediatric clinic with annual census of 12,500 and an urban, academic pediatric ED with annual census of 9,500 from October 2005 to November 2006. Caregivers of children presenting to the outpatient clinic and pediatric ED were approached by one of the investigators for consent if their child was aged 2 months to 17 years and required an IM injection as part of their medical care. Children were not
eligible if they were critically ill, had developmental delay or impaired communication making pain assessment difficult, or if they or their caregiver refused to participate. In addition, children who were previously enrolled in this investigation during a prior visit were excluded.

2.2. Study protocol

Block randomization (4 subjects in each block) was performed using the Web-based program, Research Randomizer (www.randomizer.org) [5]. Sequentially numbered, sealed subject enrollment packets were prepared before the initiation of the study. Once informed consent was obtained, the seal was broken and the child’s assignment to either the intervention or control group was completed. A standardized questionnaire was completed by all caregivers immediately after randomization of their child. After the questionnaire was completed, IM injections were administered by 5 trained nurses (2 nurses from the outpatient clinic and 3 pediatric ED nurses) who followed a strict protocol. The investigator who enrolled the patient described the injection procedure using a prepared script describing what the nurse was doing in a factual manner while the nurses performed the IM injection. All injections were given using a 25-gauge 5/8-in needle. Nurses were required to gently cleanse the area with an alcohol pad and not to rub or pinch the area before or during the injection. For children randomized to the intervention arm, nurses were instructed to place the ShotBlocker with the contact points touching the patient’s skin. They were then instructed to press firmly and administer the injection through the central opening. If more than 20 seconds elapsed between placement of the ShotBlocker and administration of the injection, nurses were instructed to start the preparation over. To ensure strict compliance with this protocol, the principal investigator made weekly assessments of the nurses’ injection administration techniques and also monitored the other investigators involved in subject recruitment. In cases where nurses deviated from the protocol, immediate remediation was provided. Immediately after the administration of the IM injections, nurses, caregivers, and children 36 months and older completed pain scores.

2.3. Measurements

The standardized questionnaire recorded demographic data including race, ethnicity, age of child, reason for visit, type of immunization(s), and the number of months since the child’s last injection. In addition, caregiver perception of their child’s pain with prior IM injections was recorded using a written horizontal 6-point Likert-type scale (0 = no pain, 5 = severe pain, as the only defined anchors). Immediately after injections were administered, caregivers, nurses, and children aged 36 months or older completed postinjection

![Flowchart of enrollment and randomization.](image)
pain scores. The Baker Wong Faces scale (0 = smiling, 5 = sobbing) was used by children aged 36 months and older to self-report their pain. This scale has been validated in this pediatric (≥36 months) population [6]. Children aged younger than 36 months did not provide a pain score. For all children, both caregivers and nurses also provided their assessment of the child’s pain using the 6-point written horizontal Likert-type scale.

In addition to the pain scores, nurses were asked to rate the difficulty of using the ShotBlocker when giving an injection. This score also uses the same 6-point written horizontal Likert-type scale, where 0 = no difficulty and 5 = most difficult. Finally, the number and location of injections given were also recorded.

2.4. Data analysis

The primary outcome was children’s self-reported pain scores. Using data from a preliminary study, where the within-group SD of pain scores was 1.4, a sample size of 32 subjects in both arms were required to achieve a power of 80% and a 2-sided \( \alpha \) of .05 to detect a mean difference in pain scores of 1.0 between the 2 groups (PS version 2.1.31). All data analyses were performed using SPSS version 15.0 (SPSS, Chicago, Ill). Categorical data are presented as frequencies and proportions. Continuous data and pain and perceived difficulty scores are presented as means with SDs. \( \chi^2 \) test or Fisher exact test was used to compare proportions, and the Mann-Whitney \( U \) test was used to compare pain and difficulty assessments. For the purpose of this investigation, the mean values of the pain and difficulty scores are provided instead of medians and interquartile ranges. It was thought that the latter would not have provided the reader with sufficient information about the differences between the 2 groups. In cases of pain and difficulty scores, the \( P \) values reflect the results of nonparametric testing, with a \( P \) value of .05 or less considered statistically significant.

3. Results

Over a 13-month period, 185 children were eligible and 165 children were enrolled, 64 of whom were old enough to provide pain scores. A flow diagram illustrating participant enrollment and group allocation is shown in Fig. 2. There were no differences in baseline characteristics between groups, including previous immunization history and caregiver-perceived pain with the most recent immunization. With this immunization, most children (92%) presented for a routine well child visit or specifically to update their immunization status. Baseline characteristics are presented in Table 1.

Perceived pain scores by nurses and parents differed for the conventional and ShotBlocker groups. Children aged 36 months or older (n = 64) did not report a difference in pain scores using transformed Baker Wong pain scores, whereas pain scores in children 72 months or older suggested there might be a difference (Table 2). Pain score distributions for children who were able to provide pain score are presented in Fig. 3A and for older children (≥72 months) in Fig. 3B. The post hoc analysis of children aged 72 months and older was conducted after it became evident that there may have been a
difference in pain scores in older children. The distribution of pain scores for caregivers and nurses are presented in Fig. 3C and D, respectively. Nurse-perceived difficulty with the ShotBlocker is presented in Fig. 4.

4. Discussion

In the United States, children receive as many as 5 immunizations at each well child visit and a total of 26 by their 6th year [7]. Given the large number of injections administered to children, pain and anxiety levels are high and have been found to detract from routine care [1]. In a study examining routine pediatric immunization practices, investigators determined that 58% of physicians did not provide children with any topical or oral pain relief [8]. Similar rates for the management of pediatric procedural pain were noted.
in recent study examining pediatric emergency medicine physicians’ self-reported pain management strategies during their fellowships. Pain management strategies were compared from 1996 and 2004. Although there was an increase in the self-reported use of analgesics over this 8-year period, only 18% were using topical/local anesthetics for painful procedures such as venipuncture by 2004 [9]. Similarly, a study examining venipuncture and injections in a pediatric hospital demonstrated that only 19% of these procedures were performed using a topical anesthetic [10].

In an effort to reduce injection pain, numerous techniques have been used. Topical anesthetics such as eutectic mixture of local anesthetics (EMLA, lidocaine 2.5% and prilocaine 2.5% Abraxis Pharmaceutical Products, Schamburg, Ill) and LMX (formerly ELA-max; Ferndale Laboratories, Inc, Ferndale, Mich) have been shown to be effective in reducing the pain associated with many painful pediatric procedures such as blood draws, placement of intravenous lines, dermatologic procedures such as intralesional injections, infiltration of local anesthetics, and digital nerve blocks [11-15]. Although relatively effective, these topical anesthetics have several limitations. Topical anesthetics require a substantial amount of time before they are effective (EMLA 60 minutes and ELA-Max 30 minutes) [11]. This time delay is often impractical in a busy clinical practice or ED. Even in settings where protocols dictate the immediate application of topical anesthetics by trained nurses at patient presentation, the need for such an application cannot always be anticipated. When this occurs, child comfort is often sacrificed for the sake of expediting care and improving overall patient throughput. Additional limitations of topical anesthetics are their associated side effects. Local side effects such as erythema, edema, and hyperpigmentation have been reported [16,17]. Allergic reactions such as allergic contact dermatitis secondary to the prilocaine and localized purpura have also been noted [17-20]. Eutectic mixture of local anesthetics has been associated with methemoglobinemia in neonates, especially in premature infants. There have been multiple case reports of infants developing methemoglobinemia during circumcision, heelsticks, venipuncture, and treatment of hemangiomas when EMLA was used as a topical anesthetic. Complications of methemoglobinemia included mottling of the skin, cyanosis, and associated hypoperfusion, with some children requiring oxygen and intravenous fluids in an intensive care setting [21-24]. Finally, there is also significant cost to these creams—up to $10 an application [11,12]. In comparison, the ShotBlocker average cost is approximately 70 cents per application [25]. Although other topical applications are available, such as vapocoolant sprays, these measures have not been consistently found to decrease immunization-associated pain, with current studies present conflicting results [26-28]. Furthermore, the sudden cooling or burning sensation caused by these sprays may further increase preinjection anxiety in children. Associated side effects of vapocoolant sprays include change in skin pigmentation, corneal damage, and dermatitis. Another risk in their use is that they are highly flammable [29].

Given the aforementioned limitations of topical anesthetics, a rapidly applied, inexpensive, noninvasive device that can reduce pain associated with IM injections would be ideal. The ShotBlocker’s theorized mechanism of action suggests that this device would be effective in reducing immunization pain. At this time, there are no peer-reviewed publications evaluating the efficacy of the ShotBlocker. An Internet search using the Google search engine using the search terms pediatric pain, shotblocker, and IM injections was conducted. This search strategy yielded 4 studies: 2 studies published only as abstracts on the Bionix site, a study published as a report in a nursing newsletter, and a masters thesis study. The first study from the manufacturer’s Web site was conducted in the Philippines and included 119 pre-kindergarten-aged children receiving one immunization. Fifty-nine children were randomized to the ShotBlocker group and 60 to the no-intervention group. Children reported their pain using the Baker Wong faces scale. Most of the children in the ShotBlocker group (93.2%) reported mild to no pain as compared to 51.7% in the no-intervention group (P<.01) [30]. The second study was conducted in the United States by the Family Physicians Association of Flower Hospital, Sylvania, Ohio, and included 99 children 5 years and older who were receiving immunizations. Although the authors concluded that the ShotBlocker significantly reduced pain and discomfort associated with routine immunizations, no data are provided in the abstract. Of the remaining 2 investigations, the first was a full-length investigation that was published in a nursing research newsletter. The investigators reported no significant difference in pain between the control or intervention group in children aged 3 months to 17 years [32]. In the second study, a graduate thesis, 89 children aged 4 to 12 years were randomized into 3 groups: a Shotblocker group (n = 29), a placebo group (n = 29), and a no-intervention group (n = 31). This study included child, caregiver, and health care professional assessments of pain. The investigator concluded that the ShotBlocker did not significantly reduce children’s pain during immunizations [33].

In contrast, the results of our study demonstrated the ShotBlocker’s effectiveness in reducing immunization pain as perceived by caregivers and nurses. Nurses reported mean pain scores of 2.6 without the ShotBlocker compared to 1.8 with the ShotBlocker. Caregivers also noted reduced pain scores of 2.6 vs 2.1, with the implementation of the ShotBlocker. Of all enrolled children, self-reported pain scores were the least affected by the ShotBlocker. However, when a subgroup of slightly older children was examined (children ≥6 years of age), the pain scores in the ShotBlocker group were lower than those in the standard of care group (P = .04). Because these differences in pain scores were revealed during the analysis phase of the study, well after data collection efforts had ceased, we were unable
to investigate further. It remains unknown if these results were due to limitations of the Baker Wong pain scale in our younger cohort or if the ShotBlocker may be more efficacious in the older pediatric population.

Nurses rated the device as easy to use, an aspect of the injection process not previously examined by other investigators. In this study, nurses rated the ShotBlocker at 1.7 using a scale of 0 to 5, with 0 as the easiest to use and 5 the most difficult. This finding is noteworthy. Had the nurses found this device difficult to use, it would have greatly limited its application in the clinical setting.

There were several limitations in this study. The first is that our study population was a convenience sample, and this introduces the possibility that our data do not reflect the general population. We attempted consecutive enrollment; however, this was not always possible on very busy clinic days or in our crowded ED with limited study personnel. A second limitation is the lack of blinding. There was no way to blind parents, children, or nurses using a placebo device. In theory, any pressure applied to the skin will act as a ShotBlocker via the gate theory mechanism of pain. Our results may additionally have been influenced by the presence of the ShotBlocker, that is, a placebo effect in the nurses and caregivers. This placebo effect may not have influenced the younger children who were unaware of the goal of the device. Yet, it may have had some bearing on the pain scores of the older children. The sample size estimation was based on children (≥36 months) able to rate their own pain score using the Baker Wong Faces scale and to provide 80% power to detect a difference of 1 on this 6-point scale. Thus, our findings still have at least a 20% chance of a type II error (failure to detect a difference when one truly exists). Most (61.2%) of the children in this study were older than 36 months. Furthermore, only 28 children were enrolled in the no ShotBlocker arm as opposed to the proposed 32. However, even if 4 additional children rated their pain at the maximum pain score of 5, there still would not have been a statistically significant difference between groups because of the predominance of younger children. Thus, the study was concluded with the enrollment of the 64th child.

In conclusion, the ShotBlocker is an easily applied device to reduce caregiver and nursing perceived pain associated with pediatric IM injections. Furthermore, it was deemed easy to use by the nurses who routinely administer these IM injections. Although we were not able to demonstrate an improvement in self-reported pain in children 36 months or older, we were able to demonstrate an improvement in pain scores in the older children who were assigned to the ShotBlocker arm. Given our encouraging findings and those of previous investigators, a larger study should be conducted using a greater number of children divided into at least 3 separate age groups [30-33]. Given the relatively low cost of this device and the minimal risks in its use, a larger trial should be conducted to ascertain whether the improvements in pain scores are maintained in various pediatric age groups.

References

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