Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?

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Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

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In

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Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not “Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?”

STUDY DESIGN: A systematic review of three nonblinded, randomized controlled trials (RCTs). All studies were published in English between 2018 and 2019.

DATA SOURCES: Three RCTs were obtained from PubMed and published in peer-reviewed journals. The studies were chosen based on their relevance to the clinical question.

OUTCOMES MEASURED: In all of the articles used for this review, the main outcome measured was pain reduction. The participants’ level of pain was measured with either the Faces Pain Scale-Revised (FPS-R) or the Oucher Scale. Self-reported pain levels were assessed either immediately after the procedure was completed, one minute after the procedure was completed, or during the procedure.

RESULTS: In the RCT conducted by Bilgen et al., there was a significant reduction in pain with the use of Buzzy® compared to the control group. The mean pain difference between the control group and Buzzy® group was 3.72. The p-value was calculated to be <0.001, making this study statistically significant with a large treatment effect. The RCT conducted by Sahiner et al. showed a mean pain difference between the control group and Buzzy® group of 1.94, with a calculated p-value of 0.008. This study was shown to be statistically significant and had a large treatment effect. In the RCT conducted by Alemdar et al., the mean pain difference was 2.36 with a p-value of 0.001. The study was found to have a large treatment effect and statistically significant.

CONCLUSIONS: Statistical significance was found in all RCTs based on the calculated p-values. The Buzzy® intervention group in each study showed a large treatment effect when comparing pain levels to the control group. The results of this review are conclusive and show that the use of Buzzy® to reduce needlestick pain in children is effective. Future studies could be conducted with blind raters.

KEYWORDS: Buzzy®, needlestick, pain, children
INTRODUCTION

Needles are used to accomplish a variety of medical procedures in both children and adults every day in outpatient and inpatient settings. There is a broad spectrum for the use of needles in the healthcare field, including medication administration, venous access, and more. More specifically, certain antibiotics such as penicillin G or ceftriaxone, are given to patients via intramuscular injections using a needle. When a patient requires continuous administration of fluids or administration of a medication directly into the venous blood stream, an intravenous (IV) catheter will be placed in the arm or hand of the patient using a needle to penetrate the skin and vein. Phlebotomy is another common medical procedure, and it is performed when a needle is used to access a vein one time to draw blood for laboratory tests.

Vaccines are a common practice in the United States and are administered to children and adults via a needle as well. The number of injections for children have increased from six to thirty total injections as the vaccine recommendations have changed over the years.¹ In the United States specifically, the recommend vaccines for all children between the ages 5 and 12 years old includes DTaP, IPV, MMR, varicella, influenza, HPV, and meningococcal disease vaccines, all requiring the use of a needle.²

Other necessary medical procedures that involve a needlestick are subcutaneous insulin injections. Children diagnosed with type 1 diabetes mellitus require daily insulin injections with a needle to manage their blood glucose levels appropriately. According to the Juvenile Diabetes Research Foundation (JDRF), there are about 200,000 people under the age of 20 years old who live with type 1 diabetes mellitus and require insulin injections in the United States.⁵ These patients must endure multiple painful injections throughout the day, every day, and at multiple sites on the body.
While a needlestick can be painful for a patient of any age, children are more susceptible to experiencing clinically significant pain than adults.\textsuperscript{6} With children, the response to pain is determined by genetic factors, prior experiences, and developmental factors.\textsuperscript{6} When a child endures a painful medical procedure such as needlesticks, negative repercussions may occur including the development of needle phobia.\textsuperscript{6} The child may become scared of needles and healthcare professionals, and they can become reluctant to cooperate during such interventions.\textsuperscript{6} If a child experiences a painful medical procedure with a needle, they may feel more anxious and tense in subsequent situations which can lead to heightened pain.\textsuperscript{6} In children, the fear of needles has grown from 25\% in 1995 to 63\% in 2012.\textsuperscript{1} The provider administering the vaccine may end up spending more time trying to console the child and get them to cooperate for the procedure. This fear and reluctance can interfere with the child receiving proper treatment for an illness or interfere with compliance to immunization schedules.

A standard needlestick procedure most commonly involves informing the patient about the procedure prior to beginning, cleaning the intended injection area, and using the proper injection technique for the type of injection being performed. A bandage can be applied over the injection site after the procedure is done. Distraction is often used in attempt to reduce needlestick pain in children by offering the patient positive reinforcement, a toy, or a sticker as a reward.

The Buzzy\textsuperscript{®} device is applied to a child’s skin to decrease the pain that is felt when a needlestick procedure is being performed, such as vaccinations, IM injections, and subcutaneous injections. The device works by utilizing the gate control theory of pain, which involves the stimulation of different types of nerve fibers in the body.\textsuperscript{8} Nerve fibers that send pain signals to the brain are called A-delta and C fibers.\textsuperscript{8,9} In contrast, the nerve fibers that send non-painful
signals to the brain, such as vibration and touch, are called A-beta fibers. The vibration from Buzzy® works to block the pain signals to the brain that come from A-delta and C fibers by stimulating the A-beta nerve fibers and activating an inhibitory response. In addition to the vibration, Buzzy® has an attachable cold pack that works to reduce pain during a needlestick procedure by using descending inhibitory pain modulation. When the cold pack is applied to the skin, C fibers are activated and block the A-delta fibers that recognize pain. By stimulating the C fibers with the cold pack, a slower pain and thermal signal is sent to the brain, activating a supraspinal modulation which leads to an increase in the body’s pain threshold. This paper evaluates three randomized controlled trials that study the use of Buzzy® to reduce needlestick pain in children compared to the pain experienced with standard needlestick care without a pain reducing intervention.

**OBJECTIVE**

The objective of this selective EBM review is to determine whether or not “Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?”

**METHODS**

The criteria that were used to select the three randomized controlled trials discussed in this systematic review included the investigation of the use of Buzzy® and its effectiveness in reducing needlestick pain in children. The studies that were chosen were found on PubMed and all of the articles were published in peer-reviewed journals using the English language. The three RCTs look at the use of the device, Buzzy®, compared to standard needlestick care and measured the outcome of pain intensity either during or after the needlestick procedure. The population being studied in this systematic review includes children between the ages 5 and 12 years old.
The keywords used to select relevant articles were “Buzzy” and “pain.” The studies were chosen based off of the age group that was studied in each article, the patient-oriented outcome measured, and their clinical relevance to the review’s question, “Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?” The inclusion criteria for the selection of studies were randomized controlled trials and children as the population being studied. Exclusion criteria included secondary studies, primary studies that were not RCTs, studies whose population was not children, and studies dated prior to 2015. The statistics reported in the articles for measuring the outcome of pain intensity were p-values, mean, standard deviation, and median. Table 1 shown below contains the demographics in the studies.

**OUTCOMES MEASURED**

The major outcome measured in the RCTs was the reduction of pain intensity for children who underwent a needlestick procedure. Subjective pain intensity was measured using the Faces Pain Scale-Revised (FPS-R) in the articles conducted by Bilgen et al.\(^{10}\) and Sahiner et al.\(^{11}\) The FPS-R uses six different facial expressions that are ranked on a scale of zero to ten according to the level of pain intensity, with zero representing no pain and ten representing the most pain.\(^{11}\) The children using this scale did not need to understand numbers or words, therefore making it an ideal way to accurately measure their pain.\(^{10}\) In the study conducted by Bilgen et al.,\(^{10}\) the children were asked to select their pain level based off of the FPS-R after the 1st minute following the needlestick. In the study conducted by Sahiner et al.,\(^{11}\) the FPS-R was given to the children to assess their pain level immediately after the needlestick.

The study conducted by Alemdar et al.\(^{12}\) measured the pain intensity of the participants using the Oucher Scale. This scale has two parts; one part consists of six pictures of children with different facial expressions based on their pain level, and the other part is a numerical scale
with the numbers 1 through 10 on it. The children who were able to determine which number on the scale was larger were able to point to the number in which they thought coordinated with their pain levels, and the children who were unable to decipher the larger of two numbers pointed to the facial expression they believed represented their pain level.

Table 1. Demographics & Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th># Pts</th>
<th>Age (yrs)</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>W/D</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alemdar^{12} (2019)</td>
<td>RCT</td>
<td>78</td>
<td>5-10</td>
<td>5-10 years old, requiring blood tests, accompanied by family member</td>
<td>Use of another local anesthetic, signs of skin infection at site, significant trauma/disease needing rapid evaluation, developmentally delayed, chronically ill, altered sensorium, allergic to lidocaine, neurosensory deficit</td>
<td>0</td>
<td>Buzzy® was applied to the injection area</td>
</tr>
<tr>
<td>Bilgen^{10} (2019)</td>
<td>RCT</td>
<td>100</td>
<td>7-12</td>
<td>Children 7-12 years old who presented to the Pediatric Emergency Clinic, required IM injection of procaine penicillin</td>
<td>Presence of a disease that causes chronic pain, neurodevelopmental disorders, analgesics use within the last 6 hrs, hx of fainting during injection, learning disabilities</td>
<td>0</td>
<td>Buzzy® was applied to the injection area</td>
</tr>
<tr>
<td>Sahiner^{11} (2018)</td>
<td>RCT</td>
<td>40</td>
<td>6-12</td>
<td>Patients diagnosed with Type 1 Diabetes Mellitus, insulin injected by the same nurse, children cognitively able to rate their pain and anxiety</td>
<td>Patients with pacemakers, infection/rash/ deteriorated skin integrity, nerve damage, critical or unstable health status, intellectual disabilities, analgesic use within 6 hrs of procedure, Reynaud’s Syndrome, SCD, unwilling to participate</td>
<td>0</td>
<td>Buzzy® was applied to the injection area</td>
</tr>
</tbody>
</table>
RESULTS

Sahiner et al.\textsuperscript{11} conducted a randomized controlled trial to evaluate the level of pain intensity children between the ages 6 and 12 years old experienced with insulin administration. The population studied included children diagnosed with type 1 diabetes mellitus who required routine insulin injections at the Child Endocrinology Department in Eskisehir Osmangazi University.\textsuperscript{11} This study was conducted between May 2015 and June 2017. The control group and the Buzzy\textsuperscript{®} intervention group each consisted of 20 children.\textsuperscript{11} The children were randomly placed in either group based upon which color ball they blindly and randomly chosen from within a black bag.\textsuperscript{11} For the control group, the participants were only informed that they were about to receive an injection.\textsuperscript{11} The intervention group used Buzzy\textsuperscript{®} during the administration of the insulin injection.\textsuperscript{11} Buzzy\textsuperscript{®} was placed on the surface of the participant’s skin, 5 centimeters above the injection site, prior to administration.\textsuperscript{11} The low frequency vibration and the cold pack were kept on the skin until the administration of insulin was complete.\textsuperscript{11}

The children were asked to record their pain level immediately after the procedure was completed using the Faces Pain Scale-Revised.\textsuperscript{11} The scale consisted of six varying facial expressions alongside a numerical scale between 0 and 10, with 0 representing no pain and 10 representing the most pain.\textsuperscript{11} The statistical data used to measure the pain intensity in the study by Sahiner et al.\textsuperscript{11} was presented as mean values, standard deviation, median, and p-values. The control group showed a mean self-reported procedural pain score of 3.2 with a standard deviation of 2.78.\textsuperscript{11} This was higher than the intervention group that used Buzzy\textsuperscript{®}, which showed a mean procedural pain score of 1.26 with a standard deviation of 1.36.\textsuperscript{11} The mean pain difference between the control group and the Buzzy\textsuperscript{®} group was 1.94, resulting in a large treatment effect.\textsuperscript{11} The median pain score for the control group was 4.00 compared to the median pain
score of the Buzzy® group which was 2.00. The calculated p-value for the self-reported procedural pain scores was 0.008, therefore statistical significance is present in this study.

Resultant values from this study are shown in Table 2 as seen below.

**Table 2. Comparison of Procedural Pain Scores of the Study Groups (data from Sahiner et al.)**

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
<th>Mean Difference Between Groups (calculated)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>3.2 (2.78)</td>
<td>4.00</td>
<td></td>
<td>1.94</td>
</tr>
<tr>
<td>Buzzy Group</td>
<td>1.26 (1.36)</td>
<td>2.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bilgen et al. conducted a randomized controlled trial that compared the level of pain intensity experienced in routine needlestick procedures compared to needlestick procedures using Buzzy®. The participants included children between the ages 7 and 12 years old who required an intramuscular (IM) injection of procaine penicillin at the Pediatric Emergency Clinic in Turkey between September 2014 and February 2015. A computer program that randomized numbers was used to randomly assign participants to the control group or the Buzzy® group. The control group and Buzzy® group each consisted of 50 children.

The Buzzy® device and the attachable cold pack were applied to the skin of the participants about 3 to 5 centimeters above the injection site. The vibration and cold pack were used for an average of 60 seconds prior to the needlestick and remained in contact with the skin until after the procedure was completed. The children in the control group received a routine administration of procaine penicillin without any accessory device to modify pain.

The outcome measured in the study by Bilgen et al. was pain intensity. The Faces Pain Scale-Revised was used to evaluate the level of pain the participants felt after the first minute following an IM injection. The statistical data for this study was presented as mean values,
standard deviation, and p-values.\textsuperscript{10} The control group demonstrated a FPS-R mean score of 7.36 with a standard deviation of 3.09 for the evaluation of pain one minute after the injection was administered.\textsuperscript{10} In comparison, the Buzzy\textsuperscript{®} group demonstrated a mean pain score of 3.64 with a standard deviation of 3.10.\textsuperscript{10} The calculated mean pain level difference between the two groups was 3.72. The p-value for the pain score one minute following the injection was <0.001, making the statistic highly significant with a large treatment effect.\textsuperscript{10} Values for this study can be seen in Table 3 as seen below.

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>Mean Difference Between Groups (calculated)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>7.36 ± 3.09</td>
<td>3.72</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Buzzy\textsuperscript{®} Group</td>
<td>3.64 ± 3.10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Alemdar et al.\textsuperscript{12} conducted a RCT to evaluate self-reported pain intensity in participants requiring blood tests and needlestick procedures. The participants were children between the ages 5 and 10 years old who required phlebotomy procedures in the Phlebotomy Unit of a Maternity and Children Training and Research Hospital in Turkey.\textsuperscript{12} This study was conducted at this location between May 2016 and September 2017. A computer program was used to randomly assign each child to a specific group.\textsuperscript{12} The control group included 39 children and they received no pain relief interventions.\textsuperscript{12} The intervention group utilized Buzzy\textsuperscript{®} and contained 39 children as well.\textsuperscript{12}

Venipuncture procedures were done by pediatric nurses on each child and required use of a Vacutainer\textsuperscript{®} system and 21G butterfly needle.\textsuperscript{12} The Buzzy\textsuperscript{®} device and its attachable cold pack were placed on the skin 3 to 5 centimeters above the venipuncture site, held in place for 30 to 60 seconds prior to the needlestick, and continued until the venipuncture was completed.\textsuperscript{12} The
children in this study by Alemdar et al.\textsuperscript{12} were asked to rate their pain using the Oucher Scale during the phlebotomy procedure.

The statistical data used to measure the level of pain experienced by each group of children was presented as mean values, standard deviation, and p-values.\textsuperscript{12} The control group showed a mean Oucher score of 5.87 with a standard deviation of 2.87 during the venipuncture procedure.\textsuperscript{12} The Buzzy® intervention group demonstrated a mean Oucher score of 3.51 with a standard deviation of 3.49.\textsuperscript{12} The p-value for Oucher scores during venipuncture was 0.001, making this data highly significant.\textsuperscript{12} The mean difference between the control group pain score and the Buzzy® group pain score is 2.36, demonstrating a large treatment effect. The values for this study can be seen in Table 4 below.

<table>
<thead>
<tr>
<th>Table 4. Oucher Score Comparisons Between the Control Group and the Intervention Group (data from Alemdar et al.\textsuperscript{12})</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (\pm) SD</strong></td>
</tr>
<tr>
<td>Control Group</td>
</tr>
<tr>
<td>Buzzy® Group</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Needles are used in a variety of everyday medical procedures such as venipuncture, antibiotic injections, insulin injections, vaccinations, and more. Many children in the United States are diagnosed with type 1 diabetes mellitus and require multiple subcutaneous insulin injections every day to survive. The recommended vaccinations have also increased over the years, leading to an increased frequency of needlesticks in children.\textsuperscript{1} The high level of discomfort felt by patients who receive a needlestick can have negative effects on their future experiences, especially in children. Children are more susceptible to clinically significant and
distressing pain.\textsuperscript{1} If a child has a painful experience with a needlestick procedure, then they may begin to develop needle phobia and fear the use of needles.\textsuperscript{1} Healthcare professionals may end up spending an excessive amount of time consoling a scared child before using a needle.\textsuperscript{4} If a child becomes uncooperative, he or she may not receive the best treatment available for their illness or they might miss a necessary vaccination and delay subsequent vaccinations.\textsuperscript{1}

This systematic review evaluated the efficacy of applying a vibrating device, Buzzy\textsuperscript{®}, with an attachable cold pack to reduce needlestick pain in children between the ages 5 and 12 years old. All three RCTs were determined statistically significant based off of their p-values.\textsuperscript{10-12} In each study, the pain level was significantly lower in the Buzzy\textsuperscript{®} group than it was in the control group that did not use a pain modulating intervention.\textsuperscript{10-12} Sahiner et al.\textsuperscript{11} demonstrated a mean pain score difference of 1.94 between the control group and Buzzy\textsuperscript{®} group. In the study conducted by Bilgen et al.,\textsuperscript{10} the mean pain score difference was 3.72. This was the largest mean pain score difference out of the three studies. Alemdar et al.\textsuperscript{12} demonstrated a mean pain score difference of 2.36. The treatment effect for all three studies was determined to be large, based upon the mean difference between control groups and Buzzy\textsuperscript{®} groups.

The studies used in this review consisted of few limitations. In all three studies, all participants including researchers, children, and nurses were not blinded to the intervention.\textsuperscript{10-12} By not being able to blind the child to the intervention, this could have induced bias in their pain scores. The studies also did not utilize blind raters, such as having a designated rater evaluate the children of the studies with the FPS-R or Oucher scale without seeing the intervention being utilized. Another limitation across all three studies includes the difference between each participants’ cultural, physical, and emotional states.\textsuperscript{12} These differences could have influenced the pain scores.\textsuperscript{12} In the RCT conducted by Bilgen et al.,\textsuperscript{10} there was one additional limitation
discussed. This study used a single researcher who stayed with every participant during the IM injections and also assessed the pain scores reported by the participants. Bias may have been induced by having the same person administer the intervention and evaluate the results of the self-reported pain scores. In the RCT conducted by Sahiner et al., some of the participants may have had lipodystrophy prior to the study being conducted due to their daily administration of insulin. A child with lipodystrophy could have a heightened or altered pain response with the subcutaneous injections being performed.

CONCLUSION

All three randomized controlled trials that were utilized to conduct this systematic review demonstrated that the use of Buzzy® effectively reduced the pain felt by children between the ages 5 and 12 years old who underwent some type of needlestick procedure. The treatment effect in each study was determined to be large based upon the mean pain score difference between control groups and Buzzy® intervention groups. Thus, the results of this review are conclusive and found statistically significant based off of the calculated p-values.

Future studies investigating the use of Buzzy® to reduce needlestick pain in children should use a larger quantity of patients in each group. The future studies should also take into consideration different cultural, emotional, and physical states of the participants and how these differences can affect self-reported pain levels. It may be beneficial to have blind raters to assess the children’s pain scale using the FPS-R or Oucher scale without seeing the intervention being used.
REFERENCES


