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Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial

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Abstract. *Background and aim of the work:* procedural pain is a significant issue for paediatric patients. In particular, needle pain is amongst the most stressful for children. Studies revealed that a large number of children do not receive adequate pain prevention during the procedures. Neglecting the prevention of needle pain can cause several psychological effects such as anxiety and phobias, and increase perceptions of pain in the future. We aimed to verify the efficacy of Buzzy System in reducing pain during venipuncture. *Methods:* A randomized control trial was conducted among 72 children aged 3 to 10 years undergoing venipuncture. Children were randomly assigned to The Buzzy with distraction cards group (experimental group) or to "magic gloves" group (control group). Perception of pain was measured through the Visual Analogue Scale (VAS), the Wong-Baker Scale (WBS) and the Numeric Rating Scale (NRS). *Results:* Sixty-four children participated in the study, 34 in the experimental group and 30 in the control group. The experimental group showed significantly lower levels of pain (p=.039; 95% CI: -2,11; -0,06) in terms of the mean=3.65±2.011; median=3, compared to the control group (mean: 4.67±2.14, median=4). Caregivers were satisfied with the Buzzy System. *Conclusion:* The Buzzy System combined to distraction cards showed a greater reduction of perceived pain than "magic glove" technique. This study underlines the importance of active involvement of caregivers during procedural pain in children. Pediatric nurses have an important role in empowering children and caregivers to be interactive during venipunctures.

Key words: venipuncture, children, procedural pain, Buzzy System, pain relief

Introduction

Pain is a sensory and unpleasant emotive experience, which derives from real or potential tissue damage (1). Procedural pain is a clinical manifestation of pain due to a diagnostic or therapeutic intervention (2). In particular, needle pain is amongst the most stressful for children (3). Furthermore, studies revealed that a large number of children do not receive adequate pain prevention during the procedures (4).

Neglecting the prevention of needle pain can cause several psychological effects such as anxiety and phobias, and increase perceptions of pain in the future (5, 6).

A study has shown that 30% of people presenting needle phobia had experienced in the past a very

painful procedure relating to the insertion of a needle, without sufficient effort by the health professionals to alleviate the pain (7).

There is considerable evidence in the scientific literature regarding the efficacy of techniques both pharmacological and non-pharmacological, for the prevention of acute procedural pain in children (8), depending on the age, personal situation, type of pain, preferences and coping abilities of the child (9).

Based on those findings, a device has been created, called Buzzy, which is composed by a bee-shaped gadget producing vibrations and cooling through freezable wings. The effect of Buzzy is based on the gate-control theory discovered by Melzack & Wall in 1965, which suggests that barriers are able to control the flow of pain information by means of the activation of nociceptive fibres. In this case, the purpose of the cold and the vibrations is to block the transmission of pain signals (10).

Several studies tested the efficacy of the Buzzy System.

In a Turkish study, involving 120 children, aged from 6 to 12 years and who underwent venipunctures, the use of Buzzy brought about a significant reduction in pain (p<.001) compared to the control group who were not given any treatment (11). This was confirmed by the study of Moadad et al. (12).

Furthermore, in the study undertaken by Canbulat et al. (13) on 176 children aged from 7 to 12, the Buzzy group showed a significant reduction in the levels of anxiety and acute pain during peripheral venous catheterization.

Another study, conducted by Baxter et al. (14), at an emergency unit examined 81 children between the ages of 4 and 18, divided into two groups, and compared Buzzy to ice spray. They also observed a reduction in median patient-reported pain in the experimental group with Buzzy (-2; 95% CI, -4 to 0).

However, this contradicts the study led by Kearl et al. (15), in which the Buzzy didn't showed superiority towards local anaesthetic (J-tip, needle free injection system) for pain reduction during venipuncture.

Two Italian studies tested the impact of the Buzzy for children. In the study by Schreiber et al. (16) carried out in the "Burlo Garolfo" hospital in Trieste, 70 children with an average age of 9, who underwent venipuncture, were examined. Of these, 34 who were in the group using the Buzzy showed lower levels of pain (p=.003) compared to the 36 in the control group (with no treatment). The second study, which was undertaken at the day hospital of the "Filippo del Ponte" hospital in Varese, included 36 children between the ages of 4 months and 14 years who all underwent venipuncture (17). The results showed an average pain score of 6.09 on the Faces, Legs, Activity, Cry and Consolability scale (FLACC scale) and 2.25 on the Visual Analogue Scale (VAS scale). In the same study parental satisfaction towards the Buzzy System was measured and revealed very positive acceptance by parents, independently of pain scores.

Figure 1. Distraction Cards
Note: Cards used by caregivers to distract the child

Usually Buzzy didn't include also distraction cards. We introduce this intervention because we would like to know if the cold and vibration effect of Buzzy will be improved by the interaction with caregivers, and test the relevance of this relationship in pain relief during invasive procedure in children.

The "Buzzy System", used in this study, associates three different components and modulations of pain:

1. Distraction – cognitive method: distracting the child with "distraction cards" (Figure 1);
2. Vibration: a mechanical effect created by applying a bee-shaped gadget a few centimeters from the needle entry point;
3. Cryotherapy effect: by a removable cold liquid device that the bee-shaped gadget has at its base.

The figure 2 shows how and where the Buzzy is used and placed.

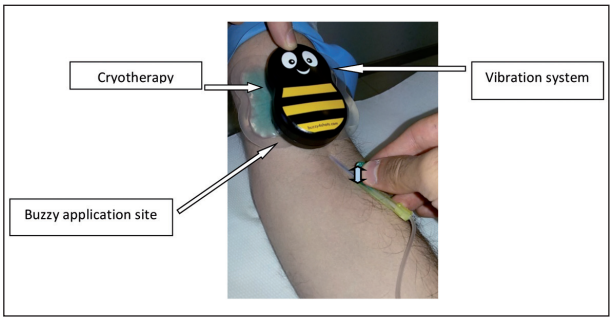


Figure 2. Buzzy Application

Aims

The main aim of our study was to evaluate the efficacy of the Buzzy System in reducing pain during venipuncture in children compared to routinely technique (magic gloves) used in the ambulatory where the study took place.

A secondary aim was to evaluate the satisfaction of the parent/caregiver in relation to the distractive techniques of the Buzzy System and their willingness to use it again for future procedures.

Therefore, our hypotheses/research questions were:

H1: Are the three effects of the Buzzy System (distraction, vibrations and cryotherapy) more efficacious in pain control during venipuncture in children from 3 to 10 years old, than the distraction with solely magic gloves technique?

H2: Are caregivers/parents satisfied with the Buzzy System?

H3: Are there differences according to gender and ages for pain perceptions during venipuncture?

To our knowledge, this is one of the few studies that compared–for children undergoing venipuncture-the Buzzy System including the systematic use of distraction cards, with other active intervention for pain reduction.

Methods

Study design

This was an open, randomized clinical trial. The study's participants were randomly assigned to two groups. The primary endpoint was the pain felt by the child at the moment of venipuncture. The study was designed in accordance with the guidelines of the Consolidated Standard for Reporting Trials CONSORT 2010 (18).

Population, Sampling and Setting

The study was conducted in the Department of Pediatrics at the ASST Fatebenefratelli-Sacco, Luigi Sacco Teaching Hospital, Milan, Italy, in a pediatric ambulatory with outpatient children.

Based on previous studies (16, 17), we hypothesized that children using the Buzzy System distraction techniques would have a mean pain level of 1.5 (SD±1.2) compared to children in the control group with a mean pain of 3.3 (SD±2.0). Considering an alpha level of 5% and a power of 90%, it was necessary to compare 27 children per group. Anticipating the fact that some children would probably drop out of the study, we increased the sample size by 30%. Therefore, the total number of children enrolled was 72.

Inclusion criteria

- Children aged 3 to 10 years.
- Children visiting an outpatient department.
- The presence of at least one caregiver/parent during the procedure who distracted the child with the distraction cards (in the case of the experimental group).
- Children of both Italian culture and language.
- Children in need for a venipuncture.

Exclusion criteria

- Children with a significant altered emotional state.
- Children unable to quantify or express their pain (e.g. severe cognitive deficit).
- Lack of parental consent.
- Absence of a caregiver/parent during the procedure.

The choice of the age group was based on scientific literature, which asserts that children in this age range were particularly responsive to distraction tech-

niques (19).

We chose to involve children of Italian culture and language to reduce variability, as we are aware of the fact that cultural factors can influence the perception of pain.

Randomization

Randomization was carried out using the block method. Blocks of six were used to maintain proportional allocation between the experimental and the control group throughout the study.

The randomization list was created using specific software: whoever assigned the children to the experimental and/or control groups did not take part in the creation of the randomization list and wasn't aware of its contents. For the randomization and assigning of the children to the experimental and control groups we used opaque envelopes. The envelopes were only opened by the nurse carrying out the venipuncture, after receiving consent from the parents of the children involved in the study.

Data collection procedure

Data was collected between September and October 2015. First author explained the study and obtained written consent from parents in the waiting room.

The venipuncture took place behind closed doors with only one child present at a time, ensuring that none of the children included in the study would be influenced by having witnessed the venipuncture on other children. Once allocated to a group, each child underwent the venipuncture using the applicable intervention (experimental or control).

Data collection instruments

Procedural pain was evaluated using an instrument, which integrates three evaluation scales: Visual Analogue Scale (VAS), Numeric Rating Scale (NRS) for children over 6 years old and Wong Baker Scale (WB) for children between 3 and 6 years. This tool showed a good validity and reliability in a pilot study conducted in Italian context and can be used to assess pain in children with different ages (20). Pain levels were documented immediately after the venipuncture.

Procedures
Experimental group

In the experimental group, children were involved in distraction techniques using the Buzzy System during venipuncture.

While the nurses placed the Buzzy with the frozen wings on children's skin, caregivers/parents were invited to interact with their children through the use of the Distraction cards, which are a small amount of images depicting various scenes set in school, countryside or outdoors, and which could be flipped through by the child. Parents continuously asked their child questions about the images, maintaining an interactive dialog during the whole venipuncture. Distraction cards were only used in the experimental group.

The nurse positioned the Buzzy at 2-5 cm from the possible venipuncture location. Before starting the venipuncture, the nurse invited the child to turn on the device in order to start the vibration. Children were offered the possibility to choose the type of vibration released by the Buzzy: continuous or intermittent.

The Buzzy remained on till the end of the venipuncture. Finally, the nurse assessed children's pain perception during procedure with the appropriate pain assessment tool.

Control group

In the ambulatory setting, the "magic glove technique" is routinely used. Before starting the venipuncture, the nurse gently rubbed the area in which the needle was placed in order to free it from the pain. The child, imagining that the nurse is putting the glove and feeling the effect of the massage on his body, would feel a certain numbness in the same area where the sensitivity is lowered.

The nurse who performed the venipuncture was the same during the whole data collection process. Whether in the control or the experimental group, none of the children received pharmacological pain therapies.

Evaluation of parental satisfaction

In order to evaluate the parents' level of satisfaction with the Buzzy System method of pain control in the child and their desire to use it again in future, we used a questionnaire.

The questionnaire was created and used by Friedel et al. (17). The questionnaire items were: 1. My child was comforted by the use of the Buzzy System during the procedure; 2. It was a positive experience; 3. I think the Buzzy System is easy to use; 4. I would like to use the Buzzy System in the future for tests carried out on my son/daughter.

Rating was based on a five points Likert-Scale: 1=No, 2=Probably not, 3=I don't know, 4=Yes, 5=Definitely.

Data analysis

Qualitative data were expressed using numbers or percentages while quantitative data used mean and standard deviation, or median and inter-quartile range (where appropriate). We evaluated the normality of the distribution of the continuous variables using the Shapiro-Wilk test. The continuous variables in the two groups were compared using Student's *t* test if normally distributed. Categorical variables, on the other hand, were compared using the Pearson Chi-square test. Given that the frequency distribution of the pain levels was not normal, we transformed them with a two ways transformation using SPSS (21). Afterwards, we compared the two distributions with *t-test* for independent sample. We calculated 95% confidence interval. A p value <0.05 was considered significant. Data analysis was conducted according to the Intention to Treat. All statistical analyses were carried out with SPSS software version 21.0 (Chicago IL, USA) (22).

Ethical considerations

The study was approved by the medical administration and the nursing institutional board of the Teaching Hospital Luigi Sacco in Milan.

Protection of personal data was ensured by not recording the name of the child included in the study. Instead of that, each child was allocated an alphanumeric code. In order to avoid errors in identification or association of the data for each child, we only noted initials and dates of birth. Given that the children were all minors, parents and caregivers were first informed by a letter about the aim of the study and the methodology used, in particular the methods for assigning the treatment. Parents were informed that their willingness to participate to the study was free, that they could refuse at any time, without any justification and without negatively impacting the care for their child. Written consent was obtained by all participants.

The research was carried out using the ICH Good Clinical Practice guidelines (23), Italian Law 211/2003 and the Helsinki declaration governing clinical experiments.

Results

A total of 72 children were enrolled between September and October 2015, subdivided into two groups of 36 children. These 72 children and their caregivers were the ones approached for the study and none of them declined participation.

Of the 72 children enrolled, 64 participated in the study, 34 in the experimental group and 30 in the control group.

Eight children were excluded as they displayed a significantly altered emotional state at the time of the venipuncture, such as levels of anxiety and fear to a degree that could compromise a valid expression of the actual perceived pain. They were so distressed that the venipuncture was postpone to another day. For this reason, we were not able to consider them in the analysis. Two were randomized to the experimental group (with the Buzzy System) and six were randomized to the control group. In the experimental group one was a girl of six years old, and the other was a boy of eight years old. Both of them were with their mother and never experienced venipuncture before. In the control group three children were girls and three were boys. Four did experienced venipuncture before and two did not. Two children were accompanied by their mothers, two by their fathers and two by both parents. In the control group, children aged from 3 to 10 years.

The distribution of the population is visible in the flow chart below (Figure 3).

The two groups did not show statistically significant differences before the procedure when compared for age, gender, number of venipuncture, if it was their first venipuncture, caregiver attending the procedure, reason for venipuncture (Table 1).

Pain was significantly lower in the experimental group than in the control group (*Student's t test*=-2.16; *df*=62; *p*=.039) (Table 2).

The experimental group showed a lower mean and median pain level (except for 3 outliers, that were included in the analysis within their group of randomization, experimental group) and a narrower interquartile range than the control group. The three outliers were two girls and one boy. Two children were with their mothers and one with both parents. Two children did experienced venipuncture before and one did not.

A greater control of pain was demonstrated with the Buzzy System combined with Distraction cards (Graph 1).

As a secondary analysis we looked at the possible influence of age and gender on the perception of pain within the same group, as evaluated in other studies (12). We chose six years as the cut-off age because it seems during data collection that the techniques employed had a greater effect on children over six years age. Considering the control group and the experimental group separately, we compared the levels of perceived pain by dividing the children into those over the age of six and those aged six or younger. No significant difference was observed (experimental group

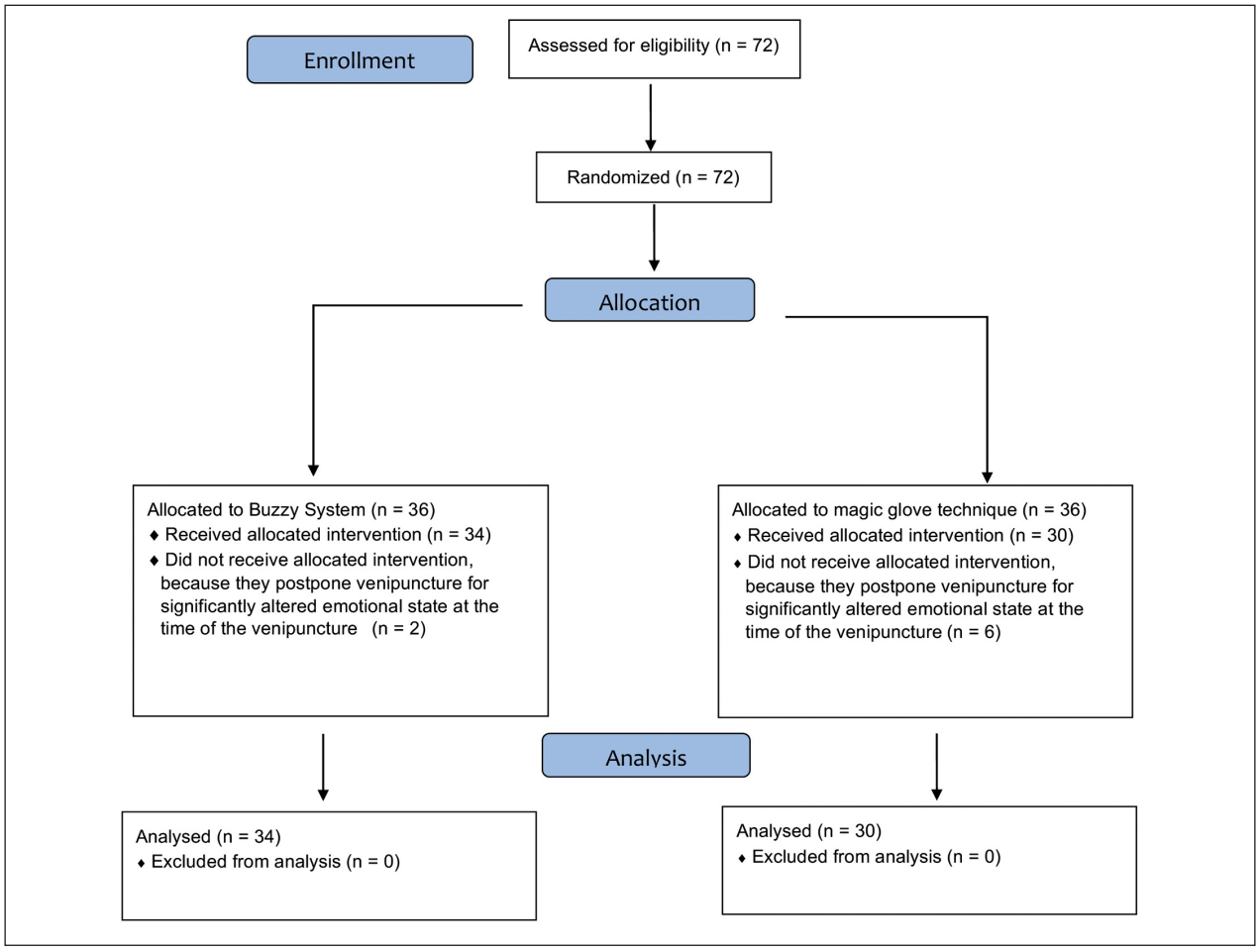


Figure 3. Flow Diagram (CONSORT, 2010)

Table 1. Characteristics of the Participants

	Experimental Group=34	Control Group=30	*p value*
Age (Mean (± SD^))	6.78 (±2.27)	6.25 (±2.12)	.31[a]
Gender (%)	n (%)	n (%)	
M (%)	17 (47.2)	14 (38.9)	.34[b]
F (%)	19 (52.8)	22 (61.1)	
First venipuncture	4 (11.1)	6 (16.7)	.50[b]
Caregiver attending the procedure	n (%)	n (%)	
Mother	17 (47.2)	18 (50)	.89[b]
Father	8 (22.2)	6 (16.7)	
Both	10 (27.8)	10 (27.8)	
Other	1 (2.8)	2 (5.6)	
Reason for venipuncture	n (%)	n (%)	
Routine blood check	13 (40)	15 (40)	.8[b]
Endocrinology check	10 (30)	7 (20)	
Allergenic check	10 (30)	10 (30)	
Other	3 (10)	4 (10)	

^*SD= Standard Deviation;* [a]= Student's *t;* [b]*= Pearson Chi square.*

Table 2. Description of pain in the two groups

	Experimental Group (N=34)	Control Group (N=30)	CI 95% *Lower*	CI 95% *Upper*	*p value*[a]
Mean ± SD^	3.66±2.02	4.74±2.07	-2.11	-.06	.039
Median [Q1; Q3][b]	3 [3;6]	4 [4;6]			

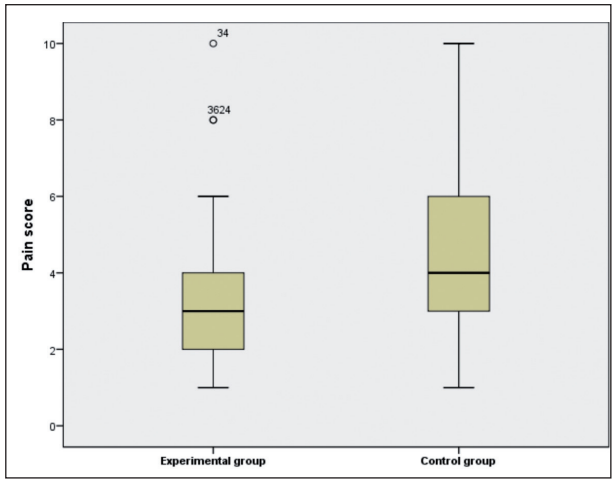
^*Standard Deviation;* [a]*t-Test for independent sample;* [b]*Q1= first quartile; Q3= third quartile*

p=.54, control group *p*=.88). Being older than six years of age was not associated with a greater or lower efficacy.

We also evaluated the possible difference gender may have had on pain perception within the same groups. Again, no significant difference was found (experimental group *p*=.96; control group *p*=.68), meaning that the difference in pain perception is not due to gender.

The secondary aim of the study was to measure the satisfaction of the caregivers/parents of the children who underwent the venipuncture with the Buzzy System.

Of the 36 children in the experimental group, two sets of parents did not want to fill out the questionnaire as 'they had no time' and two further questionnaires were not filled out as the children didn't undergo the venipuncture due to significantly altered emotional state. Thirty-two questionnaires on parental satisfac-



Graph 1. Pain Perception in Experimental and Control Groups
Note: *Pain score measured with Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), Wong Baker Scale (WBS); Experimental group= Buzzy System; Control Group= verbal distraction based on magic glove technique.*

Table 3. Description of the Results of Caregivers' Satisfaction Questionnaire for the Buzzy System.

Parents' satisfaction (n = 32)	No n (%)	Probably not n (%)	Don't know n (%)	Yes n (%)	Definitely n (%)
My child was comforted by the use of the Buzzy System during the procedure	0	1 (3.2)	6 (18.8)	17 (53)	8 (25)
It was a positive experience	0	1 (3.25)	4 (12.5)	12 (37.5)	15 (46.9)
I think the Buzzy System is easy to use	0	0	1 (3.1)	8 (25)	23 (71.9)
I would like to use the Buzzy System in the future for tests done on my son/daughter	0	0	6 (18.7)	12 (37.5)	14 (43.8)

tion with the Buzzy System were therefore collected. The use of the Buzzy System was met favorably by parents who expressed either a positive or a very positive judgment.

71.9% of parents said they would reuse the Buzzy System in a future venipuncture, while 46.9% of parents said it was definitely a positive experience. No negative opinions were expressed for any of the questions regarding the Buzzy System (Table 3).

Discussion

Our results demonstrated the efficacy of the Buzzy System combined with distraction cards in reducing the perception of pain during venipuncture compared to other distractive techniques. As far as we are aware, this study is one of the few in the international literature evaluating the efficacy of a non-pharmacological system based on the use of several methods (verbal and visual distractions, vibration, cryotherapy), to prevent procedural pain in children, compared to other distractive techniques. Differently from Moadad et al. (12), in our study we did not find a difference in pain perception considering ages and gender. This could be due to the different scales used for each category of ages during data collection. This study combines the effect of distraction, cryotherapy and vibration. Those effects have been analyzed independently in various studies.

Impact of distraction

Regarding non-pharmacological techniques, studies have shown that distraction can diminish the perception of procedural pain in children and adolescents (24-26). Although quality of trials which examined psychological interventions for needle-related pain and distress is questionable, reviews showed that there is an evidence supporting the efficacy of distraction and hypnosis (25, 27, 28). Distraction cards were found particularly powerful in reducing both pain and anxiety levels during venipunctures (29) compared to other distraction techniques such as listening to music or balloon inflation (30).

Triggering interactivity of children during distraction techniques is different than distracting passively children with a doll or a puppet. This is consistent with a study in which a high degree of children's interactivity during insulin injection was found to reduce significantly their distress (31) and with our results.

Impact of cryotherapy and vibration

The effect of cold in pain reduction was demonstrated in several studies (32, 33). Similarly, to vibration, which was found to diminish pain perception (34, 35). The mechanisms underlying those effects can be explained by the role of the gate-control theory developed by Melzack (10). However, in our study the impact of combining the cold effect (frozen wings of the Buzzy) with the vibration (produced by the Buzzy) seems to be more efficacious than the magic gloves techniques alone. The lowered pain scores founded in our study confirmed those founds in other studies related to many invasive procedures (11-13, 16, 30, 36).

Impact of combined cryotherapy, vibration and distraction

A multifaceted approach combining several techniques adapted to age and psychology of children

to prevent or reduce perception of pain is underlined by Landier et al. (37). One of this multimodal approaches is in fact the combination of cryotherapy, vibration and distraction, on which the Buzzy System relies. Mechanisms which could explain this impact can be found through the gate-control theory but also more widely in the growing research related to neurosciences, which indicates the supporting role of various divisions in the anterior cingulate and prefrontal cortices observed in hypnotic responding (38). In fact, distraction is strongly correlated to hypnosis in which some characteristics are found to be similar, namely the specific involvement of adult (nurses or parents), the possibility for the child to make a choice and finally the interactivity of the child with an adult. Compared to the complete absence of any form of treatment, the use of the Buzzy System has therefore shown itself to be efficacious in various invasive procedures, helping to reduce the pain felt by the child. In our study Buzzy System showed to be efficacious in pain reduction also when compared to other distractive techniques.

Role given to caregivers/parents during painful procedures

Acceptability of the Buzzy System by parents was largely confirmed. Just two parents did not answer to the questionnaire because of lack of time. None had a negative experience during its use. Moreover, the majority of parents would reuse the system in the future. In this aspect our results confirmed those of Friedel et al. (17). A randomized clinical trial study conducted by Liossi et al. (39) among a sample of 45 pediatric cancer outpatients exposed to venipuncture showed a beneficial effect of self-hypnosis and a reducing of parental anxiety. In pediatrics, a family-centred approach is a standard of quality care. It underpins the importance to take into consideration not only the child's experience but his relation with his parents. Reducing child's anxiety goes in parallel with comforting parental anxiety. This double effect has been underlined in various studies although focusing mostly on a chronic pain context (40-44). Giving the opportunity to parents to have an active role by using the distraction cards might empower parents in their capacity to comfort their child's pain and anxiety, instead of feeling helpless and anxious. For children having their parents secured might lower their own anxiety.

Nevertheless, the impact of the Buzzy System may be less efficacious among children who experienced high level of pain in the past and developed needle phobia. This is consistent with the findings of Goffaux et al. (45), which indicated higher doses of analgesic needed for persons who expected to experience pain.

Limitations

The first and major limitation of this study is the fact that we were not able to verify the efficacy of Buzzy System in reducing pain in children with an altered emotional state.

Perhaps this situation could have influenced results in favor to the Buzzy System. Further studies should document degree of anxiety related to needle phobia. Moreover, intervention fidelity was not measured in our study. This means that the amount of distraction provided could vary among caregivers and have an impact on the effectiveness of the intervention (46). We didn't compare Buzzy System with pharmacological intervention, such as anaesthetic, and therefore we can't compare our study to the one conducted by Kearl et al. (15). It will be interesting in the future compare the Buzzy System with distraction cards to pharmacological intervention, to verify at least its equivalence.

Finally, we were not able to match the results of parent's questionnaire with children's scores of pain, because questionnaires were strictly anonymous. It would be useful to compare children's perception of pain with parental satisfaction towards the Buzzy System and look after possible correlation. Taking these limitations, it would be vital to repeat the study conducting a pragmatic, randomized clinical trial, in which the inclusion criteria are less restrictive and therefore the external validity might be increased.

Conclusion and clinical implication

The relevance of our study is that the Buzzy System with distraction cards has proved to be efficacious in reducing pain even compared to other distractive

techniques, which underlines the relevance of all three components (vibration, cryotherapy and distraction). Preventing procedural pain is a very important aspect that nurses need to take into consideration, in order to avoid the potential trauma caused by painful procedures, preventing anxiety or even needle phobias (5,6). An important conclusion that can be drawn from this study is the fact that it is essential to involve the caregivers of the child during the procedure. Giving parents an active positive role during venipuncture empowers them to feel secure which consequently improves child's feelings of confidence. Family-centered care and partnership with parents are the core elements of quality care provided to children.

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