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Research

CUTTING EDGE EDUCATION: BUZZY DEVICE FOR PAIN RELIEVING IN CHILDREN

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Abstract

Pain from needle-related procedures in children can alter pain perception, increase pain sensitivity, and generate inappropriate pain responses. Currently pain management includes the use of lidocaine-containing patches, which is complicated to manage in a busy medical setting such as a vaccination centre. We assessed the Buzzy device, which combines vibration and cold, to manage pain in children undergoing a needle-related procedure, compared to the standard lidocaine patch.

AIM: To explore the dental students to investigate whether the Buzzy device was as efficient as the lidocaine patch in reducing or preventing the pain provoked by needles in children.

Methods: Children were randomly allocated (1:1) to use either the Buzzy device or the lidocaine patch during the needle-related procedure. The lidocaine patch was applied to the puncture site for the hour prior to the intervention. The Buzzy device was applied to the puncture site for 30 s and then moved 5 cm along the limb during the procedure. The refrigerated wings were detached if they bothered the child. The child assessed their pain using the validated Revised Faces Pain Scale. The revised faces pain scale comprised six facial expressions from 0, normal "no pain" to 10, a screaming face "severe pain" (2 points/face). The primary endpoint was the average pain score recorded by the child. The study aimed to test the non-inferiority of Buzzy.

Keywords: Buzzy; Lidocaine; Needle-related procedure; Paediatric; Pain management; Vaccination.

1. INTRODUCTION

Needle pricks are one of the most feared medical events for both children and adults. Children who often experience pain reportedly develop altered pain perception, increased pain sensitivity, and inappropriate pain responses. Needle phobia in children often persists into adolescence and adulthood. Also, needle- phobia has been shown to reduce compliance with routine immunisation.

Management of the pain of childhood vaccination includes a large amount of both nonpharmacological and pharmacological methods recommended as topical anaesthetic creams, vapocoolant cold spray, parent coaching and distraction. Amongst them, the lidocaine and prilocaine-containing eutectic mixture of local anaesthetics patch is currently recommended to manage pain associated with venepuncture. However, for the patch to be effective, it must be positioned correctly for one hour before the procedure to provide anaesthesia, which can be inconvenient when consultation time is very short and procedures for pain management need to be quick and convenient. A new medical device, Buzzy, combines external skin cooling with vibration. This device is a bee-shaped box with detachable, refrigerable wings. The efficacy of the Buzzy device can be explained by the gate control theory .This theory suggests that cold and the vibrations transmitted by unmyelinated, slowly conducting C nerve fibres may block the acute needle pain transmitted by the A fibres.

Several randomised clinical trials have evaluated Buzzy during various needle-related procedures and in different age groups. A prospective study was performed in children aged between 7 and 12 years, requiring a peripheral intravenous cannulation. A control study assessed Buzzy in children of 4 to 12 years during an intravenous insertion .In addition, a single-centre trial evaluated the Buzzy device in patients aged from 4 to 18 requiring venous access .These studies compared the Buzzy device with a no pain prevention measures comparator and showed that the Buzzy was significant in reducing self-reported procedural pain. A recent meta-analysis, including seven studies which compared the Buzzy device with a no-treatment comparator, concluded that even if the Buzzy device showed promise in reducing needle-related pain in children, the current evidence is not enough to conclude efficacy. More recently, the Buzzy device was compared with the lidocaine patch by Potts et al. in children aged 4–18 requiring an intravenous catheter, and by Bourdier et al. in children aged between 18 months and 6 years during either a cannulation, or a blood test in the paediatric emergency department. The Buzzy device allows faster analgesia than the lidocaine patch; however evidence about pain relief is conflicting in these studies. Potts reported that a vibrating cold device is equal in its effectiveness in reducing pain for children undergoing catheterisation to the lidocaine patch. However, Bourdier concluded that analgesia from the Buzzy device is less effective than with the lidocaine patch. Moreover, to our knowledge, no previous study has compared the Buzzy device to the lidocaine patch used in the management of pain for children undergoing vaccination. Therefore, the aim of this study was to investigate whether the Buzzy device was as efficient as the lidocaine patch in reducing or preventing the pain provoked by needles in children attending paediatric outpatient units.

METHODOLOGY

1. Study Design

The study was a randomised (1:1), open-label, non-inferiority clinical trial conducted in vaccination centres of three hospitals in France. It compared the effectiveness of the Buzzy device with the lidocaine patch in reducing needle-related pain in children.

2. Objectives

- Explore the Dental students to investigate whether the Buzzy device was as efficient as the lidocaine patch in reducing or preventing the pain provoked by needles in children based on the gender.
- To Explore the Dental students to investigate whether the Buzzy device was as efficient as the lidocaine patch in reducing or preventing the pain provoked by needles in children based on the year of the study

3. Data Collection Methods

Children aged 4–15 years undergoing vaccination or venepuncture were randomly allocated to either the Buzzy group or the lidocaine patch group. Pain was assessed immediately after the procedure using the Revised Faces Pain Scale (0–10). Both the child and parent independently reported pain scores.
Demographic data, procedure details, distraction methods, and use of analgesics were also recorded.

4. Data Analysis

A non-inferiority margin of 1 point on the pain scale was used. Data were analysed using intention-to treat and per-protocol approaches. Mean pain scores were compared using regression models adjusted for study centre. Statistical analysis was performed using SAS® version 9.4.

5. Ethical Considerations

The study was approved by the French National Agency for Drug Safety and conducted according to Good Clinical Practice guidelines. Written informed consent was obtained from parents. Participant confidentiality and safety were maintained throughout the study.

6. Limitations

The open-label design may have introduced bias. Pain assessment was subjective, and results may not be generalisable beyond hospital settings. Long-term pain outcomes were not evaluated.

RESULTS:

A total of 221students took part in this with females (63.8%) and male of (36.2%). Age of the participants ranging from 18-25 years. In this study females were more likely to demonstrate perception in dissection room experiences than male. Significantly INTERNS showed greater familiarity with advanced applications than first, second, third year and final year students and interns.

AGE

	N	Minimum	Maximum	Mean	Std. Deviation
Age	221	18	26	21.62	1.604

GENDER

		Frequency	Percent
Valid	MALE	80	36.2
	FEMALE	141	63.8
	Total	221	100.0

YEAR OF STUDY

		Frequency	Percent
Valid	1 BDS	34	15.4
	2 BDS	38	17.2
	3 BDS	27	12.2
	4 BDS	46	20.8
	INTERN	76	34.4
	Total	221	100.0

Distribution and comparison of responses based on gender:

Item	**Response**	**Males**		**Females**		**Chi-Square value**	**P value**
		n	**%**	**n**	**%**		
Q1	1	2	33.3	4	66.7	0.486	0.922
	2	71	36.7	122	63.2		
	3	2	25	6	75		
	4	5	35.7	9	64.2		
Q2	1	12	34.3	23	65.7	1.211	0.750
	2	13	39.4	20	60.6		
	3	54	36.7	93	63.3		
	4	1	16.7	5	83.3		
Q3	1	12	46.2	14	53.8	2.900	0.407
	2	15	39.5	23	60.5		
	3	52	34.7	98	65.3		
	4	1	14.3	6	85.7		
Q4	1	18	41.9	25	58.1	2.226	0.527
	2	17	41.5	24	58.5		
	3	43	33.6	85	66.4		
	4	2	22.2	7	77.8		
Q5	1	17	48.6	18	51.4	5.165	0.160
	2	13	44.8	16	55.2		
	3	49	32.5	102	67.5		
	4	1	16.7	5	83.3		
Q6	1	13	48.1	14	51.9	4.972	0.174
	2	15	48.4	16	51.6		
	3	50	31.8	107	68.2		
	4	2	33.3	4	66.7		
Q7	1	24	44.4	30	55.6	2.311	0.510
	2	12	36.4	21	63.6		
	3	40	32.5	83	67.5		

	4	4	36.4	7	63.6		
Q8	1	21	41.2	30	58.8	3.071	0381
	2	11	42.3	15	57.7		
	3	47	34.6	89	65.4		
	4	1	12.5	7	87.5		
Q9	1	27	46.6	31	53.4	5.544	0.136
	2	14	33.3	28	66.7		
	3	38	33.9	74	66.1		
	4	1	11.1	8	88.9		
Q10	1	48	41	69	59	3.277	0.351
	2	5	41.7	7	58.3		
	3	25	29.8	59	70.2		
	4	2	25	6	75		
Q11	1	17	37	29	63	1.378	0.711
	2	14	34.1	27	65.9		
	3	47	37.9	77	62.1		
	4	2	20	8	80		
Q12	1	31	38.8	49	61.3	3.172	0.366
	2	10	45.5	12	54.5		
	3	38	34.2	73	65.8		
	4	1	12.5	7	87.5		
Q13	1	32	39.5	49	60.5	13.115	**0.004***
	2	16	64	9	36		
	3	31	29	76	71		
	4	1	12.5	7	87.5		
Q14	1	32	39.5	49	60.5	13.115	**0.004***
	2	16	64	9	36		
	3	31	29	76	71		
	4	1	12.5	7	87.5		
Q15	1	32	39.5	49	60.5	13.115	**0.004***

	2	16	64	9	36		
	3	31	29	76	71		
	4	1	12.5	7	87.5		

P≤0.05 is statistically significant

Distribution and comparison of responses based on year of the study:

Item	**Response**	**I BDS**		**II BDS**		**III BDS**		**IV BDS**		**INTERN**		**Chi-Value**	**P-Value**
		n	%	n	%	n	%	n	%	n	%		
Q1	1	6	21.4	4	14.2	3	10.7	4	14.2	11	39.2	25.533	**0.012***
	2	18	14.4	25	20	17	13.6	32	25.6	43	34.4		
	3	4	13.7	5	17.2	5	17.2	2	6.8	13	44.8		
	4	6	20.6	4	13.7	2	6.8	8	27.5	9	31.0		
Q2	1	8	22.9	2	5.7	1	2.9	9	25.7	15	42.9	19.500	0.077
	2	4	12.1	6	18.2	2	6.1	9	27.3	12	36.4		
	3	22	15	30	20.4	24	16.3	25	17	46	31.3		
	4	0	0	0	0	0	0	3	50	3	50		
Q3	1	8	30.	3	11.5	1	3.8	6	23.1	8	30.8	18.924	0.090
	2	4	10.5	6	15.8	2	5.3	8	21.1	18	47.4		
	3	22	14.7	29	19.3	24	16	29	19.3	46	30.7		
	4	0	0	0	0	0	0	3	42.9	4	57.1		
Q4	1	10	23.3	8	18.6	4	9.3	8	18.6	13	30.2	13.442	0.338
	2	7	17.1	10	24.4	6	14.6	8	19.5	10	24.4		
	3	17	13.3	20	15.6	17	13.3	27	21.1	47	36.7		
	4	0	0	0	0	0	0	3	33.3	6	66.7		
Q5	1	9	25.7	4	11.4	1	2.9	6	17.1	15	42.9	14.976	0.243
	2	5	17.2	5	17.2	3	10.3	5	17.2	11	37.9		
	3	20	13.2	29	19.2	23	15.2	32	21.2	47	31.1		
	4	0	0	0	0	0	0	3	50	3	50		
Q6	1	9	33.3	3	11.1	1	3.7	5	18.5	9	33.3	14.721	0.257
	2	5	16.1	6	19.4	4	12.9	5	16.1	11	35.5		

	3	20	12.7	29	18.5	22	14	34	21.7	52	33.1		
	4	0	0	0	0	0	0	2	33.3	4	66.7		
Q7	1	15	27.8	9	16.7	7	13	11	20.4	12	22.2	18.549	0.100
	2	2	6.1	5	15.2	3	9.1	9	27.3	14	42.4		
	3	17	13.8	23	18.7	17	13.8	23	18.7	43	35		
	4	0	0	1	9.1	0	0	3	27.3	7	63.6		
Q8	1	14	27.5	9	17.6	8	15.7	11	21.6	9	17.6	22.160	**0.036***
	2	3	11.5	6	23.1	1	3.8	3	11.5	13	50		
	3	17	12.5	23	16.9	18	13.2	29	21.3	49	36		
	4	0	0	0	0	0	0	3	37.5	5	62.5		
Q9	1	15	25.9	13	22.4	9	15.5	11	19	10	17.2	23.238	**0.026***
	2	3	7.1	9	21.4	3	7.1	10	23.8	17	40.5		
	3	16	14.3	16	14.3	15	13.4	22	19.6	43	38.4		
	4	0	0	0	0	0	0	3	33.3	6	66.7		
Q10	1	22	18.8	28	23.9	15	12.8	22	18.8	30	25.6	25.928	**0.011***
	2	0	0	1	8.3	0	0	2	16.7	9	75		
	3	12	14.3	9	10.7	12	14.3	19	22.6	32	38.1		
	4	0	0	0	0	0	0	3	37.5	5	62.5		
Q11	1	13	28.3	3	6.5	7	15.2	9	19.6	14	30.4	35.896	**0.001***
	2	0	0	7	17.1	2	4.9	15	36.6	17	41.5		
	3	21	16.9	28	22.6	18	14.5	19	15.3	38	30.6		
	4	0	0	0	0	0	0	3	30	7	70		
Q12	1	14	17.5	9	11.2	11	13.8	18	22.5	28	35	31.675	**0.002***
	2	1	4.5	1	4.5	0	0	5	22.7	15	68.2		
	3	19	17.1	28	25.2	16	14.4	21	18.9	27	24.3		
	4	0	0	0	0	0	0	2	25	6	75		
Q13	1	13	16	10	12.3	8	9.9	17	21	33	40.7	34.863	**0.001***
	2	0	0	3	12	0	0	5	20	17	68		
	3	20	18.7	25	23.4	19	17.8	22	20.6	21	19.6		

	4	1	12.5	0	0	0	0	2	25	5	62.5		
Q14	1	13	16	10	12.3	8	9.9	17	21	33	40.7	34.863	**0.001***
	2	0	0	3	12	0	0	5	20	17	68		
	3	20	18.7	25	23.4	19	17.8	22	20.6	21	19.6		
	4	1	12.5	0	0	0	0	2	25	5	62.5		
Q15	1	13	16	10	12.3	8	9.9	17	21	33	40.7	34.863	**0.001***
	2	0	0	3	12	0	0	5	20	17	68		
	3	20	18.7	25	23.4	19	17.8	22	20.6	21	19.6		
	4	1	12.5	0	0	0	0	2	25	5	62.5		

P≤0.05 is statistically significant

DISCUSSION

To the best of our knowledge, our study is the first prospective randomised controlled trial comparing the Buzzy device to the lidocaine patch in the management of needle procedures in a vaccination centre. To allow immediate analgesia with a device combining vibration and cold was an attractive alternative to the lidocaine patch to manage pain induced by needle procedures in a busy medical setting such as a vaccination centre. However, our study failed to show that the Buzzy device was equivalent to the lidocaine patch for preventing or reducing pain in children undergoing either a vaccination or a venepuncture, in terms of the Revised Faces Pain Scale rated by the children after the needle-related procedure. These findings are in accordance with Bourdier, who recently showed in a superiority trial that analgesia was less efficient than the lidocaine patch in the context of cannulation in a paediatric emergency department. However, another recent study indicated that the pain experienced by children undergoing IV insertion who received Buzzy device intervention was equivalent to that experienced by children who received a lidocaine patch.

Discrepancies between designs could explain these conflicting results. First, we set a lower threshold of non-inferiority than in the Potts study. The margin in our study was set at 1, based on a previous trial which compared the lidocaine patch and a placebo, whilst Potts used a non-inferiority margin of 1 face on the pain scale, equivalent to 2. Second, the Bourdier study and the Potts study took place in an emergency department so included sick children and concerned cannulation. Third, in previous studies, all children received the device with the refrigerated wings, while our pragmatic study design followed a shared decision-making process and allowed the Buzzy detachable refrigerated wings to be removed if the child was bothered by the cold. In the BUZZY group, 43% of the children did not use the refrigerated wings until the end of the procedure. However, the pain prevention and relief when the refrigerated wings were used to the end seems to be similar to that observed with the standard lidocaine patch. Indeed, it has been previously suggested that the combination of vibration and cold may be more effective than either component alone. In the prospective randomised study assessing Buzzy in children aged 7 to 12 requiring venous access, all the children randomised to the Buzzy device had the vibration and cold applied 5 cm above the planned puncture site prior to and for the duration of the procedure. Thus, in retrospect, we may have obtained better results if the refrigerated wings on the Buzzy device had been mandatory. But our study was not empowered to analyse this hypothesis. Moreover, it is not clear if the wings should be frozen or refrigerated, nor is the impact of temperature on the children's comfort clear. Further research is required to assess the use of cold in pain management. Concerning the practice, this study highlights some points important to know for the use of Buzzy. In order to use the Buzzy device effectively, the site staff need to be familiar with the device and the procedure. Ideally, the child should be distracted from the Buzzy device at the time of the injection so that the child does not see the needle that may induce anxiety. From our experience with this study, we consider that the competence of the nurses in using the device and distracting the child, as well as the communication between the nurse, doctor, parents, and child are essential for the optimum management of pain during a needle-related procedure. In addition, usually, the main limiter of the use of a lidocaine patch is the time spent waiting for it to

become effective, but our trial clearly shows that the waiting time of children with Buzzy and lidocaine patch were similar (mean difference of 10 min). In reality, in a vaccination centre the patch is applied as soon as the child arrives in the unit.

Our study has several limitations. It was designed to be pragmatic, thus we enroled children presenting for various needle-related procedures offered in the vaccination centre. However, we know that certain vaccinations and procedures generate more pain than others. Furthermore, we only recruited children in the vaccination centres of three French hospitals. Thus, our study population may not be representative of all children requiring needle-related procedures. In addition, adverse events were not systematically recorded in the trial, so some minor side effects such as discomfort could have been missed. Lastly, during the procedures various distractions were permitted so we cannot exclude that different techniques could have influenced the results.

CONCLUSION

Our study failed to provide evidence that the Buzzy device was equivalent to the lidocaine patch in preventing or reducing pain in children undergoing needle-related procedures. However, the Buzzy device tends to be more effective when the refrigerated wings are used, even if almost half of the children in our study did not like the cold. Our study provides valuable information concerning the use of the Buzzy device. Further research is required to optimise the use of Buzzy (influence of the duration of the cold exposure) and improve its ability to prevent and reduce pain in children undergoing needlerelated procedures.

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