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Supported by a grant from Mayday Fund

Poster No. P3-78

Abstract

Objective: To compare a reusable, fast-acting device combining cold, vibration, and optional distraction to standard care for pediatric venous access pain relief.

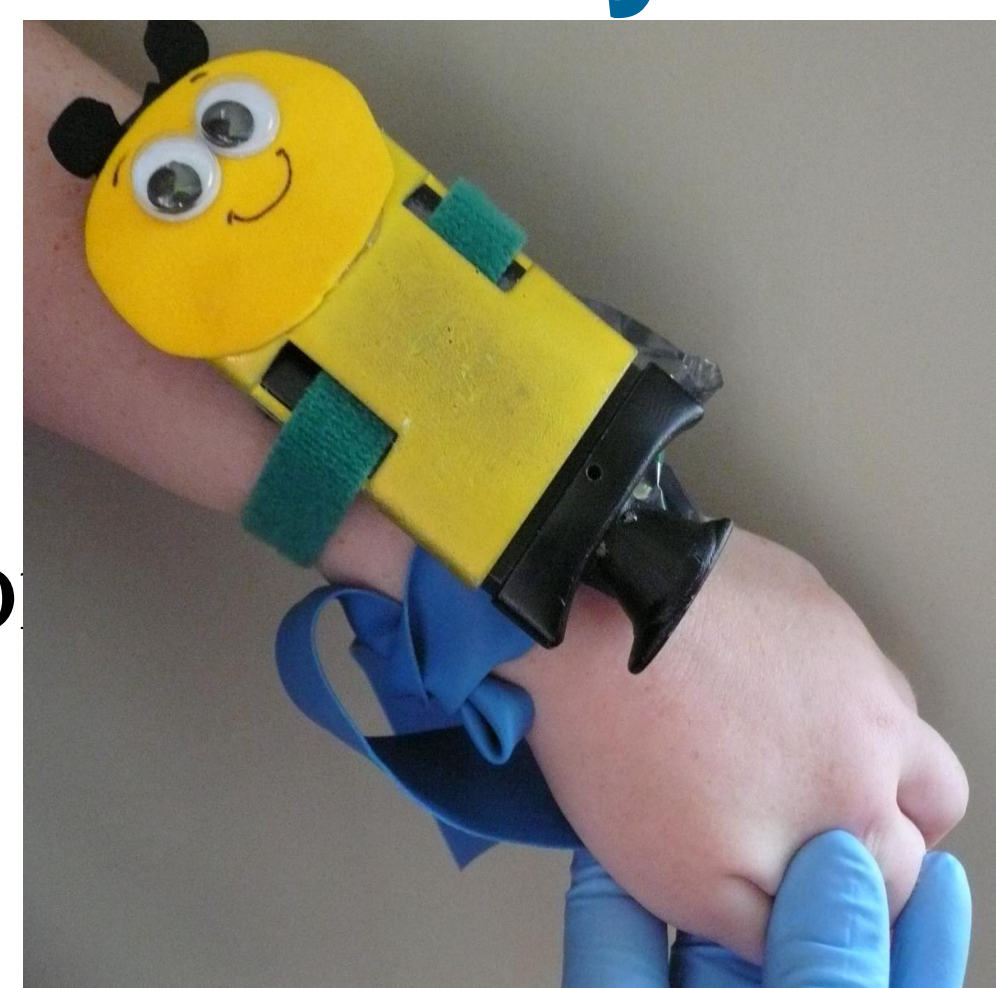
Methods: Pediatric emergency department (ED) patients were randomized to the cold vibration device placed 5-10 cm proximally throughout venipuncture or standard care control (typically vapocoolant spray), stratifying for lidocaine cream application in triage and noting distraction use in both groups. Pain was measured via self- and parent-report using the 0-10 Faces Pain Scale-Revised (FPS-R) and with coded videotaped observed behaviors. The Wilcoxon family of statistics was used for non-normally distributed data. Venipuncture success and access times were also assessed.

Results: 81 4- to 18-year-olds were randomized to the device (n=41) or standard care (n=40) (median age 10.09 years [95% confidence interval (95% CI) 8.91,10.89]. Median patient reported pain scores with the device were lower than with standard care (-2, 95%CI -4,0), as were parent-assessed pain scores (-2, 95%CI -4,-2). Observed distress behaviors were more common with standard care (2 [1,3]) than with the device (1[0,2] p=.036). A regression analysis controlling for pre-anxiety found an estimated reduction of 1.5 in child's self-reported pain score in the device group (p=0.032) and an estimated reduction of 1.8 in parent's report of child pain(p=.017). Venipuncture success was 3 times more likely with the device (p=.040). There were no device refusals.

Conclusions: The combination of cold and vibration decreased venipuncture pain significantly more than standard care without compromising procedural success. A device incorporating these elements could overcome the common barriers to needle procedure pain control.

Cold and Vibration Device "Buzzy"

- AAA batteries power motor
- Frozen ice pack
- Attached 5cm proximal
- Vibrates throughout preparation and cannulation



Subjects

Continuous and Categorical Demographic and Cannulation-related Variables of Entire Sample and Treatment Groups. Medians, 95% Confidence Intervals when appropriate.

	Entire Sample (n = 81)	Treatment Group	
		Standard Care (n = 40)	Device (n = 41)
Child Age (Median, (95% CI))	10.09 (8.91,10.89)	9.91 (6.68, 11.08)	10.10 (8.91,11.99)
Child Gender (% Male)	51.9%	45%	58.5%
Race			
% White	63%	67.5%	58.5%
% Black	12.3%	12.5%	12.2%
% Asian	1.2%	0%	2.4%
% Hispanic or Latino	16%	10%	22%
% Other	7.4%	10%	4.9%
Mother's Age (Mean; SD)	39.3	39.6(4.85)	39.15(6.38)
Mother's highest education	4.45	4.62(1.18)	4.28(1.38)
Child Pre-Procedure Anxiety (Median; 95% CI)*	2.5 (2,3)	3 (2,4)	2 (2,3)
Parent Pre-Procedure Anxiety (Median; 95% CI)	3 (3,4)	3 (3,4)	3 (2,4)
LMX4 (% Used)	48.1%	50%	46.3%
Site of Venous Access (% Hand)	61.7%	60%	63.4%
(% Antecubital Fossa)	33.3%	35%	31.7%
(% Forearm)	3.7%	5%	2.4%
(% Other)	1.2%	0%	2.4%
Type of Venous Access (% Cannulation)	90.1%	(38/40)95%	(35/41)85.4%
(% Blood Draw)	9.9%	(2/40)5%	(6/41)14.6%

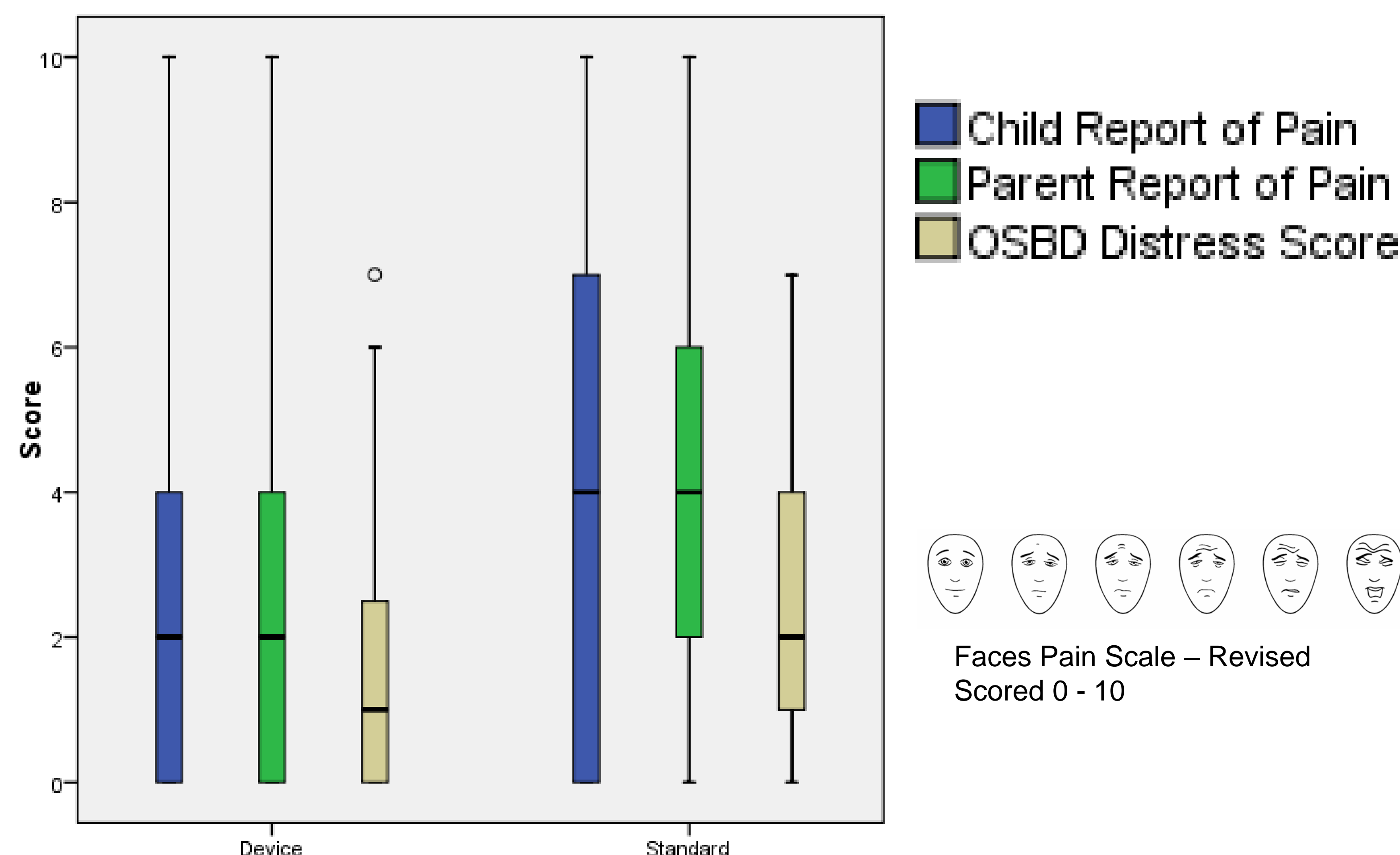
*Scored using 1 – 5 Children's Anxiety and Pain Scales

Results: IV Success, Median Pain Differences

	Treatment Group		Odds Ratio (95% CI)	p
	Standard Care (n = 40)	Device (n = 41)		
> One venous access attempt	35%	15%	3.05 (1.03,9.02)	.040
Minutes to IV Access (Mean;SD)	3.57 (2.45)	3.12 (2.17)		.44
In successful attempts	7.33 (11.42)	5.43 (6.93)		.37
Overall time				
	<i>Difference (95%CI)</i>			
Self-reported Pain (FPS-R)	4 (2, 6) *	2 (2,2)	-2(-4, 0)	.029
Parent-reported Child Pain (FPS-R)	4 (2,6) †	2 (0,4) ††	-2(-4, -2)	.005
Observational Score of Behavioral Distress	2 (1,3)	1 (0,2)	-1 (-2,0)	.036

*Missing 1: Parent reported "8", enroller documented child was "too lethargic" and would not circle or indicate face
†Missing 2: One parent stepped out of room for procedure, one asleep ††Missing 2: One parent stepped out of room for procedure, one on cell phone

Medians and IQR for Pain and Distress



Limitations

- Could not blind observational scale due to sound
- Placebo effect likely
- Pre-anxiety differed between groups (controlled in analysis)

Conclusions

- Cold and vibration device decreased venipuncture pain
- Improved venipuncture success

Implications

- A rapid reusable venipuncture pain relief method could overcome common barriers to pain control