Author(s): VS/AT
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Question: Should vapocoolants before vaccine injections vs placebo/no treatment be used for vaccine injection pain in children >3-17 years?
Settings: hospital and community clinic
Bibliography: Abbott 1995 (1,2), Eland 1981 (3,4), Cohen 2009, Cohen Reis 1997 (1), Luthy 2013 (1)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vapocoolants be applied before vaccine injections	Placebo/no treatment	Relative (95% CI)	Absolute		
Pain[1] (measured with: validated tool (Visual Analog Scale 0-3, Bieri Faces Pain Scale 0-6, Faces Pain Scale-Revised 0-10) ; Better indicated by lower values)												
4	randomised trials	serious[2]	no serious inconsistency[3,4,5]	no serious indirectness	serious[6]	none	101	127	-	SMD 0.38 lower (0.89 lower to 0.13 higher)	⊕⊕OO LOW	CRITICAL
Distress Acute [7] (measured with: validated tool (Visual Analog Scale 0-10/0-5, Bieri Faces Pain Scale 0-6) by researchers/parents; Better indicated by lower values)												
2	randomised trials	serious[2]	no serious inconsistency[3]	no serious indirectness	serious[6]	none	69	69	-	SMD 0.48 lower (1.57 lower to 0.6 higher)	⊕⊕OO LOW	IMPORTANT
Distress Pre-Procedure (measured with: validated tool (1-3 point scale) by clinician; Better indicated by lower values)												
1	randomised trials	serious[8]	no serious inconsistency	no serious indirectness	serious[6]	none	20	20	-	SMD 0.29 lower (0.33 lower to 0.92 higher)	⊕⊕OO LOW	IMPORTANT
Parent Preferences (measured with: validated tool (questionnaire); Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[6]	none	20	21	-	SMD 0.47 lower (1.09 lower to 0.15 higher)[10]	⊕⊕OO LOW	IMPORTANT

Parent Preferences (yes/no) (assessed with: validated tool (questionnaire, yes/no))												
1	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[6]	none	11/18 (61.1%)	16/22 (72.7%)	RR 0.84 (0.54 to 1.32)	116 fewer per 1000 (from 335 fewer to 233 more)	⊕⊕OO LOW	IMPORTANT
Safety[11] (assessed with: investigator report)												
1	randomised trials	serious[12]	no serious inconsistency	no serious indirectness	[13]	none	-	-	-	-		IMPORTANT
								0%		-		
Parent Fear (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[6]	none	20	21	-	SMD 0.35 lower (0.97 lower to 0.27 higher)	⊕⊕OO LOW	IMPORTANT
Fear, Procedure Outcomes, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] In the study by Abbott (1995), the sample size for the intervention (vapocoolant) group was divided by 2

[2] Immunizers, researchers, children and parents not consistently blinded; outcome assessor not consistently blinded

[3] In study by Cohen Reis (1997), vapocoolant + distraction was compared to distraction alone

[4] In study by Abbott (1995), vapocoolant administration was accompanied by suggestion that the needle would hurt less with cold cotton ball

[5] In study by Eland (1981), analysis (3) compared intervention (vapocoolant) and no cognitive information to placebo and no cognitive information; analysis (4) compared intervention (vapocoolant) and cognitive information with placebo and cognitive information. The cognitive information consisted of a statement that the needle would hurt less with the spray.

[6] Confidence interval crosses line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

[7] Study by Luthy (2013) includes children 2-12 years (mean age, 5.2 years). Results for children unable to self-report pain not separated from older children. This study is not included in the analysis of vapocoolant effectiveness for children 0-3 years due to the average age of 5.2 years. Of note, children < 3 years would not be expected to be able to provide self-report of pain.

[8] Immunizer not blinded; unclear if parents and children blinded; outcome assessor not blinded

[9] Immunizers, children and parents not blinded; outcome assessor not blinded

[10] In included study (Cohen Reis 1997), parents were willing to pay $8.40 for vapocoolant spray for future injections

[11] In one study (Cohen 2009), no adverse events were reported for the 31 children in the vapocoolant group

[12] Immunizer, child, researcher not blinded

[13] Data not pooled