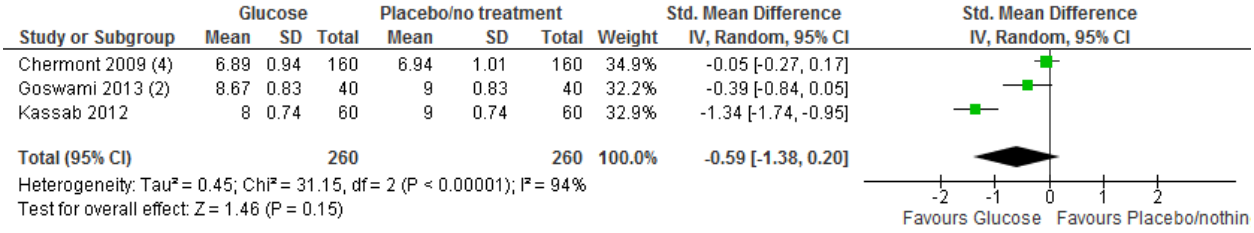
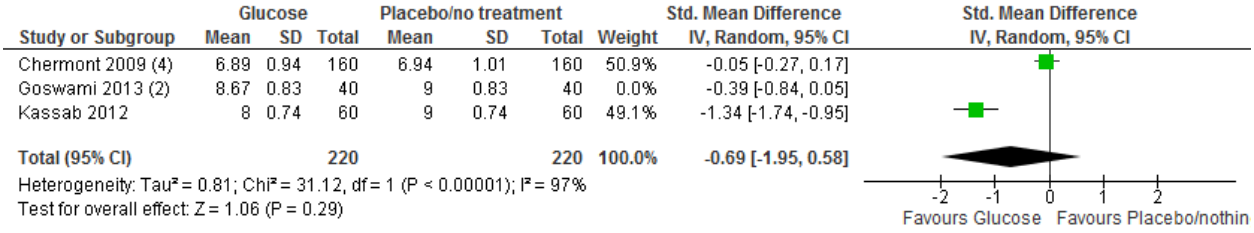
Revman Plots: Glucose child up to 2 yrs

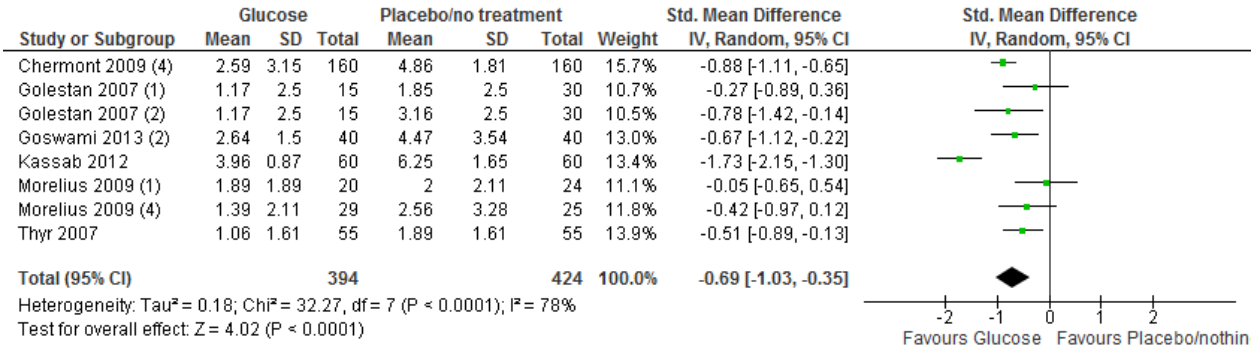
Distress Acute



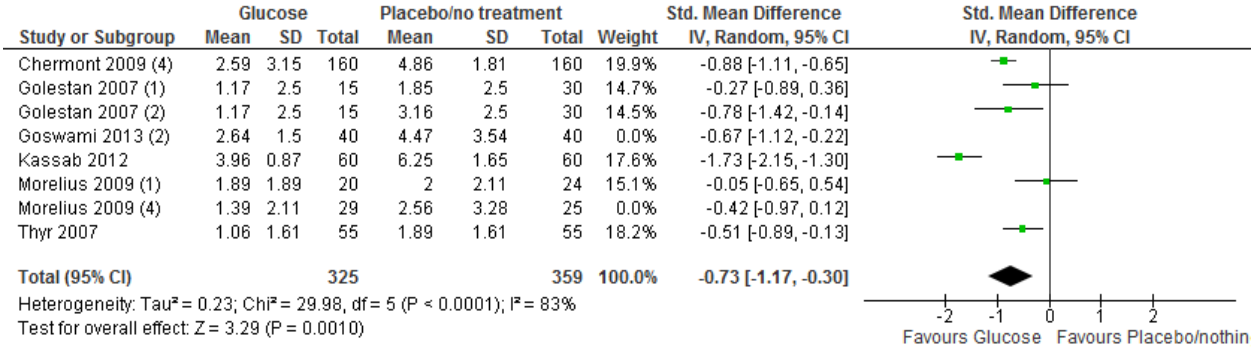
without data from study by Goswami 2013 (2) due to co-interventions (holding)



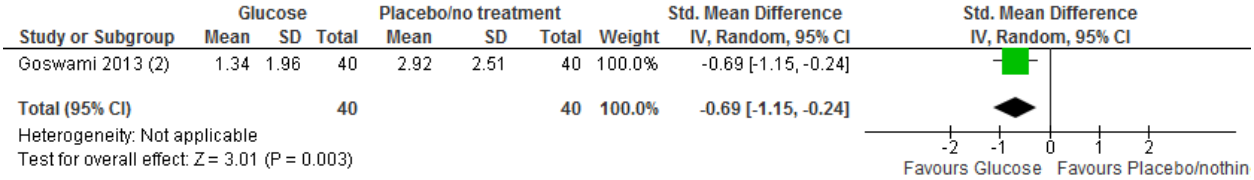
Distress Acute + Recovery



without data from study by Morelius 2009 (4) and Goswami 2013 (2) due to co-interventions (nonnutritive sucking and holding and holding, respectively)



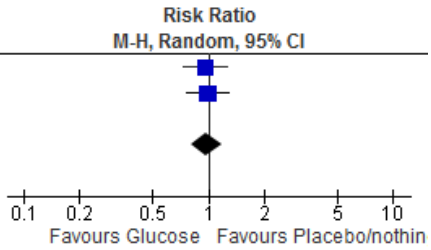
Distress Recovery



Distress Acute + Recovery (yes/no)

Study or Subgroup	Glucose Events	Glucose Total	Placebo/nothing Events	Placebo/nothing Total	Weight	Risk Ratio M-H, Random, 95% CI
Morelius 2009 (1)	16	20	20	24	47.7%	0.96 [0.72, 1.27]
Morelius 2009 (4)	23	29	20	25	52.3%	0.99 [0.76, 1.30]
Total (95% CI)		**49**		**49**	**100.0%**	**0.98 [0.80, 1.19]**
Total events	39		40			

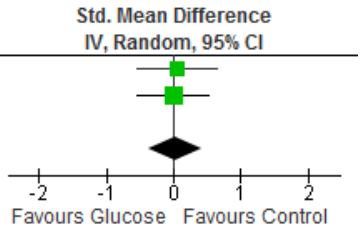
Heterogeneity: Tau² = 0.00; Chi² = 0.03, df = 1 (P = 0.87); I² = 0%
Test for overall effect: Z = 0.24 (P = 0.81)



Parent Fear

Study or Subgroup	Glucose Mean	Glucose SD	Glucose Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Morelius 2009 (1)	2.4	1.97	20	2.3	1.9	24	44.8%	0.05 [-0.54, 0.64]
Morelius 2009 (4)	2.93	2.59	29	2.94	2.58	25	55.2%	-0.00 [-0.54, 0.53]
Total (95% CI)			**49**			**49**	**100.0%**	**0.02 [-0.38, 0.42]**

Heterogeneity: Tau² = 0.00; Chi² = 0.02, df = 1 (P = 0.89); I² = 0%
Test for overall effect: Z = 0.10 (P = 0.92)



Author(s): VS/AT
Date: 2015-03-31
Question: Should glucose/dextrose solution vs placebo/no treatment be used for reducing vaccine injection pain in children up to 2 years?[1,2]
Settings: hospital, clinic
Bibliography: Chermont 2009 (4), Golestan 2007 (1,2), Goswami 2013 (2), Kassab 2012, Morelius 2009 (1,4), Thyr 2007

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Glucose/dextrose solution	Placebo/no treatment	Relative (95% CI)	Absolute		
Distress Acute[3] (measured with: validated tools (Premature Infant Pain Profile 0-18, Neonatal Infant Pain Scale 0-7, Neonatal Facial Coding Scale 0-8, Modified Behavioural Pain Scale 0-10, Modified Facial Coding Score 0-6) by researcher; Better indicated by lower values)												
3	randomised trials	no serious risk of bias	no serious inconsistency[4,5]	no serious indirectness	no serious imprecision	none	260	260	-	SMD 0.59 lower (1.38 lower to 0.2 higher)[3]	⊕⊕⊕⊕ HIGH	CRITICAL
Distress Acute + Recovery [3,6] (measured with: validated tool (Neonatal Facial Coding System 0-8, Neonatal Infant Pain Scale 0-7, Modified Facial Coding Score 0-6, cry duration) by researcher; Better indicated by lower values)												
6	randomised trials[2,7]	serious[8]	no serious inconsistency[9,10]	no serious indirectness	no serious imprecision	none	394	424	-	SMD 0.69 lower (1.03 to 0.35 lower)[3,6]	⊕⊕⊕O MODERATE	CRITICAL
Distress Acute + Recovery (yes/no) (assessed with: validated tool (cry yes/no))												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[11]	none	39/49 (79.6%)	40/49 (81.6%)	RR 0.98 (0.8 to 1.19)	16 fewer per 1000 (from 163 fewer to 155 more)	⊕⊕⊕O MODERATE	CRITICAL
Distress Recovery (measured with: validated tool (Modified Facial Coding System 0-6) by researcher; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency[12]	no serious indirectness	serious[13]	none	40	40	-	SMD 0.69 lower (1.15 to 0.24 lower)	⊕⊕⊕O MODERATE	CRITICAL

Safety[14] (assessed with: observation of infant for nausea, vomiting or physiologic instability)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[13]	none	-	-	not pooled[14]	not pooled[14]	⊕⊕⊕O MODERATE	IMPORTANT
								0%		not pooled		
Parent Fear (Acute)[15] (measured with: validated tool (Visual Analog Scale 0-10) ; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[11]	none	49	49	-	MD 0.02 higher (0.38 lower to 0.42 higher)[15]	⊕⊕⊕O MODERATE	IMPORTANT
Procedure Outcomes, Use of Intervention, Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] In 3 included studies, the concentration of glucose/dextrose was 25%; in 2 studies it was 30% and in 1 study it was 50%. The volume ranged from 1 - 2 mL.

[2] One study (Golestan 2007) compared glucose/dextrose to a no treatment group and a water comparison group. All other studies compared glucose/dextrose to a water comparison group.

[3] Additional information and data provided by 1 author (Chermont 2009)

[4] Heterogeneity can be explained by variability in infant age (from newborn to 3 months), volume of glucose/dextrose, individual administering intervention (parent or clinician), number of injections and co-interventions (holding vs. supine positioning of infant)

[5] In 1 study by Goswami 2013 (2), the additive effect of glucose/dextrose with holding was evaluated. Removal of the data from this study does not alter the meta-analytic results; distress scores are not statistically lower for the intervention (glucose/dextrose) group (SMD = -0.69 (95% CI -1.95 to 0.58))

[6] In 1 study (Thyr 2007), data from 3 different time points were combined; the sample size used for analysis was 55/group. At 3 and 5 months, infants were supine; at 12 months, infants were sitting on the knee of a parent.

[7] Parents administered the intervention in 2 studies (Kassab 2012, Thyr 2009)

[8] Immunizer and parent not consistently blinded

[9] Heterogeneity can be explained by variability in infant age (from newborn to 12 months), concentration and volume of glucose/dextrose, individual administering intervention (parent or clinician), timing of administration (from 2 minutes prior to injection, immediately before, and 30 seconds before, during and after injection), number of injections and co-interventions (holding vs. supine positioning of infant)

[10] In 1 study by Morelius 2009 (4), the additive effect of glucose/dextrose with a pacifier and holding was evaluated. In another study by Goswami 2013 (2), the additive effect of glucose/dextrose with holding was evaluated. Removal of the data from these 2 studies does not alter the meta-analytic results; distress scores are statistically lower for the intervention (glucose/dextrose) group (SMD = -0.73 (95% CI -1.17 to -0.30))

[11] Confidence intervals cross the line of nonsignificance and the sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

[12] In 1 study by Goswami 2013 (2), the additive effect of glucose/dextrose with holding was evaluated.

[13] Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

[14] In 1 study (Chermont 2009) including 320 infants, there were no reports of any adverse events as defined above.

[15] Additional information and data provided by 1 author (Morelius 2009)