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Question: Should topical anaesthetics vs placebo/control be used for reducing vaccine injection pain in adolescents >12 years and adults?¹

Settings: clinic, hospital

Bibliography: Hansen 1993, Taddio 1992

| Quality assessment | | | | | | | No of patients | | Effect | | Quality | Importance |
|---|-------------------|-------------------------|--------------------------|-------------------------|----------------------|----------------------|---------------------|-----------------|-------------------|---|------------------|------------|
| No of studies | Design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Topical anaesthetic | Placebo/control | Relative (95% CI) | Absolute | | |
| Pain (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 ² | none | 29 | 31 | - | SMD 0.85 lower (1.38 to 0.32 lower) | ⊕⊕⊕O MODERATE | CRITICAL |
| Distress Acute (measured with: validated tool (Likert scale 0-3) by researcher; Better indicated by lower values) | | | | | | | | | | | | |
| 1 | randomised trials | no serious risk of bias | no serious inconsistency | no serious indirectness | serious ³ | none | 58 | 59 | - | SMD 0.05 higher (0.31 lower to 0.41 higher) | ⊕⊕⊕O MODERATE | IMPORTANT |
| Safety (skin reactions) ⁴ (assessed with: observation of site for pallor, erythema (yes/no) by researcher) | | | | | | | | | | | | |
| 1 | randomised trials | no serious risk of bias | no serious inconsistency | no serious indirectness | serious ² | none | - | - | - | - | ⊕⊕⊕O MODERATE | IMPORTANT |
| | | | | | | | | 0% | | - | | |
| Preference ^{5,6} (assessed with: questionnaire) | | | | | | | | | | | | |
| 1 | randomised trials | no serious risk of bias | no serious inconsistency | no serious indirectness | serious ² | none | - | - | - | - | ⊕⊕⊕O MODERATE | IMPORTANT |
| | | | | | | | | 0% | | - | | |

| Distress, Fear, Procedure outcome, Safety (immunogenicity), Use of intervention, Vaccine Compliance, Memory, Satisfaction (assessed with: no data were identified for these important outcomes) | | | | | | | | | | | | |
|---|-----------------------|--|--|--|--|------|---|----|---|---|--|-----------|
| 0 | No evidence available | | | | | none | - | - | - | - | | IMPORTANT |
| | | | | | | | | 0% | | - | | |

¹ In study by Taddio (1992), vaccine was administered intramuscularly; in study by Hansen (1993), vaccine was administered subcutaneously.

² Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

³ Confidence interval crosses the line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁴ Information for safety included in GRADE profile for child 0-12 years

⁵ In study by Taddio (1992), 52/60 (87%) of participants reported that they could fit the application of the cream in their schedules. All (100%) of participants reported that the cream was not difficult to apply.

⁶ In study by Hansen (1993), children were asked about whether they would like topical anaesthetics to be used in the future and 65/111 (59%) reported that they would.