



ORIGINAL RESEARCH PAPER

Paediatrics

STUDY OF REDUCING PAIN BY TOPICAL ANAESTHETIC IN INFANTS DURING DPT COMBO VACCINATION: RANDOMIZED CONTROLLED TRIAL

KEY WORDS: Topical anesthetic patch, Vaccination, Pain score, Infants

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ABSTRACT

Aims and Objective: To study efficacy of topical anesthetic patch (lidocaine–prilocaine 5%) in reducing pain during DPT combo vaccination.

Methods: 70 patients were given cream (experimental group) and rest were given no patch (control group) by randomized method. Pain was assessed using modified behaviour pain scale for infants at the time of injection and after injection. Pain score was compared between two groups. Data was analysed and categorical tables, unpaired t test was applied.

Results: The post vaccination pain score of the infants shows difference in case and control groups. The average score of pain after vaccination in control group was 7.81±.906 and in cases was 6.50±.697. The use of emla patch pre vaccination leads to reduced pain in infants and a lower pain score after vaccination with p value <0.05.

Conclusion: The use of topical anaesthetic patch in healthy infants before vaccination leads to reduction in pain score of infants due to vaccination. Moreover there is increased compliance and follow up of parents for the subsequent visits and vaccination.

INTRODUCTION

Injections for vaccination, the most common source of iatrogenic pain in childhood, are administered repeatedly to almost all children throughout infancy, childhood and adolescence. The pain associated with such injections is a source of distress for children, their parents and those administering the injections. If not addressed, this pain can lead to preprocedural anxiety in the future, needle fear and health care avoidance behaviors, resulting in nonadherence with vaccination schedules.[1] It is estimated that up to 25% of adults have a fear of needles, with most fears developing in childhood. About 10% of the population avoids vaccination and other needle procedures because of this.

Conversely, minimizing pain during childhood vaccination can help to prevent distress, development of needle fears and subsequent health care avoidance behaviors, such as nonadherence with vaccination schedules. More positive experiences during vaccine injections also maintain and promote trust in health care providers.

In light of the prevalence of pain during vaccine injections and the potential for substantial short-term and long-term adverse sequelae, we identified a need for guidelines to address this important public health issue.[4]

AIMS & OBJECTIVE

To study efficacy of topical anesthetic patch (lidocaine–prilocaine 5%) in reducing pain during DPT combo vaccination.

JUSTIFICATION

DTP is the most painful vaccine in the childhood immunization schedule. The pain associated with these injections is a source of distress for children, their parents and those administering the injections. If not addressed, this pain can lead to preprocedural anxiety in the future, needle fears and health care avoidance behaviours, including nonadherence to vaccination schedules. [2] Studies shows that topical lidocaine-prilocaine 5% patch has no adverse effect on the antibody response to the vaccine antigens, is effective in reducing pain associated with DTwP-Hib and hepatitis B immunizations and does not result in any significant adverse reactions.[7]

METHODOLOGY

Type of study	Randomized control trial
Place of study	Sir Takhtsinhji General Hospital Bhavnagar.
Number of cases	140 cases
Duration	1 year

INCLUSION CRITERIA:

- Apparently healthy infant aged 1 month to 1 year

EXCLUSION CRITERIA:

- Age less than 1 month
- Age more than 12 month
- Neonates who were delivered before 37 week
- Congenital anomalies
- Child with central nervous system related diseases
- History of adverse effect or allergy with previous vaccination

METHODS

Infants who fulfilled above criteria were included in the study after informed written consents of parents and /or guardian.

70 patients were given cream (experimental group) and rest were given no patch (control group) by randomized method.

Lidocaineprilocaine 5% cream with occlusive dressing was applied over injection site 60 min before and removed before injection. DPT combo vaccine was given as per standard guidelines (deep intramuscular on anterolateral aspect of thigh) at the site of application. Pain was assessed by using modified behaviour pain scale for infants at the time of injection and after injection. Pain score will be compared between two groups.

Infants were observed for one hour after vaccination for any adverse effect due to vaccination and patch and if there any, notified and treated accordingly.

OUTCOMES MEASURES

Pain score was assessed in both the groups and compared.

STATISTICAL ANALYSIS

Data analysed and categorical tables, unpaired t test applied. Conclusion drawn from data.

Table 1: the pre vaccination pain score of the infants is almost the same in both case and control groups. The average score of pain before vaccination in control group was 1.63±1.194 and in cases was 1.67±1.224.

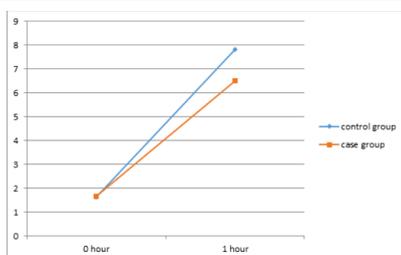
	emla patch	N	Mean	Std. Deviation	Std. Error Mean
pre-score	0	70	1.63	1.194	.143
	1	70	1.67	1.224	.146

Table 2: the post vaccination pain score of the infants shows difference in case and control groups. The average score of pain after vaccination in control group was $7.81 \pm .906$ and in cases was $6.50 \pm .697$.

	emla patch	N	Mean	Std. Deviation	Std. Error Mean
post-score	0	70	7.81	.906	.108
	1	70	6.50	.697	.083

Table 3: depicts that the usage of emla patch produces a highly significant results with p value <0.05.

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
post-score	Equal variances assumed	2.442	.120	9.624	138	.000	1.314	.137	1.044	1.584
	Equal variances not assumed			9.624	129.496	.000	1.314	.137	1.044	1.584



DISCUSSION

The DPT combo vaccination is associated with much pain in infants which is stressful to parents also to an extent. This use of topical anaesthetic patch in infants one hour before vaccination can lead to reduced pain in infants post vaccination and increased compliance and follow up of parents, thus improving immunization status.

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