

A Pilot Randomized Trial to Compare the Risk of Local Skin Infection by Preparation of Injection Site with Boiled Cotton Swabs, Alcohol Swabs and With No Swabbing

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ABSTRACT

Background: Injections are most common procedures performed by nurses, thus their responsibility to make them safe and effective. Hence the concept of injection site preparation came into practice, but there are various guidelines regarding skin preparation prior to injection leaving nurses in uncertainty. So the present study was taken up.

Methods: Immunization room, PGIMER, Chandigarh was chosen as study setting. Total of 450 subjects were enrolled from July-October 2014, using total enumeration sampling technique. The allocation was done using block randomization. Interview schedule and Observational checklist to collect data was developed and validated by experts in field of nursing and pediatrics. Parents were educated about implementation of observational checklist to detect various symptoms of infection and their observation was validated. The data was collected using the interview schedule and implementation of observational checklist by parents telephonically. **Results:** There was no statistical significant difference in occurrence of infection by using any of the three methods i.e. boiled cotton swab, alcohol swab and no swabbing for injection site preparation.

Conclusion: The study concludes that any of the above said methods can be employed to prepare the injection site prior to injection.

Keywords- injection site preparation, immunization, Boiled swabs, alcohol swabs, no swabbing

INTRODUCTION

According to the World Health Organization (WHO) and Safe Injection Global Network (SIGN), injections are most common health care procedures performed by nurses at an estimated rate of 16 billion administrations per year. [1] Approximately 1 billion injections are given yearly in course of childhood vaccination programs. [2]

It is supposed that the skin is contaminated with organisms which might cause pathological changes when introduced into the body through injection needle. This assumption lead to teaching of medical students, trainee doctors, nurses and patients to have skin prepared before injection by cleansing with some form of antiseptic to prevent infections at the injection site. [3]

From earlier times the alcohol swabs are used to sterilize the injection site prior to injection. But then there were findings that alcohol causes skin irritation. [4] Moreover alcohol can result in inactivation of live vaccines. For these reasons the practice of using boiled cotton swabs for cleaning the injection site for immunization came into use. Use of boiled cotton swabs is the most common and preferred method of injection site preparation for immunization. In the immunization handbook for medical officers, Government of India, it is recommended that if the injection site is dirty then clean it with a clean water swab

and administer the vaccine.^[4] But according to latest WHO recommendations, in collaboration of ICN it is recommended that, "Do not use cotton balls stored wet in a multi-use container." WHO has also recommended that if the skin is visibly clean then there is no need to clean the injection site prior to vaccination.^[6]

The researchers from few years have questioned the worth of skin preparation prior to administering injection. A landmark study carried out by Dann at a medical centre where more than 5000 injections were given without skin preparation to patients between 4 and 66 years of age. No cases of infection, neither systemic nor local, were identified. As a result it was concluded that infection could not be introduced via the needle from unsterilized skin.^[7] Another study was carried out by Yutin H, in which best practice in relation to the prevention of injection associated infection for the WHO was reviewed. It was found out that swabbing of clean skin prior to injection is unnecessary.^[8]

Despite these findings there is a lack of research to establish a firm evidence base for cleaning the skin prior to the administration of an intramuscular injection. For skin preparation before injection in hospitals and the routine practice is to use alcohol swabs. But for vaccination most of the institutions do not recommend alcohol swabs and boiled swabs are used for immunization to prepare skin. But WHO has mentioned not to use cotton balls stored in a multiuse container and it is also pointed out by the infection control committee of PGIMER, Chandigarh. Even no swabbing of visibly clean skin prior to injection is recommended by WHO. So the study was taken up with the objective to compare the risk of local skin infection by preparation of injection site with boiled cotton swabs, alcohol swabs and with no swabbing of visibly clean skin for DPT/ combination vaccines among infants at Advanced Pediatric Center, PGIMER, Chandigarh.

MATERIALS AND METHODS

An experimental design was adopted to compare the risk of infection at injection site using the three method of injection site preparation. The inclusion criteria were Infants receiving DPT/ combination vaccines. The study was conducted at Immunization room, Advanced Pediatric Center, PGIMER, Chandigarh. There were three methods which were used to prepare injection site prior to DPT/ combination vaccines i.e. Preparing injection site using boiled cotton swabs, Preparing injection site using alcohol swabs, No swabbing of visibly clean skin. Study sample were selected by total enumeration sampling technique from July- October 2014. Sample size for the study was 450 samples (150 in each group). Allocation was done by block randomization by day randomization. The immunization is conducted daily i.e. 6 days a week. Alternatively each protocol was implemented according to the randomization. The randomization numbers were computer generated and were sealed in opaque envelopes. The methods of skin preparation before injection administration were allocated in the different days of week.

The tools i.e. interview schedule and observational checklist and three protocols for skin preparation were prepared from the review of literature and validated by experts in the field of nursing and pediatrics. Observation checklist included various symptoms indicating local skin infection. Total 15 symptoms were included in the checklist. Intensity of symptoms was graded according to adverse events after immunization and common terminology criteria for adverse events.

Grade 1 infection means presence of any of the symptoms- tenderness with or without warmth or edema or fever 100.4°F- 101.1°F or nodule or rash

Grade 2 infection means presence of any of the symptoms - pain or edema or Lymphadenopathy or restricted limb movement or persistent crying or fever 101.2- 102.0°F or cellulitis

Grade 3 infection means presence of any of the symptoms- abscess or fever 102.1-104°F.

Reliability of tools was checked by inter-rater method. Two raters administered the same tools on same subjects. The tool was administered on 5 subjects. The inter rater reliability was checked by using Cohen Kappa index. It was found to be reliable with Kappa index 0.95.

ANMs were educated and trained to implement the procedural protocols of three methods of skin preparation.

At first contact with the researcher, the parents were educated about the implementation of the observational checklist to identify the symptoms of infection at the injection site. The parents' observations were validated by asking them to implement the observational checklist and to report the symptoms telephonically. Then the researcher visited the house to check the reliability of parents' observations. Cohen Kappa was calculated to check the validity. 60 random homes were visited and there were 55 agreements and 5 disagreements between the investigator and the parents. Cohen kappa was found out to be 0.913 which shows strong agreement with p value <0.001.

The data was collected in the months of July- October; 2014. Informed consent

was taken from parents/ guardians of each study subject enrolled. Using the interview schedule, the data was collected from the parent/ guardian. At the first contact with parents at the time of vaccination, their address and phone numbers were collected. ANM administered the DPT/ combination vaccines vaccine using the three protocols under the supervision of Principal Investigator

The checklist was used to check for local skin infection in post procedural follow ups from day 1 to day 7, i.e. a week or till the infection subsides by the parents. The parents were contacted telephonically from the same day to the 7th day of vaccination or till the infection subsides and they were asked to implement the observational checklist and to report the various symptoms included in the observational checklist.

Calculations were done with the help of SPSS 16.0 program. The data was analyzed using descriptive and inferential statistics. Various statistical measures were used such as measures of central tendency, measures of dispersion, percentages and parametric tests i.e. ANOVA and repeated measure ANOVA and the findings were interpreted and presented with the help of tables, graphs and diagrams.

RESULTS

Table1: Socio demographic profile of child. N= 450

Sample characteristics	Methods of injection site preparation before injection			χ^2 df p value
	Boiled Swab (n=150) n(%)*	Alcohol Swab (n=150)n(%)**	No Swabbing (n=150) n(%)***	
Age of child (months)				
<2	76 (50.7)	70 (46.7)	69 (46.0)	5.125
2-4	69 (46.0)	70 (46.6)	69 (46.0)	4
>4	5 (3.3)	10 (6.7)	12 (8.0)	0.277
Sex				0.529
Male	90 (60.0)	94 (62.6)	96 (64.0)	2
Female	60 (40.0)	56 (37.4)	54 (36.0)	0.767
Weight of child (kg)				
<2.51	8 (5.3)	9 (6.0)	5 (3.3)	5.986
2.51-4.51	73 (48.7)	66 (44.0)	60 (40.0)	6
4.52-6.51	56 (37.3)	61 (40.7)	62 (41.3)	0.231
>6.52	13 (8.7)	14 (9.3)	23 (15.4)	

Age (months): Mean± SD (range) - *1.97± 1.081 (1.10-8), **2.25± 1.138 (1.10-5.21), ***2.24± 1.206 (1.10 – 6.00),
Weight (Kg): Mean± SD (range) - *4.58 ± 1.323 (1.93-8.17), **4.62± 1.322 (1.90-7.63),*** 4.83± 1.353 (2.10-7.95),

Table 1 illustrates socio demographic profile of infants. The study subjects were equally distributed in each of the arm. Among the subjects of the boiled swab arm

and alcohol swab arm most of them were in the age group of below 4 month. In the no swabbing arm, 46% of the study subjects were below 2 months of age as well as in

the age group of 2-4 months. There were a higher proportion of males in all the three arms. The study subjects were in the range of 1.93-8.17 kg with mean weight 4.58± 1.323 in the boiled swab arm, 1.90-7.63 kg with mean weight 4.62± 1.322 in the alcohol swab arm and 2.10-7.95 kg with mean weight 4.83± 1.353 in the no swabbing arm of injection site preparation before injection. All the three arms were homogenous for age, gender and weight. (p value >0.05 as per chi square test).

Socio demographic profile of parents

Most of the parents were educated up to secondary level and above. In the three arms the occupation of the mothers was house wife in most of the cases and almost half of the fathers were professionals. The mean income of the parents in the boiled swab arm was Rs25007± 23835.91 with range of Rs 4000-150000. While in the second arm, (alcohol swab), the range of income was Rs3000-1000000 with mean income Rs20627± 19083.81. In no swabbing arm the monthly income of parents was in the range of Rs3500-175000 with mean income Rs25207± 27727.36. All the groups were homogenous in nature for educational and occupational status of parents and monthly income of family (p value> 0.05 as per chi-square test).

Most of the study subjects were administered pentavac and easy five in all the three arms of the study. The 1st dose of

vaccine was given to half of the study subjects in the three arms of the study. The results depict the homogenous nature of all the three groups for type of vaccine administered and for dose of vaccine (p value >0.05 as per chi-square test).

Symptoms reported by parents telephonically

Almost all the study subjects had fever on the day of vaccination which reduced to half on day 1. Persistent crying was present on the day of vaccination only. Redness, tenderness, swelling was present on the same day of vaccination and decreased on day 1. Very few (2.6%) subjects had painless nodule formulation in the boiled swab arm and resolved by 10th-25th day of vaccination. In the alcohol swab arm 2.0% subjects had formed painless nodule at the injection site and it resolved by 15th-20th day of vaccination. While in no swabbing group 0.6% of subjects had painless nodule which was resolved by 25th day after vaccination.

Intensity of infection among subjects

Table 2 compares the intensity of infection among three arms of injection site preparation. On day of vaccination, 4.6% of subjects had no infection, 78.6% had Grade 2 infection and 16.6% had Grade 1 infection in the boiled swab arm. While in alcohol swab arm 2.6% had no infection, 27.3 had Grade 1 infection and 70.0% had Grade 2 infection.

Table 2: Intensity of infection among subjects. N=450

Days	Intensity of infection	Methods of injection site preparation before injection			χ ² /Fisher Exact df p value
		Boiled swab (n=150) n (%)	Alcohol swab (n=150) n (%)	No swabbing (n=150) n (%)	
Day 0	No infection	7 (4.6)	4 (2.6)	6 (4.0)	4.656 2 0.097
	Grade 1	25 (16.6)	41 (27.3)	32 (21.3)	
	Grade 2	118 (78.6)	105 (70.0)	112 (74.6)	
Day 1	No infection	68 (45.3)	75 (50.0)	63 (42.0)	3.731 2 0.155
	Grade 1	81 (54.0)	71 (47.3)	86 (57.3)	
	Grade 2	1 (0.6)	4 (2.6)	1 (0.6)	
Day 2	No infection	140 (93.3)	137 (91.3)	137 (91.3)	1.820 2 0.403**
	Grade 1	10 (6.6)	12 (8.0)	13 (8.6)	
	Grade 2	----	1 (0.6)	----	
Day 3	No infection	146 (97.3)	144 (96.0)	147 (98.0)	1.109 2 0.687*
	Grade 1	4 (2.6)	6 (4.0)	3 (2.0)	
Day 4-7	No infection	146 (97.3)	147 (98.0)	149 (99.3)	1.780 2 0.546*
	Grade 1	4 (2.6)	3 (2.0)	1 (0.6)	

*Yates correction ** Fisher Exact

In no swabbing arm 4.0% were having no infection, 21.3% had Grade 1 infection and 74.6% had Grade 2 infection. On 1st day after vaccination, half of the subjects had no infection and by next day almost all the subjects had no infection among the three arms. On day 7th, 8 subjects had of painless nodule, which resolved by 10- 25 days. There was no statistical significant difference in intensity of symptoms between the three arms (p value>0.05 as per chi-square test).

Comparison of presence of local skin infection after vaccination between and within the arms

Comparison of presence of local skin infection after vaccination from day 0 to day 7 between the three arms i.e. boiled cotton swabs, alcohol swabs and no swabbing of visibly clean skin and within

the three arms was done. There was no statistical significant difference in presence of local skin infection after vaccination from day 0 to day 7 between and within the three arms (p value >0.05 as per ANOVA test)

Comparison of presence of local infection after vaccination at injection site

Table 3 depicts the comparison of three of the arms boiled cotton swabs, alcohol swabs and no swabbing of visibly clean skin for preparation of injection site in occurrence of infection at injection site. Comparison of three study arms in pairs with each other showed that there is no statistical significant difference in local skin infection after vaccination between arms(p value>0.05 as per Bonferroni and Dunnett T3 test).

Table 3: Comparison of presence of local infection after vaccination at injection site N= 450

(A) local infection at injection site	(B) local infection at injection site	Mean Difference (A-B)	p value*	95% Confidence Interval	
				Lower Bound	Upper Bound
Bonferroni					
Boiled cotton swabs	alcohol swabs	.010	1.00	-0.034	0.054
	no swabbing	.008	1.00	-0.036	0.052
Alcohol swabs	no swabbing	-.001	1.00	-0.046	0.042
Dunnett T3					
Boiled cotton swabs	alcohol swabs	.010	0.94	-0.037	0.057
	no swabbing	.008	0.95	-0.033	0.052
Alcohol swabs	no swabbing	-.001	1.00	-0.044	0.042

*Repeated measure ANOVA

Management of fever and care of injection site

As reported by parents almost all the study subjects were administered antipyretics in the three arms. In boiled swab arm 43.1% were administered more than 3 doses. While 37.4% were administered more than 3 doses in alcohol swab arm and 44.5% in no swabbing arm. Most of the study subjects were administered antipyretics for two days in the three arms. There was no statistical significant difference among the three arms for number of doses of antipyretics and number of days of antipyretics administration (p value>0.05 as per chi-square test).

Few subjects applied ice (7.3%) on the injection site to relieve tenderness and pain in all the three arms of the study and 2.0% of subjects applied vicks only in boiled swab arm. The application was done for 2 days among the three of the study arms. No statistical significant difference was there among the three arms for care of injection site (p value>0.05 as per chi-square test).

DISCUSSION

Injections are the commonest procedures performed by nurses all around the world. While providing any type of injection it is necessary to make it safe, i.e. it should not harm the patient and the health care provider. In effort to make the

injections safe, the concept of injection site preparation came into practice to employ infection control.

There are different guidelines followed by different health care institutions leaving nurses in an uncertain situation as to prepare the skin or not. Moreover there is lack of evidence to prove this that whether swabbing or no swabbing will lead to any infection at injection site. So the present study was undertaken with an objective to compare the risk of local skin infection by preparation of injection site with boiled cotton swabs, alcohol swabs and with no swabbing of visibly clean skin for DPT/combination vaccines among infants.

Though there are guidelines present to administer the injections but still every health professional follows what they are comfortable with. So to maintain the uniformity in administering the vaccine, three different protocols were developed for the three methods of skin preparation. The ANM's were educated and trained to implement the three procedural protocols. Re-demonstrations were taken to ensure the correct implementation of the protocols.

Parents are the best observers to detect any changes in their child at the earliest. So at first contact the parents were educated about the implementation of observational checklist to identify the symptoms of infection and their observation was validated. The follow up was done telephonically to identify the symptoms of infection using observational checklist by the parents. There are studies that are conducted in the past (Reilly et al) showing effectiveness of telephonic follow up. The effectiveness of telephonic follow up in order to estimate the rate of orthopedic surgical site infection in the community was measured and it was found an effective method of identifying infection after discharge from hospital. [9]

Literature reports that the abscess formation at injection site occurs within 7 days of injection administration and the other symptoms like swelling, redness usually appears within 48 hours. [10] So the

follow up was planned for 7 days or till the infection subsides. The follow up was extended beyond 7 days as to observe any symptom which could be infectious later on.

Studies report that DPT vaccine causes local redness, limited limb movement, local pain, swelling, fever, persistent crying. [10,11] It is also mentioned in the adverse events following immunization: interpretation and clinical guide. Antipyretics are recommended for fever following an immunization. [12] Similar events had been reported in present study by parents. There was gradual reduction in the symptoms from day 0 of vaccination to day 7 after the vaccination as this is the normal course for DPT/Combination vaccines. Most of the infants presented with fever, swelling, tenderness at the injection site, restricted limb movement. Painless nodule formation was there in few of the infants. The symptoms which were present in the infants were effects of DPT/combination vaccines as most of them resolved by the day 2nd after vaccination. No serious local skin infection was reported in the study subjects among any of the study arms.

In the present study it had been seen that there was no statistical significant difference in occurrence of local skin infection at the injection site among the three arms (p value= 1.00). Similar results were found in the study conducted by Dann TC which showed the same results that there is no local skin preparation even without preparation of skin. [7] One more study in which alcohol swabs and no swabbing were compared for local skin infection before venesection and the results were found to be non-significant. [13]

The study results concluded that any of the three methods can be employed to prepare the injection site prior to vaccination, whether prepare skin with boiled cotton swabs, alcohol swabs or do not prepare the visibly clean skin. The study recommended that no swabbing of visibly clean skin for preparation of injection site is equally safe and effective as preparing skin with boiled cotton swabs and alcohol swabs.

The sample size of the study was small to generalize the findings. Similar studies can be replicated in different setting with larger sample for longer duration to generalize the findings.

CONCLUSION

The study concludes that there is no statistical significant difference in the occurrence of injection site infection in three groups of injection site preparation i.e. boiled cotton swab, alcohol swabs and no swabbing of visibly clean skin prior to injection.

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