

**Research Article****4% Chlorhexidine versus Methylated Spirit Cleansing of the Umbilical Cord in the Prevention of Omphalitis****Usama Masood, Ayesha Kiran, Afifa Ghauri  
and Muhammad Aamir**<sup>1</sup>Post Graduate Resident, Department of Pediatric Medicine, Bahawal Victoria Hospital,Bahawalpur <sup>2</sup>Woman Medical Officer, THQ Hospital, Yazman<sup>3</sup>Woman Medical Officer, Govt. Maternity Hospital, Paathi Ground, Lahore<sup>4</sup>Post Graduate Resident, Department of Medicine, Mayo Hospital, Lahore**ABSTRACT**

**Introduction:** There are a number of antiseptics which are being used for umbilical cleansing. These include alcohol, methylated spirit, silver sulphadiazine, iodine, chlorhexidine; and dyes such as triple dye, gentian violet, acriflavine and eosin) and/or topical application of antibiotics and even human milk.

**Objectives:** To compare the efficacy of 4% chlorhexidine with methylated spirit in the cleansing of the umbilical cord for the prevention of omphalitis.

**Study Design:** Randomized clinical trial.

**Study duration:** 27<sup>th</sup> July 2017 to 26<sup>th</sup> January 2017.

**Settings:** Pediatric Medical Unit 1, Bahawal Victoria Hospital, Bahawalpur.

**Materials & Methods:** A total of 96 healthy full term babies weighing 2.5Kg or more delivered through vaginal delivery of either gender were included. Patients who will need antibiotics were excluded. The group A was considered as Chlorhexidine group while group B as Methylated spirit group. The researcher himself examined the umbilicus for signs of omphalitis.

**Results:** Gestational age in this study was from 37 to 41 weeks with mean gestational age of  $38.92 \pm 1.18$  weeks. In this study, efficacy (prevention of omphalitis or normal shedding of umbilicus within seven days of start of therapy) was seen in 45 (93.75%) patients in group A (4% chlorhexidine) and in 38 (79.17%) patients in group B (methylated spirit) with p value of 0.037 which is statistically significant.

**Conclusion:** This study concluded that efficacy of 4% chlorhexidine is more as compared to methylated spirit for the prevention of omphalitis.

**Keywords:** omphalitis, chlorhexidine, methylated spirit.

**INTRODUCTION**

Pakistan rank at 23<sup>rd</sup> number of countries with highest under 5 mortality.<sup>1</sup> About every year nearly 45% of all under 5 child deaths are amongst the neonatal period (babies in their first 28 days of life). Three quarters of all newborn deaths occur in the first week of life. Sepsis is one the three major causes of neonatal mortality in Pakistan. The main source of infection is through umbilical cord.<sup>2</sup> The application of antiseptic reduces the neonatal morbidity and mortality in developing countries.<sup>3-5</sup>

There is considerable debate among health care professionals about the most effective newborn umbilical cord care. Historically, there has been a wide range of recommended practices related to umbilical cord care that have included a variety of cleansing agents and techniques. Recent research has indicated that, in the context of modern infection control policies, the current standard of umbilical cord care may be based on historic practices and traditions rather than scientific investigation and

justification. These studies recommend abandoning the traditional use of antimicrobials for soap and water or natural healing.<sup>6, 7</sup>

Originally, cord care addressed concerns for bacterial colonization and subsequent infection; however, the relationship between umbilical colonization and infection was unclear. Delayed cord separation has also been proposed to increase the incidence of infection.<sup>8</sup> The use of antimicrobial umbilical cord treatment such as isopropyl alcohol (alcohol) has consistently been proven to lengthen the time of cord separation. Yet, alcohol continues to be routinely used as an antimicrobial agent for the purpose of cord drying and is recommended by health care providers as an agent to hasten cord separation.<sup>9</sup>

There are a number of antiseptics which are being used for umbilical cleansing. These include alcohol, methylated spirit, silver sulphadiazine, iodine, chlorhexidine; and dyes such as triple dye, gentian violet, acriflavine and eosin) and/or topical application of antibiotics (for example, bacitracin, neomycin, nitrofurazone, or tetracycline, or moisture absorbing powders) and even human milk.<sup>10-12</sup> These antiseptics cause 27% to 56% reduction in the rate of omphalitis.<sup>5</sup> Sinha A et al 2015 showed in their review that chlorhexidine cord care in the community setting resulted in a 50% reduction in the incidence of omphalitis and a 12% reduction in neonatal mortality.<sup>13</sup>

The methylated spirit is commonly used in Pakistan for umbilical cord cleansing. But there are no studies available nationally or locally on methylated spirit in the prevention of omphalitis. Moreover there is only one study available on chlorhexidine in Pakistan that was conducted by Soofi S et al 2012 and showed that the incidence of omphalitis was 3.7% in newborn treated with 4% chlorhexidine.<sup>14</sup> So this study was planned. The comparison of the two drugs will guide us for the better choice of drug in the prevention of omphalitis and thus making policy to decrease neonatal

mortality and morbidity.

## OBJECTIVE

To compare the efficacy of 4% chlorhexidine with methylated spirit in the cleansing of the umbilical cord for the prevention of omphalitis.

## MATERIALS & METHODS

**STUDY DESIGN:** Randomized clinical trial.

**SETTING:** Pediatric Medical Unit 1, Bahawal Victoria Hospital, BahawalPur.

**DURATION OF STUDY:** 27<sup>th</sup> July 2017 to 26<sup>th</sup> January 2017.

**SAMPLE SIZE:** There is no study available to compare the efficacy of chlorhexidine with methylated spirit. Sample size is calculated from the study conducted by Soofi S et al 2012<sup>14</sup> in Pakistan that showed the efficacy of chlorhexidine in the prevention of omphalitis was 96.3%. 20 newborns were observed following administration of methylated spirit for the development of omphalitis in our ward setting for seven days. 16 out of 20 newborn babies had normal shedding of umbilicus within seven days of start of therapy, 4 newborn babies however developed redness around the umbilical site with pus. Efficacy in prevention of omphalitis was found to be 80%, the design effect was taken as 1. Since the ratio of sample size (for each group) was 1:1 the sample size was calculated as 96 (48 in each group) taking confidence level at 95% and power taken at 80% calculated through sample size software available at <http://select-statistics.co.uk/calculators/sample-size-calculator-two-proportions/>.

**SAMPLE TECHNIQUE:** Non-probability, consecutive sampling.

## SAMPLE SELECTION:

### a. Inclusion Criteria:

1. Healthy full term babies weighing 2.5Kg or more delivered through vaginal delivery in the hospital setting
2. Of either sex
3. Presenting within 6 hours of life.

**b. Exclusion Criteria:**

- 1- Newborns who will need antibiotics within 48 hours of life
- 2- Those with umbilical catheters.

**DATA COLLECTION PROCEDURE:**

The researcher kept in contact with the registrar of the Gynecology department for information on any delivery conducted in the Gynecology Department. The informed consent was taken from parents or guardian. The study was approved by the local ethical committee. The patients were allotted group A or group B by the lottery method. Their demographic data as well as brief history and weight (as shown in Performa given in annexure-A) was taken. The group A was considered as Chlorhexidine group while group B as Methylated spirit group. The researcher taught the mother or accompanying person that, after washing hands, how to apply the drugs to the tip of the cord, the stump and around the base of the stump. The baby received her first dose by the mother or accompanying person in the researcher's presence and was asked to repeat application once daily for five days. Researcher was in contact through mobile phone daily with mother/father to avoid non-compliance. The researcher himself gave drug 4% chlorhexidine to accompanying person of group A and methylated spirit to accompanying person of group B for use at home. They were asked to bring the baby immediately if umbilicus becomes red. Otherwise they were brought the baby at day 7. The researcher himself

**Table-I:** Baseline characteristics of neoantes (n=96)

	Group A (n=48)		Group B (n=48)		Total (n=96)	
	No. of patients	% age	No. of patients	% age	No. of patients	% age
<b>Gestational age</b>	<b>38.88 ± 1.18</b>		<b>39.29 ± 1.18</b>		<b>38.92 ± 1.18</b>	
37-39 weeks	34	70.83	26	54.17	50	52.08
40-41 weeks	14	29.17	22	45.83	36	47.92
Male	26	54.17	25	52.08	51	53.13
Female	22	45.83	23	47.92	45	46.87
<b>Weight</b>	<b>3.50 ± 0.46</b>		<b>3.60 ± 0.53</b>		<b>3.54 ± 0.51</b>	
2.5-3.5	22	45.83	20	41.67	42	43.75
>3.5	26	54.17	28	58.33	56	56.25

examined the umbilicus for signs of omphalitis (if there is oozing of pus from the umbilicus along with the presence of redness in the peri umbilical area), otherwise efficacy was noted (prevention of omphalitis or normal shedding of umbilicus within seven days of start of therapy). Data was entered in Performa.

**DATA ANALYSIS:**

The data was analyzed in SPSS Version 17. Mean ± S.D were presented for gestational age and weight of newborn. Frequencies and percentage were presented for gender, educational status of mother, father and efficacy. Two groups were compared in terms of efficacy applying Chi Square Test. p value less than 0.05% was taken as significant.

**RESULTS**

Gestational age in this study was from 37 to 41 weeks with mean gestational age of 38.92 ± 1.18 weeks. The mean gestational age in group A was 38.88 ± 1.18 weeks and in group B was 39.29 ± 1.18 weeks. Distribution of patients according to gender of baby is shown in Table II. Mean weight of baby was 3.54 ± 0.51 kg (Table I). In this study, efficacy (prevention of omphalitis or normal shedding of umbilicus within seven days of start of therapy) was seen in 45 (93.75%) patients in group A (4% chlorhexidine) and in 38 (79.17%) patients in group B (methylated spirit) with p value of 0.037 which is statistically significant (Table II).

**Table II:** Comparison of efficacy between both groups.

EFFICACY	Group A (n=48)		Group B (n=48)		P-value
	Frequency	% age	Frequency	% age	
Yes	45	93.75	38	79.17	<b>0.037</b>
No	03	6.25	10	20.83	

## DISCUSSION

Annually about 3.3 million neonatal deaths occur around the world;<sup>15</sup> of these, more than 30% are caused by infections.<sup>16, 17</sup> Some of these infections start as umbilical cord infection. The umbilical cord area supports growth of some innocuous or beneficial microorganisms (commensals) whereas others are harmful (eg, *Clostridium tetani*). Sources of these bacteria include the mother's birth canal, the environment in which the neonate is delivered and hands of the person assisting with the delivery. Cord infection may be localized to the umbilical cord (omphalitis) or, after entry into the blood stream, become systemic (eg, neonatal sepsis).

Data on the incidence of omphalitis in low-income countries is generally scarce, the available data estimate the risk to range between 2 and 77 per 1000 live births in hospital settings, with fatality rates of between 1% and 15% depending on the definition of omphalitis used.<sup>18</sup> Community-based data show even higher infection rates: for example, 105 per 1000 live births in Nepal, 217 per 1000 live births in Pakistan and about 197 per 1000 live births in India.<sup>18, 19</sup> Remarkably, no data are currently available from most countries in Africa where most deliveries still occur at home and where neonatal mortality remains high.

As cord infections should be preventable in most cases, it is important to identify best cord care practices to reduce neonatal mortality and morbidity and offer an alternative to widespread potentially harmful traditional practices.<sup>20</sup> Examples of such practices include use of traditional herbs mixed with cooking oil or water that has been used to wash an adult woman's genitals (numbati) or application of ash, breast milk, fluid from pumpkin flowers,

powder ground from local trees, cow dung, ghee and saliva that may be applied to the cord area and which may be harmful.<sup>21, 22</sup>

I have conducted this study to compare the efficacy of 4% chlorhexidine with methylated spirit in the cleansing of the umbilical cord for the prevention of omphalitis. Gestational age in this study was from 37 to 41 weeks with mean gestational age of  $38.92 \pm 1.18$  weeks. In this study, efficacy (prevention of omphalitis or normal shedding of umbilicus within seven days of start of therapy) was seen in 45 (93.75%) patients in group A (4% chlorhexidine) and in 38 (79.17%) patients in group B (methylated spirit) with p value of 0.037 which is statistically significant. Sinha A et al 2015 showed in their review that chlorhexidine cord care in the community setting resulted in a 50% reduction in the incidence of omphalitis and a 12% reduction in neonatal mortality.<sup>13</sup>

Soofi et al., (n = 9741) reported a reduction of omphalitis in the CHX cleansing group (RR 0.44, 95% CI: 0.29–0.67),<sup>14</sup> whereas Mullany et al., (n = 14,887) reported a reduction by 32–75% depending on the definition of the omphalitis (severe redness and pus: RR 0.25, 95% CI: 0.12–0.53; pus and moderate or severe redness or severe redness alone: RR 0.46, 95% CI: 0.36–0.56; redness extending to base of umbilicus: RR 0.68, 95% CI: 0.58–0.80). This reduction of severe omphalitis was even bigger if the intervention was within 24 hours of birth (incidence rate ratio 0.13, 95% CI: 0.07–0.31).<sup>23</sup> Arifeenet al., (n = 29,760) reported a reduction in severe infection (redness with pus) in the multiple CHX cleansing group (RR 0.35, 95% CI: 0.15–0.81) and a lesser reduction in the single CHX cleansing group (RR 0.77, 95% CI: 0.40–1.48).<sup>24</sup>

Low-quality evidence from small hospital-

based studies (N = 946) suggests that use of antimicrobials has no effect on cord infection.<sup>25, 26</sup> Pezzati et al., (Italy, n = 244) compared 4% CHX with salicylic sugar powder in preterm babies but reported only 1 case of sepsis in each arm,<sup>25</sup> whereas Ahmadpour et al.,<sup>11</sup> (Iran, n = 312), Erenel et al.,<sup>27</sup> (Turkey, n = 150), Hsu et al.,<sup>28</sup> (Taiwan, n = 150) and Suliman et al.,<sup>26</sup> (United States, n = 90) reported no or very few cases of omphalitis or sepsis when newborns were randomized to cord care approaches including breast milk, 96% alcohol, silver sulfadiazine, triple dye, olive oil or dry cord care.

In a meta-analysis, there were three cluster-randomised community trials (total participants 54,624) conducted in Nepal, Bangladesh and Pakistan that assessed impact of CHX application to the newborn umbilical cord for prevention of cord infection and mortality. Application of any CHX to the umbilical cord of the newborn led to a 23% reduction in all-cause neonatal mortality in the intervention group compared to control [RR 0.77, 95 % CI 0.63, 0.94; random effects model, I<sup>2</sup>=50 %]. The reduction in omphalitis ranged from 27 % to 56 % compared to control group depending on severity of infection.<sup>3</sup>

Currently, umbilical cord care practices vary in different region of country and no uniform protocol is being followed. At health facility level, a variety of local antiseptics are being practiced for cord care including triple dye, alcohol, antibiotic ointment, povidone iodine, soap and water or no treatment at all and none of these have proven superior in limiting sepsis. Unhygienic cord care practices are prevalent in community settings.<sup>29</sup> People are still using traditional substances like turmeric, ash, surma, powder and mustard oil etc. for cord care.<sup>30</sup>

## CONCLUSION

This study concluded that efficacy of 4% chlorhexidine is more as compared to methylated spirit for the prevention of

omphalitis. So, we recommend that 4% chlorhexidine should be used routinely for the prevention of omphalitis as well as morbidity and mortality of our population.

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