EFFECTIVENESS OF CHLORHEXIDINE IN PREVENTION OF UMBILICAL SEPSIS: A HOSPITAL BASED STUDY

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ABSTRACT: BACKGROUND: Umbilical sepsis is an important cause of neonatal morbidity and mortality. Severe omphalitis necessitates the administration of parenteral antibiotics with a consequent prolongation of hospital stay. AIMS: To assess whether simple protocolised interventions for cord care with locally available chlorhexidine is effective in reducing the incidence of umbilical sepsis. **METHODS**: This is a retrospective study. A protocol was introduced for daily cord care using 0.5% chlorhexidine gluconate followed by cleaning with sterile water for all newborns in Government Medical College, Ernakulam (formerly Co-operative Medical College, Kochi, Kerala). The incidence and severity of omphalitis was audited for a 3 month period subsequent to this practice change and was compared with the incidence of omphalitis during the same 3 month period in the preceding year. **RESULTS**: Eighty six babies were in the pre-intervention group and seventy seven in the chlorhexidine group were compared and both the groups were similar with respect to gestational age, sex, mode of delivery and parenteral antibiotic use. There was a significant difference with regard to the overall incidence of omphalitis after chlorhexidine use. Incidence of omphalitis was 44% in the pre-intervention group as compared to 6.5% in the chlorhexidine group (p value<0.05). **CONCLUSION:** Local administration of 0.5% chlorhexidine is effective in preventing umbilical sepsis. KEYWORDS: Chlorhexidine, omphalitis.

INTRODUCTION: Neonatal deaths contribute to more than 40% of the annual under-five mortality. Neonatal mortality is 32/1000 live births in India¹. The common three causes are infections, asphyxia and prematurity. 21-71% of deaths occurring in neonatal intensive care units of developing countries are due to infections ²⁻⁴. Umbilical cord is an easy portal of entry for organisms as contamination can lead to omphalitis, blood stream infection and death.

Umbilical infections are an important cause of neonatal morbidity and mortality in developing countries with incidence rates as high as 55-197 per 1000 live births in community-based studies.⁵Cord care is an important part of immediate neonatal care to reduce umbilical sepsis. Though dry cord care was recommended by WHO⁶, a large community based study in Nepal of the application of chlorhexidine to the umbilical cord reported a 75% reduction in severe omphalitis.⁷

Following an increasing incidence of umbilical sepsis with the dry cord care, the department of Pediatrics, Government Medical College, Ernakulam, reviewed the literature and evidence available and formulated a clinical protocol regarding umbilical cord care with chlorhexidine. As there was difficulty in procuring 4% chlorhexidine as used in the Nepal trial, 0.5% chlorhexidine gluconate in alcohol base which is easily available was chosen as an alternative. This was introduced in April 2008. 3 months after implementation, the effectiveness of this was audited with the comparison being the incidence of umbilical sepsis during the same months in the preceding year as documented through file review.

ORIGINAL ARTICLE

AIMS: To assess whether simple protocolised intervention with chlorhexidine for cord care would be an effective preventive strategy for umbilical sepsis in a low resource setting.

MATERIALS AND METHODS: This is a retrospective study. The protocolised cord care was implemented from April 2008 in the Neonatal Unit and postnatal ward of Government Medical College, Ernakulam, Kerala (formerly Co-operative medical College, Kochi). Institutional research and ethics approval was obtained. All babies >32 weeks gestation admitted between May and July (3 months) were included in the intervention as safety of use of chlorhexidine in preterm <32 weeks and low birth weight babies is not proven.⁽⁸⁾ 2.5 % chlorhexidine v/v in 70% ethanol (0.5% chlorhexidine gluconate) was used as this was easily available. At birth the cord was cut and no antiseptic was applied. At the first postnatal examination, usually within 24 hours, the cord was inspected and chlorhexidine application advised daily until discharge.

The method of administration involved was using cotton wool ball which was moistened with the chlorhexidine solution and was used to gently clean the cord stump, the base and the skin immediately around the base. A sponge holder was used to hold the cotton wool ball. Spirit soaked gauze was used to wipe the sponge holder between each use. No change in hand washing practice was advised or implemented. To minimize exposure and reduce chances of contact dermatitis, a second cotton ball moistened with sterile saline was applied to the same area after 5 minutes of contact time.

The above procedure was done by the nurses on the neonatal unit and postnatal ward. During the hospital stay of the neonate, the cord was evaluated daily. To avoid bias, the evaluation for the presence of omphalitis and detection of side effects if any, was performed by 3 trained pediatricians independently. Umbilical swabs for culture were not taken as patients availing of the services of Government Medical College belong to the lower socio economic status and could not afford the investigation.

Omphalitis was classified as a)mild if redness (or swelling) was limited to the cord stump while b)moderate was defined as inflammation extending to the skin at the base of the stump (i e, <2 cm extension onto the abdominal skin) and c) severe if affecting an area 2 cm or more from the cord ⁹. Incidence of umbilical sepsis after the introduction of the protocol for duration of 3 months (May-July 2008) was compared with incidence of umbilical sepsis in the same 3 months of the previous year (May-July 2007). The two groups were compared with regard to clinical parameters, septic screen and parenteral antibiotic use against the incidence of umbilical sepsis using percentages and chi-square tests as appropriate.

RESULTS:

Characteristics	Pre intervention	Chlorhexidine
	group (n=86)	group (n=77)
Delivery		
Normal	41 (47.6%)	34 (44.1%)
Caesarean section	45 (52.3%)	43 (55.8%)
Sex		
Male	50 (58.1%)	41 (53.2%)
Female	36 (41.7%)	36 (46.7%)
Gestation		
34 weeks	2 (2.3%)	2 (2.5%)
35-36 weeks	6 (7%)	5 (6.5%)
≥ 37 weeks	78 (90.7%)	72 (93.5%)
Birth weight		
1.75<2 kg	6 (7%)	3 (3.9%)
2-2.5 kg	12 (14%)	22 (28.5%)
2.5-3 kg	38 (44.1%)	22 (28.5%)
>3 Kg	30 (34.8%)	30 (38.9%)
	Table 1	

Omphalitis	Pre intervention group (n=86)	Chlorhexidine group (n=77)	
Mild	10 (11.6%)	1 (1.3%)	
Moderate	22 (25.6%)	4 (5.2%)	
Severe	6 (6.9%)	0 (0%)	
Total number with omphalitis	38 (44.1%)	5 (6.5%)	
Table 2: Comparison with omphalitis and their severity between both groups			
p<0.01			

<0.01

There were no deaths during the study period.

RESULTS: There were 86 babies in the pre-intervention group and 77 in the chlorhexidine group. Both the groups were similar with regard to the mode of delivery, gender and gestational age. There was greater percentage of low birth weight babies in the chlorhexidine group. 4% were <2 kg and 28.5% were between 2-2.5 kg as against 7% and 14% in the pre-intervention group.(Table 1) The parenteral antibiotic use in the chlorhexidine group was 37% compared to 30% in the pre-intervention group, but this was not statistically significant.

There was a greater number of omphalitis of all categories in the pre-intervention group with the total number being 44% in the pre-intervention group and 6.5% in the chlorhexidine group. This was statistically significant (Table 2).

There was no documented adverse reaction to chlorhexidine.

ORIGINAL ARTICLE

DISCUSSION: These data support the existing evidence that umbilical cord care with chlorhexidine can reduce the incidence of omphalitis.⁷ There were no neonatal deaths during the period in both the years in our hospital.

Severe omphalitis did not occur in the chlorhexidine group and there was an overall reduction in omphalitis. There were no side effects. This is similar to the results from the study from Nepal.⁷ This protocol is being followed till date in Government Medical College, Ernakulam, Kerala with good results.

Subsequent to the period of our study numerous community based trials have been replicated in Bangladesh, Pakistan, Tanzania and Zambia which have demonstrated results similar to our study.¹⁰⁻¹³

In a more recent hospital based study from Haryana, there was no statistical difference in the babies who received dry cord care and those who in the chlorhexidine group with regard to umbilical infection and probable sepsis though there was a significant reduction in blood culture proven sepsis.¹⁴ The study populations from Nepal also documented a significant reduction in neonatal mortality. In Nepal the protective effect of the intervention was most apparent when the chlorhexidine application was in the first 24 hours of life.⁷

All the babies in our hospital are seen within 24 hours by a trained pediatrician and once daily application until the time of discharge was followed by us. The 3 completed trials showed lower rates of omphalitis with multiday application. The Bangladesh study recorded a reduced risk of serious cord infection with multi day application though there was no difference in mortality between those who received single cord cleansing and multiday application.⁸

The Nepal government since the completion of the trial has implemented the Chlorhexidine Navi Care programme which uses a day 1 only regimen of application of 4% chlorhexidine gel supplied as a single use tube.¹⁵

Chlorhexidine is a broad spectrum antibiotic used in surgical cleaning products. It has been used in perineal and vaginal washes in 4% concentration.¹⁶ The adverse effects reported are skin breakdown, burns in very low birth weight babies and risk of neurotoxicity in preterm babies.¹⁷ But all subsequent studies which have been done till date have not shown any evidence of toxic effects even in babies in whom transcutaneous absorption could have occurred.⁹

Chlorhexidine is found to be safe in concentrations of up to 4% in aqueous base.¹⁸ Due to ease of procurement we used 2.5% chlorhexidine v/v in 70% ethanol (0.5% chlorhexidine gluconate) was used. Application of chlorhexidine was followed by wiping the same area with sterile water moistened cotton ball after 5 minutes. There were no observed adverse effects with this practice.

Our study has its limitations. Assessment for umbilical sepsis could be done only for the period of hospital stay. We did not include babies less than 32 weeks or less than 1500 grams as there were safety issues. There is also the possibility that the reduction in omphalitis may not be only due to chlorhexidine but also due to the alcohol content.¹⁹ Considering the fragility of the newborn skin further research may be needed to examine if 0.5 % chlorhexidine as a single application will be sufficient to reduce omphalitis. Another area of focus would be the need to determine the lowest concentration of chlorhexidine that can be effective in reducing omphalitis.

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ORIGINAL ARTICLE

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