

Comparison of Umbilical Cord Cleansing Using Sterile Water and Povidine Iodine-Spirit During Early Neonatal Period: A Double Blind Randomized Control Trial

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ABSTRACT

Aim: To compare the effect of umbilical cord care with Povidine Iodine- Spirit on umbilical infection in early neonatal period.

Materials and Methods: Prospective double blinded randomized controlled study was undertaken to evaluate the effect of daily cleansing of the umbilical cord of term infants with Spirit (Alcohol) –Povidine Iodine combination). This was also compared to the retrospective data obtained for the prevailing practice of keeping the umbilical cord dry.

Results: 1518 infants were included in the study. (462 in the “cord care group”, 496 in the “water” placebo group, & 560 in “Dry”

retrospective group). There was an overall reduction in the clinically screened and evaluated “umbilical infection” in the Povidine –Iodine group. This was attributable to a greater reduction in the mixed bacterial (Colonizer/ commensals) isolates. The Relative Risk for *Staph. aureus* was lesser when the cord was kept dry (RR 0.6, $p < 0.01$) and sterile water (Placebo) group (RR 0.7, $p < 0.01$).

Conclusion: Avoiding the antiseptic cleansing increased the RR for commensal / mixed bacterial over growth that would probably facilitate umbilical cord separation.

Keywords: Umbilical care, Omphalitis

INTRODUCTION

Care of the umbilical cord has always been an integral part of essential newborn care. The potential of the large umbilical vessel being a conduit for bacterial invasion of the infant’s blood circulation has prompted care givers to be vigilant about the status of the umbilical cord until it falls off and the umbilicus has its appropriate cutaneous cover. Umbilical infection has for long been considered a nidus for the more morbid neonatal conditions of sepsis and meningitis. No difference in the incidence of omphalitis had been observed in various studies while comparing the practice of keeping the cord dry to those using local antiseptics. Further studies had been recommended in this matter [1].

Detection of umbilical infections during the early neonatal period has always been the prerogative of a vigilant care giver. Individual or combination of features like foul smelling umbilicus, umbilical discharge with or without foul smell, peri-umbilical redness have all been considered as features of early umbilical inflammation [2].

It is recognized that bacterial colonization does not necessarily represent a pathological event, and often hastens the separation of the umbilical stump. This has made the thin line between colonization and early umbilical infection even more confabulating. It has been our practice to take an umbilical swab culture of all infants with the earlier mentioned clinical features suspicious for umbilical infection. A diagnosis of Early Umbilical infection was considered based on bacteria isolated. Those with “mixed bacterial” isolates or reported as “scanty growth” were considered as colonizers.

Incidence of umbilical infection has had a wide range of reportage ranging from 1.9% -19.8% from India [3,4]. Early discharge from hospital has become the norm for full term uncomplicated deliveries. Seeking out umbilical infections before discharge from hospital has become even more difficult—a task further complicated by the “Bacterial Colonization” vs “Early bacterial Infection” debate. Umbilical “infection” was clinically suspected at some stage before discharge in approximately 10% of term infants at our center, it has been our practice to follow the practice of keeping the cord dry until the stump separates.

This study was undertaken to see if a daily antiseptic cleansing (spirit-povidine iodine-spirit) was better than using no local antiseptics, in preventing early umbilical infection in neonates. It was our intention to assess the non-inferiority of avoiding antiseptics for routine care of the umbilical cord. The study was initiated after clearance from the hospital ethics committee for evaluation of non- inferiority of the prevalent practices of umbilical cord cleansing.

OBJECTIVE

Assessing the effect of daily cleansing umbilical cord stump with spirit-povidine iodine-spirit on umbilical infection during the early neonatal period.

MATERIALS AND METHODS

Place: Malankara Orthodox Syrian Church Medical College Hospital.

Period of Study: August 2009 to July 2010.

Study Design: Consisted of two components- 1) Prospective double blinded randomized placebo controlled study to assess the effect of povidine iodine; 2) Retrospective inclusion of a third arm of the study where the umbilical cord is kept dry to assess the confounding effect of the placebo cleansing. The placebo controlled study was designed with a sample size of 430 in each arm, calculated for 80% power and 95% CI, with the aim of reducing by 50% the approximate incidence of early umbilical infections as observed in the hospital data (10%). Approximately 1000 infants were targeted for inclusion in phase of the study.

All term infants delivered at our hospital and not receiving any systemic antibiotics were included in the study. Infants in whom systemic antibiotics were commenced for other reasons and those in who were discharged before 72 hours of life were excluded.

The two groups - Cord care (C) (Spirit – Povidine) and Placebo (P) were grouped into block sizes of 4 into 6 balanced combinations, (CCPP, CPCP, CPPC, PCPC, PCCP, PPCC). Each of these blocks of four was placed in separate unmarked sealed envelopes. Thus six unmarked envelopes were made available to the nursing station

of the postnatal ward for every 24 infants admitted to the ward. An unmarked envelope was picked randomly by the charge nurse and handed over to the investigator (GC) to proceed with selection of the infants into groups of care. If the envelope had the block 'CCPP', the 1st and 2nd infant received 'Cord Care', and the 3rd and 4th infants had 'Placebo' care. The 'Cord care group' (C) had umbilical stumps cleansed once a day by sequentially wiping with spirit, followed by Povidine iodine (Betadine® Wokhardt) and subsequently wiped again with spirit. Each step was done after the earlier solution had dried. Care was taken to see that there was no remnant Povidine iodine on the umbilical stump or base and no external differences discernable about the method used for cleansing. The 'Placebo group' (P) was similarly triple wiped using sterile water, and a dried after the process. The investigator doing the cleansing was not involved in the daily clinical care of these infants. The clinical nurse and the doctors responsible for the routine postnatal care of the infants were unaware of the mode of cord cleansing done and thus were blinded.

The routine care of the infants was followed as per the hospital protocol. Umbilical swab cultures were taken when ever umbilical infection was suspected on clinical examination. The cleansing of the cord was continued as per the designated group by the investigator (GC) who was blind to the clinical decisions being taken about the infant.

The 2nd Author (KKD) was blinded to both the intervention, as well as the clinical decisions of the caregiver of the post natal ward vis-a-vis umbilical status of infants. At the end of the study period, all the relevant charts were reviewed by KKD and decoded for analysis of data.

The second component of the study design consisted of a third arm of infants whose cord had been kept "DRY" as per the hospital protocol was included retrospectively by analysing of case records of infants born during a three months period immediately preceding the study. This group was utilized to assess if sterile water cleansing as 'Placebo' affected the bacterial growth on the umbilical cords that are otherwise routinely kept dry without any additional cleansing. Bacterial isolates in the 3 groups - Cord Care, Placebo and Dry were analysed and compared.

Umbilical swab cultures showing single isolates or predominantly single isolates were considered as 'Umbilical Infection' and those showing mixed growths or reported as 'scanty growth' was considered as 'colonization'.

Time to cord separation was not analysed as most infants were discharged by 96 hours of life or before where total separation had not been achieved.

RESULTS

A total of 1518 infants were included for the study [Table/Fig-1]. 747 were male & 771 female infants. There were 462 infants in the "cord care group", 496 in the "water" group and 560 in the "Dry" group. The "Dry" group comprised of the 560 infants included for the study from three months immediately preceding the RCT period, where the umbilical stump as per the hospital protocols were kept dry and without any cleansing interventions, with all other inclusion criteria being the same as the RCT groups. Forty two infants in the cord-care group and 77 of the placebo group were suspected to have omphalitis, and swabs sent for culture. Thirty eight of the former and seventy six of the placebo group had bacterial isolates with

Study	Cord care	Placebo (water)	Dry	Total
	462	496	560	1518
Unsuspected/ unswabbed	420	419	431	1270
Suspected and swabbed	42	77	129	248
No isolates	4	1	7	12
Isolates	38	76	122	236
Gram +ve	30	40	60	130
Gram -ve	6	12	14	32
Mixed	2	24	48	74

[Table/Fig-1]: Overview of the study

negative culture being reported in the rest. Omphalitis had been clinically suspected in 129 infants in the "Dry" group. One hundred twenty two of these had positive umbilical cord cultures. *Staph aureus* was the commonest isolate [Table/Fig-2].

While the methods of cleansing did not show any difference in the relative risk for Gram -ve isolates, there was significant difference in the risk for Gram +ve and commensal (mixed) growth between the "cord care" group and others [Table/Fig-3]. There was no difference between the "Placebo" and the "Dry" group. This could imply that the observations of the RCT using sterile water as placebo could be extrapolated to the practices of the cord being kept dry.

Keeping the cord dry and avoiding antiseptic cleansing provided a greater opportunity for commensals growth and reduced the chances for isolated *Staph. aureus* growth: Infants with bacteria isolated from the umbilical swab were treated with the appropriate antibiotics. None of them progressed to fulminant neonatal sepsis.

DISCUSSION

Umbilical cord infection has been incriminated for long as a source for progressive neonatal sepsis. Keeping the cord dry has been the normal practice at our center. Colonization of the umbilical cord by bacteria and the resultant low grade inflammation has been often considered as a mechanism that facilitates early cord separation.

Cleansing the umbilical cord with sterile water was as good as keeping the cord dry, and did not offer any added advantage regarding bacterial colonization.

Alcohol cleansing in comparison to sterile water had been reported to show no reduction bacterial colonization [5]. Chlorhexidine for cord care has been reported to reduce the incidence of neonatal sepsis, despite having no significant effect on the incidence of umbilical infection [6].

Extensive Reviews [1] have not been able to recommend any specific method for cord care. Keeping the cord dry seems to be the trend in most developed countries. Few researchers feel that topical antimicrobials have a role only where obviously harmful practices of cord care is prevalent in the community [7]. Reports from Turkey observed no differences between the traditional methods of cleaning the umbilical cord with breast milk, using povidine-iodine or keeping the cord dry [8].

It has been our observation in the current study that there was a gross reduction in the bacterial isolates in infants treated with sequential cleansing of the cord with alcohol (spirit) -povidine

	<i>Staph. aureus</i>	<i>Klebsiella</i>	<i>Entero-bacter</i>	<i>E.coli</i>	<i>Acineto-bacter</i>	Mixed	Total
Cord care (%)	30 (79.2 %)	2 (5.2%)	2 (5.2%)	2 (5.2%)	0	2 (5.2%)	38 (100%)
Placebo	44 (57.9%)	10 (13.2%)	2 (2.6%)	4 (5.3%)	4 (5.3%)	12 (15.8%)	76 (100%)
Dry	60 (49.2%)	0	4 (3.3%)	0	4 (3.3%)	54 (44.3%)	122 (100%)
Total	134 (56.7%)	12 (5.1%)	8 (3.4%)	6 (2.5%)	8 (3.4%)	68 (28.8%)	236 (100%)

[Table/Fig-2]: Specific bacterial isolates of swabs taken for suspected umbilical infection

Mode of Care	Gram+ve isolates RR, 95%CI (p)	Gram -ve Isolate RR, 95%CI (p)	Mixed / Commensal Growth RR, 95%CI (p)
Dry Vs Placebo	0.9, (0.7 -1.2) (p = 0.66)	0.7, (0.35 - 1.5) (p = 0.4)	1.25, (0.8 - 1.85) (p = 0.3)
Placebo vs Cord care	0.7, (0.5 - 0.9) (p = 0.008)	1, (0.4 -2.5) (p = 1)	6, (1.5 - 24) (p =0.002)
Dry vs Cord care	0.6, (0.49 - 0.7) (p < 0.001)	0.7, 0.3 - 1.76 (0.6)	7.5 ,(1.9 - 29.3) (p<0.001)

[Table/Fig-3]: Relative Risk, 95% CI and p-value for isolates using different modes of umbilical cord care

iodine combination. This relative reduction was achieved more by decreasing the mixed/commensals growth [Table/Fig-1]. It was interesting to note that in the absence of antiseptic cleansing, there was a higher chance of mixed bacterial over growth than that of *Staph. aureus*. Would this imply that antiseptic cleansing increases the relative risk of *Staph. aureus* over growth with the resultant potential for fulminant infections? While it would seem preferable to have some colonization to facilitate cord separation, the over growth of a single species of bacteria would seem to be more sinister.

LIMITATION OF THE STUDY

The timing for separation of the cord could not be documented, as most of the infants were discharged by 96 hours of life.

CONCLUSION

Perhaps it would be safer to avoid cleaning methods that inhibit the mixed growth of commensal bacteria, as this could result in inadvertent overgrowth of a single species of pathogenic bacteria.

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