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Original Article

# PROSPECTIVE RANDOMIZED CONTROLLED TRIAL INVESTIGATING THE IMPACT OF ANTISEPTIC VERSUS NON-ANTISEPTIC CORD CARE ON THE RATE OF OMPHALITIS IN NEWBORNS

**Kamran Zakria[a*], Taj Muhammad[b], Akhtar Muneer [c]**

[a]Tehsil Head Quarter Paharpur, Khyber Pakhtunkhwa, Pakistan
[b]Mufti Mehmood Memorial Teaching Hospital Dera Ismail Khan, Khyber Pakhtunkhwa, Pakistan
[c]Department of Microbiology, Gomal University Dera Ismail Khan, Khyber Pakhtunkhwa, Pakistan

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***Corresponding Author:**
Dr. Kamran Zakria
dr.kamizakria@gmail.com

## ABSTRACT

**Background**: Omphalitis, also known as umbilical cord infection, is a potentially fatal condition that affects newborns, characterized by inflammation and infection of the umbilical stump. **Methods**: Eighty newborn infants from maternity centers in Dera Ismail Khan were enrolled in the study. Participants were randomly assigned to either antiseptic cord care group or non-antiseptic cord care group. The primary outcome measure was the incidence of omphalitis, while secondary outcomes included sepsis, cellulitis, abscess formation, and duration of hospital stay. Baseline demographic and clinical characteristics were collected, and appropriate statistical techniques were utilized for data analysis. **Results**: The antiseptic care group had the lower incidence of omphalitis (5%) compared to non-antiseptic care group (12.5%). Although not statistically significant, the trend favored antiseptic care in reducing complications. There were no significant differences in sepsis, cellulitis, abscess formation, duration of hospital stay, or parental satisfaction between the two groups. **Conclusion**: Antiseptic cord care demonstrated a potential protective effect against omphalitis in newborns, although observed differences were not statistically significant. These findings support the use of antiseptic care as a standard practice in newborns.





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## INTRODUCTION

Omphalitis, also known as umbilical cord infection, is a potentially life-threatening condition affecting newborn neonates [1]. It is illustrious by inflammation and infection of umbilical stump, which is the remnant of the umbilical cord after it is severed shortly after birth. Omphalitis poses a substantial threat to the health of neonates, as it can result in the variety of complications, including sepsis, cellulitis, abscess formation, and even death if left untreated [2,3].

During pregnancy, the umbilical cord is a vital connection between the mother and developing fetus, providing oxygen, nutrients, and eliminating waste [4,5]. After delivery, umbilical cord is clamped and cut, leaving behind umbilical stump. This remaining tissue is susceptible to colonization and infection by pathogenic microorganisms in the surrounding environment. Poor hygiene practices, inadequate cord care, unsterile delivery conditions, and a newborn's compromised immune system all contribute to the development of omphalitis [6,7].

Variables such as geographic location, socioeconomic status, healthcare practices, and obstetric and neonatal risk factors can influence the incidence and severity of omphalitis [8,9]. In settings with limited access to appropriate healthcare and sanitation, where omphalitis rates are typically higher, the associated morbidity and mortality rates are of great concern [10].

Typically, omphalitis is treated with a prompt diagnosis, the initiation of an appropriate antibiotic regimen, and meticulous wound care. However, most favorable approach to cord care for preventing omphalitis is still the topic of debate and clinical investigation [11]. Historically, antiseptic solutions, such as chlorhexidine or alcohol, have been extensively used to cleanse and prevent infection of the umbilical stump. Growing evidence suggested, however, that basic, non-antiseptic care, such as keeping the umbilical cord clean and dry, may be equally effective and less expensive [12,13].

This study proposed a prospective randomized controlled trial for examining effect of the antiseptic versus non-antiseptic cord care on the incidence of omphalitis in newborns. By comparing the outcomes of these two approaches, we contributed to the development of evidence-based guidelines for optimal cord care practices and potentially enhance neonatal health outcomes. It involved the random enrolment of a cohort of newborn neonates, with half of the participants receiving antiseptic cord care and the other half receiving non-antiseptic cord care. The choice of antiseptic solution and protocol for non-antiseptic care was based on established guidelines and previous research in the field. The incidence of omphalitis, diagnosed based on clinical signs and, laboratory findings were primary outcome measure.

## MATERIAL AND METHODS

This study was prospective randomized controlled trial designed for comparing the effects of antiseptic versus non-antiseptic cord care on incidence of omphalitis in newborns (Figure 1). Eighty newborn infants from maternity centers of Dera Ismail Khan were recruited during 2022-23.

Inclusion requirements included newborn neonates within a given age range, such as 0-7 days, babies born after 37 weeks of gestation, infants with no known congenital abnormalities or significant medical conditions, babies born vaginally or by caesarean section, infants whose parents or legal guardians consented to their participation in the study. While, exclusion standards included infants born before 37 weeks of gestation, infants with the validated immunodeficiency disorder diagnosis, infants who required immediate surgical intervention or who have a known surgical condition that affected the umbilical region at the time of enrolment, and infants with a history of omphalitis or other umbilical infections are excluded. Infants born to mothers with infectious diseases known to increase the risk of omphalitis transmission (e.g., active genital herpes, HIV infection) and infants whose parents or legal guardians refuse to give informed consent for study participation were also not included in the study.

Participants were assigned randomly to either antiseptic cord care group or non-antiseptic cord care group. Using computer-generated random numbers or a randomization table, randomization sequence was generated. Using sealed envelopes, allocation secrecy was maintained.

Infants in this cohort received antiseptic care for their umbilical cords. The antiseptic solution, concentration, and method of application were adhere to established guidelines and clinical practice protocols. Infants in this cohort receive non-antiseptic care for their umbilical cords. Using standardized techniques, such as cleaning the stump with a sterile, dry cloth and ensuring proper hygiene during diaper changes, the stump was kept clean and dry.

The incidence of omphalitis (Figure 2), diagnosed based on clinical signs and





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symptoms such as erythema, edema, purulent discharge, and adjacent cellulitis, was the primary outcome measure. Secondary outcomes included sepsis, cellulitis, abscess formation, and duration of hospital stay. Participants' baseline demographic and clinical characteristics, such as maternal age, gestational age, birth weight, and mode of delivery, were collected. Approach to caring for the umbilical cord, including the antiseptic solution utilized, was documented.

Throughout the duration of the study, participants were attentively monitored for the development of omphalitis or any other complications. Follow-up visits were scheduled according to the standard protocol for postnatal care, and if necessary, additional evaluations were conducted.

The data was analyzed utilizing appropriate statistical techniques. Using chi-square tests and Fisher's exact test, incidence of omphalitis and other outcomes were compared between antiseptic and non-antiseptic cord care groups.

This investigation was adhered to ethical guidelines and principles. The institutional approval was obtained. The parents of the infant participants provided informed consent, ensuring that they are aware of the study's objectives, procedures, and potential risks and benefits.

Figure 1: Group allocation of the infants in RCT

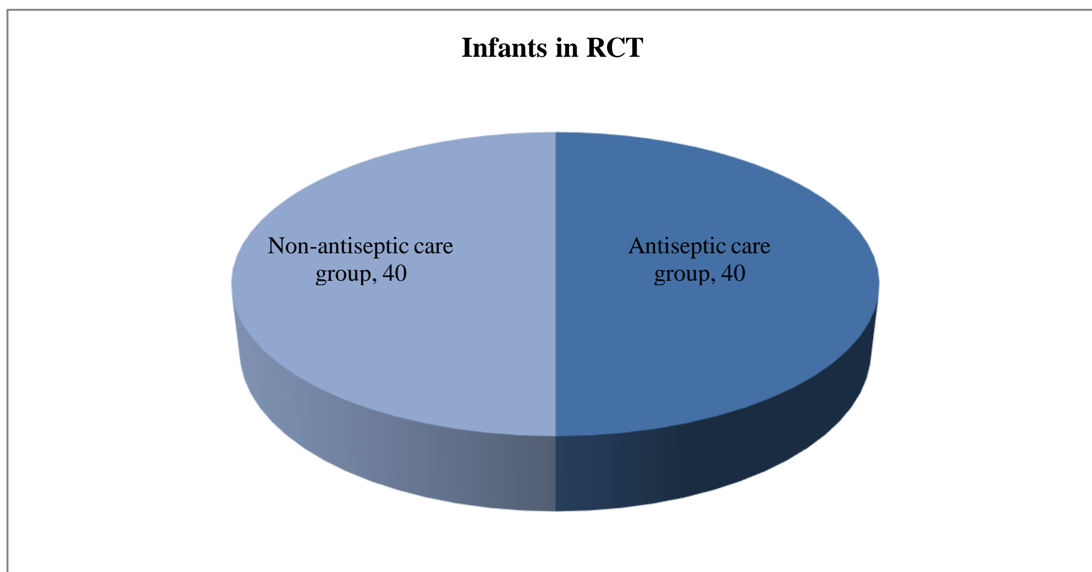


Figure 2: Clinical preview of omphalitis

## RESULTS

The demographic and clinical distinctiveness of study participants (n=80) along with their corresponding frequencies and p-values were analyzed and interpreted. Participants were divided into three categories based on maternal age: <25 years, 26-35 years, and >36 years. Among the participants, highest frequency (58.75%) was observed in the 26-35 years age group ($p<0.05$), followed by the <25 years group (32.50%), and the >36 years group (8.75%). The participants were categorized based on gestational age into two groups: <7 months and >7 months. The majority of participants (83.75%) had a gestational age greater than 7 months ($p<0.05$), while 16.25% had a gestational age of less than 7 months. Participants were divided into two groups based on birth weight: <3 kg and >3 kg. The majority of participants (66.25%) had a birth weight greater than 3 kg ($p<0.05$), while 33.75% had a birth weight less than 3 kg. The





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participants were classified into two categories based on delivery mode: vaginal delivery and cesarean section. The frequency distribution reveals that the majority of participants (73.75%) were delivered vaginally ($p<0.05$), while 26.25% were delivered via cesarean section (Table 1).

Comparison of outcome measures between two groups revealed that in antiseptic care group, 2 participants (5%) developed omphalitis, while in non-antiseptic care group, 5 participants (12.5%) had omphalitis. In the antiseptic care group, 3 participants (7.5%) developed sepsis, compared to 5 participants (12.5%) in non-antiseptic care group. Both the antiseptic and non-antiseptic care groups had 3 participants (7.5%) with cellulitis. In the antiseptic care group, 4 participants (10%) developed abscess formation, while in the non-antiseptic care group, 7 participants (17.5%) had abscess formation. Overall, the total number of complications (including omphalitis, sepsis, cellulitis, and abscess formation) was 12 (30%) in antiseptic care group and 22 (55%) in non-antiseptic care group (Table 2).

Mean recovery time in antiseptic care group was 11.32 days with a standard deviation (SD) of 2.30, while in non-antiseptic care group, it was 14.98 days with an SD of 3.76. Mean hospital stay in antiseptic care group was 1.0 days with an SD of 0.3, while in non-antiseptic care group, it was 1.7 days with an SD of 0.9. In antiseptic care group, 31 participants (out of 40) reported being satisfied, while 9 participants reported dissatisfaction. In non-antiseptic care group, 17 participants reported satisfaction, while 33 participants reported dissatisfaction (Table 3). Based on p-values obtained, there was no statistically significant difference observed in the recovery time, hospital stay, or parental satisfaction between antiseptic care group and non-antiseptic care group ($p>0.05$).

Table 1: Participants' baseline demographic and clinical characteristics

| S. No | Demographic and clinical characteristics | No. of participants (n=80) | Frequency (%) | p-value |
|---|---|---|---|---|
| 1 | Maternal age (years)<br><25<br>26-35<br>>36 | <br>26<br>47<br>07 | <br>32.50<br>58.75<br>8.75 | **0.00001*** |
| 2 | Gestational age (months)<br><7<br>>7 | <br>13<br>67 | <br>16.25<br>83.75 | **0.00001*** |
| 3 | Birth weight (Kg)<br><3<br>>3 | <br>27<br>53 | <br>33.75<br>66.25 | **0.00009*** |
| 4 | Mode of delivery<br>Vaginal<br>C-section | <br>59<br>21 | <br>73.75<br>26.25 | **0.00001*** |

***indicated that the value is significant**

Table 2: Incidence of omphalitis and complications

| S. No | Measure outcome | Antiseptic care group (n=40) | Non-antiseptic care group (n=40) | χ2 | p-value |
|---|---|---|---|---|---|
| 1 | Omphalitis | 02 (5) | 05 (12.5) | 0.4811 | 0.4879 |
| 2 | Sepsis | 03 (7.5) | 05 (12.5) | 0.0921 | 0.7615 |
| 3 | Cellulitis | 03 (7.5) | 05 (12.5) | 0.0921 | 0.7615 |
| 4 | Abscess formation | 04 (10) | 07 (17.5) | 0.2775 | 0.5983 |
| Total complications | | 12 (30) | 22 (55) | 1.5294 | 0.2161 |

Table 3: Clinical outcomes of the omphalitis

| S. No | Measure outcome | Antiseptic care group (n=40) | Non-antiseptic care group (n=40) | p-value |
|---|---|---|---|---|
| 1 | Recovery time (Mean±SD) days | 11.32±2.30 | 14.98±3.76 | 0.8629 |
| 2 | Hospital stay (Mean±SD) days | 1.0±0.3 | 1.7±0.9 | 0.4259 |
| 3 | Parental satisfaction (Yes/No) | (31/09) | (17/33) | 0.1356 |





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## DISCUSSION

The present study aimed to compare impact of antiseptic versus non-antiseptic cord care on the incidence of omphalitis in newborns. Omphalitis is a serious infection of umbilical cord stump that can lead to significant morbidity and mortality in neonates. Understanding the most effective approach to cord care is crucial for ensuring the well-being of newborns [14].

This study demonstrated that incidence of omphalitis was lower in antiseptic care group (5%) compared to the non-antiseptic care group (12.5%). This finding suggests that antiseptic cord care may provide a protective effect against the development of omphalitis. Although the difference was not statistically significant, the trend observed is clinically relevant and supports the use of antiseptic care in newborns [15].

Furthermore, the study evaluated secondary outcomes, including sepsis, cellulitis, abscess formation, duration of hospital stay, and parental satisfaction. Incidence of sepsis, cellulitis, and abscess formation was generally lower in antiseptic care group compared to non-antiseptic care group, although the differences were not statistically significant. These findings suggest a potential trend towards reduced complications with antiseptic care [16,17].

The mean recovery time and duration of hospital stay were slightly shorter in the antiseptic care group compared to the non-antiseptic care group, but again, the differences were not statistically significant. These results indicate that both antiseptic and non-antiseptic care approaches can result in satisfactory healing and recovery times. It is important to note that the duration of hospital stay was generally short in both groups, suggesting that omphalitis and related complications did not lead to prolonged hospitalization in most cases [18].

Interestingly, the analysis of parental satisfaction revealed that a higher proportion of participants in the antiseptic care group reported being satisfied compared to the non-antiseptic care group. This finding suggests that parents may perceive antiseptic care as a more effective and reassuring approach. However, it is important to consider that parental satisfaction is subjective and can be influenced by various factors, including individual beliefs, previous experiences, and cultural practices [19-20].

The results of this study provide valuable insights into the impact of antiseptic versus non-antiseptic cord care on the incidence of omphalitis and related outcomes in newborns. While the differences observed were not statistically significant in most cases, there was a consistent trend suggesting a potential benefit of antiseptic care in reducing the incidence of omphalitis and associated complications. These findings support existing guidelines and clinical practice protocols that recommend the use of antiseptic solutions for cord care [13].

However, it is important to acknowledge some limitations of the study. Firstly, the sample size was relatively small, which may have limited the statistical power to detect significant differences. Future studies with a larger sample size are warranted to validate the findings and provide more robust evidence. Additionally, the study was conducted in specific maternity centers in Dera Ismail Khan, which may limit the generalizability of the results to other populations and settings [21].

## CONCLUSION

This prospective RCT provided evidence suggesting that antiseptic cord care had beneficial impact on reducing the incidence of omphalitis in newborns, although the differences observed were not statistically significant. The study added to the existing literature and supported the use of antiseptic care as the standard approach for newborns. Further research with larger sample sizes is recommended to confirm these findings and explore the potential impact on other outcomes such as long-term morbidity and mortality.

## CONFLICT OF INTEREST

None.

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