Journal of
Babol University of Medical Sciences
JBUMS
e-ISSN: 2251-7170 p-ISSN: 1561-4107

# Effect of Eau de Dalibour on Umbilical Cord Separation and Prevent Infection in Neonates

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**Article Type**

**Research Paper**

**Received:**
**May 9th 2023**
**Revised:**
**Jul 8th 2023**
**Accepted:**
**Aug 23rd 2023**

## ABSTRACT

**Background and Objective:** Sepsis is the third most common cause of death, and the umbilical cord is a significant source of sepsis in the first month of life. This study aimed to compare the effect of Eau de Dalibour and distilled water on umbilical cord separation time and infection in neonates at Kowsar Hospital of Qazvin University of Medical Sciences.

**Methods:** This clinical trial was conducted on 76 infants in two groups of 38 people, using Eau de Dalibour and distilled water as a placebo. In the Eau de Dalibour group, 2-3 ml of the drug was used on the umbilical stump from 3 hours after birth and once every 12 hours until 2 days after the separation of the umbilical cord. In the distilled water group, the same procedure was done with distilled water. Finally, the time of separation of the umbilical cord and signs of infection in both groups were investigated and compared.

**Findings:** There were no significant differences between the two groups in terms of gestational age, sex, or birth weight. Umbilical cord separation time was significantly shorter in the Eau de Dalibour group than in the placebo group (5.1±2.4 and 7.44±2.3 days respectively; $p<0.001$). There were no cases of infection in the intervention or placebo group.

**Conclusion:** According to the results of this study, the application of Eau de Dalibour to the remaining part of the cord reduces the cord separation time and can be used for safe and affordable cord care.

**Keywords:** *Umbilical Cord, Eau de Dalibour, Separation Time, Neonate*.

**Cite this article:** Habibi M, Bahadoran E, SamieeRad F, Mohammadi N, Lashgari S. Effect of Eau de Dalibour on Umbilical Cord Separation and Prevent Infection in Neonates. *Journal of Babol University of Medical Sciences*. 2024; 26: e29.

## Introduction

More than one-fifth of all newborn fatalities are caused by infectious illnesses (1). Sepsis is the third leading cause of death during the first month of life. Compared to other causes of neonatal sepsis, umbilical cord infection can rapidly progress to neonatal sepsis and contribute to the highest risk of death, with an estimated mortality rate of 7-15% (2, 3). In developed countries, omphalitis affects newborns at a rate of 0.7%, whereas in developing countries, it affects 6-8% (4). Low birth weight, premature rupture of membranes, maternal infection, umbilical catheterization, non-sterile delivery, prolonged labor, and inappropriate cord care are among the risk factors for omphalitis.(5-7)

Bacteria in the mother's genitals and environment settle quickly in the umbilical cord after birth, increasing the risk of umbilical cord infection, particularly during the first 2-3 days after birth (8). Pathogens, including skin and enteric bacteria, such as Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli, Klebsiella, Pneumoniae, and Proteus mirabilis, which cause infection, occur mostly during the first few days. Necrotic tissue and clotted arteries inside the umbilical cord provide an excellent environment for bacteria to grow and cause sepsis (9, 10). Variety of agents are used to care the umbilical cord, mainly alcohol, triple dye, povidone iodine, chlorhexidine, and silver sulfadiazine (2, 11). Due to the side effects of different methods of umbilical cord care, a common recommendation for umbilical cord care is to keep it dry (12, 13).

Infection of soft tissues around the umbilicus is referred to as omphalitis. It is characterized by erythema and induration around the umbilical stump, and may be accompanied by purulent discharge (14). Sepsis is the most frequently mentioned omphalitis complication (15). Necrotizing fasciitis, peritonitis, intestinal necrosis, small bowel evisceration, liver abscess, and portal vein thrombosis are a few other consequences that have been documented (16, 17).

Eau de Dalibour, composed of 1.5% zinc sulfate and 0.5% copper sulfate (as a mild local cumulative), has antiseptic and astringent properties for the disinfection of lesions and soothing itching and inflammation. Copper sulfate has been used to treat umbilical granulomas and to prevent recurrence (18). Eau de Dalibour treated superficial wounds in children with pyoderma, impetigo, and intertrigo, had no side effects, and prevented aggravation of these diseases in the absence of medical centers (19).

The best practices for caring for the umbilical cord remain unclear. Unsanitary substances are still applied to the umbilicus in resource-limited countries, and healthcare workers use different substances based on their preferences and experiences. Therefore, safe and effective cord care regimens are needed for the umbilical cord. The present randomized clinical trial was conducted to compare the effects of topical application of Eau de Dalibour and distilled water on cord separation and infection in healthy neonates.

## Methods

After approval by the Ethics Committee of Qazvin University of Medical Sciences with the code IR.QUMS.REC.1397.292 and registered in the Iranian Clinical Trials Registration Center with the code IRCT20190122042456N1, this prospective, single-blind, randomized and controlled trial was conducted on 76 babies born in Kowsar Hospitalin Qazvin. All necessary information about the method of using Eau de Dalibour as well as the objectives of the study were provided to the parents and the informed consent form was signed.

Neonates were selected from among patients in the Neonatal Department of Kowsar Hospital. The sample size was calculated based on a study conducted in 2008 (20) with the following parameters: $\alpha$=0.05, power=90%, $\beta$=0.1, P1=58.3%, P2=16%, using G*power 3,0,10 software. Based on the calculation made, a total of 30 babies in each group were required, and considering the case of 25% dropout, the final sample size of 38 people in each group was estimated. Eligible neonates were randomly allocated in a 1:1 ratio to the intervention or control group. Randomization was performed on the basis of permuted block sizes of 4 and the use of a table of random numbers. The intervention group was treated with Eau de Dalibour (120 ml, Kimiagar Toos, Iran), and the placebo group was treated with distilled water only.

The umbilical cords of all newborns were cut under sterile conditions in the delivery room and no antiseptic agent was used on the stump. The inclusion criteria were newborns with a gestational age of 37-42 weeks; weight≥ 2.5 kg; Apgar score> 7 at minutes 1 and 5, rupture of membranes for no longer than 12 h, and no sign of meconium-stained amniotic fluid. The exclusion criteria were respiratory distress, metabolic disease, congenital disorders, any other problems that required immediate evaluation and NICU admission, and neonates of mothers with postpartum fever, mastitis, or urogenital infection.

Any cutaneous complication, itching, redness, and swelling after the first use of Eau de Dalibour was considered as a side effect of Eau de Dalibour. Before discharge, all parents received instructions on how to properly care for the umbilical cord, and performed the procedure accurately under staff supervision. Primary home care providers encouraged meticulous hand washing. Parents are also trained on infection symptoms, including umbilical discharge, redness (inflammation), and swelling (edema) of the cord stump and the skin at the base of the stump (14). Parents were unaware of the type of drug used. In the Eau de Dalibour group, we recommended that all mothers scrub 2-3 ml of Eau de Dalibour on the umbilical stump using sterile gauze or swab beginning 3 h after birth and once every 12 h until 2 days after separation of the cord. Mothers in the distilled water group were advised to perform the same procedure with distilled water. All mothers in the two groups were asked not to cover the cord with diapers or a bathe until the cord was separated. All mothers in both groups received forms to record symptoms of umbilical cord infection including erythema, swelling, and umbilical discharge, and cord separation time. The mothers completed these forms at home for two days after umbilical cord separation and were allowed to follow up for any problems with their newborns. The researcher called mothers daily to get informed of the date and hour of cord separation as well as signs of infection. Two days after cord separation, the physician checked the cords of the newborns for signs of omphalitis.

Finally, the data were analyzed by SPSS software version 22 using descriptive indices, independent t test and chi-square, and $p<0.05$ was considered significant.

## Results

The results of the present study showed no significant differences between the two groups in terms of gestational age, sex, or birth weight (Table 1).

In general, the mean separation time was 5.2±1.4 and 7.44±2.3 days in the intervention and comparison groups, respectively. The shortest cord separation time in both groups was three days, and the longest cord separation time in the Eau de Dalibour and placebo groups was 9 and 13 days, respectively. There was a significant difference in umbilical cord separation time between the two groups (P=0.0001). No infections were reported in any of the groups.

**Table 1. Comparison of gestational age, sex, and birth weight between the intervention and placebo groups**

| Group<br>Variable | Eau de Dalibour<br>Number(%) | Placebo<br>Number(%) | p-value |
|---|---|---|---|
| **Gestational age (Week)** | | | |
| >37 weeks | 34(89.5) | 35(92.1) | 0.692 |
| 35-37 weeks | 4(10.5) | 3(7.9) | |
| **Sex** | | | |
| Male | 23(60.5) | 19(50) | 0.356 |
| Female | 15(39.5) | 19(50) | |
| **Birth weight** | | | |
| >3500 | 11(28.9) | 6(15.8) | 0.169 |
| 2500-3500 | 27(71.1) | 32(84.2) | |
| **Type of delivery** | | | |
| Vaginal | 37 (97.4) | 36(97.2) | 0.555 |
| Cesarean section | 1 (2.6) | 2(5.2) | |
| **Mother's age (years)** | | | |
| <20 | 3(7.9) | 6(15.8) | |
| 20-30 | 25(67.5) | 22(57.9) | 0.540 |
| >30 | 10(26.3) | 9(23.7) | |
| **Mother's education** | | | |
| Middle school | 5(13.1) | 7(18.4) | |
| High school | 22(57.9) | 19(50) | 0.742 |
| Academic | 11(28.9) | 12(31.6) | |
| **Time of rupture of the amniotic membrane** | | | |
| During birth | 11(28.9) | 16(42.1) | |
| 0.5-6 hours before birth | 23(60.5) | 17(44.7) | 0.379 |
| 6-12 hours before birth | 4(10.5) | 5(13.1) | |

## Discussion

In this study, the findings showed that the use of Eau de Dalibour has no side effects and can reduce the time of separation of the umbilical cord of babies compared to distilled water. Omphalitis was not observed in any infant. Delay in the separation of the umbilical cord is associated with various complications such as bacterial infections (21). Infection of the umbilical cord can be limited to the umbilical cord (Omphalitis) or spread through the bloodstream, causing neonatal sepsis (8).

According to previous results by Habibi et al., Eau de Dalibour and ethanol are equally effective in preventing omphalitis, but Eau de Dalibour causes umbilical cord detachment to occur significantly faster in neonates (20). In Carney's case report, Eau de Dalibour could also prevent omphalitis in adults and be an effective treatment (22). Significant antibacterial efficacy is found in copper sulphate salts against multidrug resistant nosocomial pathogens (23). Additionally, a clinical trial on the impact of copper sulfate on umbilical granulomas was conducted by Fiaz et al. (24) and Annapurna et al. (25), and the results suggested a treatment range of 95.5% to 100% with no side effects and recurrences.

According to WHO, daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) is advised to the umbilical cord stump during the first week of life for newborns who are born at home in environment with high neonatal mortality, while dry cord care (keeping the cord clean with water without application of anything and leaving it exposed to air or loosely covered by a clean cloth) for infants born in health facilities and at home in low neonatal mortality settings (13, 26-28). In low-resource settings, cord cleaning with 4% chlorhexidine may lower the risk of neonate mortality and sepsis (omphalitis) (29). Nonetheless, it has been shown to lengthen the period of separation compared with alternative therapies (26, 27).

Human milk is another accessible source for umbilical cord care. Through the use of immunologic substances, proteolytic enzymes, and polymorphonuclear leukocytes found in the cord, human milk has the potential to speed up the complex procedure of cord separation. (30). In a study conducted by Madian et al., human milk could significantly accelerate the cord separation compared to distilled water and alcohol and mean time of cord separation days were 6.72±1.66, 8.22±2.52 and 11.9±3.1, respectively with significant differences between groups (31).

Data on umbilical cord separation and infection were gathered through telephone interviews with mothers, in contrast to direct observations by healthcare experts. It is likely that the mothers forgot the precise time of cord separation or applied other chemicals to the cord. The results of the current study, which focused on term neonates delivered in sterile settings, should not be applied to include neonates delivered at home. To determine microbial colonization, similar research should be conducted using umbilical cord sampling.

Eau de Dalibour can reduce the umbilical cord separation time in neonates and does not cause any skin problems. Eau de Dalibour can be used as an easy, affordable, and available care for the umbilical cord in areas where access to health centers is limited.

**Conflict of interest:** The authors declare no conflict of interest.

## Acknowledgment

We would like to thank the Clinical Research Development Unit of Kowsar Hospital of Qazvin University of Medical Science.

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