

Research

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Umbilical Cord Care After the First Day From Birth: A Case Control Study in a Northeastern Italian Hospital

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ABSTRACT

Background: Recently the use of antibacterial agents to clean and dry the stump of the newborns' umbilical cord (UC) after birth has been abandoned by many neonatal units. Aim of this study was to compare the occurrence of adverse events (AEs), time to UC separation and caregivers' satisfaction among newborns treated with *dry cord care* versus 70% alcohol after one day from birth in an Italian Hospital.

Methods: From June 2014 to September 2014, 100 infants were enrolled for the study. Soon after birth, all the newborns were treated in the same way: their UC was cleansed with 70% alcohol, using a sterile gauze. One day after the birth, in the control group the UC was regularly cleansed with 70% alcohol twice a day, while in the case group, from the first nappy change, *dry cord care* was performed cleansing the UC with sterile saline solution (NaCl 90%), using a sterile gauze twice a day. In all cases UC was left without any dressing upon it as well. The time to UC separation and any AEs (local and systemic infections, haemorrhage, granuloma formation) were reported by mothers. Carers' perception regarding the two procedures were collected by a questionnaire between 6 and 24 hours after birth, and 1 month later.

Results: We found a significant difference in the mean cord separation time between the two groups [*dry cord care*: 9.1 days (standard deviation (SD)=3.1] versus 70% alcohol: 11.3 days (SD=4.6); $p<0.01$], while no significant AEs and carers' satisfaction on the procedures resulted. Instead, change of treatment at home was more frequent in *dry cord care* group (23.9% versus 6.1%; $p<0.01$).

Conclusions: This study confirms that *dry cord care* is an easy, accepted and safe method of handling the UC in healthy newborn infants born in a high-income hospital setting.

KEYWORDS: Umbilical cord care; Dry cord care; 70% alcohol; Cord separation time; Caregivers' satisfaction.

INTRODUCTION

The umbilical cord (UC) which connects the baby and placenta in uterus (the womb) is made of blood vessels and connective tissue. It is covered by a membrane that is normally bathed in amniotic fluid. After birth, cutting the cord physically and symbolically separates the mother and her baby. The cord stump (CS) dries, falls off and the wound heals.¹

The cord usually separates between 5 and 15 days after birth. Before the separation, the remaining stump can be considered to be a healing wound and thus a possible route for infection through the vessels into the baby's blood stream.¹

Soon after a normal delivery, the skin of the newborn baby including the CS is colonised mainly by non-pathogenic bacteria such as coagulase negative *Staphylococci* and *Diphtheroid* bacilli. Pathogenic bacteria such as *Coliforms* and *Streptococci* may also be present on the skin² and can track up the CS causing infection.

In the developing countries, one third of the deaths are caused by infections, mostly because of the delivery environment (generally the community and the houses). Cord infection may be localised to the UC (omphalitis) or, after its entry into the blood stream, it becomes systemic (e.g., neonatal sepsis).² The most observed infections upon the CS and the abdominal surface are due to bacterial omphalitis with polymicrobial aetiology,³ but also to *Clostridium tetani*.⁴ The onset of the symptoms is usually observed between the 5th and the 9th day of life.

While there is a general agreement about the clean technique for cutting the cord using a sterile cutting instrument (blade or scissors) and regards to clean hands to avoid infection, there is less accord on what is the best care of the CS.¹

Internationally, the World Health Organisation (WHO) has advocated since 1998 for the use of dry UC care (keeping the cord clean without application of anything - where anything stands for a dye, an antiseptic, or an antibiotic - and leaving it exposed to air or loosely covered by a clean cloth, in case it becomes soiled it is only cleaned with water).⁵ Also the American Academy of Paediatrics considers no antiseptic treatment to be superior to any other⁶ and the guidelines from the German Association for Neonatology and Paediatric Intensive care recommend clean care and keeping the UC dry.⁷

On the basis of a Cochrane review¹ and other several studies,⁸⁻¹² WHO recommends daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the UC stump during the first week of life for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births), while *dry cord care* for newborns born in health facilities and at home in low neonatal mortality settings.

According to the literature, *dry cord care* can be performed in several different ways, even though it is called with the same name. In some studies¹³ it was defined as the act of cleansing the UC and the surrounding area with water ad soap, whereas in others it was described as the act of letting the UC dry without the application of any solution whatsoever.¹³

Aim of this study was to compare the occurrence of all adverse events (AEs) and the cord separation time among newborns treated with *dry cord care* versus 70% alcohol in an Italian Hospital to give a valid recommendation to clinicians. Further endpoints were caregivers' acceptance of treatment and satisfaction with it.

MATERIALS AND METHODS

Study subjects were recruited from June 2014 to September 2014 at a Northeastern Italian Hospital, where about 500 deliveries take place annually. The minimum sample size (N=100) was calculated using the formula of estimating a single population (N=500) portion, taking 15% proportion of 6% margin of error and 95% confidence level.

Infants were considered eligible according to the inclusion criteria reported in Table 1 which are in line with inclusion criteria in other similar studies.^{11,14} After obtaining written consent by parents, during the considered period the first 50 subjects were assigned to control group and the last 50 infants to case group (*dry cord care*).

NEWBORNS' INCLUSION CRITERIA TO THE RESEARCH
Birth between the 37 th and the 42 nd week of pregnancy
Vaginal and caesarean section
Apgar score of ≥ 7 at 5 minutes after birth
Birth weight $\geq 10^{\text{th}}$ percentile
Without inborn or genetic disorder
No maternal complication during pregnancy or delivery
Parental consent
Italian speaking parents

Table 1: Criteria to including newborns in the experimental study.

Soon after birth, the newborns of both groups were treated in the same way following the hospital procedure: their UC was cleansed with 70% alcohol using a sterile gauze. A dry gauze was wrapped around the stump and fixed with a net. This dressing was usually supposed to stay in place for at least 24 hours, if not contaminated. Then the treatment was changed after the first 24 hours: in the control group the UC was regularly cleansed twice a day with 70% alcohol with a sterile gauze and left without any dressing upon it, while in the case group *dry cord care* was performed from the first nappy change cleansing the UC with sterile saline solution (NaCl 90%), using a sterile gauze twice a day, and left without any dressing upon it as well. In case of urine or meconium/faeces contamination, these procedures had to be performed more often in order to reduce the consequent risk of infection.

A researcher collected new born's and mother's data: delivery (natural, caesarean section, vacuum extractor), birth weight, parenthood order, sex, type of breast feeding at discharge, mother's age and education.

A questionnaire (available on request), organised in different pathways for primipare and pluripare, was administered to mothers in two moments: at first soon after birth, between the 6th and the 24th hour after delivery, in hospital and one month after child birth at home by phone. Variable investigated were: mother's knowledge about the UC care, anxiety level in hospital and at home regards the treatment, type of breastfeeding at home,

occurrence of AEs and their treatments, cord separation time, changes in cord care procedures at home, alternative products, access to outpatient care, carers' opinion about the treatment in terms of satisfaction, anxiety and compliance to the instructions given by hospital personnel.

Parents were asked to record signs of UC local or systemic infections categorised into four gradations (none, mild, moderate, or severe) according Mullany.¹⁰ Mild was defined as redness or swelling limited to the CS only; moderate was defined as less than 2 cm extension onto the abdominal skin at the base of the CS; and severe was defined as spreading noticeably (≥ 2 cm) outward from the base of the stump. In case of systemic infection (also known as neonatal sepsis), the describing criteria were the admission diagnosis of the newborn in the Paediatric Unit, the contingent analysis and the cultural exams. The study also detected the umbilical granuloma that is the most common umbilical abnormality in the neonate.¹¹

Criterion to define CS fall was the complete detachment of the stump from the newborn's abdominal surface.

Ethical approval for this study was not needed, because *dry cord care* was already approved by the scientific community.

Data collected were entered in an Excel spreadsheet and were analysed using the statistical software SPSS, version 20. Pearson Chi-square test and Mann – Whitney test, for mean comparison, were used. Statistical significance was defined as $p \leq 0.05$.

RESULTS

One hundred inborn healthy term infants were recruited from June 2014 to September 2014 distributed equally in experimental

group (*dry cord care*) and control group (70% alcohol). It was possible to collect a full data set from 95 of them, whereas 5 of mothers did not attend the follow up.

Table 2 shows the newborns' and mothers' characteristics in the two groups under study.

Table 3 reports questions administered to mothers at home one month after childbirth: type of breastfeeding at home, occurrence of AEs, changes in cord care procedures at home, use of alternative products and cord separation time. The incidence percentage of granuloma was 2.2% in *dry cord care* group. 11.0% (5/46) of *dry cord care* group mothers went to paediatrician and 4.1% (2/49) of control group ones.

Table 4 describes mothers' knowledge, satisfaction and anxiety regards to UC treatment. Regards to previous knowledge about UC care, primipare reported health professionals (paediatric nurses, midwives) as principal sources of information, while magazines, internet, opinions of relatives and friends as alternative sources, while pluripare acquired knowledge during previous pregnancies. Only *dry cord care* obtained a score ≤ 4 in 3 cases in question on satisfaction with treatment management and results. This satisfaction was related to the doubts about the practice and not regards to the occurrence of AEs.

Pluripare that experienced both treatments were asked to give a preference on them: 40.9% (9/22) chose *dry cord care*, 31.8% (7/22) referred 70% alcohol and 27.3 (6/22) did not express their opinion.

DISCUSSION

Even if in 2013 WHO recommended clean *dry cord care* for infants born in health facilities and at home in low neonatal mor-

INFANTS		dry cord care group N(%) Total=46	70% alcohol group N(%) Total=49	p value
Type of delivery	Natural	27(58.7%)	37(75.5%)	0.15
	Caesarean section	14(30.4%)	7(14.3%)	
	Vacuum extractor	5(10.9%)	5(10.2%)	
Birth weight (g)	Mean (SD)*	3410.91(368.02)	3298.27(402.73)	0.18
Parenthood order	First-born	22(47.8%)	27(55.1%)	0.31
	Second-born	22(47.8%)	17(34.7%)	
	Third-born	2(4.3%)	5(10.2%)	
Sex	Female	23(50.0%)	20(40.8%)	0.37
	Male	23(50.0%)	29(59.2%)	
Breastfeeding at discharge	Breast	45(97.8%)	46(93.9%)	0.34
	Formula	1(2.2%)	3(6.1%)	
	Combination	/	/	
MOTHERS		dry cord care group n=46	70% alcohol group n=49	p value
Age(years)	Mean (SD)*	32.0(5.3)	32.7(5.0)	0.4
Education	Primary school	1(2.2%)	/	0.18
	Secondary school	3(6.5%)	14(28.6%)	
	High school	28(60.9%)	20(40.8%)	
	University	14(30.4%)	15(30.6%)	

*standard deviation

Table 2: Baseline characteristics of subjects (infants and mothers) in the two groups under study.

Questions		dry cord care group N(%) Total=46	70% alcohol group N(%) Total=49	p value
Method of infant feeding at home	Breast	33(71.7%)	32(65.3%)	0.79
	Formula	5(10.9%)	7(14.3%)	
	Combination	8(17.4%)	10(20.4%)	
Adverse Events	No	36(78.3%)	40(81.6%)	0.78
	Yes	10(21.7%)	9(18.4%)	
Type of Adverse Event	Mild infection	2(20%)	2(22.2%)	0.62
	Moderate infection	/	/	
	Severe infection	/	/	
	Redness, bleeding	7(70%)	7(77.8%)	
	Granuloma	1(10%)	/	
	Systemic disease	/	/	
Procedure change at home	No	35(76.1%)	46(93.9%)	<0.01
	Yes	11(23.9%)	3(6.1%)	
Alternative products	Silver nitrate	1 [§] (9.1%)	1 [§] (33.3%)	/
	Peroxide	1 [^] (9.1%)	1 [^] (33.3%)	
	70% Alcohol	8 [4] [^] [4] [§] (72.7%)	/	
	Pomade	/	1 [§] (33.3%)	
	Eosine	1(9.1%)	/	
Cord separation time (days)	Mean (SD) [*]	9.1 (3.1)	11.3 (4.6)	<0.01
	Range	3-16	3-23	/
	Median	10	12	/

*standard deviation
 §medical decision
 ^autonomous caregivers' decision

Table 3: Questions administered to mothers at home one month after childbirth, distributed in the two groups under study.

Questions		dry cord care group N(%) Total=46	70% alcohol group N(%) Total=49	P value
Background knowledge	Yes	35(76.1%)	39(79.6%)	0.76
	No	11(23.9%)	10(20.4%)	
	Yes among pluripare	24/46(52.2%)	24/49(49.0%)	0.76
Satisfaction (score:0-10) [*]	Mean (SD) [§]	8.8(2.0)	9.4(1.1)	0.21
	Range	1-10	5-10	/
Anxiety in hospital	Yes	5(10.9%)	7(14.3%)	0.61
	No	41(89.1%)	42(85.7%)	
Anxiety at home	Yes	1(2.2%)	2(4.1%)	0.59
	No	45(97.8%)	47(95.9%)	

* score 0-10: 0 corresponds=no satisfaction and 10=maximum level of satisfaction
 § standard deviation

Table 4: Questions administered to mothers regards to knowledge, satisfaction and anxiety about the umbilical cord treatment. distributed in the two groups under study.

tality settings, healthcare working in neonatal unit and caregivers use different procedures to care the UC according their experiences and their preferences. Also in high-income countries, where mortality is very low, important outcomes in the first month¹ of life regards to UC care must include more frequently AEs such as irritation, redness of the navel wall, weeping and bleeding of the navel, rarely infections like omphalitis, sepsis, and umbilical granuloma and the time to separation of the UC stump.¹¹

This case-control study compared two UC care procedures: *dry cord care* and 70% alcohol. *Dry cord care* is the procedure in which the umbilical stump is kept “clean and dry without applying anything” where anything stands for a dye, an antiseptic, or an antibiotic.⁵ In this study *dry cord care* was performed from the first nappy change cleansing the UC with sterile saline solution (NaCl 90%), using a sterile gauze twice a day, and left without any dressing upon it as well. The research, confirming data shown in other trials conducted in healthy term infants born in high-income or middle-income hospital set-

ting,^{2,15-17} found no difference in occurrence of UC AEs between the two groups, that also did not have statistically significant differences in percentages distribution of baseline characteristics of newborns (type of delivery, birth weight, parenthood order, sex, breastfeeding at discharge and at home) and of mothers (age, education).

In literature the mean UC separation time ranged from 4 to 16 days depending on the intervention and study setting.^{2,10,17} Studies which applied nothing to the cord had mean separation times of about nine/ten days.¹⁴⁻¹⁷ Meta-analysis of four studies with alcohol as the comparator showed a trend towards cord separation being significantly prolonged in the alcohol group but there was no significant difference in cord separation,¹ while the present study showed a statistical difference between the two groups: in *dry cord care* the mean UC separation time was about 2 days before of control group one (9 days versus 11 days). In literature the clinical impact of delays of cord separation is unknown, but it has social and cost implications: delay makes mothers anxious, and it increases the number of domiciliary

midwife visits to home.¹⁸ It follows that health workers and families prefer more rapid cord separation.² The present research confirms that the mothers in the *dry cord care* group have less anxiety even if the absolute number is very low.

This study detected also the occurrence of granuloma. It is an over growing tissue during the healing process of the belly button, usually occurs in reaction to a mild infection. It is not a congenital abnormality but represents continuing inflammation of granulation tissue, that has not yet epithelialized.¹⁹ In the present study the incidence percentage of granuloma was equal to 2.2% in *dry cord care* group much lower than the finding of Kapellen et al¹¹ of 11.7%.

About mothers' compliance to the technique, the study showed that caregivers used different products more often in *dry cord care* group than in the 70% alcohol group. In some cases, this was a personal decision based on knowledge and beliefs, in others the reason of the change was a medical prescription due the onset of a complication. There was a variety of alternative products that caregivers used from pomade to peroxide and of course the shift to 70% alcohol. An interesting finding was the utilization of silver nitrate in two cases because there were opposing opinions about the application of this product upon the UC. In fact a prolonged use of silver nitrate can cause the onset of chemical burns to the newborns' skin. For this reason, literature advises a more conservative approach to the infective complications of the umbilical area (granuloma) such as a 70% alcohol treatment.^{20,21}

Regards to caregivers' perception about the UC care, the research highlighted no differences between the experimental and control group us in satisfaction with management and results of the treatment and in anxiety reported by mothers at home. The few cases that expressed a scarce satisfaction with *dry cord care* were not connected to the onset of complications, but only to scepticism among an experimental treatment. The literature offers other examples of studies that considered the carer's opinion about *dry cord care* compared with other techniques. For instance between chlorhexidine powder and *dry cord care*, chlorhexidine seems to be the favourite one, therefore the carers would administer this treatment to their next child.¹¹ In the present study the researcher asked pluripare, experimented both the treatments in different pregnancies, which they preferred and why. About 40% of them would administer *dry cord care* to their next child appearing to more gentle and comfortable for the newborn.

Taking into account the costs of the two treatments, *dry cord care* resulted less expensive than 70% alcohol: a 250 ml bottle of 70% alcohol costs 5.10 €, where the same amount of sterile saline solution costs 1.20 €.

The study had three limitations. First, it was conducted on babies and their mothers who were only eligible for selection criteria, and it may not be generalised to other cultures or countries. The second limitation is related to difficulties of

standardised procedures in collecting the culture samples from UC in home setting. Therefore it was not possible to provide the determination of microorganisms responsible of detected complication. Third, data on UC complications and treatments was obtained by telephone interview of mothers and not through direct observation by healthcare professionals. Of course before hospital discharge, parents were instructed to look for the warnings signs of UC complications and to contact their healthcare provider if in doubt.

CONCLUSION

This case-control study compared two different procedures for the UC care in infants born in a high-come hospital: *dry cord care versus 70% alcohol*. No statistically significant differences between the two UC care practices resulted regards to the occurrence of UC AEs (local infection, systemic disease, granuloma, bleeding, etc.) and to the caregivers' satisfaction, while time of UC separation was significant shorter in *dry cord care* group and more frequently mothers' *dry cord care* group changed the treatment at home.

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CONFLICTS OF INTEREST

The authors have no competing interests.

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