EVIDENCIAS EN PEDIATRÍA
Toma de decisiones clínicas basadas en las mejores pruebas científicas
www.evidenciasenpediatria.es

Critically Appraised Articles

Is it necessary to clean the umbilical cord with antiseptics?

Martín Masot R[1], Orejón de Luna G[2]
[1]*Department of Paediatrics. Área Hospitalaria de Granada. Granada. Spain.*
[2]*CS General Ricardos. Madrid. Spain.*

Correspondence: Gloria Orejón de Luna, gloriaglo04@gmail.com

English key words: umbilical cord, dry care, antiseptics, omphalitis, newborn.
Palabras clave en español: cordón umbilical, limpieza en seco, antisépticos, recién nacido, onfalitis.

Reception date: June 6, 2017 • **Acceptance date:** June 8, 2017
Publication date: June 14 , 2017

Evid Pediatr. 2017;13:16.

HOW TO CITE THIS ARTICLE

Martín Masot R, Orejón de Luna G. ¿Es necesario limpiar el cordón umbilical con antisépticos? Evid Ped. 2017;13:16.

This article is available at http://www.evidenciasenpediatria.es/EnlaceArticulo?ref=2017;13:16
 • ISSN: 1885-7388

Is it necessary to clean the umbilical cord with antiseptics?

Martín Masot R[1], Orejón de Luna G[2]
[1]*Department of Paediatrics. Área Hospitalaria de Granada. Granada. Spain.*
[2]*CS General Ricardos. Madrid. Spain.*

Correspondence: Gloria Orejón de Luna, gloriaglo04@gmail.com

Artículo original: GGras-Le Guen C, Caille A, Launay E, Boscher C, Godon N, Savagner C, *et al*. Dry care versus antiseptics for umbilical cord care: a cluster randomized trial. Pediatrics. 2017;139 pii: e20161857.

Abstract

Authors' conclusions: in full-term new-borns from developed countries, applying antiseptics to the umbilical cord versus just keeping it clean and dry, was not superior to prevent omphalitis, in addition to being costly higher. Therefore, this practice can be replaced by keeping the cord clean and dry.

Reviewers' commentary: for new-borns without risk factors in developed countries, keeping the umbilical cord clean and dry is a good procedure to prevent omphalitis in the new-born. More studies would be needed to assess its efficacy in situations of clinical or epidemiological risk, as well as in the case of developing countries.

Key words: umbilical cord, dry care, antiseptics, new-born, omphalitis.

¿Es necesario limpiar el cordón umbilical con antisépticos?

Resumen

Conclusiones de los autores del estudio: en recién nacidos a término de países desarrollados, aplicar antisépticos frente a mantener el cordón umbilical limpio y seco, además de ser más costoso, no fue superior para prevenir onfalitis. Por ello, se podría reemplazar esta práctica por mantener el cordón limpio y seco.

Comentario de los revisores: en nuestro medio y en recién nacidos sin factores de riesgo, parece que mantener limpio y seco el cordón umbilical es un buen procedimiento para evitar la onfalitis en el recién nacido. Serían necesarios más estudios para valorar su eficacia en situaciones clínicas o epidemiológicas de riesgo, así como en países en vías de desarrollo.

Palabras clave: cordón umbilical, limpieza en seco, antisépticos, recién nacido, onfalitis.

STRUCTURED ABSTRACT

Objective: to assess whether keeping the umbilical cord (UC) dry and clean is not inferior to the use of antiseptics to prevent omphalitis in newborns.

Design: noninferiority, cluster-randomized, 2-period crossover and unmasked study.

Setting: maternity units at 6 university hospitals in France.

Study population: the study included 8698 newborns (NBs) of more than 36 weeks' gestational age; 293 were lost to followup (3.4%). Exclusion criteria: serious congenital malformation, admission to Intensive Care Unit, and families with anticipated barriers to adherence.

Intervention: children were clustered by maternity ward and time period and randomly assigned to the two different groups in a crossover design with two study periods of 4 months' duration (3 months of treatment and 1 of followup), separated by a 3-month washout period. During the antiseptic care period (intervention group [IG]), the stump was cleaned one to three times a day with an antiseptic solution (alcohol with chlorhexidine, 70% alcohol or chlorhexidine solution). During the dry care period (control group [CG]), the stump was washed with water and nonantiseptic liquid soap and then carefully dried twice a day. The IG consisted of

4404 NBs and the CG of 4294 NBs. Both health care staff and the parents of NBs received written information on the correct cleaning procedure. Parents were encouraged to make an appointment if there were any abnormalities in the cord stump in the first 28 days, after which the researchers contacted the families by phone.

Outcome measures: the primary outcome was the development of omphalitis in the first 28 days of life, defined as purulent or malodorous discharge from the umbilical stump, periumbilical erythema, oedema or tenderness in the region. When suspected, NBs were assessed by other paediatricians. Other outcome variables included: time elapsed to separation of cord, parental satisfaction, hospital admission and development of infection and antibiotic therapy in the first 28 days of life. The authors assumed a proportion of omphalitis of 0.2% and established a noninferiority margin of 0.4%.

Main results: there were three cases of omphalitis in children that received dry care (0.07%) and none in children treated with antiseptics. The crude risk difference (RD) in the antiseptic group was 0.07% in the intention-to-treat analysis, with a 95% confidence interval (CI) of –0.03% to 0.21%. Medical visits for umbilical cord problems were more frequent in the CG, although the adjusted risk difference (ARD) of 0.72 (95 CI, –0.01 to 1.45; $P = .052$) was not statistically significant. There were no statistically significant differences in any of the other variables, either.

Conclusion: in developed countries, the use of antiseptics compared to keeping the umbilical stump dry and clean in term NBs is not only more costly, but also is not superior in preventing omphalitis. Thus, antiseptic care could be replaced by dry care.
Conflicts of interest: none disclosed.

Funding source: funded by a French research grant.

COMMENTARY

Justification: omphalitis is an infection of the umbilical cord stump and surrounding tissues that develops in NBs. Bacterial colonisation of the UC is frequent and may be a gateway for other neonatal infections. The incidence of omphalitis is 0.7% in developed countries, and it at least six time higher in developing or poor countries,[1,2] where there can be up to approximately 217 cases per 1000 live births and with an associated mortality of 77 out of 1000 live births.[3] Different approaches to UC care have been proposed, some of which are more heavily founded in customs and beliefs than scientific evidence, so it would be interesting to study which approach is most efficacious, easiest and least.

Scientific rigour and validity: this was a well-designed clinical trial. The use of a cluster and crossover design allowed the recruitment of a larger sample of NBs and ensured an adequate comparison of the control and intervention groups. Randomisation was performed correctly and the groups were homogeneous, with no differences in the baseline characteristics of mothers and NBs. Newborns with risk factors for omphalitis were excluded, with the exception of NBs delivered at home. Masking was not possible due to the obvious differences in the intervention, which should not have had an impact on the diagnosis of omphalitis but may have influenced the number of related visits. The population was clearly defined, as were the tested intervention and endpoints. The followup was completed in both groups, and there were few losses. The authors performed per protocol and intention-to-treat analyses.

Clinical relevance: based on the results of the study, keeping the UC clean and dry is not less efficacious than antiseptic care, with a noninferiority margin of 0.4%, which entails an assumption that 1 case of omphalitis per 250 NBs is not inferior (number needed to treat), when there were actually more cases in the dry care group (difference at the limit of statistical significance, which corresponded to 1 case in every 1429 RNs). Other studies of similar characteristics[4] and systematic reviews and meta-analyses[5,6] have also concluded that dry UC care is an easy, simple and safe method for healthy NBs in developed countries. Furthermore, some studies[5] have reported that the time to separation of the umbilical cord increases and parental involvement in UC care decreases with the use of antiseptics. However, we must take into account that the noninferiority margin established by the authors was based on an assumed incidence of omphalitis of 0.2%, while the incidence of omphalitis ranges between 0.08 and 0.7% in developed countries[1,2] and is much higher in developing countries and NBs with risk factors.[3] In fact, studies that have assessed risk factors such as countries with limited resources, preterm birth and/or admission to NICU[3,7,8] have found that antiseptic care of the UC, specifically with chlorhexidine, is more efficacious in reducing the risk of omphalitis and neonatal sepsis. Last of all, in this study there were more frequent visits for UC symptoms in the CG, but it was not clear whether there was actually a greater morbidity or the reason was a heightened vigilance in parents, as has been described by other authors.[9] This factor could increase the cost of dry care due not to the treatment itself, but to the increase in health care services, which would contradict the authors' conclusion that dry care is less costly.

Applicability to clinical practice: the evidence suggests that in NBs with no risk factors in Spain, keeping the UC clean and dry is a good strategy to prevent omphalitis as long as an incidence of 1 case of omphalitis per 1429 NBs is considered acceptable. The incidence of omphalitis in each maternity ward will determine the applicability to clinical practise, which should be evaluated on a case-by-case basis. Further studies are required to assess the efficacy of dry care in high-risk clinical or epidemiological situations and in developing countries.

Conflicts of interest: the authors of the commentary have no conflicts of interest to declare.

REFERENCES

1. Pérez-Moneo Agapito B, Pérez Butragueño M, Molina Amores C. Onfalitis neonatal. En: Guía-ABE. Infecciones en Pediatría. Guía rápida para la selección del tratamiento antimicrobiano empírico [online] [accessed on 08/06/2017]. Available at: www.guia-abe.es/temas-clinicos-onfalitis-neonatal
2. Stewart Dan, Benitz W and Committee on fetus and newborn. Umbilical cord care in the newborn infant. Pediatrics. 2016;138:e20162149.
3. Karumbi J, Mulaku M, Aluvaala J, English M, Opyo N. Topical umbilical cord care for prevention of infection and neonatal mortality. Pediatr Infect Dis J. 2013;32:78-83.
4. Quattrin R, Iacobucci K, de Tina AL, Gallina L, Pittini C, Brusaferro S. 70% alcohol versus dry cor care in the umbilical cord care: a case control study in Italy. Medicine. 2016;95:e3207.
5. Imdad A, Bautista RM, Senen KA, Uy ME, Mantaring JB, Bhutta ZA. Umbilical cord antiseptics for preventing sepsis and death among newborns. Cochrane Database Syst Rev. 2013; 31: CD008635.
6. Zupan J, Garner P, Omari A. Topical Umbilical cord care at birth. Cochrane Database Syst Rev. 2004:CD001057.
7. Sharma D, Gathwala G. Impact of chlorhexidine cleansing of the umbilical cord on cord separation time and neonatal mortality in comparison to dry cord care - a nursery-based randomized controlled trial. J Matern Fetal Neonatal Med. 2014;27:1262-5.
8. Gathwala G, Sharma D, Bhakhiri B. Effect of topical application of chlorhexidine for umbilical cord care in comparison with conventional dry cord care on the risk of neonatal sepsis: a randomized controlled trial. J Trop Pediatr. 2013;59:209-13
9. Janssen PA, Selwood BL, Dobson SR, Peacock D, Thiessen PN. To dye or not to dye: a randomized, clinical trial of a triple dye/alcohol regime versus dry cord care. Pediatrics. 2003;111:15-20.