

A COUPLE OF SQUIRTS A DAY KEEPS THE DOCTOR AWAY. A CLUSTER RANDOMIZED CONTROLLED TRIAL OF ALCOHOL-BASED HANDRUBS FOR PREVENTION OF INFECTIOUS DISEASE IN CHILDREN

Juan C. Correa, *División de Salud Comunitaria, Fundación Santa Fe de Bogotá, Colombia*

Diana Pinto, *Fedesarrollo. Departamento de Epidemiología Clínica y Bioestadística, Pontificia Universidad Javeriana, Colombia*

Lucas Salas, *División de Salud Comunitaria, Fundación Santa Fe de Bogotá, Colombia*

Juan Camacho, *División de Salud Comunitaria, Fundación Santa Fe de Bogotá, Colombia*

Martín Rondón, *Departamento de Epidemiología Clínica y Bioestadística, Pontificia Universidad Javeriana, Colombia*

Juliana Quintero, *Centro de Estudios e Investigaciones en Salud, Fundación Santa Fe de Bogotá, Colombia*

Background and Aims: This first cluster randomized controlled trial in a developing country setting sought to investigate if the use of alcohol-based handrub (ABH) reduced the incidence of acute diarrhoea (ADD) and respiratory infection (ARI) in children under five years. Handwashing with soap and water is known to be effective to prevent these illnesses, but alternatives are needed for settings where it is impractical.

Methods: The trial was performed in childcare centres with limited tap water availability located in six Colombian towns. Participants were randomly assigned to use ABH as a complement to handwashing (intervention arm: 21 centres/794 children); or to continue previous handwashing practices (control arm: 21 centres/933 children). Cases were identified through teacher-reported signs and symptoms of illness. Adverse events were monitored. Hazard ratios were obtained using Cox proportional hazards multivariate regression shared frailty models.

Results: Child-days of surveillance totalled 336,038. Attrition rate was 14%. For both diseases the hazard ratio did not differ during the first trimester of the trial. However, after this period the hazard ratios favour the intervention arm. The respective estimated risk of ADD for the second and third trimesters among children in the intervention group was 55% and 44% of the risk in the control group ($p < 0.001$). The respective estimated risk of ARI for trimesters two and three among children in the intervention group was 80% and 69% of the risk in the control group ($p < 0.001$). No adverse events occurred.

Conclusions: Alcohol-based handrub gels effectively prevent acute diarrhoea and respiratory infection and are safe. These results corroborate the findings of studies done in more affluent societies. National public health policies for prevention of these diseases should consider use of gels. Further research about the cost-effectiveness of ways to facilitate long-term behaviour change and technology adoption in diverse cultural contexts is needed.

References:

1. World Health Organization. The world health report 2007 : a safer future : global public health security in the 21st century. Geneva, Switzerland: WHO Press; 2007 [cited 2009 Jul]. Available from: <http://www.who.int/whr/2007/en/index.html>.
2. World Health Organization. Revised Global Burden of Disease (GBD) 2002 Estimates: Incidence, prevalence, mortality, YLL, YLD and DALYs by sex, cause and region, estimates for 2002 as reported in the World Health Report 2004.: World Health Organization Publications.; 2004 [updated 2004; cited Mayo 16, 2007]; Available from: <http://www.who.int/healthinfo/bodgbd2002revised/en/index.html>.
3. Acosta-Ramírez N, Peñaloza RE, Rodríguez-García J. Carga de Enfermedad Colombia 2005: Resultados Alcanzados. Bogotá, D.C., Colombia: Pontificia Universidad Javeriana, Centro de Proyectos para el Desarrollo (CENDEX); 2005 Oct Contract No.: Document Number].
4. UN Millenium Project 2005, Lenton R, Wright AM, Lewis K. Health, dignity, and development: what will it take?, Task Force on Water and Sanitation. London: Earthscan; 2005 [cited. Available from: <http://www.unmillenniumproject.org/documents/WaterComplete-lowres.pdf>.
5. Bloomfield SF, Aiello AE, Cookson B, O'Boyle C, Larson EL. The effectiveness of hand hygiene procedures in reducing the risks of infections in home and community settings including handwashing and alcohol-based hand sanitizers. *American Journal of Infection Control*. 2007;35(10):S27-S64.
6. Boyce JM, Pittet D, Healthcare Infection Control Practices Advisory Committee, Society for Healthcare Epidemiology of America, Association for Professionals in Infection Control, Infectious Diseases Society of America, et al. Guideline for Hand Hygiene in Health-Care Settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. *Morbidity & Mortality Weekly Report Recommendations & Reports*. 2002 CE1-4, 2002 Oct 25;51(RR-16):1-45.
7. Larson E. A causal link between handwashing and risk of infection? Examination of the evidence. *Infection Control*. 1988 Jan;9(1):28-36.
8. The International Bank for Reconstruction and Development/The World Bank, BNWP, Water and Sanitation Program. Hand washing manual: A guide for developing a hygiene promotion program to increase handwashing with soap. The World Bank; 2005 [updated 2005; cited Mayo 16, 2007]; Available from: http://www.globalhandwashing.org/Publications/Handwashing_Handbook.pdf.
9. United Nations Development Programme. Informe de desarrollo humano 2006. Más allá de la escasez: Poder, pobreza y la crisis mundial del agua. Palgrave Macmillan, VHPS.; 2006 [updated 2006; cited Mayo 16, 2007]; Available from: http://hdr.undp.org/hdr2006/report_sp.cfm.
10. World Health Organization, Unicef. Joint Monitoring Programme (JMP) for water supply and sanitation. 2006 [updated 2006; cited Mayo 16, 2007]; Available from: <http://www.wssinfo.org/en/welcome.html>.
11. Pittet D. Compliance with hand disinfection and its impact on hospital-acquired infections. *J Hosp Infect*. 2001 Aug;48(Suppl A):S40-6.
12. Larson EL, Lin SX, Gomez-Pichardo C, Della-Latta P. Effect of Antibacterial Home Cleaning and Handwashing Products on Infectious Disease Symptoms: A Randomized, Double-Blind Trial. *Ann Intern Med*. 2004 March 2, 2004;140(5):321-9.
13. Pickering AJ, Boehm AB, Mwanjali M, Davis J. Efficacy of Waterless Hand Hygiene Compared with Handwashing with Soap: A Field Study in Dar es Salaam, Tanzania. *Am J Trop Med Hyg*. 2010 February 1;82(2):270-8.
14. Sandora TJ, Taveras EM, Shih M-C, Resnick EA, Lee GM, Ross-Degnan D, et al. A Randomized, Controlled Trial of a Multifaceted Intervention Including Alcohol-Based Hand Sanitizer and Hand-Hygiene Education to Reduce Illness Transmission in the Home. *Pediatrics*. 2005 September 1, 2005;116(3):587-94.

15. California State Department of Education. Techniques for Preventing the Spread of Infectious Diseases. Sacramento.; California State Dept. of Education.; 1983 Contract No.: Document Number].
16. Geiger BF, Artz L, Petri CJ, Winnail SD, Mason JW. Fun with Handwashing Education. Birmingham: University of Alabama.; 2000 Aug Contract No.: Document Number].
17. Roberts A, Pareja R, Shaw W, Boyd B, Booth E, Mata JI. A Tool Box for Building Health Communication Capacity. Washington, DC.: HEALTHCOM, US Agency for International Development (USAID); 1995 [cited. Available from: <http://www.globalhealthcommunication.org/tools/29>].
18. Stark P. Handwashing technique. Instructor's Packet. Learning Activity Package. Sacramento: California State Dept. of Education.; 1982 Contract No.: Document Number].
19. Roberts L, Jorm L, Patel M, Smith W, Douglas RM, McGilchrist C. Effect of Infection Control Measures on the Frequency of Diarrheal Episodes in Child Care: A Randomized, Controlled Trial. *Pediatrics*. 2000 April 1, 2000;105(4):743-6.
20. Roberts L, Smith W, Jorm L, Patel M, Douglas RM, McGilchrist C. Effect of Infection Control Measures on the Frequency of Upper Respiratory Infection in Child Care: A Randomized, Controlled Trial. *Pediatrics*. 2000 April 1, 2000;105(4):738-42.
21. Killip S, Mahfoud Z, Pearce K, Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. *Annals of Family Medicine*. [Research Support, U.S. Gov't, P.H.S.]. 2004 May-Jun;2(3):204-8.
22. McGraw KO, Wong SP. Forming Inferences About Some Intraclass Correlation Coefficients. *Psychological Methods*. 1996;1(1):30-46.
23. Shrout PE, Fleiss JL. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychological Bulletin*. 1979;86(2):420-8.
24. StataCorp. Loneway -Large one-way ANOVA, random effects, and reliability. *Stata Base Reference Manual I-P: Release 10*. College Station, TX: StataCorp LP; 2007. p. 194-9.
25. Grove GL, Zerweck CR, Heilman JM, Pyrek JD. Evaluation of Hand Skin Condition in Two 5-Day Surgical Scrub/Hand Washing Studies Comparing a New Waterless/Brushless, Chlorhexidine Gluconate/Ethanol-Emollient Antiseptic Hand Preparation and Hibiclen®. In press 2000.
26. Clayton DG, Cuzick J. Multivariate Generalizations of the proportional hazard models (with discussion). *J R Stat Soc Ser A*. 1985;148:82-117.
27. Cleves MA, Gould WW, Gutierrez RG. An introduction to survival analysis using Stata, Revised Edition. College Station, Texas, USA: Stata Press; 2004.
28. Kelly PJ, Lim LL-Y. Survival Analysis for recurrent event data: an application to childhood infectious diseases. *Stat Med*. 2000;19:13-33.
29. Moulton LH, Dibley MJ. Multivariate Time-to-event models for studies of recurrent childhood diseases. *Int J Epidemiol*. 1997;26:1334-9.
30. Nielsen GG, Gill RD, Andersen PK, Sorensen TI. A Counting process approach to maximum likelihood estimation in frailty models. *Scand J Stat*. 1992;19:25-43.
31. Wintrebert CMA. Statistical modelling of repeated and multivariate survival data. Leiden: Leiden University Medical Center (LUMC), Leiden University; 2007.
32. Symons MJ, Moore DT. Hazard rate ratio and prospective epidemiological studies. *J Clin Epidemiol*. 2002;55(9):893-9.
33. Aiello AE, Coulborn RM, Perez V, Larson EL. Effect of Hand Hygiene on Infectious Disease Risk in the Community Setting: A Meta-Analysis. *Am J Public Health*. 2008 August 1, 2008;98(8):1372-81.
34. Ejemot R, Ehiri J, Meremikwu M, Critchley J. Hand washing for preventing diarrhoea. *Cochrane Database Syst Rev*. 2008 Jan 23(1):CD004265.
35. Secretaría Distrital de Salud. Boletín ERA No. 50. In: Grupo ERA, Área de Vigilancia en Salud Pública, editors. Bogotá, D.C.: Alcaldía Mayor de Bogotá.; 2009. p. 22.
36. Allegranzi B, Sax H, Bengaly L, Richet H, Minta DK, Chraiti MN, et al. Successful Implementation of the World Health Organization Hand Hygiene Improvement Strategy in a Referral Hospital in Mali, Africa. *Infect Control Hosp Epidemiol* 2010;31(2):133-41.