

Vaginal Chlorhexidine for GBS Prophylaxis.- Abstracts

J Matern Fetal Neonatal Med 2002 Feb; 11(2):84-8. *Chlorhexidine vaginal flushings versus systemic ampicillin in the prevention of vertical transmission of neonatal group B streptococcus*, at term. Facchinetti F, Piccinini F, Mordini S, Volpe A. Department of Gynecology, Obstetrics and Pediatric Sciences, University of Modena and Reggio Emilia, Italy.

OBJECTIVE: To investigate the efficacy of intrapartum vaginal flushings with chlorhexidine compared with ampicillin in preventing group B streptococcus transmission to neonates. **METHODS:** This was a randomized controlled study, including singleton pregnancies delivering vaginally. Rupture of membranes, when present, must not have occurred more than 6 h previously. Women with any gestational complication, with a newborn previously affected by group B streptococcus sepsis or whose cervical dilatation was greater than 5 cm were excluded. A total of 244 group B streptococcus-colonized mothers at term (screened at 36-38 weeks) were randomized to receive either 140 ml chlorhexidine 0.2% by vaginal flushings every 6 h or ampicillin 2 g intravenously every 6 h until delivery. Neonatal swabs were taken at birth, at three different sites (nose, ear and gastric juice). **RESULTS:** A total of 108 women were treated with ampicillin and 109 with chlorhexidine. Their ages and gestational weeks at delivery were similar in the two groups. Nulliparous women were equally distributed between the two groups (ampicillin, 87%; chlorhexidine, 89%). Clinical data such as birth weight (ampicillin, 3,365 +/- 390 g; chlorhexidine, 3,440 +/- 452 g), Apgar scores at 1 min (ampicillin, 8.4 +/- 0.9; chlorhexidine, 8.2 +/- 1.4) and at 5 min (ampicillin, 9.7 +/- 0.6; chlorhexidine, 9.6 +/- 1.1) were similar for the two groups, as was the rate of neonatal group B streptococcus colonization (chlorhexidine, 15.6%; ampicillin, 12%). *Escherichia coli*, on the other hand, was significantly more prevalent in the ampicillin (7.4%) than in the chlorhexidine group (1.8%, $p < 0.05$). Six neonates were transferred to the neonatal intensive care unit, including two cases of early-onset sepsis (one in each group).

CONCLUSIONS: In this carefully screened target population, intrapartum vaginal flushings with chlorhexidine in colonized mothers display the same efficacy as ampicillin in preventing vertical transmission of group B streptococcus. Moreover, the rate of neonatal *E. coli* colonization was reduced by chlorhexidine.

BMJ 1997 Jul 26;315(7102):216-9; discussion 220 Comment in: BMJ. 1997 Jul 26;315(7102):199-200. *Effect of cleansing the birth canal with antiseptic solution on maternal and newborn morbidity and mortality in Malawi: clinical trial*. Taha TE, Biggar RJ, Broadhead RL, Mtimavalye LA, Justesen AB, Liomba GN, Chipangwi JD, Miotti PG. Department of Epidemiology, School of Hygiene and Public Health, Johns Hopkins University, Baltimore MD 21205, USA. **OBJECTIVE:** To determine if cleansing the birth canal with an antiseptic at delivery reduces infections in mothers and babies postnatally. **DESIGN:** Clinical trial; two months of no intervention were followed by three months of intervention and a final month of no intervention. **SETTING:** Queen Elizabeth Central Hospital (tertiary care urban hospital), Blantyre, Malawi. **SUBJECTS:** A total of 6965 women giving birth in a six month period and their 7160 babies. **INTERVENTION:** Manual wipe of the maternal birth canal with a 0.25% chlorhexidine solution at every vaginal examination before delivery. Babies born during the intervention were also wiped with chlorhexidine. **MAIN OUTCOME MEASURES:** Effects of the intervention on neonatal and maternal morbidity and mortality. **RESULTS:** 3635 women giving birth to 3743 babies were enrolled in the intervention phase and 3330 women giving birth to 3417 babies were enrolled in the non-intervention phase. There were no adverse reactions related to the intervention among the mothers or their children. Among infants born in the intervention phase, overall neonatal admissions were reduced (634/3743 (16.9%) v 661/3417 (19.3%), $P < 0.01$), as were admissions for neonatal sepsis (7.8 v 17.9 per 1000 live births, $P < 0.0002$), overall neonatal mortality (28.6 v 36.9 per 1000 live births, $P < 0.06$), and mortality due to infectious causes (2.4 v 7.3 per 1000 live births, $P < 0.005$). Among mothers receiving the intervention, admissions related to delivery were reduced (29.4 v 40.2 per 1000 deliveries, $P < 0.02$), as were admissions

due to postpartum infections (1.7 v 5.1 per 1000 deliveries, $P = 0.02$) and duration of hospitalization (Wilcoxon $P = 0.008$).

CONCLUSIONS: Cleansing the birth canal with chlorhexidine reduced early neonatal and maternal postpartum infectious problems. The safety, simplicity, and low cost of the procedure suggest that it should be considered as standard care to lower infant and maternal morbidity and mortality.

Int J Antimicrob Agents 1999 Aug;12(3):245-51 *Vaginal disinfection with chlorhexidine during childbirth.* Stray-Pedersen B, Bergan T, Hafstad A, Normann E, Groggaard J, Vangdal M. Department of Gynecology and Obstetrics, Aker Hospital, University of Oslo, Norway. The purpose of this study was to determine whether chlorhexidine vaginal douching, applied by a squeeze bottle intrapartum, reduced mother-to-child transmission of vaginal microorganisms including *Streptococcus agalactiae* (*Streptococcus* serogroup B = GBS) and hence infectious morbidity in both mother and child. A prospective controlled study was conducted on pairs of mothers and their offspring. During the first 4 months (reference phase), the vaginal flora of women in labor was recorded and the newborns monitored. During the next 5 months (intervention phase), a trial of randomized, blinded placebo controlled douching with either 0.2% chlorhexidine or sterile saline was performed on 1130 women in vaginal labor. During childbirth, bacteria were isolated from 78% of the women. Vertical transmission of microbes occurred in 43% of the reference deliveries. In the double blind study, vaginal douching with chlorhexidine significantly reduced the vertical transmission rate from 35% (saline) to 18% (chlorhexidine), ($P < 0.0001$, 95% confidence interval 0.12-0.22). The lower rate of bacteria isolated from the latter group was accompanied by a significantly reduced early infectious morbidity in the neonates ($P < 0.05$, 95% confidence interval 0.00-0.06). This finding was particularly pronounced in *Str. agalactiae* infections ($P < 0.01$). In the early postpartum period, fever in the mothers was significantly lower in the patients offered vaginal disinfection, a reduction from 7.2% in those douched using saline compared with 3.3% in those disinfected using chlorhexidine ($P < 0.05$, 95% confidence interval 0.01-0.06). A parallel lower occurrence of urinary tract infections was also observed, 6.2% in the saline group as compared with 3.4% in the chlorhexidine group ($P < 0.01$, 95% confidence interval 0.00-0.05). This prospective controlled trial demonstrated that vaginal douching with 0.2% chlorhexidine during labor can significantly reduce both maternal and early neonatal infectious morbidity. The squeeze bottle procedure was simple, quick, and well tolerated. The beneficial effect may be ascribed both to mechanical cleansing by liquid flow and to the disinfective action of chlorhexidine:

Lancet 1992 Jul 11;340(8811):65-9. Comment in: Lancet. 1992 Sep 26;340(8822):791; discussion 791-2. Lancet. 1992 Sep 26;340(8822):792. *Prevention of excess neonatal morbidity associated with group B streptococci by vaginal chlorhexidine disinfection during labor.* The Swedish Chlorhexidine Study Group. Burman LG, Christensen P, Christensen K, Fryklund B, Heigesson AM, Svenningsen NW, Tullus K. National Bacteriological Laboratory, Stockholm, Sweden. *Streptococcus agalactiae* transmitted to infants from the vagina during birth is an important cause of invasive neonatal infection. We have done a prospective, randomized, double-blind, placebo-controlled, multi-centre study of chlorhexidine prophylaxis to prevent neonatal disease due to vaginal transmission of *S. agalactiae*. On arrival in the delivery room, swabs were taken for culture from the vaginas of 4483 women who were expecting a full-term single birth. Vaginal flushing was then done with either 60 ml chlorhexidine diacetate (2 g/l) (2238 women) or saline placebo (2245) and this procedure was repeated every 6 h until delivery. The rate of admission of babies to special-care neonatal units within 48 h of delivery was the primary end point. For babies born to placebo-treated women, maternal carriage of *S. agalactiae* was associated with a significant increase in the rate of admission compared with non-colonized mothers (5.4 vs 2.4%; RR 2.31, 95% CI 1.39-3.86; $p = 0.002$). Chlorhexidine reduced the admission rate for infants born of carrier mothers to 2.8% (RR 1.95, 95% CI 0.94-4.03), and for infants born to all mothers to 2.0% (RR 1.48, 95% CI 1.01-2.16; $p = 0.04$). Maternal *S. agalactiae* colonization is associated with excess early neonatal morbidity, apparently related to aspiration of the organism, that can be reduced with chlorhexidine disinfection of the vagina during labor.

Eur J Obstet Gynecol Reprod Biol 1989 Apr;31(1):47-51 *Prevention of group B streptococci transmission during delivery by vaginal application of chlorhexidine gel* Kollee LA, Speyer I, van Kuijk MA, Koopman R, Dony JM, Bakker JH, Wintermans RG. Department of Pediatrics, University Hospital, Nijmegen, The Netherlands. In a prospective study in 227 parturients, carriage of group B streptococci was established to be 25%. In carriers, transmission of streptococci to the newborn occurred in 50%. 10 ml of a chlorhexidine gel containing hydroxypropylmethylcellulose was introduced into the vagina during labor in 17 parturients, who were known to be carriers of group B streptococci from the first trimester of pregnancy. In none of the newborns from these mothers colonization by group B streptococci did occur. Vaginal application of chlorhexidine may prevent transmission of group B streptococci, and serve as an alternative to intrapartum prophylaxis using antibiotics. A large multicenter randomized controlled study should be performed to confirm this hypothesis.

Eur J Obstet Gynecol Reprod Biol 1985 Apr;19(4):231-6. *Chlorhexidine for prevention of neonatal colonization with group B streptococci. III. Effect of vaginal washing with chlorhexidine before rupture of the membranes.* Christensen KK, Christensen P, Dykes AK, Kahimeter G. A single vaginal washing with 2 g/l of chlorhexidine was performed before rupture of the membranes in 19 parturients who were urogenital carriers of group B streptococci (GBS). Two (11%) of the infants became colonized immediately after birth, in contrast to 16 of 41 (39%) infants to controls ($P=0.02$). A significant reduction of GBS colonization of the ear ($P=0.02$) and umbilicus ($P=0.01$) was noted. Taken together, 2 of 57 (4%) cultures obtained at birth were positive in the chlorhexidine group, in contrast to 30 of 123 (24%) among the controls (P less than 0.01). These findings raise hope for the design of a simple washing procedure which might prevent serious infections in the early neonatal period with GBS but also with other chlorhexidine-sensitive organisms.