

## Milk protein supplement may help prevent sepsis in very low birth-weight infants

## October 6 2009

Very low birth-weight newborns who received the milk protein lactoferrin alone or in combination with a probiotic had a reduced incidence of late-onset sepsis, according to a study in the October 7 issue of *JAMA*.

"Infections are the most common cause of death in premature infants and a major threat for poor outcomes," the authors write. Late-onset sepsis, i.e., infections arising after the perinatal period (immediately before and after birth), mainly occur in the hospital and affect 21 percent of very low birth-weight (VLBW; less than 3.3 lbs) neonates (generally the first four weeks after birth), according to background information in the article. Bovine lactoferrin (BLF; a milk glycoprotein) inhibits the growth of a wide variety of bacteria, fungi, and viruses and has been shown to exhibit even higher in vitro antimicrobial activity than human lactoferrin. Whether lactoferrin can reduce the incidence of sepsis is unknown. In animal tests, the probiotic Lactobacillus rhamnosus GG (LGG) improved the activity of lactoferrin but has not been studied in infants.

Paolo Manzoni, M.D., of S. Anna Hospital, Torino, Italy, and colleagues examined whether oral supplementation with BLF alone or in combination with LGG reduces late-onset sepsis in VLBW neonates. The randomized trial was conducted in 11 Italian neonatal intensive care units and included 472 VLBW infants who were assessed until discharge for development of sepsis. Infants were randomly assigned to receive orally administered BLF alone (n = 153), BLF plus LGG (n = 151), or



placebo (n = 168) from birth until day 30 of life (day 45 for neonates less than 2.2 lbs. at birth). Demographic, clinical and management characteristics of the 3 groups were similar, including type of feeding and intake of maternal milk.

Forty-five infants had a first episode of late-onset sepsis. The researchers found that overall, late-onset sepsis occurred less frequently in the BLF and BLF plus LGG groups (9/153 [5.9 percent] and 7/151 [4.6 percent], respectively) than in the control group (29/168 [17.3 percent]). The decrease occurred for bacterial as well as fungal episodes. The sepsis-attributable risk of death was significantly lower in the two treatment groups. No adverse effects to treatment occurred.

"Prevention of neonatal sepsis relies on hygiene measures, cautious use of invasive procedures, medication stewardship, administration of fresh maternal milk, and early diagnosis. Nevertheless, none of these interventions is fully effective in decreasing the burden of the disease and overall have not been subjected to randomized controlled trials. This study has demonstrated that supplemental BLF, either alone or in combination with LGG, reduces first episodes of late-onset sepsis in VLBW infants," the authors conclude.

More information: JAMA. 2009;302[13]:1421-1428.

Source: JAMA and Archives Journals (<u>news</u>: <u>web</u>)

Citation: Milk protein supplement may help prevent sepsis in very low birth-weight infants (2009, October 6) retrieved 2 May 2024 from <a href="https://medicalxpress.com/news/2009-10-protein-supplement-sepsis-birth-weight-infants.html">https://medicalxpress.com/news/2009-10-protein-supplement-sepsis-birth-weight-infants.html</a>

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