

OBJECTIVE. The goal was to investigate the efficacy of orally administered probiotics in preventing necrotizing enterocolitis for very low birth weight preterm infants.

METHODS. A prospective, blinded, randomized, multicenter controlled trial was conducted at 7 NICUs in Taiwan, to evaluate the beneficial effects of probiotics in necrotizing enterocolitis among very low birth weight infants (birth weight: <1500 g). Very low birth weight infants who survived to start enteral feeding were eligible and were assigned randomly to 2 groups after parental informed consent was obtained. Infants in the study group were given *Bifidobacterium bifidum* and *Lactobacillus acidophilus*, added to breast milk or mixed feeding (breast milk and formula), twice daily for 6 weeks. Infants in the control group were fed with breast milk or mixed feeding. The clinicians caring for the infants were blinded to the group assignment. The primary outcome measurement was death or necrotizing enterocolitis (Bell's stage ≥ 2).

RESULTS. Four hundred thirty-four infants were enrolled, 217 in the study group and 217 in the control group. The incidence of death or necrotizing enterocolitis (stage ≥ 2) was significantly lower in the study group (4 of 217 infants vs 20 of 217 infants). The incidence of necrotizing enterocolitis (stage ≥ 2) was lower in the study group, compared with the control group (4 of 217 infants vs 14 of 217 infants). No adverse effect, such as sepsis, flatulence, or diarrhea, was noted.

CONCLUSION. Probiotics, in the form of *Bifidobacterium* and *Lactobacillus*, fed enterally to very low birth weight preterm infants for 6 weeks reduced the incidence of death or necrotizing enterocolitis. *Pediatrics* 2008;122:693–700

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This trial has been registered at www.clinicaltrials.gov (Identifier NCT00540033).

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Key Words

probiotics, necrotizing enterocolitis, very low birth weight infants

Abbreviations

NEC—necrotizing enterocolitis
VLBW—very low birth weight
PVL—periventricular leukomalacia
CLD—chronic lung disease
IVH—Intraventricular hemorrhage

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