

Chua et al. 2017

Effect of Synbiotic on the Gut Microbiota of Caesarean Delivered Infants: A Randomized, Double-blind, Multicenter Study (Julius study)

Aim

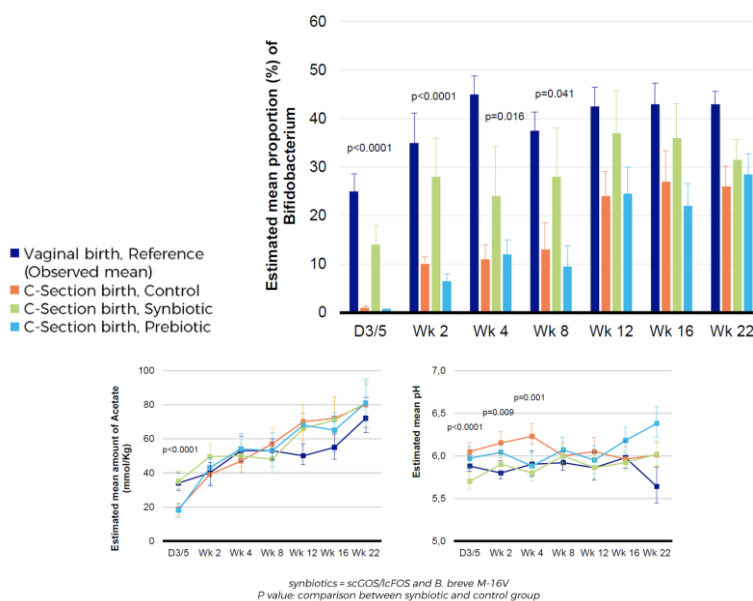
- ✓ Caesarean birth has been associated with increased risk of immune and metabolic diseases later in life, likely due to altered gut microbiota. The aim of the study was to investigate :
 - The effect of scGOS/lcFOS and *Bifidobacterium Breve* M-16V on the gut microbiota of caesarean born infants

Methods and study design

- ✓ Set-up: randomized, double-blind, controlled intervention study
- ✓ Time and location: June 2011- April 2013 in Singapore and Thailand
- ✓ 153 healthy term infants born by C-section
- ✓ Study arms:
 - N=50 – Control group: IF with no scGOS/lcFOS
 - N=51 – Prebiotic group: IF with 0.8 g/100 ml scGOS/lcFOS
 - N=52 – Synbiotic group: IF with 0.8 g/100 ml scGOS/lcFOS and *B. breve* M-16V at 7.5×10^8 cfu/100 mL
 - N=30 – Reference group: non randomized, vaginally born infants
- ✓ Duration: from birth until week 16
- ✓ Study design:
 - Stool samples were collected at day 3, day 5, week 2, week 4, week 8, week 12, week 16, and week 22
 - The primary outcome: total fecal bifidobacteria
 - Secondary parameters: Bifidobacterium species abundance, other members of the gut microbiota, pH, short-chain fatty acid (SCFA), and lactate and safety parameters (anthropometry, gastrointestinal tolerance, adverse events [AEs]).

Results:

- ✓ The bifidogenic effect was sign. higher until 2 months of age in the synbiotic group
 - ✓ The prebiotic group showed increase of bifidobacterial during intervention, but not statistically sign. compared to control
 - ✓ The synbiotic mixture leads to sign. increased levels of acetate and a decreased fecal pH compared to the control group
 - ✓ Synbiotic formula resulted in sign. lower abundance of Enterobacteriaceae compared to control group
 - ✓ Post-hoc analysis showed a lower percentage of subjects with AEs-related skin disorders in the synbiotic group compared to the control group
- ... coming closer to the reference of vaginally born infants



Conclusions:

- ✓ This study showed that supplementation with synbiotics (scGOS/lcFOS and *Bifidobacterium Breve* M-16V) restores the delayed Bifidobacterium colonization in C-section delivered infants, and modulates the production of acetate and acidification of the gut.
- ✓ These observed physiological conditions, described as indicator of gut health, resemble the ones observed in vaginally born infants

Relevance:

- ✓ This study helps to
 - support our core milk category and BlackJack portfolio product (esp. C-section/Immunocare) by showing strong data on the benefit of synbiotics in C-section born infants restoring the delayed gut microbiota colonisation
 - it also helps to build awareness and increase the evidence and potential benefits of sybiotics for healthy infants and for those exposed to risk factors
 - enrich our extensive research in scGOS/lcFOS (9:1)