Evidence-based Neonatology Synopsis

PURPOSE
The main goal of evidence based neonatology synopsis is to inform and alert neonatal practitioners of the latest advances in neonatal literature. Our reviews focus on high quality, practice changing original research articles and systematic reviews. These articles are summarized and presented with a commentary of a clinical expert. Commentators are selected by the editorial team and invited to select articles based on pre-specified criteria.

Dextrose Gel is Superior to Feeding Alone in Neonatal Hypoglycemia

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CONTEXT
Neonatal hypoglycemia is a common problem that affects up to 15% of otherwise healthy babies and is a leading cause of preventable brain damage in infants. Current practice includes additional feedings and frequent blood glucose checks, some newborns however require intravenous glucose administered in an intensive care setting, which interferes with mother – infant bonding and the establishment of breast-feeding.

OBJECTIVES
To assess whether treatment with 40% dextrose gel was more effective than feeding alone for reversal of neonatal hypoglycemia in at-risk babies late preterm and term babies.

MATERIALS AND METHODS
A randomized, double-blind, placebo-controlled trial at a tertiary center in Waikato Women’s Hospital in New Zealand between December 1, 2008 and November 31, 2010. The researchers enrolled 514 at-risk babies from within 2 days of birth.

Population
Inclusion
Babies aged 35-42 weeks’ gestation, younger than 48-h-old and at risk of hypoglycemia. Risk factors were being the infant of a diabetic mother, being preterm (35 or 36 weeks’ gestation), being small (birth weight <10th centile or <2500 g) or large (birth weight >90th centile or >4500 g), or other reasons such as poor feeding.

Exclusion
• Previous treatment for neonatal hypoglycemia
• Serious congenital malformation
• Terminal disorders
• Skin abnormalities that would prevent the use of the continuous glucose monitor.

Interventions
Buccal 40% dextrose gel. Newborns were encouraged to feed.

Control
2% carboxymethyl cellulose a placebo gel, which was identical in appearance to the dextrose gel.

Outcomes
Primary outcomes
Primary outcome was treatment failure, defined as a blood glucose concentration of <2.6 mmol/L after two treatment attempts.

Secondary outcomes
• Newborn intensive care unit (NICU) admission
• Breastfeeding frequency
• Total volume and frequency of expressed breast milk and formula
• Rebound and recurrent hypoglycemia after successful treatment
• Total time with interstitial glucose levels <2.6 mmol/L.
Allocation
A computer-generated blocked randomization, with variable block sizes, to assign babies (1:1) who became hypoglycemic to either 40% dextrose gel or placebo gel. Randomization was stratified by maternal diabetes (yes or no) and birth weight (small, appropriate, or large).

Blinding
The study was double-blinded. The placebo gel was identical in appearance to the treatment packs, the hospital pharmacist had no involvement in the study. In addition, clinicians, families and all study investigators were all masked to group allocation until data analysis was complete.

Follow-up
Five babies were omitted from analysis as a result of a randomization error.

RESULTS
The use of dextrose gel nearly halved the likelihood of treatment failure (blood glucose concentration of <2.6 mmol/L 30 min after the second of 2 doses of gel) compared with placebo (16 [14%] vs. 29 [24%]; relative risk, 0.57; 95% confidence interval [CI]: 0.33-0.98; P = 0.04). There were no reported serious side effects.

CONCLUSION
Treatment with dextrose gel was effective in prevention of hypoglycemia in newborns infants compared with placebo. It is inexpensive and simple to administer. Dextrose gel should be considered for first-line treatment to manage hypoglycemia in late preterm and term babies in the first 48 h after birth.

COMMENTARY
This study has shown that treatment with dextrose gel is more effective than the current practice to counter hypoglycemia in babies who were considered to be high risk. Dextrose gel is inexpensive (the cost is about $2/infant) and simple to administer which assures infants stay with their mothers and avoid being admitted to the NICU and are more likely to be successfully breastfed after discharge. This randomized controlled trial (RCT) however, is the only so far conducted study, with few methodological flaws, including: small sample size and exclusion of more than half of the babies in the study from this analysis due to issues with the timing/placement of the interstitial glucose probe or measurement of the interstitial glucose concentration at the time of placement. The above limitations therefore, make definitive conclusions difficult to be drawn, furthermore we still have knowledge gap to what is the best dose and frequency of this treatment strategy and whether it has consistent efficacy in a broader newborn population.

IN SUMMARY
Until more RCT using a larger sample size and correcting for the above mentioned limitations are in, the use of dextrose gel may sounds promising, simple, useful and cheap treatment strategy particularly in resource-poor countries in which neonatal hypoglycemia is more prevalent.

Abstracted from
Harris DL, Weston PJ, Signal M, Chase JG, Harding JE. Dextrose gel for neonatal hypoglycemia (the sugar babies study): A randomized, double-blind, placebo-controlled trial. Lancet. 2013 Dec 21;382(9910):2077-83.S0140-6736(13)61645-1.