

A Randomized Controlled Trial of Glycerin Suppositories During Phototherapy in Premature Neonates

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Keywords


glycerin suppositories
hyperbilirubinemia
phototherapy
premature neonates

ABSTRACT

Objective: To determine if glycerin suppositories were effective in reducing total duration of phototherapy in premature neonates. We hypothesized that glycerin suppositories would have no effect on phototherapy duration or total serum bilirubin levels.

Design: Prospective randomized controlled double-blinded trial.

Setting: Level IV NICU.

Participants: Neonates born between 30 weeks, 0 days and 34 weeks, 6 days gestational age who developed physiologic hyperbilirubinemia needing phototherapy. 

Methods: Neonates were randomized to the no-suppository group or to the suppository group. Neonates were randomized to receive glycerin suppositories every 8 hours while under phototherapy or to a sham group. The primary outcome was total hours of phototherapy. Secondary outcomes included peak total serum bilirubin levels, time from start to discontinuation of phototherapy, rate of decline in bilirubin levels, repeat episodes of phototherapy, and number of stools while the neonates received phototherapy.

Results: A total of 39 neonates were assigned to the no-suppository group and 40 to the suppository group. Withholding suppositories was not inferior to providing suppositories. The total hours of phototherapy were not longer (i.e., noninferior) among neonates not provided suppositories (61 ± 53 hours) than among those given suppositories (72 ± 49 hours). There were no differences in peak bilirubin levels, rate of bilirubin decline, or repeat episodes of phototherapy.

Conclusion: Routine use of glycerin suppositories among preterm neonates who receive phototherapy does not affect bilirubin levels or phototherapy duration.

JOGNN, ■, ■-■; 2017. <http://dx.doi.org/10.1016/j.jogn.2016.10.008>

Accepted October 2016

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The authors report no conflict of interest or relevant financial relationships.



Neonatal jaundice or unconjugated hyperbilirubinemia is one of the most common clinical problems in the neonatal period (Maisels, 2005). Bilirubin overproduction, delayed hepatic clearance, and increased enterohepatic recirculation of bilirubin all contribute to neonatal jaundice (Bader, Yanir, Kugelman, Wilhelm-Kafil, & Riskin, 2005). Delayed meconium evacuation, resulting in increased enterohepatic recirculation, may be an important factor contributing to the development and persistence of neonatal jaundice (Chen, Ling, & Chen, 1995). Previous studies in term neonates have shown that early meconium evacuation is associated with lower peak total serum bilirubin (TSB) levels and decreased risk for clinically significant neonatal jaundice (Boyer & Vidyasagar, 1987; DeCarvalho,

Robertson, & Klaus, 1985; Gourley, Zhanahai, Kremer, & Kosorok, 2005; Salariya & Robertson, 1993).

Some investigators have proposed that the use of laxatives to stimulate early meconium evacuation might lower the level of peak TSB by decreasing enterohepatic recirculation (Srinivasjois, Sharma, Shah, & Kava, 2011). However, authors of studies in healthy term neonates have reported no benefit from rectal glycerin in reducing peak TSB levels, and no data exist on whether they affect the length of therapy (i.e., phototherapy) that might be applied for hyperbilirubinemia (Bader et al., 2005; Chen et al., 1995; Srinivasjois et al., 2011; Weisman et al., 1983). Limited data exist on the potential benefit of glycerin

Increasing stool frequency may decrease bilirubin, but this is an unsupported therapy.

suppositories in premature neonates, although their use is a common practice to increase stooling in the case of hyperbilirubinemia (Haider et al., 2007; Khadr et al., 2011; Livingston et al., 2015; Shah, Chirinian, & Lee, 2011; Shinde, Kabra, Shobha, Avasthi, & Ahmed, 2014).

In neonates, β -glucuronidase activity in the small intestine facilitates the reconversion of conjugated bilirubin into unconjugated bilirubin that is necessary for intestinal absorption and enterohepatic recirculation of bilirubin. Premature neonates have increased β -glucuronidase enzyme activity compared with term neonates, which causes increased enterohepatic recirculation. This increased enterohepatic recirculation in premature neonates could result in differences in the effectiveness of increased stool evacuation from that seen in full-term neonates. Glycerin suppositories are not without risk. They can lead to rectal fissures and tears, bloody stools, and unnecessary vagal stimulation. In their recent meta-analysis, Livingston et al. (2015) suggested a possible relationship between glycerin suppositories or enema use and necrotizing enterocolitis.

We studied the routine administration of glycerin suppositories to premature neonates under phototherapy in a NICU. The aim of our study was to determine if glycerin suppositories were effective in reducing the total duration of phototherapy in premature neonates. On the basis of data from full-term neonates, we hypothesized that glycerin suppositories initiated concomitantly with phototherapy would have no effect on reducing the duration of phototherapy or TSB in premature neonates. We chose phototherapy duration, the therapy that suppository use might spare, as the primary outcome.

Methods

A prospective, double-blind, randomized controlled trial was performed over 15 months. Recruitment and enrollment took place during each neonate's hospitalization at the University of Rochester Golisano Children's Hospital NICU. Approval by the attending physician to approach the parents was obtained. The University of Rochester Institutional Review Board reviewed and approved the research before initiation of the

Table 1: Management of Hyperbilirubinemia in Healthy Preterm Infants (<35 weeks)

Birth Weight, g	Total Serum	
	Bilirubin, mg/dl, Phototherapy Level	Exchange Transfusion Level
>2,500 & preemie	15	20
2,251–2,500	13	18
2,001–2,250	12	17
1,751–2,000	11	16
1,501–1,750	10	15
1,251–1,500	9	14
1,001–1,250	8	13
<1,000	7	12

Note. From *House Staff Manual*, Golisano Children's Hospital Neonatal Intensive Care Unit. Guidelines are for infants at appropriate gestational age. For large-for-gestational-age infants, hydropic infants, etc., consider using criteria for the next lower weight category.

study. Written, informed consent was obtained from parents before study procedures began. The clinical trial was registered on clinicaltrials.gov (NCT01746511).

Setting

The study was conducted in a 52-bed, Level IV, tertiary referral NICU. The unit serves as the Regional Perinatal Center for the New York State Finger Lakes Region and admits critically ill newborns from Rochester and 13 surrounding counties. The NICU, which admits 1,200 newborns yearly, provides care for all neonatal medical and surgical problems, including advanced therapy for cardiac and pulmonary diseases, such as cardiac surgery and extracorporeal membrane oxygenation.

Sample

All neonates born between 30 weeks, 0 days and 34 weeks, 6 days gestation who developed physiologic hyperbilirubinemia and required phototherapy were eligible for enrollment. Decisions about phototherapy were made by the clinical team using specific, weight-based protocols to respond to bilirubin levels (see Table 1). The exclusion criteria included any neonate with nonphysiologic hyperbilirubinemia (defined as known positive Coombs test result, hematocrit level < 5th percentile for gestational age, and ABO blood type or Rh factor incompatibility); any neonate with bilirubin level within 2 mg/dl of

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