Timing of Circumcision and Breastfeeding Frequency: A Multicenter, Randomized Clinical Trial

OBJECTIVE: To date, there is little in the literature that describes any relationship between newborn circumcision, its timing, and breastfeeding outcomes. We sought to determine if the timing of circumcision in term, healthy newborns affects exclusive breastfeeding rates during the first 6 months of life.

METHODS: One hundred and forty-eight maternal-infant dyads were enrolled in a randomized, multicenter, clinical trial between June 2016 and July 2019. Study participants included parent-infant dyads who desired both circumcision and breastfeeding. Newborns were randomized into 3 groups for circumcision: “early,” circumcised within 24 hours of delivery; “intermediate,” circumcised between 24 to 72 hours of age; and “late,” circumcised between 1 and 3 weeks of age. The primary outcome was exclusive breastfeeding duration, assessed at discharge, 2 weeks, and 2, 4, and 6 months.

RESULTS: Baseline characteristics between groups were similar. Exclusive breastfeeding decreased more rapidly over 6 months in the intermediate group (by 74%, 89% to 23%), as compared to the early (by 34%, 81% to 53%) or late (by 50%, 88% to 44%) groups (P = .04). Exclusive breastfeeding was less common in the intermediate group (circumcision between 24 and 72 hours), as compared to the early and late circumcision groups, at each measured time point beyond 2 weeks of age.

CONCLUSIONS: Circumcision before 24 hours of age may be advantageous with respect to increased exclusive breastfeeding throughout the first 6 months of life. Deferral of circumcision beyond the immediate newborn period was not superior to performing the procedure within the first 24 hours.
Associations between newborn circumcision, its timing, and breastfeeding difficulty are the subject of frequent, informal discussions among newborn providers; yet, no significant relationship has been reported in the literature. Any potential relationship between circumcision and breastfeeding outcomes is important because exclusive breastfeeding is the most common surgical procedure for males in the United States, and the health benefits of exclusive breastfeeding are widely accepted.1 Over one-half of US newborn males undergo circumcision.2

Two observational studies found no relationship between circumcision and breastfeeding outcomes.4,5 A detailed retrospective study reported that rates of breastfeeding initiation were not different among those who were circumcised within the first 24 hours of life versus later in the birth hospitalization.3 Another recent retrospective analysis revealed circumcision in the newborn nursery had no effect on rates of exclusive breastfeeding, neonatal jaundice, need for phototherapy or length of hospital stay.6 Notwithstanding this observational evidence regarding circumcisions as they relate to breastfeeding, many newborn providers believe that early circumcision, specifically within the first 24 hours of life, interferes with breastfeeding initiation and establishment.7,8 Because of these prevalent beliefs, circumcision might not occur before infants are discharged from the newborn nursery, or may delay discharge if there is a prescribed waiting period. This study seeks to determine if these beliefs are valid.

Specifically, we sought to determine if there is a relationship between the timing of newborn circumcision and breastfeeding establishment and maintenance through the first 6 months of life. To eliminate the biases inherent in observational studies, we conducted a multicenter clinical trial in which the timing of elective circumcision was randomized, and rates of exclusive breastfeeding were followed for 6 months.

**METHODS**

We conducted a multicenter, prospective, randomized clinical trial from June 2016 to July 2019. Participating sites included a children’s hospital in the Northeast United States, as well as 2 military treatment facilities (1 in the South-Central United States and another located on the West Coast). The well newborn nurseries at all 3 sites average 1300 to 1500 deliveries per year and are staffed by general pediatricians. The trial was composed of 3 study groups: (1) an early group, in which infants were circumcised between 6 and 24 hours of life in the newborn nursery, (2) an intermediate group, whose circumcisions were performed at >24 hours but <72 hours of life and before discharge from the nursery, and (3) a late group circumcised between 1 to 3 weeks of age in the outpatient setting. Study groups were selected to be within standard of care for the newborn circumcision procedure, and to reflect current practice standards at hospitals across the United States. Infants were assigned to 1 of the 3 study groups using a computer-generated table of random numbers. The randomization sequence was not revealed to any of the investigators. A study administrator created numbered, sealed envelopes containing group assignments. After obtaining informed consent, the investigator accessed the numbered envelope corresponding to the participant’s order of enrollment, which then determined group assignment. There was a temporary protocol breech at 1 site where the ordered list was placed in the nursery workspace for recruitment of 10 consecutive subjects near the end of the study; strict order was still maintained. The list was returned to a locked office after this was discovered, and standard protocol continued until study completion. Our primary outcomes were exclusive breastfeeding at 2 weeks, and 2, 4, and 6 months of age; our independent variable was age at time of circumcision. The investigators posed the clinical hypothesis that breastfeeding outcomes might improve with early circumcision, or that at least breastfeeding outcomes would not be harmed by earlier circumcision timing.

We included all newborn males born at our institutions whose parents desired circumcision for their sons, were breastfeeding in the nursery, and had consented for participation in our study. Exclusion criteria were gestational age <38 weeks, twins or multiples, NICU admission or observation, maternal age <18 years, parental refusal of vitamin K administration after delivery, or maternal intention to strictly formula feed at time of delivery. There was not a prerequisite for first void before the circumcision procedure. All infants were circumcised by pediatricians using either the Gomco or Mogen technique and were provided local anesthetic before the procedure (1% lidocaine to achieve dorsal penile nerve block). In addition, all infants were given oral sucroze during the procedure.

Data collected on each maternal-infant dyad included: gestational age, maternal demographics and pregnancy history, family income, presence of spouse or partner, infant birth weight, time of birth, time of circumcision, breastfeeding status during hospital stay and at time of discharge (exclusive versus formula supplemented), and whether mother received lactation support during her postpartum stay. In addition, we collected data on mode of delivery, length of hospitalization, and any non-NICU complications such as hyperbilirubinemia or observation for suspected sepsis. All data were collected by study investigators from the participants’ electronic health records. Feeding patterns were assessed via phone, text message, and/or e-mail follow-up at 2 weeks, 4 and 6 months of age. Specifically, follow-up questions included: (1) Are you still breastfeeding your infant, and if so, what percentage of feedings are breast milk (100%, >50%, or <50%)? (2) If there is not exclusive breastfeeding, what is the primary reason: maternal reasons (perceived inadequate supply, breastfeeding pain, back to work, or maternal choice), or infant reasons (poor latch)? (3) How long did you stay
home with your baby before returning to work? (if applicable).

This study protocol was approved by the institutional review boards at all 3 participating sites and followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. The trial was registered at ClinicalTrials.gov (identifier NCT03619369). The authors acknowledge there was an unintended lapse in time of initial registration of this trial, which occurred after the first patient had been enrolled.

Before beginning enrollment in the study, we determined a sample size of 120 newborns (40 in each arm of our trial) using the PASS V14 sample size estimation statistical package (NCSS LLC, Kaysville UT) for a log-rank test based on a 30% difference in proportion still breastfeeding with an α of 0.05 and to achieve power of 0.8. Estimating a 15% dropout at the time of primary outcome assessment at 6 months, we selected a target recruitment goal of 140 mother-infant dyads. Statistical analyses other than power analysis were performed by using Stata V15.0 (Stata Corp, College Station TX).

Means and standard deviations for continuous variables and rate estimates for categorical variables were calculated and tabulated to describe the baseline variables. To assess group differences for baseline variables, a 1-way analysis of variance was used.

To assess breastfeeding among groups, we calculated and tabulated mean percentage of exclusive breastfeeding each time point for each group. To assess the “survival” (the pattern of decline) of exclusive breastfeeding through the 5 time points (0, 0.5, 2, 4, and 6 months) by each group, we used survival analysis methods. A 3-curve log-rank test compared the decline across the time periods of exclusive breastfeeding among the 3 groups and 2-curve log-rank tests by using a Holm-Bonferroni correction of P values as a multiple comparison method to identify the group pairs responsible for the overall decline. Kaplan-Meier survival curves were plotted for the 3 groups (not shown).

Over one-half of babies who met criteria for the study were not enrolled because of parents declining to consent. The most common reason cited for declination of consent was parent desire to have the circumcision performed before nursery discharge. Families were not willing to accept the risk of randomization into the late circumcision group; 3 families that originally consented for participation immediately withdrew when they were randomized to have the circumcision performed in the outpatient setting. Many parents expressed that returning for an extra outpatient appointment was an inconvenience, and some voiced concerns over additional costs of transportation. At 1 study site, after a year of minimal enrollment, gas cards were provided to families as an incentive for participation because many families travel far distances from home to the medical center, a barrier not present at the other 2 participating institutions. One $100 card was provided at enrollment, and a second $100 card was given to those assigned to the group needing to make a return trip. At another study site, outpatient circumcisions were performed at the same time as the 2-week well visit, in an effort to minimize unnecessary travel for families.

RESULTS

We enrolled 148 infants across 3 study sites. Forty-nine babies were randomized to be circumcised in the first 24 hours of life, 51 infants were randomized to 24 to 72 hours of life, and 48 infants were randomized to the outpatient setting between 1 and 3 weeks of age (Fig 1). All infants had the procedure performed in the time period dictated by their randomization.

Key demographic variables for each of the 3 study groups are summarized in Table 1. As expected in a randomized trial, there were no statistical differences among our 3 study groups when considering gestational age, birth weight, maternal age, race and ethnicity, parity, length of hospital stay, or delivery method. Over one-half of the participants were non-Hispanic White (53%), 12% identified as Black, 13% Hispanic, 15% Asian or Pacific Islander, and 6% “other” (P = .84). We found no statistical difference between groups with respect to need for phototherapy or evaluation for suspected sepsis (P = .87), lactation consultations that occurred during the newborn nursery stay (P = .91), or presence of a spouse or partner during the newborn period (P = .70).

Figure 2 reveals the rates of exclusive breastfeeding by circumcision group for each time point (at discharge, 2 weeks, and 2, 4, and 6 months). The rates at discharge were similar (between 80% and 90%, P = .537, Fisher’s exact test) for all 3 groups.

An examination of Fig 2 reveals that, although breastfeeding rates in all 3 groups declined over the follow-up period, the early group declined the least, with 52% exclusive breastfeeding at 6 months. The intermediate group declined the most, with 23% exclusive breastfeeding at 6 months. The late group had an outcome in between, with 44% of couples still exclusively breastfeeding at 6 months. Confirming evidence of the clinical importance of these outcomes, we performed a 3-curve log-rank test yielding P = .036, followed by pairwise log-rank tests yielding P = .027 between the early and intermediate groups, P = .021 between the intermediate and late groups, and P = .914 between the early and late groups. The first 2 P values were significant and the third not, by the Holm-Bonferroni multiple comparisons adjustment. The most common reasons reported at follow-up for maternal cessation of breastfeeding were “perceived inadequate milk supply” or simply, “maternal choice.”

DISCUSSION

In this multicenter, prospective, randomized study, infants circumcised at <24 hours of life were more likely to be exclusively breastfed from 2 weeks through 6 months of age than were those circumcised at 24 to 72 hours. Circumcision after 1 week did not confer any improvements in exclusive
breastfeeding as compared to performing the procedure within the first 24 hours. The time of circumcision that appeared to be most detrimental to exclusive breastfeeding over time was the current care standard of circumcision between 24 and 72 hours.

It is well accepted that breastfeeding is the best source of nutrition for most infants. Breastfed infants are known to have a reduced risk of asthma, obesity, ear and respiratory infections, and sudden infant death syndrome. Breastfeeding also offers benefits to mothers, including decreased risk of hypertension, Type 2 diabetes mellitus, and cancer. Low rates of breastfeeding account for over $3 billion dollars in medical costs for mothers and infants in the United States annually. The gap between current rates of exclusive breastfeeding and reaching goals set by the Centers for Disease Control and Prevention leads to an excess 721 pediatric and 3340 maternal deaths annually in the United States (lifetime mortality based on modeling). Optimizing and supporting exclusive breastfeeding for mothers and babies is an investment in the health of 2 individuals.

There have been limited previous observational studies on any potential relationship between circumcision status or timing and breastfeeding outcomes. In 2008, A New Zealand cohort study of 635 live births reported no difference in breastfeeding outcomes among circumcised versus uncircumcised boys. In an examination of bottle-fed newborns, volumetric comparison of pre-and postprocedure feedings found no significant differences in intake. Neither of these studies addressed optimal timing for neonatal circumcision should parents desire this procedure for their male infant. A 2016 retrospective cohort study of nearly 800 breastfed babies reported no significant association between the timing of elective newborn circumcision during the immediate newborn period and rates of exclusive breastfeeding in the first 2 weeks of life. A 2020 cross-sectional study found no increase in in-hospital supplementation by circumcision status. However, these 2 studies were limited by retrospective or cross-sectional designs and, therefore, risk of selection bias, as well as short follow-ups in the postnatal period.

Breastfeeding rates decline substantially over the first 6 months postpartum. In 2015, the Centers for Disease Control and Prevention reported that 83% of US infants were breastfeeding at the time of birth, decreasing to 52% of infants exclusively breastfeeding at 2 months of age and to 39% and 25% at 4 and 6 months, respectively. Infants in all 3 arms of our study were breastfeeding at rates comparable to the national average at birth; however, infants in our intermediate circumcision group fell below national averages by 6 months of life. Our results suggest that circumcision in the first 24 hours for otherwise healthy term infants may optimally support
breastfeeding through the first 6 months of life, because these infants demonstrated the highest rates of breastfeeding among our study participants through 6 months of age. In 2016, a large retrospective study found no association between timing of circumcision and breastfeeding rates at the 2-week well visit. Notably, unadjusted regression models did reveal that infants who were circumcised earlier in life, and who had shorter inpatient stays, were more likely to be exclusively breastfeeding at the time of hospital discharge (this significance did not persist in the multivariable regression model).5 Exclusive breastfeeding at the time of hospital discharge is specifically important, because it has been shown that mothers who are exclusively breastfeeding their infants when they leave the hospital are more likely to be breastfeeding exclusively at the 2-month well visit.4 Additionally, exclusive breastfeeding in the nursery is a goal of the Healthy People 2020 initiative12 and has been a core measure for Joint Commission accreditation since 2014.13 Importantly, another recent retrospective analysis reported that circumcision had no effect on rates of exclusive breastfeeding, jaundice, or length of newborn nursery stay.6 These previous studies are limited by their retrospective design, short follow-up period, and lack of an outpatient, late circumcision group.

There was a trend toward longer length of hospital stay (54 hours, \( P = .08 \)) in our intermediate circumcision group, although this was not statistically significant. The circumcision procedure itself may explain this longer length of stay, which may contribute to suboptimal breastfeeding establishment. Evidence suggests that the odds of formula supplementation double with each additional inpatient day in the newborn nursery.14 This may be because infants are more wakeful on the second day of life and tend to feed more on the second night; mothers are commonly more fatigued on the second night after delivery, and providers are more likely to offer formula supplementation to mothers who complain of fatigue during these shifts, which are considered natural sleeping hours.14 If there is a transient effect of circumcision on breastfeeding, it may be better to complete the procedure in the first 24 hours so that when the more alert period and more frequent feedings of the second 24 hours ensues, some effects of the procedure may have subsided.

The current study is unique in its prospective look at breastfeeding rates

### TABLE 1

Descriptive Statistics and \( P \) Values (Analysis of Variance Except FET for Cesarean Delivery) for Key Ancillary Variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Early, (&lt; 24)h</th>
<th>Intermediate, 24–72(h)</th>
<th>Late, 1–3(wks)</th>
<th>( p^a )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (wk)</td>
<td>39.6 (0.91)</td>
<td>39.5 (0.89)</td>
<td>39.6 (0.83)</td>
<td>.821</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>3502 (447.0)</td>
<td>3449 (422.7)</td>
<td>3581 (447.5)</td>
<td>.351</td>
</tr>
<tr>
<td>Maternal age (y)</td>
<td>30 (4.7)</td>
<td>30 (5.6)</td>
<td>28 (5.1)</td>
<td>.174</td>
</tr>
<tr>
<td>Parity (number)</td>
<td>1.7 (0.79)</td>
<td>2.0 (1.23)</td>
<td>1.9 (1.06)</td>
<td>.456</td>
</tr>
<tr>
<td>Length of stay (h)</td>
<td>49 (15.3)</td>
<td>54 (18.5)</td>
<td>46 (16.0)</td>
<td>.086</td>
</tr>
<tr>
<td>Cesarean delivery rate (%)</td>
<td>22.7</td>
<td>26.0</td>
<td>18.6</td>
<td>.737</td>
</tr>
</tbody>
</table>

* One-way analysis of variance for first 5 variables; Fisher’s exact test for cesarean delivery.

![Figure 2](https://example.com/figure2.png)

**FIGURE 2** Rates (%) of exclusive breastfeeding by circumcision group at times 0 (discharge), 0.5, 2, 4, and 6 months. The reduction in rate of breastfeeding over time is apparent. A Kaplan-Meier analysis over the entire time showed a greater drop-off in the “intermediate” policy group compared to the other groups (\( P = .036 \)). The early circumcision group shows the best outcome. Fisher’s exact tests were used to assess statistical differences among the three groups at each follow-up point (\( P \) values shown above the bars). Int, intermediate.
after circumcision performed at 3 separate time points, all of which meet current standards of care in the United States. Strengths of our study include its multicentered, prospective, and randomized design, 6-month follow-up period, as well as the inclusion of a diverse patient population at 3 medical centers in geographically distinct regions. Limitations include small numbers (although adequately powered) and no inclusion of late-preterm infants. The authors acknowledge that there are multiple factors that contribute to breastfeeding success. We were unable to specifically account for all of these; however, we would not expect confounders to differ among the 3 groups given our randomized study design. With respect to phone follow-up with study participants, investigators making these calls were not uniformly blinded to the participants’ assigned study group, and the questions asked regarding breastfeeding continuance, though straightforward, were not specifically prevalidated before the study. Over one-half of study participants were military dependents, with 100% insurance coverage and excellent access to health care, which may limit generalizability. Enrollment was difficult and limited primarily by parental desire to have the circumcision completed in the hospital, before nursery discharge.

Our findings suggest the best timing for circumcision of healthy term newborns, to optimize breastfeeding success, is between 6 and 24 hours of life. This would also eliminate the need for parents to remain inpatient longer to accommodate the procedure or make unnecessary return trips to the hospital.

CONCLUSIONS

Our results are the first to suggest that there is no inferiority to circumcision before 24 hours of life. Early circumcision may convey an advantage which leads to increased breastfeeding success throughout the first 6 months postpartum. These findings advocate for elimination of hospital policies that limit circumcisions for stable term newborns before 24 hours of age. Deferment of circumcision to the outpatient setting after breastfeeding establishment did not result in improved breastfeeding outcomes. Parents preferred to have circumcision completed during the nursery stay, citing inconvenience and transportation costs associated with outpatient circumcision as the most common reasons for declination to study participation. Early circumcision between 6 and 24 hours of age for otherwise healthy, stable term newborns is a potential nursery practice change that translates to improved breastfeeding outcomes, with likely associated concomitant improvements in health outcomes.

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REFERENCES