

Circumcision bleeding complications: Neonatal intensive care infants compared to those in the normal newborn nursery

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These data were presented at the IUSM OB/GYN Research Day June 2012.

Disclosures:

The authors report no conflicts of interest.

Abstract

PURPOSE: To determine if a significant difference exists in the bleeding complications following circumcision in neonates admitted to neonatal intensive care unit (NICU) versus the normal newborn nursery (NNN).

MATERIALS AND METHODS: Observational cohort study of 260 infants undergoing circumcision with Gomco clamp. Vitamin K was given to neonates at delivery.

Demographic data, procedural characteristics, bleeding complications, and interventions were recorded. The bleeding rates of the two groups were compared using chi square.

RESULTS: NICU neonates experienced increased bleeding complications versus NNN neonates (22% vs 9.6%, $P=0.029$). No differences were found regarding gestational age at delivery, age at circumcision, and birth weight. Neonates with circumcision performed at ≥ 5 days of life experienced increased rates of bleeding complications versus those performed at ≤ 4 days (28% vs. 10.3%, $P=0.023$). All neonates with circumcision performed ≥ 5 days of life were initially admitted to the NICU.

CONCLUSION: NICU neonates had increased rate of bleeding complications following circumcision when compared to the NNN neonates. There was an increased rate of bleeding complications in neonates who undergo circumcision at ≥ 5 days of life. Further research may help to determine if redosing of Vitamin K is necessary for circumcision at > 4 days.

Keywords:

Gomco, neonate, vitamin K, circumcision, complication

Introduction:

Circumcision is the most frequent operation performed on males in the United States (1). Though the exact prevalence is unknown, it can range as high as 89% in certain regions of the country (2). It is also the most commonly performed operation on males throughout the world, with one in three men circumcised globally (3).

Given the commonality of this procedure, one would expect that it has been well studied; however there is little research published pertaining to the topic of bleeding complications after circumcisions in neonates. Most of the research focuses on HIV and disease transmission prevention. There are also studies concerning pain control and penile cancer prevention. There are very few studies that look at the complications associated with circumcision and no studies to our knowledge that compare bleeding complications in neonates that are sent to the neonatal intensive care unit (NICU) after birth versus the normal newborn nursery (NNN). The incidence of bleeding complications from circumcision ranges from 0.1-35% depending on the limited evidence reported (1) and varies with type of device used and operator experience. One study that specifically looked at bleeding complications when using a Gomco device for circumcision, quoted an incidence of 4.47% (4).

Anecdotally, we noted that circumcisions performed on infants admitted to the NICU had more bleeding complications than neonates who were admitted to the normal newborn nursery. However, we were unable to find any studies to support this observation. The hypothesis for this study is that there is a significant difference in bleeding complications in neonates admitted to the NICU versus the NNN. The primary

objective of the study was to determine the bleeding complication rates of infants admitted to the NICU compared to those admitted to the newborn nursery.

Materials and Methods:

This study was an observational prospective cohort study of 260 infants undergoing routine circumcision over a 9-month period at a large urban county hospital. Inclusion criteria were live-born male infants undergoing circumcision. All infants had maternal consent for the procedure. Exclusion criteria included known penile anatomical abnormalities (such as hypospadias), blood dyscrasias, and known liver disease. All infants undergoing circumcision were automatically enrolled in the observational study. Approval for the study was obtained from the governing institutional review board.

All of the circumcisions performed during this study were done according to standard practice and manufacturer's recommendations. Circumcision is offered to parents of all live-born male infants prior to infant discharge from the hospital. The parents are informed that it is an elective procedure, are counseled on the risks of circumcision, and asked to sign a consent form for the procedure if they choose to have their child undergo circumcision. After consent was obtained, the infant was taken to the procedure room when cleared for the procedure by the pediatrician. In our institution, obstetricians performed all circumcisions. A "time-out" was performed prior to the start of all procedures. A dorsal penile block using 1% lidocaine without epinephrine was performed. All circumcisions were performed with a Gomco clamp. The clamp size was at the discretion of the surgeon performing the procedure. If bleeding occurred, the intervention to obtain hemostasis was at the discretion of the operating physician. After

the procedure the infant's penis was wrapped in petroleum jelly gauze and the infant was monitored by nursing staff to evaluate for bleeding complications. If a bleeding complication occurred, the operating physician was notified to manage the complication. The surgeon performing the circumcision was not blinded to the nursery admission status of the infant but the status was not routinely known or discussed before the procedure.

Data collection sheets were utilized to capture the length of procedure, the presence of bleeding complication, intervention utilized, and the duration of the intervention. A chart review was then performed for both infant and mother to determine variables such as gestational age at delivery and at circumcision, type of Vitamin K given, fetal weight, and maternal and fetal complications.

Based on initial observations, it was estimated that the rate of bleeding complications in infants admitted to the newborn nursery (NNN) was 1% versus 20% in infants admitted to the NICU. There are fewer circumcisions for NICU infants with an approximate NICU: NNN ratio of approximately 1:8. Given this ratio, 19 NICU circumcisions and 152 NNN circumcisions were necessary to demonstrate a statistically significant difference (alpha 0.05, 80% power). Rates and categorical variables were compared with chi-square analysis and continuous variables with t-test.

Results:

Between June, 2011 and April, 2012 there were 260 total circumcisions performed at our institution. Fifty circumcisions were performed on NICU admissions and 209 on infants admitted to the newborn nursery. One infant had missing data and

was not included in the analysis.

In general, characteristics of the infants were similar across groups. There were no statistically significant differences in mean gestational age at time of delivery, age at time of circumcision in days, length of time taken to perform the circumcision, or weight at birth (Table 1).

The overall bleeding complication rate in our population was 11.9% (n=31). Most bleeding complications occurred in the first 29 minutes following circumcision (28/31, 98.8%) Most initial bleeding complications were managed with direct pressure (29/31, 93%). Two initial bleeding episodes were managed with silver nitrate (6.5%). Several neonates required more than one intervention to manage the bleeding complication, with three requiring the placement of a suture.

Neonates admitted to NICU had more bleeding complications when compared with infants admitted to the newborn nursery (22% vs 9.6%, $P=0.029$). In comparing those neonates with bleeding complications to the infants who did not have a bleeding complication there were no statistically significant differences in gestational age at delivery, age at circumcision in days, length of time taken for the circumcision, or fetal weight at delivery (Table 2).

To analyze for potential impact of day of life on bleeding complications the data were stratified to circumcisions performed at 0-4 days of life versus greater than 5 days of life. A statistically significant difference in bleeding complication rates was noted in neonates with circumcisions performed at 5 days of life or greater (28% vs. 10.3%, $P=0.023$).

Discussion:

We found a statistically significant increase in the bleeding complication rate following routine circumcision in neonates who were admitted to the NICU compared to infants admitted to the NNN. Additionally, there was an increased rate of bleeding complications in neonates who undergo circumcision after 4 days of life, as is seen commonly in the population of neonates who are sent to the NICU. This finding may be related to administration of Vitamin K at birth. Vitamin K is routinely administered by injection to both neonates in the NICU and the normal newborn nursery at the time of birth. Vitamin K is active 6 hours after administration, has a peak action at 12 hours, and has reduced action by 36 hours. It is given to reduce bleeding complications. Thus, if the exogenous Vitamin K is out of the newborn's system and production of Vitamin K by the newborn has not become sufficient yet, this may lead to the observed higher bleeding complication rate after circumcisions performed at or beyond the 5th day of life. Given this observation, three research questions logically follow:

1. Should those neonates undergoing circumcision at day 5 of life or greater be given another dose of Vitamin K?
2. Would redosing of Vitamin K be sufficient to prevent potential bleeding complications in this population of neonates?
3. Should protocols for circumcision be altered for neonates admitted to the NICU to account for a greater risk of bleeding at the time of circumcision?

Due to the paucity of research concerning circumcision, there are minimal data with which to compare our results. The rate of bleeding complications in our study was higher than that presented by Feinberg for the Gomco clamp at 4.47% (4). At our institution, a vast majority of the circumcisions are performed by Ob/Gyn residents with direct faculty supervision. The increased rate of bleeding complications may have been related to operator experience as was noted in that study. We did not directly track the level of resident who performed each procedure. Due to the volume of circumcisions performed by our residents (>6000 deliveries per year), we do not believe lack of experience is an explanation for bleeding rate differences. Manufacturer recommendations for the Gomco clamp were followed when performing the circumcisions.

The strengths of this study include its prospective design and the size of the study population to detect a difference in bleeding complication rates. Results can be generalized to other institutions with Level 3 neonatal intensive care units presuming that the acuity of the infants admitted to each prospective level is similar. These data should be confirmed in other populations before intervention trials with Vitamin K would be justified.

This study was limited by several factors including the continuum of operator experience that existed in those performing the circumcisions. The difference in operator experience may have been a confounding factor. However, we did not note a temporal trend in bleeding complication rates by month of the year (data not shown). Additionally, NICU admission criteria may be based both on protocols but also on the subjective observations of the pediatric staff. Our study did not demonstrate a statistically

significant difference in bleeding complications based on gestational age at delivery or fetal weight, some of the objective measures utilized in determining to which nursery a neonate is admitted. We did not capture the reason for NICU admission. The question that remains is whether or not there is an unrecognized confounding factor that may impact bleeding complication rates in the NICU population that we were unable to capture in this analysis. For instance, we did not record all medications and supplements received by the infant. Additionally, this study was not designed to evaluate maternal factors that may have influenced bleeding complication rates.

Our data support the hypothesis that there is an increase in the post-circumcision bleeding complication rate in neonates who are admitted to the NICU versus the normal newborn nursery. To our knowledge, this is the first report comparing bleeding complications in these populations. Additional research is needed to confirm and further evaluate those factors that may contribute to bleeding complications. If confirmed, a randomized trial of a repeat dose of Vitamin K in NICU infants undergoing circumcision at day 5 of life or greater may be an appropriate next step to help prevent bleeding complications at the time of circumcision and could potentially lead to a change in standard practice. Alternatively, a randomized trial of an altered protocol for the circumcision procedure may be considered to evaluate if by simply altering the time of clamping with the Gomco, one could reduce the need for additional intervention for bleeding following circumcision.

Acknowledgements:

None

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Table 1: Baseline characteristics of infants admitted to NICU vs newborn nursery

	Newborn Nursery n=209	NICU n=50	P value
Gestational age at delivery (weeks)	38.91 (1.19)	37.84 (2.52)	0.170
Age at Circumcision (days)	1.15 (0.57)	11.92 (14.18)	0.730
Length of Circumcision (minutes)	10.3 (4.77)	11.04 (4.96)	0.952
Birth Weight (grams)	3313 (468)	3160 (692)	0.506
Bleeding complication requiring treatment	20 (9.6%)	11 (22.0%)	0.029

Data are presented as mean (Standard Deviation) or as n (%)

Table 2: Comparison of characteristics of neonates with bleeding complications vs no bleeding complication.

	Bleeding n=31	No Bleeding n=228	P Value
Gestational age at Delivery (weeks)	38.61 (1.69)	38.72 (1.58)	0.730
Age at Circumcision (days)	6.23 (13.30)	2.82 (6.30)	0.170
Length of time taken to complete circumcision (minutes)	10.48 (5.26)	10.43 (4.75)	0.952
Newborn Weight at Delivery (grams)	3342 (480)	3276 (527)	0.506

Data are presented as mean (Standard deviation)