Evaluating Clinical Outcomes of an Advanced Practice Provider-Led Newborn Circumcision Clinic

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OBJECTIVE To determine the safety and efficacy of advanced practice provider (APP)-performed newborn circumcisions (NBCs), we reviewed outcomes of NBCs performed by pediatric urologists and APPs. We hypothesize comparable clinical outcomes between the groups.

METHODS All urology performed NBCs during a 5-year period were reviewed, including time surrounding implementation of the APP-led clinic. Return to emergency department (ED) rates, return to operating room (OR) rates, and intraprocedure bleeding requiring intervention were reviewed. Fisher exact and Mann-Whitney testing were utilized.

RESULTS There were no statistically significant differences in rates of intraprocedure bleeding, return to ED in 30 days, return to OR for revision or other related penile surgery, or the overall number of patients with complications between the groups. Thirteen patients had complications in the APP cohort, compared to 8 in the urologist cohort. There was a difference in age and weight, with urologists performing NBCs on older and heavier patients. There was no difference in clinical outcomes between children over and under 10 pounds (4.5 kg). There was a significant difference in the need for revision circumcision when comparing children older vs younger than 30 days (1.9% vs 0%, $P = 0.034$).

CONCLUSION An APP-led NBC clinic is both safe and feasible. The widely used age and weight cutoffs for NBC need to be further evaluated, as there was no significant difference in clinical outcomes. This practice design provides pediatric urologists more time to focus on the most complex patients, both in the clinic and OR. UROLOGY 127: 97–101, 2019. © 2019 Elsevier Inc.

Male circumcision is one of the oldest and most commonly performed procedures in the world. An estimated 80.5% of males aged 14-59 in the United States are circumcised.[1] Overwhelmingly, male circumcisions are performed in the neonatal period,[2] utilizing one of a variety of circumcision clamps. These circumcisions take place under local anesthesia in a physician's office and occur before the newborn has garnered the ability to recollect life events. A 2008 review of pediatric urology certification/case logs unsurprisingly demonstrated more than 10% of the average pediatric urologists case load was comprised of circumcisions.[3]

In 2012, the American Academy of Pediatrics released the organization's collective position on circumcision.[4] The group posits circumcisions performed on a child remain at the discretion of the parent, while the details of the statement provided ample scientific background demonstrating the healthcare benefits of circumcision. The taskforce even suggested that third-party payment is warranted.[4] The growing population in the United States combined with the significant amount of data outlining the benefits of newborn circumcision (NBC) suggests that this procedure will become more and more prevalent. Furthermore, with the well-documented shortage of pediatric urologists in this country, we are facing a dilemma to provide timely, safe, and satisfactory NBCs by well-trained providers.

This dilemma extends beyond circumcisions, reaching into many subspecialties with a heavy volume of quick, relatively small procedures. Recognizing this shortage, the utilization of advanced practice providers (APPs) has come to the forefront of patient care in various surgical specialties. A multitude of studies from various fields provide evidence that APPs can safely perform basic procedures ranging from ED thoracostomy insertions, to upper endoscopies, to orthopedic physiotherapy.[5-7] A recent study by Giramonti and Kogan out of Buffalo, New York,

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Table 1. Overall demographics and complication rates

Total Included N = 551	Variable	N (% or range)
Variable	Age (days)	23.8 (2-80)
	Weight:	
	Pounds	8.6 (5.5-13.4)
	Kilograms	3.9 (2.5-6.1)
	Total unique patients with any complication	21 (3.8%)
	Revision circumcision	2 (0.4%)
	Return to OR, NBC related, nonrevision	4 (0.7%)
	Total return to OR	6 (1.1%)
	Bleeding	15 (2.7%)
	ED in 30 days	2 (0.4%)
Race		
	White	294 (53.5%)
	Black	164 (29.7%)
	Asian	32 (5.8%)
	Unable to obtain	57 (10.3%)
Ethnicity		
	Hispanic	135 (24.5%)
	Non-Hispanic	416 (75.5%)

described their successful experience with training a nurse practitioner to perform simple penile procedures in the operating room.[8] While the aforementioned study reviewed a single institution's experience with operating room (OR)-performed circumcisions in children >6 months of age, this idea can be extrapolated to include the most minor procedures performed in each surgical specialty. In this article, we review our institution's experience with an APP-led NBC clinic and compare the clinical outcomes of circumcisions performed at this clinic to those performed by pediatric urologists.

METHODS

In 2012, our institution developed a novel approach to the NBC as there was an incongruence between the number of patients desiring this procedure and the number of qualified providers available to provide the service. This recognition led to the development of an APP-led NBC clinic staffed entirely by APPs trained to perform this procedure. APPs performing NBCs at our institution are physician assistants and nurse practitioners by training. Circumcision training was led by attending urologists with specific requirements outlined in order for the APP to be recognized as qualified. Initially, the APP was required to observe 10 NBCs, followed by first-assisting on 10, and finally performing 10 on their own with direct attending supervision. Once these 30 procedures were completed to the satisfaction of the attending urologist, the APP was deemed qualified and able to perform NBCs on their own with only indirect attending supervision. Indirect supervision was defined as the attending surgeon being within 10 minutes of the procedure room in case an issue or question were to arise which required his/her expertise.

After IRB review, a database query for all NBCs (CPT code 54150: circumcision, newborn with clamp) performed in the urology department between the years 2012 and 2016 was conducted. Circumcisions performed in 2012, the year prior to implementation of the APP NBC clinic, were included in order to capture more attending performed NBCs for our comparison group. Patients were followed to 2016 to allow adequate postprocedure time to evaluate the need for revision circumcisions.

Data collected included patient demographics, age, and weight at time of procedure, return to ED within 30 days, return to OR for revision circumcision, and role of provider performing the procedure (APP vs attending). Thorough chart review was performed to collect data on the quantity of lidocaine injected, size of Gomco used, and return to OR for any postcircumcision-related procedure such as takedown of skin bridges or lysis of adhesions. NBCs performed with non-Gomco clamps such as the Mogen clamp and Plastibell device were excluded. All ED visits within 30 days of the procedure to evaluate if these visits were related to the circumcision were reviewed. All postprocedural complications related to circumcision requiring admission to outside hospitals were also reviewed.

Statistical analyses were performed by a statistician with utilization of Fisher exact and Mann-Whitney testing.

RESULTS

A total of 586 patients were identified as having a circumcision in the urology office during the time period queried. Thirty-one patients were excluded due to use of the Plastibell device. Four patients' circumcisions were cancelled due to abnormal pathology such as hypospadias. After evaluating the difference in provider for these 4 cancelled procedures (Table 1), these patients were excluded from the dataset. After all exclusions, 551 patients remained which met all inclusion criteria. Three hundred fourteen NBCs were performed by APPs compared to 237 by attending pediatric urologists.

Thorough chart review attempted to obtain all desired data points. However, due to variability in documentation, some data points—such as weight, ethnicity, and race—were incompletely obtained. Due to the large provider pool in the area, many patients were followed up elsewhere thus limiting the ability to obtain all desired information.

Details of the entire cohort, including rate of circumcision cancellation, can be seen in Table 1. The average age for the entire cohort was 23.8 days. The average weight of the entire cohort was 8.6 pounds (3.9 kg). A total of 6 patients required a

Table 2. Advanced practice provider (APP) vs urologist outcomes

Variable Name	Size	Advanced Practice Provider (APP) Available N	APP Count (%)	Urologist Available N	Urologist Count (%)	Fisher Exact Test *P* Value
Overall complications		314	13 (4.1)	237	8 (3.4)	0.64
Revision circumcision		314	1 (0.3)	237	1 (0.4)	1
30-day return to ED		314	2 (0.6)	237	0 (0)	0.51
All NBC-related penile surgery (including revision circumcisions)		314	2 (0.6)	237	4 (1.7)	0.41
Gomco size	1.10	314	17 (5.4)	224	5 (2.2)	<0.0001
	1.30		205 (65)		100 (45)	
	1.45		89 (28)		94 (42)	
	1.60		3 (1)		25 (11)	
Intraprocedure bleeding		314	11 (3.5)	237	4 (1.7)	0.29
Weight >10 pounds (4.5 kg)		314	17 (5.4)	237	37 (16)	<0.0001
Office circumcision cancelled		318	4 (1.3)	237	0 (0)	0.14

Variable	Advanced Practice Provider (APP) N	APP Mean ± SD	Urologist N	Urologist Mean ± SD	*P* Value
Lidocaine (mL)	314	0.8 ± 0.07	213	0.96 ± 0.4	<0.0001
Weight in pounds (kg)	307	8.4 ± 1.1 (3.8 ± 0.5)	165	8.9 ± 1.5 (4 ± 0.7)	0.0063
Age (days)	314	20.3 ± 7.4	237	28.4 ± 13.4	<0.0001

return to the OR for NBC-related events—2 patients required revision of their circumcision and 4 required penile surgery such as lysis of adhesions or takedown of skin bridges which went beyond the feasibility to safely perform in the office. Fifteen patients were noted to have bleeding during the procedure which required some form of intervention ranging from application of manual pressure, to utilization of electrocautery, to placing stitches in order to stop the bleeding. Two patients returned to the emergency room within 30 days of NBC for an issue related to the NBC itself. Both of these instances were related to postprocedure bleeding with no invasive interventions required in either case.

Two hundred ninety-four of the 551 patients in the final cohort were white, 164 were black or African-American, 32 were Asian or Asian-American, and the remainder did not have race documented within the system (Table 2). Ethnic classification demonstrated that 24.5% of the final cohort was Hispanic (135/551). Statistical analysis failed to demonstrate any statistically significant differences between the APP and attending urologist subgroups in regards to race or ethnicity.

There were no statistically significant differences between APPs and attending urologists with regards to clinical outcomes such as rates of bleeding, identification of abnormalities precluding NBC, return to OR for circumcision revision, return to OR for penile surgery related to prior NBC, and return to the ED within 30 days in relation to the NBC (Table 2). The only statistically significant variable was the distribution in size of Gomco clamp used with APPs using 1.3 size 65% of the time, while attending urologists more evenly utilized the 1.3 and 1.45 clamps (45% and 42%, respectively; $P < 0.0001$). Further testing did show additional significance when evaluating the number of babies greater than 10 pounds (4.5 kg) who received NBC. The attending urologist group performed NBC on far more babies weighing more than 10 lbs (4.5 kg) than did the APP subgroup (37 vs 17, respectively, $P < 0.0001$).

Attending urologists used more lidocaine, on average, than did the APPs (0.96 ± 0.41 mL vs 0.8 ± 0.07 mL, respectively, $P < 0.0001$). Infant weight was also significantly different when comparing the 2 groups with attending urologists performing NBCs on heavier patients (8.9 (4) ± 1.5 (0.7) lbs (kg) vs 8.5 (3.9) ± 1.1 (0.5) lbs (kg), $P < 0.0063$). Age was found to be statistically significant as well, with attending urologists performing NBCs on older babies, on average (28.4 ± 13.4 days vs 20.3 ± 7.4 days, respectively, $P < 0.0001$).

Further analysis then focused on outcome differences based on patient characteristics found to be significantly different between the APP and attending groups. Since weight was significantly larger for the attending group, we looked at our institutions' weight cutoff for NBC of 10 pounds (4.5 kg). This weight cutoff is utilized at other institutions around the country therefore is felt to be an accurate representation of the practice patterns at large within pediatric urology clinics. The cohort was separated by weight between children over 10 pounds (4.5 kg) and children less than 10 pounds (4.5 kg) (Table 3). There were no statistically significant differences in complication rates between the 2 groups. Distribution of Gomco size utilization remained significantly different between these 2 groups, as expected. Quantity of lidocaine used and age in days of the patient were also significantly difference between the heavier and lighter babies, based on Mann-Whitney analysis.

Next, the cohort was separated according to age categories, again based on the oft-used age cutoff of 30 days for NBCs. When looking at children less than vs more than 30 days of age, utilizing Fisher exact testing, there was a statistical difference in return to OR for revision circumcision ($P = 0.034$), distribution of Gomco clamp size utilized ($P < 0.0001$), and weight over 10 pounds (4.5 kg) ($P < 0.0001$, Table 3). Children older than 30 days were more likely to require a circumcision revision (2% vs 0%, respectively, $P = 0.034$). When considering all NBC-related penile surgeries, including circumcision revision, there was no difference between

Table 3. Weight and age comparisons

Variable Name	Size	Weight Not Over 10 lbs (4.5 kg) Available N	Weight Not Over 10 lbs (4.5 kg) Count (%)	Weight Over 10 lbs (4.5 kg) Available N	Weight Over 10 lbs (4.5 kg) Count (%)	Fisher Exact Test *P* Value
Revision circumcision		418	1 (0.2)	54	1 (1.9)	0.216
30-day return to ED		418	2 (0.5)	54	0 (0)	1
All NBC-related penile surgery (including revision circumcisions)		418	4 (1)	54	1 (1.9)	0.457
Gomco size	1.10	410	19 (4.6)	51	1 (2)	<0.0001
	1.30		262 (64)		12 (24)	
	1.45		119 (29)		30 (59)	
	1.60		10 (2.4)		8 (16)	
Intraprocedure bleeding		418	11 (2.6)	54	3 (5.6)	0.21

Variable Name	Size	Age Not Over 30 Days Available N	Age Not Over 30 Days Count (%)	Age Over 30 Days Available N	Age Over 30 Days Count (%)	Fisher Exact Test *P* Value
Revision circumcision		449	0 (0)	102	2 (2)	0.034
30-day return to ED		449	2 (0.5)	102	0 (0)	1
All NBC-related penile surgery (including revision circumcisions)		449	4 (0.9)	102	2 (2)	0.31
Gomco size	1.10	441	19 (4.3)	97	3 (3.1)	<0.0001
	1.30		266 (60)		39 (40)	
	1.45		143 (32)		40 (41)	
	1.60		13 (2.9)		15 (15)	
Intraprocedure bleeding		449	13 (2.9)	102	2 (2)	1
Weight >10 pounds (4.5 kg)		397	27 (6.8)	75	27 (36)	<0.0001

the older and younger group. Similarly, there were no differences in the rates of the other complications reviewed. As would be expected, weight and lidocaine usage were significantly different between the older and younger cohort (Table 3).

DISCUSSION

Routine circumcision, especially NBC with a clamp, is traditionally viewed as a very low-risk surgical procedure. However, every surgical procedure has inherent risks. Complication rates are determined by many factors including anatomical variations, medical comorbidities, and patient age. A 2010 meta-analysis by Weiss et al demonstrated that the median frequency of any adverse event following circumcision was 1.5%.[9] Horowitz showed in 2001 that performance of Gomco circumcision in the newborn period was extremely safe with a complication rate of 0%. However, when the Gomco clamp was utilized on older infants (>3 months), there was a 30% postoperative bleeding rate requiring intervention.[10] This study helped lead the way to stricter guidelines for the performance of Gomco circumcisions. At our institution, the APP-led circumcision clinic has strict age (less than 30 days) and weight (less than 10 pounds [4.5 kg]) cutoffs that patients must meet in order to qualify for the in-office procedure. However, the attending pediatric urologists may perform NBCs on older and larger patients at their own discretion. This flexibility can be seen in this study as attending physicians, on average, performed NBCs on larger and older infants.

Across the country and throughout the world, physician extenders such as nurse practitioners, physician assistants, and other advanced practice providers have served as a valuable source of productivity in the healthcare landscape. Utilization of APPs allows the attending surgeon to focus more time and energy on more complex cases while simultaneously allowing productivity in the practice to continue. While a cost benefit analysis of an APP-led circumcision clinic was not performed, it is easy to see that there is a clear financial benefit to this construct. The cost-to-time value of a physician exceeds that of an APP—expectedly so, given the longer and more specialized training the surgeon receives which commands higher on-average salaries for the surgeon. Therefore, having the surgeon spend his/her time on more complex cases instead of performing office circumcisions is inherently more cost effective.

In Zimbabwe, cost difference between midwife- and doctor-performed circumcisions was investigated with the not so surprising finding that midwife circumcisions cost less.[11] Along these lines, in 2016, the *Journal of Midwifery and Women's Health* released a comprehensive overview of the elements of patient care within the midwife's armamentarium, which included NBC,[12] furthering the notion that APPs and other physician extenders are able to and should perform these procedures in the United States.

Many studies have shown the safety of APP-performed interventions. Within the field of adult urology, APPs have been performing prostate biopsies, urodynamic testing, injections for the treatment of priapism, and even

routine office cystoscopies[13] with no demonstrable safety concerns. In pediatric urology, we showed that the complication rate was not statistically different between our 2 cohorts—supporting our hypothesis that APPs are able to perform NBCs safely. While Kogan et al demonstrated the efficacy of having a well-trained NP perform circumcisions in the OR, we demonstrate a similar concept for circumcisions performed in the office. To our knowledge, this is the first study to date examining the safety and efficacy of an APP-led NBC clinic.

Our study is not without its limitations given its retrospective nature. There are inherent differences in the groups which cannot be overlooked or accounted for given the formality that exists in the APP-led clinic vs the more flexible and variable attending circumcisions. One such example of this limitation can be seen in that 4 NBCs were cancelled by the APPs while none were cancelled by attending urologists—this is likely due to the more rigorous and regimented documentation requirements of the APPs compared to the attending urologists. Other limitations include the inability to perfectly collect all postprocedure data as some patients follow up at outside institutions. Additionally, early on in the APP-led clinic, there was a requirement for postoperative follow-up appointments—a requirement which faded after time and which never existed for the attending urologist. Due to this, the ability to capture postoperative complications was improved for APPs.

A notable finding was the statistically significant difference in circumcision revisions between babies >30 days old and those less than 30 days of age. While this difference was found to be statistically significant, when looking at the raw numbers we see that only 2 circumcision revisions took place in the entire cohort and these both occurred in the older cohort. Conversely, zero revisions were required in the younger cohort. So, while statistically significant, the clinical significance does not corroborate these results.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.01.038.

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