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Timely orchiopexy by 18 months of age: Are we meeting the standards defined by the 2014 AUA guidelines?

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Keywords
Orchiopexy; Health disparities; Pediatric urology

Abbreviations
AUA, American Urological Association; CRWD, Cerner Real World Data; CPT, Current Procedural Terminology; IQR, Interquartile Range; ICD, International Classification of Diseases

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Summary

Background
Cryptorchidism is one of the most common reasons for pediatric urology referral and one of the few pediatric urologic conditions in which there are established AUA guidelines that recommend orchiopexy be performed before 18 months of age. While access to timely orchiopexy has been studied previously, there is no current study with data from a national clinical database evaluating timely orchiopexy after the AUA guidelines were published. Additionally, prior studies on delayed orchiopexy may have included patients with an ascended testis, which is a distinct population from those with true undescended testicles.

Objectives
To evaluate in a national, clinical database if timely orchiopexy improved after the AUA guidelines were published in 2014. In particular, we aim to evaluate a younger group of patients, 0–5 years of age, in an effort to account for potential ascending testes.

Study design
Using Cerner Real-World Data™, a national, de-identified database of 153 million individuals, we analyzed pediatric patients undergoing orchiopexy in the United States from 2000 to 2021. We included males 0–18 years old and further focused on the subset 0–5 years. Primary outcome was timely orchiopexy, defined as age at orchiopexy less than 18 months. Predictor variables included race, ethnicity and insurance status. Statistical analyses were performed using logistic regression.

Results
Of the total 17,012 individuals identified as undergoing orchiopexy, 9274 were ages 0–5 at the time of surgery. Comparing time periods pre and post AUA guidelines (2000–2014 versus 2015–2021), we found a significant difference in the proportion of timely orchiopexy (51% versus 56%, respectively; $p < 0.0001$) (Figure). In multivariable analyses, Hispanic (OR = 0.65, $p < 0.0001$), African American (OR = 0.74, $p < 0.0001$), and Native American males (OR = 0.66, $p = 0.008$) were less likely to have timely orchiopexy compared to non-Hispanic White males. Individuals without insurance (OR = 0.81, $p = 0.03$) or with public insurance (OR = 0.88, $p = 0.02$) were less likely to have timely orchiopexy as compared to those with private insurance.

Conclusions
Nearly a decade after publication of the AUA cryptorchidism guidelines, a large proportion of patients are still not undergoing orchiopexy by 18 months of age. This is the first study to show that timely orchiopexy has improved among patients 0–5 years, but the majority of patients are still not undergoing timely orchiopexy. Health disparities were apparent among Hispanic, African American, Native American, and uninsured males, highlighting the need for further progress in access to pediatric surgical care.

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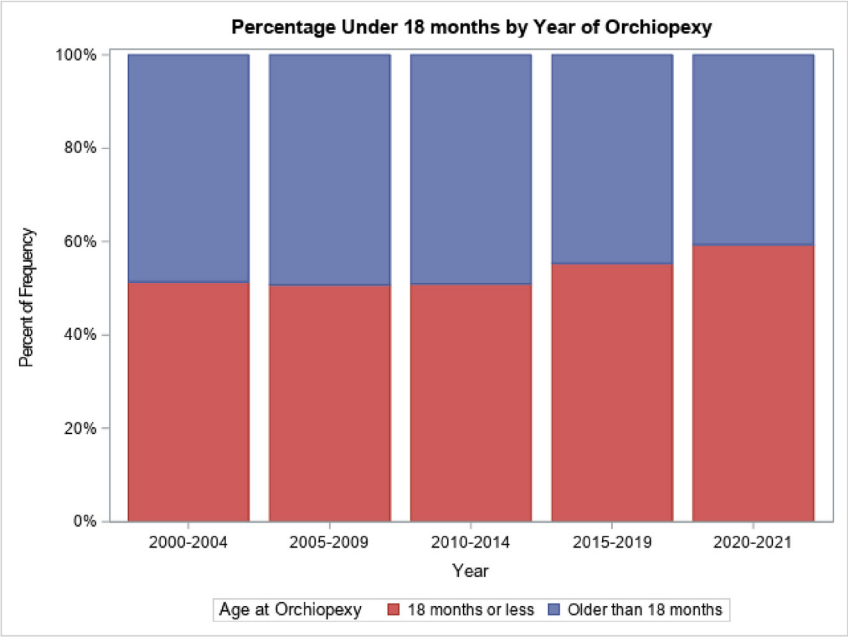

Summary Figure Percentage of Patients 18 Months and Younger by Year of Orchiopexy among the Sub-Set of Individuals Aged 0-5 Years (n = 9,274).

Introduction

Cryptorchidism occurs in approximately 4% of male infant births and is one of the most common reasons for pediatric urology referral [1]. Timely referral of cryptorchidism is important as this condition is a known risk factor for testicular malignancy; pre-pubertal orchiopexy results in a two to six fold reduction in risk of cancer development [2]. In addition, prompt orchiopexy is essential for preserving fertility with testicular biopsy of cryptorchid testes showing decreased number of germ cells if the orchiopexy is delayed [3].

Studies conducted over a decade ago reported the mean age at orchiopexy was 4.4 years and only 18—38% of children underwent orchiopexy prior to age two [4,5]. In 2014, the American Urological Association (AUA) published guidelines on timely referral for cryptorchidism recommending that patients undergo orchiopexy within the first 18 months of life [2]. Since the publication of the AUA cryptorchidism guidelines, studies published on timely orchiopexy have either been from single centers, based on administrative claims databases or not nationally representative [6—8]. There is no current study with data from a national clinical database evaluating timely orchiopexy after the AUA guideline publication.

Time to referral for cryptorchidism and time to surgical correction have been identified as markers for health disparities in the pediatric population both prior to and after the AUA cryptorchidism guideline publication [7—10]. Established risk factors for delayed orchiopexy are African American race, Hispanic ethnicity, and public or no health insurance [4,7,8]. One potential concern of database studies on delayed orchiopexy is that patients with an ascended or ascending testicle are included. These patients are those who had a normal testicular exam at birth but later presented with a high testicle related to cremasteric reflex and/or linear growth. Therefore, it is a distinctly different population from those with true undescended testicles. Prior studies on ascending testis patients found that the peak prevalence was between 8 and 11 years of age [11]. In order to account for this, prior studies of timely orchiopexy have excluded patients with history of retractile testis as a large portion of retractile testicles may ascend [12]. In this study, we aim to address this potential confounding effect - by conducting a sub-analysis of a younger group of patients 0—5 years of age.

Using the Cerner Real-World Data™ (CRWD), a large national database that includes 153 million individuals, we seek to evaluate timely orchiopexy after the AUA guidelines publication as well as assess the existence of health disparities among this group of patients. We also aim to evaluate a younger group of patients 0—5 years of age in an effort to account for potential ascending testes.

Materials and methods

Data source

The *CRWD* is a large de-identified database collated by Cerner Corporation®. This database consists of Electronic Health Record data from over 120 Cerner Health Systems across the United States. As of December 2021, roughly 38% of the data is derived from the Eastern states, 32% from the Central-Southern states and 28% from Western states [13]. The database is composed of clinical data that can fit into a structured query language table including data on demographics, encounters, conditions, laboratory tests,

Table 1 Demographic, visit, and facility data among patients undergoing orchiopexy in CRWD.

Characteristic	n (%) N = 17,012	
Median age at orchiopexy (IQR)	4.1 (1.3–9.1)	
Race/Ethnicity		
Hispanic	4212	(25)
Non-Hispanic White	8605	(51)
African American	1494	(9)
Asian American	432	(2.5)
Native American	311	(2.0)
Mixed or Unknown race	1958	(10.5)
Insurance		
Private	5838	(34)
Public/Medicaid	4390	(26)
None/Self-pay	961	(6.0)
Unknown	5823	(34)
Facility Type		
Academic Hospital	4793	(28)
Children's Hospital	7492	(44)
Regional/Community	4727	(28)
Year of Orchiopexy		
2000–2004	903	(5.5)
2005–2009	2044	(12)
2010–2014	3908	(23)
2015–2019	8048	(47.5)
2020–2021	2109	(12)

Table 2 Bivariate associations between patient, visit and facility variables and timely orchiopexy (defined as age 18 months or less).

Variables	OR (95% CI)[a]		*P* value
Race/Ethnicity			
Non-Hispanic White	1.0	(ref)	
Hispanic	0.83	(0.76–0.90)	<0.001
African American	0.81	(0.71–0.91)	<0.001
Asian American	1.4	(1.2–1.7)	0.002
Native American	0.73	(0.56–0.95)	0.02
Mixed or Unknown Race	0.99	(0.89–1.1)	0.88
Insurance			
Private	1.0	(ref)	
Public/Medicaid	0.96	(0.88–1.03)	0.29
No Insurance	0.85	(0.73–0.99)	0.04
Unknown insurance	0.68	(0.62–0.74)	<0.001
Facility Type			
Academic Hospital	1.0	(ref)	
Children's Hospital	1.0	(0.92–1.08)	0.98
Regional/Community	0.70	(0.64–0.76)	<0.001
Year of Orchiopexy			
2015–2021	1.0	(ref)	
2000–2014	0.97	(0.91–1.04)	0.38
P trend			0.58[b]

[a] OR = odds ratio, 95% CI = 95% confidence interval.
[b] *P* value from trend test.

clinical measurements, surgical procedures, and other clinical events [14]. The 2021 quarter 3 version of CRWD was used and included more than 153 million patients and 1.5 billion encounters across all care settings and age groups, including 13,488,305 patients with genitourinary conditions (International Classification of Diseases (ICD)-10 codes N00–N99). The size and longitudinal nature of this unique database can be leveraged for advanced analytics in pediatric research.

Data acquisition

After institutional review board approval (IRB #210565) was obtained, a database analysis was conducted of individuals who underwent orchiopexy identified by Current Procedural Terminology (CPT) codes (54640, 54650, 54690, 54692) and Systemized Nomenclature of Medicine codes from the CRWD from 2000 to 2021. Inclusion criteria were individuals 18 years of age and younger undergoing orchiopexy for congenital cryptorchidism including both unilateral and bilateral cryptorchidism. We excluded patients with hypospadias, acute testicular torsion, any previous diagnosis of retractile testes, and those undergoing prophylactic orchiopexy for intermittent torsion. For included patients, we collected the following variables: year of orchiopexy, age at orchiopexy, race, ethnicity, first digit of zip code, type of facility where orchiopexy was performed (standalone children's hospital, academic hospital (other than standalone children's hospital), regional or community hospital), insurance status and if insured, type of insurance.

Outcome and predictor variables

Our primary outcome was age at orchiopexy. Timely orchiopexy was defined as having this procedure prior to the child reaching 18 months of age, based on the published AUA guidelines [2]. We examined potential predictive factors associated with delayed surgery such as insurance status, race, ethnicity, year of surgery, and type of surgical facility. When comparing timely orchiopexy before and after AUA guidelines, we used data from 2000 to 2014 versus 2015–2021. We used a wider timeframe in the pre-AUA guidelines group in order to maximize the number of patients included for comparison.

Statistical analysis

Analyses were performed using SAS Statistical Software version 9.4 (SAS Institute, Cary, NC, USA). All statistical tests were two-tailed with p values less than 0.05 considered significant. Categorical variables were summarized using counts and percentages, and continuous variables were summarized using median and interquartile range. Bivariate analyses of predictor variables were analyzed using logistic regression to calculate odds ratios and corresponding p values. Multivariable logistic regression was used to estimate the association of predictor variables with age at orchiopexy while controlling for other predictors in the model. Adjusted odds ratios and corresponding confidence intervals and p values were calculated. We included race/ethnicity, insurance status and facility type in the

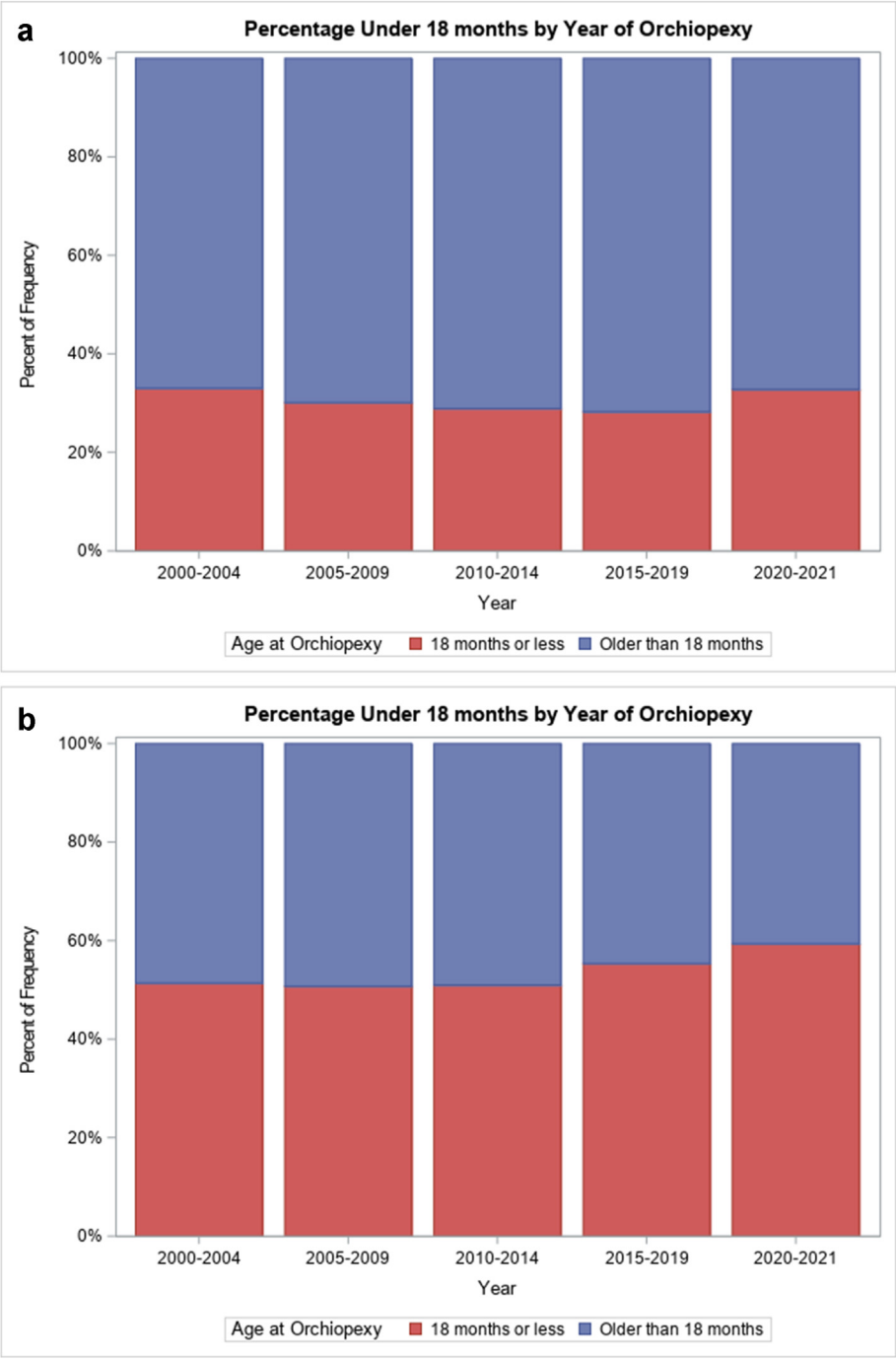

Fig. 1 (a). Percentage of patients 18 months and younger by year of orchiopexy among all individuals aged 0—18 years (N = 17,012). (b). Percentage of patients 18 months and younger by year of orchiopexy among the sub-set of individuals aged 0—5 years (n = 9274).

multivariable model as these predictors have been found in previous publications to be associated with significant differences in timely orchiopexy [4,7,8]. To better estimate the rate of timely orchiopexy and limit the number of patients included with ascended testes, we conducted a sub-analysis of our data in which we restricted to individuals aged 0—5 years at the time of surgery.

Results

Descriptive analysis

From the initial 25,700 individuals identified from CRWD, 17,012 were included with age at time of surgery between

Table 3 Multivariable associations between race/ethnicity, insurance and facility type and timely orchiopexy (age 18 months or less) (N = 17,012).

Variables	Adjusted OR (95% CI)[a]		*P* value
Race/Ethnicity			
Non-Hispanic White	1.0	(ref)	
Hispanic	0.76	(0.70–0.83)	<0.001
African American	0.77	(0.68–0.88)	<0.001
Asian American	1.3	(1.03–1.5)	0.03
Native American	0.80	(0.61–1.04)	0.09
Mixed or Unknown Race	0.97	(0.87–1.1)	0.52
Insurance			
Private		1.0	(ref)
Public/Medicaid	1.1	(0.99–1.19)	0.06
No Insurance	0.83	(0.71–0.96)	0.01
Unknown insurance	0.74	(0.68–0.81)	<0.001
Facility Type			
Academic Hospital	1.0	(ref)	
Children's Hospital	1.06	(0.97–1.15)	0.20
Regional/Community	0.70	(0.64–0.77)	<0.001

[a] OR = odds ratio, 95% CI = 95% confidence interval.

0 and 18 years. Exclusions were testicular torsion (n = 450), hypospadias (n = 564), retractile testes (n = 1910), prophylactic orchiopexy (n = 2106), >18 years (n = 2596), missing age at orchiopexy (n = 533), and erroneous year of orchiopexy (n = 529). Patient and facility characteristics are summarized in Table 1.

Bivariate analysis

Among males 0–18 years of age, only 29% underwent orchiopexy by 18 months of age, with a median age of 4.1 years. Age at orchiopexy significantly differed by race/ethnicity ($p < 0.001$); African American (OR = 0.81, 95% CI: 0.71–0.91, $p < 0.001$), Hispanic males (OR = 0.83, 95% CI: 0.76–0.90, $p < 0.001$), and Native American males (OR = 0.73, 95% CI: 0.56–0.95, $p = 0.02$) were less likely to have timely orchiopexy compared to non-Hispanic White males (Table 2). Asian American males were more likely to have timely orchiopexy (OR = 1.4, 95% CI: 1.2–1.7, $p = 0.002$) than non-Hispanic Whites. Patients with no insurance were significantly less likely to have timely orchiopexy than patients with private insurance (OR = 0.68, 95% CI: 0.73–0.99, $p = 0.04$). On bivariate analysis of year of orchiopexy for individuals ages 0–18, the likelihood of timely orchiopexy appeared stable over time. We found no significant trend during the years 2000–2021 (p trend = 0.58) (Fig. 1a). Comparing the time periods before guideline publication (2000–2014) versus afterwards (2015–2021), there was no significant difference in proportion of timely orchiopexy (30% versus 29%, respectively; $p = 0.38$). Compared to orchiopexy patients at academic hospitals, patients undergoing orchiopexy at a regional or community hospital were less likely to undergo timely orchiopexy ($p < 0.001$).

We conducted a sub-analysis of the data limiting to individuals five years or younger at the time of orchiopexy; this subset included 9274 individuals. The median age at time of orchiopexy in the subset was 1.4 years, with 54% having orchiopexy before 18 months of age. Comparing the time periods pre and post AUA guidelines (2000–2014 versus 2015–2021), we found a significant difference in the proportion of timely orchiopexy (51% versus 56%, respectively; $p < 0.001$). The trend over the years 2000–2021 was also statistically significant with a larger percentage of timely orchiopexies occurring in the more recent years among individuals 5 years and younger ($p < 0.001$) (Fig. 1b).

Multivariable analysis

In multivariable analyses of individuals 0–18 years, adjusting for race/ethnicity, insurance, and facility type, African American males (OR = 0.77, 95% CI: 0.68–0.88, $p < 0.001$) and Hispanic males (OR = 0.76, 95% CI: 0.70–0.83, $p < 0.001$) were less likely to have timely orchiopexy compared to non-Hispanic White males (Table 3). Asian males (OR = 1.3, 95% CI: 1.03–1.5, $p = 0.03$) were more likely to have timely orchiopexy than non-Hispanic Whites. Individuals without insurance were less likely to have timely orchiopexy than those with private insurance (OR = 0.83, 95% CI: 0.71–0.96, $p = 0.01$). Children undergoing orchiopexy at regional or community hospitals were less likely to have a timely orchiopexy on multivariable analysis than those treated at an academic facility (OR = 0.70, 95% CI: 0.64–0.77, $p < 0.001$). We also conducted sensitivity analyses removing missing insurance and the results were consistent with the findings in the larger subset.

In the five years and younger subset, multivariable analyses of timely orchiopexy with race/ethnicity, insurance and facility type were similar to the overall cohort (Table 4). Hispanic (OR = 0.65, 95% CI: 0.59–0.73, $p < 0.001$),

Table 4 Multivariable associations between race/ethnicity, insurance and facility type and timely orchiopexy (age 18 months or less) restricting to individuals five years of age and under at the time of surgery (n = 9274).

Variables	Adjusted OR (95% CI)[a]		*P* value
Race/Ethnicity			
Non-Hispanic White	1.0	(ref)	
Hispanic	0.65	(0.59–0.73)	<0.001
African American	0.74	(0.63–0.86)	<0.001
Asian American	0.92	(0.72–1.2)	0.50
Native American	0.66	(0.48–0.90)	0.008
Mixed or Unknown Race	0.87	(0.76–0.99)	0.03
Insurance			
Private	1.0	(ref)	
Public/Medicaid	0.88	(0.79–0.98)	0.02
No Insurance	0.81	(0.67–0.98)	0.03
Unknown insurance	0.77	(0.70–0.86)	<0.001
Facility Type			
Academic Hospital	1.0	(ref)	
Children's Hospital	1.2	(1.1–1.3)	<0.001
Regional/Community	0.77	(0.69–0.86)	<0.001

[a] OR = odds ratio, 95% CI = 95% confidence interval.

African American (OR = 0.74, 95% CI: 0.63–0.86, $p < 0.001$), and Native American males (OR = 0.66, 95% CI: 0.48–0.90, $p = 0.008$) were significantly less likely to have timely orchiopexy than non-Hispanic White males, after adjusting for insurance and facility type. No significant differences were found between Asian and non-Hispanic Whites in this subset. Public insurance (OR = 0.88, 95% CI: 0.79–0.98, $p = 0.02$) and no insurance (OR = 0.81, 95% CI: 0.67–0.98, $p = 0.03$) were markers of delayed age at orchiopexy compared with private insurance, with adjustment for race/ethnicity and facility type.

Discussion

In this study, we found that among males 0–18 years of age, only 29% underwent timely orchiopexy before 18 months as defined by the 2014 AUA cryptorchidism guidelines [2]. However, when we limited our analysis to individuals five years old and under to account for potential testicular ascent, a larger percentage of patients (54%) underwent timely orchiopexy. Furthermore, when examining pre and post AUA guidelines in the five years and under group, we noted a small but significant improvement in timely orchiopexy with 51% from 2000 to 2014 compared to 56% timely orchiopexy from 2015 to 2021.

We found that the vast majority of patients 0–18 years did not undergo timely orchiopexy by 18 months of age, which is consistent with prior studies [4–7]. This poor adherence to the guideline recommended timing for orchiopexy is concerning as delayed orchiopexy is associated with subfertility of the affected testis and increased risk of testicular cancer [15]. We hypothesized that following the introduction of the AUA guidelines in 2014, more surgeries would occur by 18 months of age. However, our rate of timely orchiopexy of 29% and median age at orchiopexy of 4.1 years is relatively unchanged from the findings of Kokorowski et al. in the Physician Health Information System database from 2010 in which 43% had orchiopexy before age two and the median age at orchiopexy was 4.4 years [4]. Our results on patients five years and younger is consistent with Yiee et al. who investigated a subset of Physician Health Information System database patients in the same age range and found that 61% of privately insured patients and 54% of patients with public or no insurance had a timely orchiopexy [8]. Our finding that more timely orchiopexies have been performed from 2015 to present is novel, and has not been shown in any previous studies. In addition to the AUA guidelines in 2014, Medicaid expansion has increased insurance access, which may be contributing to the improvement in timely orchiopexy [16].

We observed that African American, Hispanic and Native American males had significantly lower rates of timely orchiopexy than non-Hispanic White males. Data on health disparities in age at orchiopexy has been published previously on African Americans and Hispanics [4,7] but not for Native Americans. While we expected boys with public insurance would have a lower rate of timely orchiopexy than boys with private insurance as demonstrated previously [4,7], this was not observed. However, we did find that boys without insurance were more likely to have a delayed orchiopexy, which is in agreement with previous studies [7]. We also identified surgery outside of an academic or children's hospital to be a risk factor for delayed orchiopexy, which is similar to previous studies reporting fewer timely orchiopexies at lower volume hospitals [8]. In the subset of patients five years and younger, these same health disparities remained significant with the addition of public insurance being a risk factor for delayed orchiopexy.

The differences between our findings in the overall pediatric population 0–18 years and the subset 0–5 years are likely multifactorial but one factor that may play a larger role in the older patients is testicular ascent. A recent prospective study found that 39% of delayed orchiopexy referrals were secondary to an ascended testis and these patients had a normal testicular exam at birth [17]. Similarly, Guven et al. found that among orchiopexies performed after four years of age, 45% were due to testicular ascent and the peak prevalence of testicular ascent was 8–11 years of age [11]. The phenomenon of ascended testes is not well described and there is no specific diagnosis code for ascended testes, which makes it difficult to identify in large database studies. In boys with testicular ascent, the delay in orchiopexy is due to their pathophysiology and likely not reflective of health disparities in access to care or delayed diagnosis of cryptorchidism. This is important to consider as delayed orchiopexy is an established marker for health disparities in pediatric urology and if it were to become a quality metric, it would be difficult to differentiate true undescended testis from ascending testis without a separate diagnosis code. However, we do believe that a portion of the children in the older age group have a delayed orchiopexy for a true undescended testis and their delay in referral may reflect underlying health care disparities.

Our study does have limitations. While the CRWD is large and contains patients of differing insurance statuses from hospital systems across the nation, it is a de-identified database and we did not have access to patients' individual medical records. We were also unable to access or analyze any visit that occurred outside of the Cerner medical record system. For example, referral from the primary care provider to a surgeon has been noted as the key factor in timely orchiopexy [7] but we did not have data on age at patient referral relative to the age at orchiopexy. Other limitations were missing data on insurance status and inability to differentiate between primary orchiopexy and revision orchiopexy based on CPT code, although revision orchiopexy is rare. In addition, while we identified established healthcare disparities involving race/ethnicity and insurance status, we were unable to investigate the underlying causes for these disparities in our dataset, including socioeconomic status.

Conclusions

This robust national analysis found that nearly a decade after publication of the AUA cryptorchidism guidelines, a large proportion of patients are not undergoing timely orchiopexy. However, we did find a small but significant increase in timely orchiopexy in the subset of patients under five years of age. Hispanic, African American, Native American and uninsured males had significantly lower rates of timely orchiopexy across all age groups, which highlights health care disparities

among these groups. Additionally, testicular ascent may account for some of the delayed orchiopexies and until a diagnosis code for ascending testis is available, future studies of health disparities in orchiopexy should focus on a younger age group. These results demonstrate that the goal for timely orchiopexy is still not often achieved, and more directed efforts are needed in pediatric centers throughout the U.S. to improve timely orchiopexy.

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Conflicts of interest

The authors have no conflicts of interest to report.

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