# Misuse of ultrasound for palpable undescended testis by primary care providers: A prospective study

Nathan C. Wong, MD;<sup>\*</sup> Rahul K. Bansal, MD, MBBS, MS, MCh;<sup>\*</sup> Armando J. Lorenzo, MD, FRCSC;<sup>†</sup> Jorge DeMaria, MD, FRCSC;<sup>†</sup> Luis H. Braga, MD, PhD<sup>\*</sup>

"Department of Surgery (Urology), McMaster Children's Hospital, McMaster University, Hamilton, ON; "Department of Surgery (Urology), Hospital for Sick Children, University of Toronto, ON

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## Abstract

**Introduction:** Although previous evidence has shown that ultrasound is unreliable to diagnose undescended testis, many primary care providers (PCP) continue to misuse it. We assessed the performance of ultrasound as a diagnostic tool for palpable undescended testis, as well as the diagnostic agreement between PCP and pediatric urologists.

**Methods:** We performed a prospective observational cohort study between 2011 and 2013 for consecutive boys referred with a diagnosis of undescended testis to our tertiary pediatric hospital. Patients referred without an ultrasound and those with non-palpable testes were excluded. Data on referring diagnosis, pediatric urology examination and ultrasound reports were analyzed.

**Results:** Our study consisted of 339 boys. Of these, patients without an ultrasound (n = 132) and those with non-palpable testes (n = 38) were excluded. In the end, there were 169 pateints in this study. Ultrasound was performed in 50% of referred boys showing 256 undescended testis. The mean age at time of referral was 45 months. When ultrasound was compared to physical examination by the pediatric urologist, agreement was only 34%. The performance of ultrasound for palpable undescended testis was: sensitivity = 100%; specificity = 16%; positive predictive value = 34%; negative predictive value = 100%; positive likelihood ratio = 1.2; and negative likelihood ratio = 0. Diagnosis of undescended testis by PCP was confirmed by physical examination in 30% of cases, with 70% re-diagnosed with normal or retractile testes.

**Conclusion:** Ultrasound performed poorly to assess for palpable undescended testis in boys and should not be used. Although the study has important limitations, there is an increasing need for education and evidence-based guidelines for PCP in the management of undescended testis.

#### Introduction

Undescended testis or cryptorchidism is one of the most common congenital genitourinary anomalies affecting newborn males, occurring in about 5% at birth and 1.6% at 3 months of age.<sup>1</sup> It is defined as the absence of one or both testes in the normal scrotal position. The most useful classification is determining palpable versus non-palpable undescended testis, as management is determined by location and actual presence of the testis. The current diagnostic standard is careful clinical examination of a boy in several positions by an experienced examiner. To best assess for testicular position, boys should be examined in the supine and if possible, the upright cross-legged, squatting and standing position. To minimize the effects of the cremasteric reflex, patient distraction, a warm room and hands, use of liguid soap and repeat examination may assist in localization of the testes. Even though undescended testis is one of the most common pediatric genital problems seen by primary care providers (PCP), such as pediatricians, there are sparse guidelines on its management.<sup>2</sup>

The initial diagnoses of undescended testis are usually made by PCP, who refer to pediatric urologists or surgeons for subsequently management. Despite ample evidence that imaging studies do not help in managing boys with non-palpable testes, PCP continue to adopt various forms, in particular ultrasound, prior to referral for undescended testis.<sup>3-5</sup> Up to 96.4% of surveyed pediatricians reported using ultrasound to evaluate undescended testis.<sup>6</sup> Similar practices have been observed in our catchment area, as many boys have already undergone ultrasonic evaluation of palpable undescended testis which could have been easily detected by physical exam prior to urological referral.

The routine use of ultrasound in the setting of non-palpable testes has little or no added benefit.<sup>3</sup> A meta-analysis of 12 studies which examined the use of pre-operative ultrasound to evaluate non-palpable testes showed that ultrasound had a sensitivity of 45% and specificity of 78%. Ultrasound was unreliable to localize non-palpable testes and did not rule out intra-abdominal testes. The study concluded that eliminating the use of ultrasound would not change the management in boys with non-palpable testes.

However, the use of ultrasound in boys with palpable testes has not yet been well-studied. Thus, we performed a prospective study to assess the utility of ultrasound as a diagnostic tool of palpable undescended testis at our centre, as well as to assess the agreement between PCP and pediatric urologist diagnosis by clinical examination.

#### Methods

We designed a research-ethics-board-approved prospective longitudinal study to evaluate consecutive boys (age <18 years) referred to our tertiary pediatric hospital with a referring diagnosis of undescended testis between March 2011 and October 2013. Boys without an ultrasound and boys with non-palpable testis were excluded. Non-palpable testis was selected as one of the exclusion criteria as there is previous evidence that ultrasound is not a valuable test for the diagnosis of non-palpable testis.

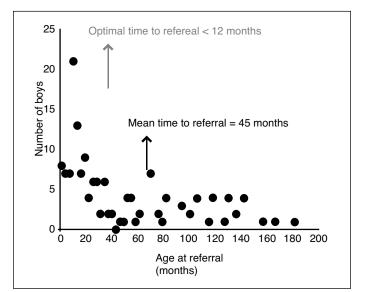
Over the course of about 3 years, the referral letters and ultrasound findings of boys with undescended testis were appraised and extracted for the true reason of referral according to our pre-defined inclusion and exclusion criteria. Boys underwent standardized history and physical examination by 1 of the 2 experienced pediatric urologists at our centre. Examination of the scrotum was made in patients in the supine position, as well as the frog-legged if there was any doubt, using hand lubricant when necessary. Normal testes were defined as testes that resided in the middle to lower part of the scrotum, while retractile testes were defined as testes in the upper scrotum or lower inguinal canal that could be manipulated into the middle or lower scrotum without spermatic cord tension (those testes remained in the scrotum after manipulation, showing no retraction to the inguinal region). True undescended testes were defined as testes that were non-palpable or palpable in the lower or upper inguinal canal, or those that could be manipulated into the upper scrotum with spermatic cord tension. Boys with indeterminate findings underwent repeat examination to distinguish retractile testes from true undescended testis.

Demographic information, including age, PCP referral diagnosis, ultrasound reports obtained prior to referral describing the presence of unilateral or bilateral undescended testis, and physical examination by a pediatric urologist, was defined a priori as important data to be collected. Data were analyzed using Research Electronic Data Capture (REDCap) software. Intraclass correlation coefficient (ICC) was used to measure agreement between ultrasound and pediatric urologists' examination and between PCP and the pediatric urologists' diagnosis. We calculated sensitivity (Sn), specificity (Sp), positive (PPV) and negative predictive values (NPV), and positive (LR+) and negative likelihood ratios (LR-) of ultrasound to diagnose undescended testis.

#### Results

Between March 2011 and October 2013, 339 boys referred with a diagnosis of undescended testis were prospectively entered into our database, with 87 boys having bilateral undescended testis. Patients without an ultrasound (n = 132) and those with non-palpable testes (n = 38) were excluded, leaving 169 boys that comprise our study cohort. Ultrasound was performed in 50% of referred boys identifying 256 testes as undescended. Age at time of referral was 45 ± 3.3 months, with only 21% of boys being referred within 12 months of age (Fig. 1). The ultrasonic finding of undescended testis was confirmed by pediatric urology examination in only 34% of boys (Cronbach's  $\alpha$  = 3.55, ICC = 0.10 (95% confidence interval [CI] -0.05–0.26).

The performance of ultrasound as a diagnostic test for undescended testis was: Sn = 100% (95% Cl 95%–100%); Sp = 16% (95% Cl 11%-22%), PPV = 34% (95% Cl 28%–41%); NPV = 100% (95% Cl 88%–100%), LR+ = 1.2 (95% Cl 1.1–1.3), and LR- = 0.7 (95% Cl 0.3–1.9) (Table 1). Diagnosis of undescended testis by PCP was confirmed by pediatric urology examination in only 30% of cases, with 70% being re-diagnosed as normal or retractile testes (Cronbach's  $\alpha$  = 0, ICC = 0 [95% Cl -0.12–0.12]).



*Fig. 1.* Age of boys referred with a diagnosis of palpable undescended tests and ultrasound prior to referral. Median age was 26 months and mean age group was 46.1 +/- 43.2 months. Optimal age of surgical management is between 6 and 12 months.

Physical examination				
		+	-	
Ultrasound	+	78 (TP)	150 (FP)	PPV = 34%
	-	0 (FN)	28 (TN)	NPV = 100%
		Sn = 100%	Sp = 16%	

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### Discussion

Although diagnosis of undescended testis is established through physical examination by an experienced specialist, initial assessment and referral lies in the hands of PCP. In our study, ultrasound was performed in 50% of boys with a referral diagnosis of undescended testis and it was shown to perform poorly to diagnose palpable undescended testis with low specificity and low agreement with pediatric urologists' physical examination. Of all the referrals in our study, only 43% were true undescended testis with the remaining 57% shown to be retractile or normal testes by the pediatric urologists' assessment. Furthermore, an ultrasound showing undescended testis slightly increased the probability of a boy having true undescended testis from 30% to only 34%.

Retractile testes may be even more difficult to differentiate from undescended testis with the use of ultrasound due to factors, such as the cold gel temperature, pressure of the ultrasound probe pushing the testes towards the inguinal region, and concurrent stimulation of the cremasteric muscle. The routine use of ultrasound may increase anxiety and confusion in boys and their families. Even worse, the misuse of ultrasound may cause a delay in optimal surgical care and adds to the financial burden to the Canadian healthcare system.<sup>7</sup> In a 2-year Canadian study, 46% of referred patients had at least 1 ultrasound prior to a specialist visit, with cost estimates demonstrating that \$28 779 CAD was misspent over this time period.<sup>7</sup>

A 10-year population-based study demonstrated the widespread overuse of ultrasound for undescended testis, leading to a delay from diagnosis to referral to a surgical specialist.<sup>8</sup> In that study, the mean time from diagnosis to specialist evaluation was 5 months in boys who underwent a pre-referral ultrasound compared to 2 months in boys who did not. In our series, the median age of the boys at the time of referral was 45 months, with 73% of boys referred well beyond the recommended age of <12 months for appropriate surgical management.<sup>9,10</sup> The overuse of ultrasound also adds to the burden on the Canadian healthcare system.

A large retrospective study was undertaken by Kanaroglou and colleagues with boys with undescended testis in Ontario, Canada. The authors found that 33.5% had at least 1 previous ultrasound and these children with pre-referral ultrasound had an approximate 3-month delay in definitive surgical management.<sup>11</sup> Over a 10-year period, the use of pre-referral ultrasound was increasing over time and was estimated to cost about \$270 000 CAD. In the setting of a healthcare system with limited resources, the misuse of ultrasound diverts the use of equipment and time from ultrasound technologists away from the management of conditions for which it is actually indicated. Further, ultrasound was only able to correctly predict physical exam findings in only 54% of boys, similarly to a flip of a coin.

A prospective study of 118 boys analyzing the referral patterns of undescended testis showed that ultrasound had been performed for 25% of boys and it incorrectly indicated undescended testis for 48% of boys.<sup>12</sup> Further, only about 50% of boys had undescended testis, with most errors in diagnosis made in boys between 1 to 10 years old, suggesting a difficulty in distinguishing true undescended testis from retractile testes.

To quantify PCP knowledge of undescended testis in the United States, Shnorhavorian and colleagues used a webbased survey and reported that 53% of PCP had minimal to no exposure to urology during training, 66% referred patients with retractile testes to surgical specialists, and nearly 20% delay until puberty to refer patients with undescended testis.<sup>13</sup> Most referrals for undescended testis were either from family practitioners (37%) or pediatricians (42%), with no difference in ultrasound ordering practices.<sup>8</sup> This highlights the need for increased evidence-based recommendations along with improved training and education for PCP in dealing with disorders of testicular descent.

Our study has its limitations. In particular, we were unable to include boys in whom ultrasound had correctly located the testes in the scrotal sac and thus were never referred to begin with. Further, the observed delayed referral of some of these boys could be due to the process of ascending testes, instead of an actual delay in the referral and management of undescended testis. Finally, the testis of some boys who may have initially had undescended testis at the time of examination by PCP or ultrasound may have descended by the time of the pediatric urology assessment, leading to the demonstrated disagreement.

There are, however, clinical scenarios, such as undescended testis associated with ambiguous genitalia, intersexuality or hypospadias, where ultrasound should be used to evaluate Müllerian structures.<sup>14</sup> Regardless, boys with suspected undescended testis should be evaluated by physical examination and referred to a surgical specialist promptly between the ages of 6 to 12 months for optimal surgical management.

#### Conclusion

In this prospective study, ultrasound performed poorly as a diagnostic tool in detecting palpable undescended testis in

young boys, with a specificity of only 16%. It should not be routinely used as it may delay optimal surgical management and adds to the financial burden to the healthcare system. Agreement between PCP and pediatric urologists in the diagnosis of palpable undescended testis was only 30%, prompting for an increasing need for education, as well as evidence-based guidelines directed towards PCP for the management of boys with suspected undescended testis.

Competing interests: The authors declare no competing financial or personal interests.

This paper has been peer-reviewed.

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Correspondence: Dr. Luis H. Braga, McMaster Children's Hospital (McMaster University), 1200 Main St. West HSC 4E19, Hamilton, ON L8N 3Z5; braga@mcmaster.ca