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## **Prevalence, repairs and complications of hypospadias: an Australian population-based study**

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**Key words:** Hypospadias, prevalence, surgical repair, complications

## **ABSTRACT**

**Objective:** To investigate hypospadias prevalence and trends, rate of surgical repairs and post-repair complications in an Australian population.

**Methods:** Hypospadias cases were identified from all live born infants in New South Wales, Australia, 2001-2010 using routinely collected birth and hospital data. Prevalence, trends, surgical procedures or repairs, hospital admissions and complications following surgery were evaluated. Risk factors for re-operation and complications were assessed using multivariate logistic regression.

**Results:** There were 3,186 boys with hypospadias in 2001-2010. Overall prevalence was 35.1 per 10,000 livebirths and remained constant during the study period. Proportions of anterior, middle, proximal and unspecified hypospadias were 41.3%, 26.2%, 5.8% and 26.6%, respectively. Surgical procedures were performed in 1,945 (61%) boys, with 1,718 primary repairs. The overall post-surgery complication rate involving fistulas or strictures was 13%, but higher (33%) for proximal cases. Complications occurred after one year post-repair in 52.3% of cases and up to five years. Boys with proximal or middle hypospadias were at increased risk of re-operation or complications, but age at primary repair did not affect the outcome.

**Conclusions:** One in 285 infants were affected with hypospadias, 60% required surgical repair or correction and one in eight experienced complications. The frequency of late complications would suggest that clinical review should be maintained for more than one year post-repair.

## INTRODUCTION

Hypospadias represents a urogenital congenital anomaly amongst boys characterized by an abnormal ventral opening of the urethral meatus between the distal glans of the penis and perineum. It remains one of the most common anomalies in boys. Population-based studies have reported large variation in prevalence among different regions, from 4 cases per 10,000 births in Japan[1] to 74 per 10,000 in the USA.[2] Prevalence rates may not be comparable due to differences in population, environment, settings and surveillance systems with local monitoring therefore desirable.[3] There has been debate about prevalence trends over the past decade, with some countries reporting annual increases,[4] while others have reported stable rates.[5]

The main form of treatment for hypospadias has been surgical repair, aiming not only to correct the functionality of the penile urethra but also to improve cosmetic appearance. The age at repair, severity of hypospadias, complexity of the repair techniques, surgeon expertise and the variable wound healing capacity of the penile tissue appear to be important factors determining the outcome of repair.[6] International guidelines recommend repair between 6 and 18 months of age,[7] however, some studies have found no difference in outcomes based on the age at the time of repair,[8] whilst others have reported fewer complications following repairs performed before one year.[9] Depending on the severity and technique, re-operation rates can range from 4% to 35%,[10] and one study found an average of five additional procedures required to achieve satisfactory results after a failed repair.[11] Recent systematic reviews have reported overall complications rates ranging from 14% to 16%[12] and up to 37% for severe cases.[13] However, most were small single centre studies, with limited follow-up duration and did not report loss to follow-up. Surgeon perceptions and reporting of complication rates may also

differ,[14] and there would seem conflicting information about the timeframe of occurrence of complications to determine an ideal follow-up period.[15] A recent survey of surgeons reported that nearly 60% follow-up their patients for less than 6 months,[16] yet studies suggest that nearly half of complications may only be diagnosed after the first year following surgery.[17] Current information on population-based hypospadias prevalence, trends, rates of surgical repairs and follow-up of health outcomes appear highly important for optimal clinical decision making treatment, management and pre-operative counselling of parents.

The aims of this population-based study were to investigate the prevalence, trends, surgical repairs and post-surgical complications of hypospadias and to examine risk factors associated with re-operation and post surgical complications.

## **METHODS**

### **Study population and data sources**

The study population included all live born males diagnosed with hypospadias in New South Wales (NSW), Australia between January 2001 and December 2010. The infant's birth and hospital information were obtained from the Perinatal Data Collection (PDC) and the Admitted Patient Data Collection (APDC). The PDC is a statutory surveillance system that covers all livebirths and stillbirths in NSW. The APDC represents a census of all in-patient hospital admissions from NSW public and private hospitals. All diagnosis and procedures for each admission were coded according to the International Classification of Diseases, Australian Modification (ICD-10-AM) and the Australian Classification of Health Interventions (ACHI),

respectively. Coding was performed by professional clinical coders utilizing coding software. Longitudinal linkage of individual records provided health information from birth and any subsequent infant hospital admissions record available until June 2012, with a minimum of 1.5 years follow up for all cases. The NSW Centre for Health Record Linkage conducted linkage of data sets, independent of the research. Ethics approval was obtained from the NSW Population and Health Services Research Ethics Committee.

Hypospadias cases were identified from the APDC using the ICD-10-AM code Q54 (Appendix). To facilitate the generalization of our results, we used the classification by Duckett,1996 to categorize the ICD-10-AM coded hypospadias types into four groups:[18] 1) anterior: which included balanic hypospadias; 2) middle: penile hypospadias, 3) proximal: penoscrotal and perineal hypospadias and 4) unspecified: which included other and unspecified hypospadias. Isolated hypospadias was identified if no other congenital anomaly was recorded at birth or in any subsequent hospital admissions. For those diagnosed with other anomalies, boys with chordee, undescended testis and other genitourinary anomalies were differentiated from all other anomalies.

### **Outcomes and explanatory variables**

The main study outcomes included type of hypospadias repairs or procedures, re-operations or complications after surgical repair and re-admissions. Relevant hypospadias repairs or procedures identified using ACHI codes were divided into primary hypospadias repairs, secondary repairs and associated procedures. Post-surgical complications were defined as conditions affecting the urethra or penis that required surgical intervention and were identified

with relevant diagnosis codes (Appendix). Re-operations were defined as any subsequent procedures including hypospadias repairs (excluding planned second stage repairs), repair of complications and other secondary repairs. Re-admissions to hospital following repair were classified as any re-admissions associated with surgical wound complication within 28 days and any genitourinary related admissions post 28 days (ICD-10-AM: N00 –N99).

Explanatory variables included in the study were diagnosis of coexistent congenital anomalies, preterm birth (<37 weeks gestation), age at first hypospadias record, age at first surgical procedure or repair, hospital volume of repairs, public or private health care insurance status and time to occurrence of complications after repair. Age at first surgical procedure or repair was categorized into less than and more than 18 months of age based on international recommendations.[7] Hospital type was included as a proxy for patient case-mix and was categorized into tertiary pediatric hospitals (n=3) versus non pediatric hospitals (n=42).

### **Statistical analysis**

Prevalence of overall hypospadias was examined as total number of reported cases per 10,000 live births in NSW, 2000-2010. Annual prevalence was plotted and trend assessed between 2001-2009 to ensure a minimum follow-up of 2.5 years. Poisson regression analysis was used to calculate the average annual percentage change in rate over time. All bivariate analyses were conducted using chi square test, with multivariable logistic regression used to estimate the association between type of hypospadias with re-operation and post-surgical complications. All analyses were performed using SAS, 9.3 (SAS Institute, Cary, NC, USA).

## RESULTS

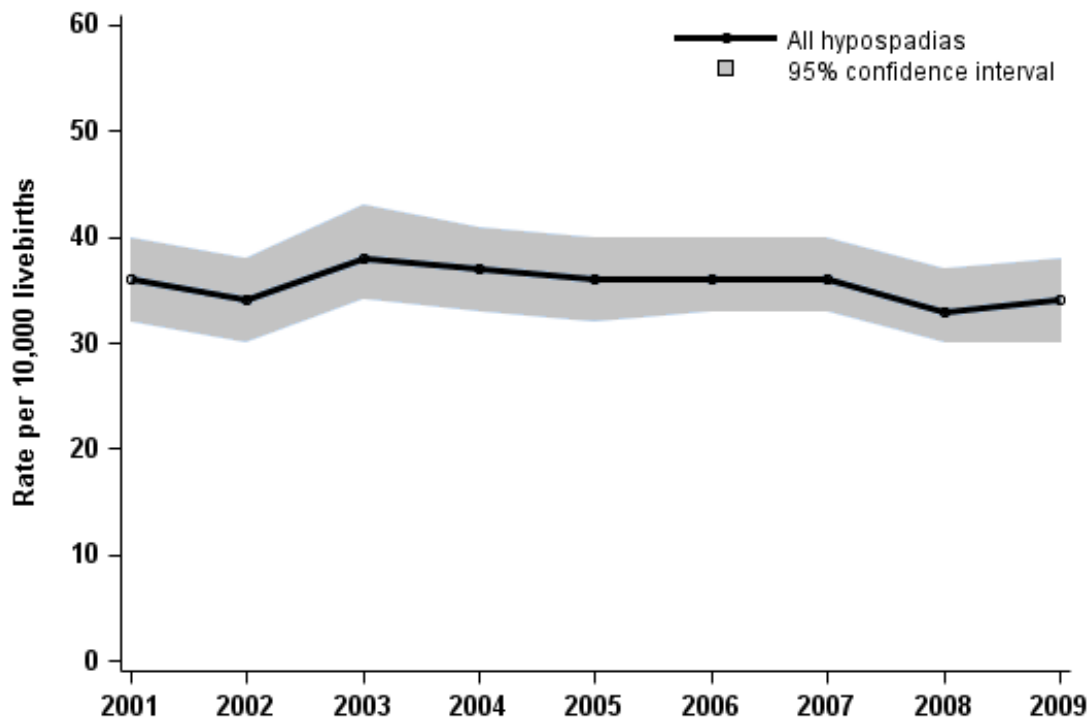
A total of 906,753 infants were born in NSW between 2001 and 2010. There were 3,186 hypospadias cases recorded during the study period, representing an overall prevalence of 35.1 cases per 10,000 live births (95% confidence interval, CI: 33.9-36.4). **Table 1** presents the characteristics of cases by type of hypospadias. Anterior hypospadias was the most common type comprising 41.3% of cases, 26.2% were middle, 5.8% were proximal and 26.6% were unspecified hypospadias. Isolated hypospadias represented 60.2% of total cases, 18.2% had chordee, 3.5% had undescended testis and 12.6% had other non-genitourinary congenital anomalies. **Figure 1** illustrates the annual trend in hypospadias with the total prevalence remaining constant between 2001-2009 (average annual change -0.8%; 95% CI: -2.2% to 0.6%;  $P=0.3$ ). There were 2,600 (81.6%) boys with hypospadias recorded at birth, with the remainder diagnosed in out-patient visits after birth but mostly recorded in our data at the time of surgery at a median of 12 months of age (interquartile range, IQR: 7.2-16.8). Compared with boys diagnosed at birth, those recorded after birth had higher rates of chordee (17.8% vs 3.2%,  $P<0.001$ ) and undescended testis (4.5% vs 2.6%;  $P=0.02$ ) recorded at birth.

**Table 1:** Characteristics of cases by type of hypospadias, NSW, 2001 - 2010

	<b>Anterior</b> n=1,316 (41.3%)	<b>Middle</b> n=836 (26.2%)	<b>Proximal</b> n=185 (5.8%)	<b>Unspecified</b> n=849 (26.6%)	<b>Total</b> n=3,186
	n(%)	n(%)	n(%)	n(%)	n(%)
<b>Isolated hypospadias</b>	768 (58.4)	495 (59.2)	44 (23.8)	611 (72.0)	1,918 (60.2)
<b>Coexistent with<sup>a</sup></b>					
Chordee	292 (22.2)	155 (18.5)	75 (40.5)	58 (6.8)	580 (18.2)
Undescended testis <sup>b</sup>	43 (3.3)	22 (2.6)	25 (13.5)	20 (2.4)	110 (3.5)
Other genitourinary anomalies	106 (8.1)	79 (9.4)	53 (28.6)	37 (4.4)	275 (8.6)
Congenital anomalies of other organs <sup>c</sup>	140 (10.6)	103 (12.3)	69 (37.3)	90 (10.6)	402 (12.6)
<b>Preterm birth (&lt;37 weeks)</b>	200 (15.2)	119 (14.2)	70 (37.8)	143 (16.8)	532 (16.7)
<b>Time of first record</b>					
At birth	970 (73.7)	696 (83.3)	163 (88.1)	771 (90.8)	2,600 (81.6)
Post birth <sup>d</sup>	346 (26.3)	140 (16.7)	22 (11.9)	78 (9.2)	586 (18.4)
Median (IQR) age at later record in months	12.7 (9.2 - 18.6)	12.7 (8.0 - 17.1)	10.0 (4.0 - 15.3)	7.3 (5.6 - 13.3)	12.1 (7.8 - 17.7)
<b>Deaths</b>	9 (0.7)	-	-	18 (2.1)	36 (1.1)

<sup>a</sup> Not mutually exclusive; IQR: Interquartile range; <sup>b</sup> Treated only; <sup>c</sup> Excluding minor congenital anomalies i.e. tongue-tie, naevus, skin tags, unstable hip and feet defects; <sup>d</sup> Mostly recorded in our data at the time of surgery  
 - Numbers <5 not presented

**Figure 1:** Trends of hypospadias cases by year of birth





**Table 2:** Characteristics of boys undergoing hypospadias surgical repair in NSW, 2001 - 2012

	<b>Anterior (n=1,316)</b>	<b>Middle (n=836)</b>	<b>Proximal (n=185)</b>	<b>Unspecified (n=849)</b>	<b>Total (n=3,186)</b>
	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Number of boys with hypospadias procedures or repairs<sup>a</sup></b>	1,031 (78.3)	611 (73.1)	168 (91.0)	135 (15.9)	1,945 (61.0)
<b>Age at first procedure or repair</b>					
<12 months	443 (43.0)	275 (45.0)	55 (32.7)	68 (50.4)	841 (43.4)
12 – 24 months	454 (44.0)	276 (45.2)	94 (56.0)	52 (38.5)	876 (45.0)
24+ months	134 (13.0)	60 (9.8)	19 (11.3)	15 (11.1)	228 (11.7)
<b>Hypospadias repair<sup>b</sup></b>					
Any primary repair	874 (66.4)	557 (66.6)	168 (91.0)	119 (14.0)	1,718 (53.9)
Meatotomy and hemircumcision	191 (18.5)	91 (14.9)	5 (3.0)	9 (6.7)	296 (15.2)
Glanuloplasty	99 (9.6)	58 (9.5)	11 (6.5)	47 (34.8)	215 (11.1)
Urethroplasty	61 (5.9)	93 (15.2)	49 (29.2)	65 (48.1)	268 (13.8)
Distal hypospadias, single stage repair	549 (53.2)	312 (51.1)	0	0	861 (44.3)
Proximal hypospadias, single stage repair	0	52 (8.5)	95 (56.5)	0	147 (7.6)
Staged repair: 1st stage	29 (2.8)	48 (7.9)	44 (26.2)	25 (18.5)	146 (7.5)
Staged repair: 2nd stage	12 (1.2)	35 (5.7)	49 (29.2)	8 (5.9)	104 (5.3)
Secondary surgical procedures	206 (20.0)	168 (27.5)	80 (47.6)	58 (43.0)	512 (26.3)
<b>Associated procedures</b>					
Examination with erection test	260 (25.2)	151 (24.7)	39 (23.2)	10 (7.4)	460 (23.7)
Circumcision	159 (15.4)	61 (10.0)	5 (3.0)	11 (8.1)	236 (12.1)
Correction of chordee	235 (22.8)	126 (20.6)	61 (36.3)	16 (11.9)	438 (22.5)
<b>N of boys admitted for repairs or procedures<sup>c</sup></b>					
No admission	285	225	17	714	1,241
1 admission	948 (91.9)	485 (79.4)	99 (58.9)	118 (87.4)	1,650 (84.8)
2 admissions	78 (7.6)	119 (19.5)	54 (32.1)	13 (9.6)	264 (13.6)
3+ admissions	5 (0.5)	7 (1.1)	15 (8.1)	4 (3.0)	31 (1.6)
<b>Median (IQR) time between repairs in months</b>	10.1 (7.0 - 17.1)	9.2 (6.0 – 15.6)	7.9 (6.0 – 11.9)	6.4 (3.4 – 9.2)	9.0 (6.2 – 15.4)
<b>Re-admissions within 28 days after repair</b>	52 (5.0)	28 (4.6)	20 (11.9)	4 (3.0)	104 (5.3)
<b>N of boys with hospital re-admissions with a genitourinary diagnosis after repair</b>	121 (11.7)	108 (17.7)	69 (41.1)	18 (13.3)	316 (16.2)

<sup>a</sup> Proportion of all boys diagnosed with hypospadias; <sup>b</sup> Not mutually exclusive as some boys may have more than one repair;

<sup>c</sup> One or more repairs or procedures per admission; IQR: interquartile range

Overall, 1,945 (61.0%) boys had a surgical procedure or repair, the majority (n=1,718, 88%) having primary hypospadias repair. The median age (IQR) at repair was 12.7 (9.6-17.3)

months and the maximum was 72 months, but boys born premature (n=270) had repairs later at a median of 13.9 months (IQR: 10.4-19.6). Of the boys who had a repair, 84.8% required only one, while additional repairs or procedures were performed in 8.1%, 20.6%, 40.2% and 12.6% of boys with anterior, middle, proximal and unspecified hypospadias, respectively. The total proportion of boys admitted within 28 days post repair was 5.3% but almost 12% for proximal hypospadias.

Overall, 316 (16.2%) of boys were readmitted to hospital for genitourinary conditions following repair with increasing rates for more severe cases (**Table 2**).

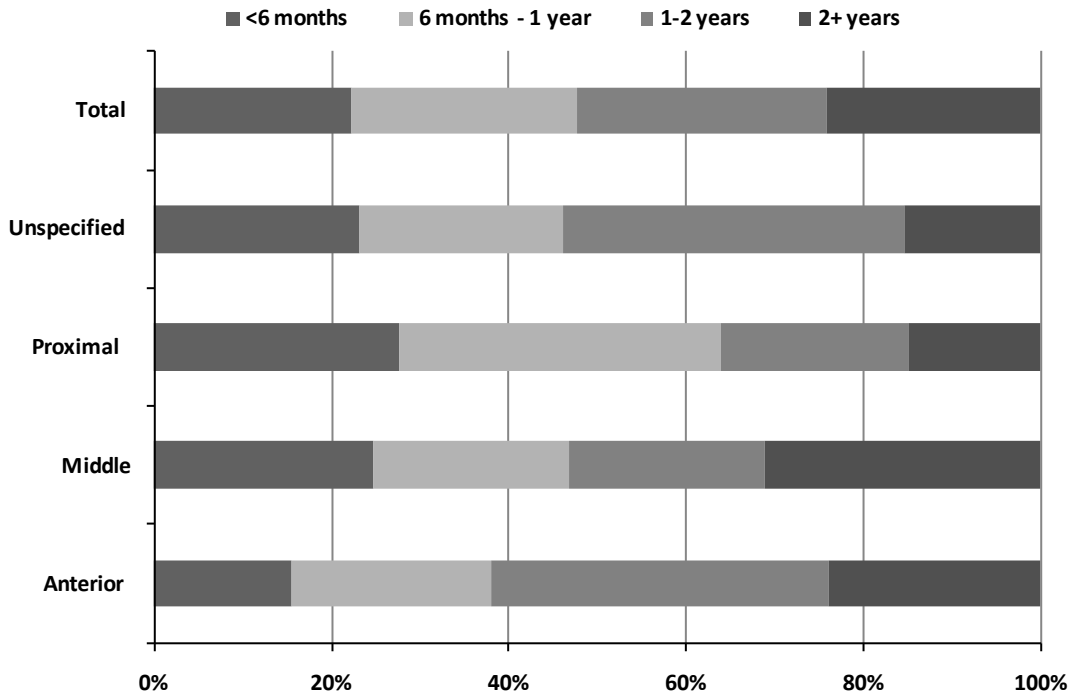
Of the boys with primary hypospadias repair, 13.7% (n=236/1,718) presented with post-surgical complications, including 9.4% and 33.3% for distal and proximal cases, respectively. Complications included urethral fistula (n=189, 11%), meatal stenosis or urethral stricture (n=137, 8.0%), urethral diverticulum (n=21, 1.2%) and other urethral complications such as infections (n=8, 0.4%). Complications rates differed by type of repair ranging from 3.6% for meatotomy/ hemi-circumcision to 13.7% for distal hypospadias single stage repair and a high of 24.8% and 28.7% for proximal hypospadias single stage and two stage repairs. Half (52.3%) of first complications occurred after one year following repair and up to 61 months; although two thirds occurred within one year of repair for boys with proximal hypospadias (**Figure 2**).

Diverticulum was more likely to occur before one year than after one year (10% vs. 1.8%;  $P=0.01$ ), but there was no difference in timing for the rest of complications ( $P=0.9$ ).

Complications and subsequent repairs were associated with increasing severity of hypospadias; however age at repair, hospital volume, associated congenital anomalies and year of surgery had

no significant effect (**Table 3**); while private health insured patients were less likely to have re-operations (P=0.04).

**Figure 2:** Timing of first complication following primary hypospadias repair



**Table 3:** Association between risk factors with re-operation and post surgical complications

	<b>n</b>	<b>Re-operation</b>	<b>Complications only</b>
		Adjusted OR [95% CI] <sup>a</sup>	Adjusted OR [95% CI] <sup>a</sup>
<b>Type of hypospadias</b>			
Anterior	857	1.0 [Reference]	1.0 [Reference]
Middle	553	1.88 [1.41, 2.52]	1.59 [1.14, 2.22]
Proximal	168	4.26 [2.86, 6.35]	5.05 [3.32, 7.68]
Unspecified	140	0.93 [0.51, 1.69]	1.14 [0.61, 2.13]
<b>Age at primary surgery</b>			
0 – 18 months	1,341	1.0 [Reference]	1.0 [Reference]
18+ months	377	0.83 [0.60, 1.14]	0.81 [0.56, 1.16]
<b>Hospital type</b>			
Tertiary pediatric	1,177	1.0 [Reference]	1.0 [Reference]
Non pediatric	541	0.90 [0.67, 1.20]	0.89 [0.64, 1.23]
<b>Health care insurance status</b>			
Public	889	1.0 [Reference]	1.0 [Reference]
Private	829	0.75 [0.57, 0.98]	0.82 [0.61, 1.10]
<b>Hypospadias coexistent with other congenital anomalies</b>			
No	1,309	1.0 [Reference]	1.0 [Reference]
Yes	409	1.33 [0.98, 1.79]	1.07 [0.76, 1.50]
<b>Year of repair</b>			
		0.98 [0.93, 1.03]	0.96 [0.91, 1.02]

<sup>a</sup>Adjusted for: type of hypospadias, age at primary repair, hospital volume, health care insurance status,

presence of other congenital anomalies and year of repair; OR: odds ratio; CI: Confidence interval

Of the 1,241 (39.0%) boys with hypospadias who did not undergo surgical repairs or procedures during the study period, the majority were unspecified (57.5%), followed by anterior (23.0%), middle (18.1%) and proximal hypospadias (1.4%). Of the boys without repair, half (638) had no recorded hospital admission after birth; a lower proportion had coexistent congenital anomalies (n=314; 25.3%) and only a small proportion (n=68) had related hospital admissions.

## DISCUSSION

This research represents one of the few population-based cohort studies of the management and treatment of hypospadias with long term follow-up of health outcomes. Our results indicate that hypospadias was diagnosed among 1 in 146 boys and that the overall prevalence remained constant in NSW over the past decade. We found that almost two-thirds of boys diagnosed with hypospadias had primary repair. Of those who had repair, 13% experienced a complication, although this rose to 33% for proximal cases with middle and proximal cases having a three to five-fold increased risk of re-operation or complication. Half of all complications occurred after one year following repair, however age at repair was not associated with re-operation or complication.

The prevalence of hypospadias in our study was comparable with contemporary reports from Western Australia.[19] It was double or more compared with Japan[1] or Denmark[20] and remains lower compared with the USA.[21] More recently, no significant change was reported by Pan-Europe Monitoring (EUROCAT) in 2001-2010,[22] while an apparent decreasing trend has been reported for many countries including Australia, New Zealand, USA, Iran, UK and Mexico.[5] An overarching explanation for changes in hypospadias trends remains elusive. Hypospadias may increase from maternal exposure to environmental endocrine-disrupting substances; however, their overall effect on hypospadias development remains uncertain.[23] Increasing trends may also be the result of the inclusion of more mild cases by registries or improved recognition and documentation of cases referred for repair.[3] Basic recognition and recording of diagnosis may have been a key element in our study with nearly forty percent of

boys diagnosed at birth having no subsequent record of hospital admission for any related treatment or procedure. On further analysis, the majority of these cases (80%) were initially diagnosed as anterior or unspecified which suggests these were predominately very mild and/or resolved and did not require any further treatment or intervention. Although, we cannot exclude that in some cases surgical repair was performed outside the scope of the study or that some boys may have moved out-of-state for treatment. However, the later was potentially minimal as there was only a 2% out-of-state migration rate reported at the time of the study.[24]

Our complication rates for proximal hypospadias repair ranged from 25% to 29% and between 4% and 14% for distal repairs. Re-operation rates ranged from 32% and 34%; and between 8% and 16% for proximal and distal hypospadias repairs, respectively. Two other recent large multicenter studies have reported complication and re-operation rates following primary hypospadias repair. One found complications in 26.2% of 1,679 boys who underwent proximal hypospadias repair[25] and the other found second surgery rates ranging between 4.1% and 9.4% for distal hypospadias repair and between 32.2% and 34.5% for proximal hypospadias repair in 5,326 boys.[10] However, one study included only patients treated at pediatric hospitals[25] and in the other the median follow-up time of patients after repair was 25 months,[10] whilst ours was 60 months.

Current international guidelines recommend that hypospadias repairs should be performed between 6 and 18 months for best possible outcomes.[7] We found that repairs performed after 18 months of age were not associated with increased complications or a greater risk of additional

surgery. Another population based-study reported that age at primary repair does not influence secondary surgery rates overall, but older age at repair was associated with an increased rates of meatotomy or urethral dilation for strictures: this effect may be due to the proximity of toilet training in older patients and therefore voiding problems were detected sooner.[10] A systematic review identified fewer complication rates in studies from the USA, where repairs were performed earlier, compared with Europe and China. These studies were small (involving <150 patients) and differences in complication rates may also be explained by the disparity in surgery and training practices among countries.[12] Nevertheless, early repairs remain recommended as perioperative management of urinary drainage and analgesia would generally be easier for both surgeon and parents in younger boys. In addition, subsequent toilet training may be more challenging in boys with severe hypospadias, whilst late repair may be associated with adverse psychosexual outcomes in later life.[26] We also found that privately insured patients were less likely to have re-operations which may be associated with accessibility to more experienced surgeons, [10] however, results are borderline and may be due to chance.

Our findings of over half of complications occurring after one year and up to five years following repair highlights that long-term follow-up is essential for early detection and treatment of complications, although this needs to be balanced against the potential adverse psychological impact of unnecessarily prolonged review of the boys external genitalia in the absence of any symptoms.[17] Currently, some recommend short follow-up period after surgery, however, this hypothesis has been supported by results from short follow-up periods that may be insufficient to detect all complications.[27]

The main strength of the study was the use of a large population-based cohort of boys with surgeries performed across 42 hospitals that allowed multi-center assessment with up to 6 years follow-up. The health datasets used have been recognized to be accurate and reliable according to validation studies reporting high levels of agreement with medical records.[28] One of the limitations of the study was that a quarter of cases were recorded as unspecified hypospadias, and we were unable to identify the type. Despite this lack of information, only a small proportion required repair or procedure suggesting that the majority of these were mild anterior cases. Furthermore, for those undergoing repair, results did not change when we excluded these cases in the evaluation of risk factors for complications. This limitation may be explained to some degree by the inability of some health care providers to confidently determine the position of the urethral meatus or by incomplete reporting of the position of the urethra to allow accurate recording of the type of hypospadias.

In conclusion, between 2001 and 2011, one in 285 boys was affected with hypospadias in NSW, Australia and the prevalence was constant overtime. Over sixty percent of cases had surgical repair. The risk of complications after repair was generally low, although they occurred in one third of proximal cases. Age at repair was not a risk factor for complications and a large proportion were found after one or more years following primary repair. Therefore, a long-term follow-up protocol would seem appropriate for proper supervision of these patients and to ensure optimal male reproductive and urinary health.



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**Conflict of Interest:** The authors have no conflict of interest to report.

### **Contributors' Statement:**

Drs Schneuer and Nassar conceptualized and designed the study, conducted the statistical analysis, drafted the initial manuscript, and approved the final manuscript as submitted.

Dr Holland provided clinical advice, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Drs Pereira and Bower provided statistical advice, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

**What is already known on this topic**

Recent reports on hypospadias trends have been inconsistent and surgical repair rates and outcomes come from single-centre small studies with short follow-up.

There is a lack of population-based information about repair rates, risk assessment and timing of complications following repair

**What this study adds**

Hypospadias trend have been stable in the past decade.

Two thirds require surgical repair or correction and one in eight experience complications; which occur mostly after one year following repair.

Age at repair does not impact surgical outcomes

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