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# Natural history and consequence of patent processus vaginalis: An interim analysis from a multi-institutional prospective observational study

Jason D. Fraser<sup>a,\*</sup>, Yara K. Duran<sup>a</sup>, Katherine J. Deans<sup>b</sup>, Cynthia D. Downard<sup>c</sup>, Mary E. Fallat<sup>c</sup>, Samir K. Gadepalli<sup>d</sup>, Ronald B. Hirschl<sup>d</sup>, Dave R. Lal<sup>e</sup>, Matthew P. Landman<sup>f</sup>, Charles M. Leys<sup>g</sup>, Grace Z. Mak<sup>h</sup>, Troy A. Markel<sup>f</sup>, Peter C. Minneci<sup>b</sup>, Thomas T. Sato<sup>e</sup>, Shawn D. St. Peter<sup>a</sup>, on behalf of the Midwest Pediatric Surgery Consortium

<sup>a</sup> Department of Surgery, Children's Mercy Kansas City, 2401 Gillham Road, Kansas City, MO 64108, United States

<sup>b</sup> Center for Surgical Outcomes Research, The Abigail Wexner Research Institute and Department of Surgery, at Nationwide Children's Hospital, Department of Surgery, The Ohio State University College of Medicine, Columbus, OH, United States

<sup>c</sup> Division of Pediatric Surgery, Hiram C. Polk, Jr., M.D. Department of Surgery, University of Louisville, Louisville, KY, United States

<sup>d</sup> Section of Pediatric Surgery, Department of Surgery, University of Michigan, Ann Arbor, MI, United States

<sup>e</sup> Division of Pediatric Surgery, Department of Surgery, Medical College of Wisconsin, Milwaukee, WI, United States

<sup>f</sup> Division of Pediatric Surgery, Department of Surgery, Indiana University School of Medicine, Indianapolis, IN, United States

<sup>g</sup> Division of Pediatric Surgery, Department of Surgery, University of Wisconsin School of Medicine and Public Health, Madison, WI, United States

<sup>h</sup> Section of Pediatric Surgery, Department of Surgery, The University of Chicago Medicine, Chicago, IL, United States

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## ABSTRACT

**Background:** The prevalence and natural history of patent processus vaginalis (PPV) are unknown. An interim analysis was performed of a multi-institutional, prospective, observational study in neonates undergoing laparoscopic pyloromyotomy during which bilateral inguinal canals were evaluated.

**Methods:** Infants under 4 months undergoing laparoscopic pyloromyotomy were enrolled at 8 children's hospitals. The presence of a PPV was evaluated and measurements recorded. Patients with a PPV were undergoing annual phone follow-up to 18 years of age. Interim analysis was performed.

**Results:** In a cohort of 610 patient, 80 did not have a PPV examined, 4 had consent issues and were excluded, leaving 526 patients. Of these, 433 (82%) were male, median age 1.2 months (IQR 0.9, 1.6), median weight 3.89 kg (IQR 3.4, 4.46), and EGA 39 weeks (IQR 37, 40). There were 283 PPVs, 132 bilateral (47%), 116 right (41%), and 35 left (12%). Patients with a PPV were significantly younger (1.1 months (IQR 0.9, 1.5) vs 1.3 months (IQR 0.9, 1.7),  $p=0.02$ ), weighed less (3.76kg (IQR 3.35, 4.26) vs 3.9kg (IQR 3.4, 4.5)  $p=0.03$ ) and had a significantly lower EGA at birth (38 weeks (IQR 37, 40) vs 39 weeks (IQR 38, 40)  $p=0.003$ ). Of 246 eligible infants, 208 (85%) responded to at least one annual follow-up. Two patients had an inguinal hernia repair for a symptomatic hernia, 49- and 51-days post pyloromyotomy. One had an orchiopexy and incidental inguinal hernia repair 120 days post pyloromyotomy; for a total of 3 (1.2%) hernia repairs. No additional hernias were identified in 116 patients with the PPV patients who have been followed for > 1 year.

**Conclusions:** The presence of a PPV at the time of pyloromyotomy is common but the need for hernia repair is rare within the first year of life. Continued long-term longitudinal follow-up of this cohort is needed.

**Level of Evidence:** II

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## 1. Introduction

The lifetime risk of developing an inguinal hernia makes it one of the most common surgical conditions occurring in an estimated

27% of males and 3% of females [1–2]. The underlying anatomy leading to an indirect inguinal hernia is a patent processus vaginalis (PPV), which is the peritoneal reflection that precedes descent of the testis and is a peritoneal lined passageway along the course of the spermatic cord in males or round ligament in females [3]. The natural history of the processus vaginalis is that it should close after descent of the testis is complete, although the timing of this

\* Corresponding author.

E-mail address: [jdfrazer@cmh.edu](mailto:jdfrazer@cmh.edu) (J.D. Fraser).

is imprecise [4]. If it remains patent, it can be a conduit for fluid that results in a communicating hydrocele if the processus vaginalis communicates with the tunica vaginalis around the testis. If the tunica vaginalis obliterates but the process vaginalis remains patent, the hernia will be incomplete and end in the groin. When the opening into the peritoneal cavity is large, bowel or other structures may enter the canal presenting as a symptomatic hernia [5]. The natural history of a PPV in the absence of a symptomatic hernia is relatively unknown leading to inconclusive recommendations on managing PPVs when found incidentally or when found on the contralateral side during inguinal hernia repair. There is a study from Canada where an individual pediatric surgeon followed 6361 of his patients longitudinally. A contralateral hernia developed in 5%, 95% within the first 5 years, and was not sex or age specific [6]. Additionally, there is evidence that infant PPVs may regress, some suggest up to two years of age, but this rate is unknown [2]; although most scrotal hydroceles due to only a patent tunica vaginalis with a closed processus vaginalis will resolve by one year of age.

Acknowledging that the natural history of the timing of obliteration of the processus vaginalis is indistinct, we launched a multi-center study to follow a large cohort of patients prospectively up to of age 18 years. Our aim was to better understand the frequency and timing of the appearance of an inguinal hernia in a group of infants who had the incidental finding of a PPV at the time of another procedure. To determine need for continued study feasibility and need for continued enrollment, we elected to perform this interim analysis and report on our initial four-years of recruitment and the available follow-up.

## 2. Methods

Following institutional board approval (IRB#16020156), 8 centers from the Midwest Pediatric Surgery Consortium ([www.mwspc.org](http://www.mwspc.org)) participated in this prospective observational study of infants undergoing laparoscopic pyloromyotomy who had their inguinal canals examined for the presence of a PPV (a defect in the peritoneum in the inguinal ring). The time of the operation for PPV evaluation and length of time to examine for PPV presence was not specified. The PPV was recorded by location (right, left, bilateral), size (millimeters as estimated by the measurements from the 3mm pyloric grasper dimensions that was provided to each center at the outset of the study), estimated depth if the bottom of the PPV could be visualized, and if the scrotum/labia insufflated. If no PPV was found, the patient was not included in follow up.

Written consent was obtained from the caregiver of patients with a PPV and they were followed annually, initially via phone calls from the primary institution which then transitioned to phone calls, texts, and emails per parental preference. We also distributed refrigerator magnets to families to remind them to expect future contact.

When the study began, all patients were enrolled preoperatively. However, shortly after study initiation, an IRB amendment was submitted to allow parental consent and patient enrollment postoperatively when a PPV was found. Patients were, and will continue to be, followed yearly up to age 18 to determine the incidence and timing of any subsequent inguinal hernia and/or inguinal hernia repair. The presence or occurrence of a hydrocele was not evaluated in this study.

An interim analysis was completed to assess the need for additional recruitment and for continued study feasibility. Descriptive statistics were utilized and reported as medians with interquartile ranges and percentages. The Mann-Whitney U test was used for comparison of continuous data. A p-value less than 0.05 was considered statistically significant.

**Table 1**

Demographic comparison of infants with and without a PPV found at laparoscopy.

	PPV (+)n=286	PPV (-)n=243	P
Age (months)	1.1 (IQR 0.9, 1.5)	1.3 (IQR 0.9, 1.7)	<b>0.02</b>
Weight (kg)	3.76 (IQR 3.35, 4.26)	3.9 (IQR 3.4, 4.5)	<b>0.03</b>
Sex (male)	250 (88%)	183 (75%)	<b>&lt; 0.001</b>
EGA (weeks)	38 (IQR 37, 40)	39 (IQR 38, 40)	<b>0.003</b>

**Table 2**

Intraoperative PPV measurements.

PPV + Left 167	PPV+ Right 247
Insufflated 24 (14%)	Insufflated 41 (17%)
See bottom 70 (42%)	See bottom 101 (41%)
Depth mm 3mm (2,5)	Depth mm 4mm (2,8)
Width mm 3mm (2,4)	Depth 3mm (2,5)

## 3. Results

### 3.1. Patient Demographics

At the time of interim analysis, 610 patients were enrolled. There were 80 patients who did not have a PPV examined at the time of laparoscopic pyloromyotomy and were excluded, 4 were excluded due to consent issues, leaving 526 patients for analysis. Of these, 433/526 (82%) were male. The median age at laparoscopic pyloromyotomy was 1.2 months (IQR 0.9, 1.6) and the median weight was 3.9 kg (IQR 3.4, 4.5), EGA 39 weeks (IQR 37, 40). There were no hernias noted in these patients pre-pyloromyotomy.

### 3.2. PPV Status

There was a total of 283 PPVs (53.8%), with 132 bilateral (47%), 116 right (41%), and 35 left (12%). Patients with a PPV were significantly younger (1.1 months (IQR 0.9, 1.5) vs 1.3 months (IQR 0.9, 1.7),  $p=0.02$ ) and weighed less (3.76kg (IQR 3.35, 4.26) vs 3.9kg (IQR 3.4, 4.5)  $p=0.03$ ) at the time of laparoscopic pyloromyotomy, were more commonly male (88% vs 75%,  $p < 0.001$ ) and had a significantly lower estimated gestational age (EGA) (38 weeks (IQR 37, 40) vs 39 weeks (IQR 38, 40)  $p=0.003$ ) than those that did not have a PPV found at laparoscopy (Table 1).

There were 414 total PPV dimension measurements (bilateral not separated) recorded and those are included in Table 2. As noted, right-sided PPV is more common, but there is a similar depth of right and left PPV's as determined by ability to visualize the bottom of the PPV.

### 3.3. Follow-up Data

At the time of this interim analysis, there were 246 patients eligible for an annual follow-up survey, meaning they had reached at least one year of study enrollment. Of these, 208 have responded to any follow-up contact, leaving a global follow-up rate of 84.6%. Thus far, 22 patients have reached the 4-year follow-up milestone, 16/22 (73%) responded, with no inguinal hernias reported. At the 3-year follow-up milestone, 36/77 (47%) responded, with no inguinal hernias reported. At the 2-year follow-up milestone, 64/151 (42%) responded, with no inguinal hernias reported. At the 1-year follow-up milestone 130/219 (59%) responded, with 3 inguinal hernias. No additional asymptomatic or symptomatic hernias or hernia repairs were identified in 116 patients with PPV who have been followed for > 1 year. All inguinal hernias discovered were managed operatively. Thus, in 246 PPVs, the overall rate of inguinal hernias found to date was 1.2% (3/246), all of which occurred in the first year.

**Table 3**  
Intraoperative PPV findings in the 3 infants who went on to hernia repair.

Patient	Sex	Right PPV width	Right Scrotal/Labial Insufflation?	Left side PPV width	Left Scrotal/Labial Insufflation?	Symptomatic Presenting Side	Hernia Side Repaired	Days to hernia repair
1	Male	2mm	No	4mm	No	Right side	Bilateral	49
2	Male	10mm	No	10mm	No	Right undescended testicle	Right, + orchiopexy	120
3	Male	3mm	No	N/A	No	Right side	Right	51

### 3.4. Hernia repair

The 3 patients that underwent inguinal hernia repair are detailed in Table 3. Patient 1, who had bilateral PPVs noted on laparoscopy, presented with symptoms of an incarcerated right inguinal hernia necessitating urgent bilateral inguinal hernia repair 49 days post laparoscopic pyloromyotomy. Patient 2, who had bilateral PPVs, was found to have a right undescended testicle and underwent right orchiopexy and incidental inguinal hernia repair 120 days post laparoscopic pyloromyotomy. Patient 3, who had a right PPV, presented with a right inguinal hernia and underwent a right inguinal hernia repair.

## 4. Discussion

In this prospective multi-center observational study of infants undergoing laparoscopic pyloromyotomy, we found a high incidence of incidental PPV at the time of surgery, but the need for inguinal hernia repair to date has been low (1%). All 3 of these patients have undergone inguinal hernia repair within the first 120 days post-pyloromyotomy. The two infants with symptomatic hernias had repairs less than two months post pyloromyotomy. The other patient had the hernia repaired at the time of an orchiopexy for a known undescended testicle. This patient was included in this analysis as having an inguinal hernia as he fit the pre-determined study criteria of undergoing an inguinal hernia repair, albeit at the time of an orchiopexy. With the stated goal of examining appearance and timing of repair of inguinal hernias, it is important for such patients to be included to assess this natural history of PPVs. While our overall rate of PPV positivity is 54%, we do not have a true patient denominator as some of the patients were enrolled post-operatively with a known PPV. We can state with relative certainty that the rate of PPV in this population is high. This rate is concordant with a previous report where 76/165 (46%) patients undergoing laparoscopic pyloromyotomy had a PPV [7].

There are two pediatric studies examining the PPV status in children undergoing non-hernia laparoscopy. In the first study the median age was 12.4 years, with 9.1% having a PPV, and 10% (4 children) returning for hernia repair at a median age of 16 years, 22 months after laparoscopy [8]. Patients in the other series were younger with a median age of 8.1 years but had a 20% or higher rate of finding a PPV. In the latter study, 13% returned for hernia repair with a younger median age of 17 months at a median of 9 months from laparoscopy. Of interest, among infants who had pyloric stenosis repair, the incidence of PPV was 50% and 16% returned for a hernia repair [7]. A limitation of this study was that retrospective follow-up occurred at a single time point with a phone call. These studies suggest that the overall risk of developing a hernia is low with a PPV but much higher than what we are currently seeing in our population of infants. Another similar prospective study, which excluded infants, showed 4 inguinal hernias developed in 35 PPVs (11%) at a median age of 4.75 years with a median return of 12 months after identification of the PPV [9].

In our series of 526 patients, with up to four years of follow-up, only 3 patients, (1.2%) have developed an inguinal hernia and all in

the first year of follow-up. Other studies that have reported time to hernia repair have shown ranges of 1 – 66 months [7–9]. This reinforces a rationale for continued prospective follow-up of our patients through adulthood, given that the median age at repair in one such study with known PPVs was 16 years [8].

Based on what is known about the developmental phases of testicular descent and the expected obliteration of the PPV sometime after the testis is in the scrotum, and the known higher incidence of inguinal hernias in premature babies because of this, our patients with a PPV were found to weigh significantly less, be significantly younger at the time of operation and have been born at a significantly earlier EGA than those without a finding of a PPV during laparoscopic pyloromyotomy. Although our cohort are not preterm, the patients with PPV were born younger (median EGA 38 weeks vs 39 weeks) and this fits with the knowledge that preterm infants are at increased risk of inguinal hernia development. Moreover, our cohort demonstrated a right-sided predominance, which is consistent with other published studies [10].

We achieved 80% follow-up with our patients for at least one milestone touchpoint although the single yearly follow-up rates are between 40–50%. Our highest follow-up rate (72%) is with the 4-year cohort, which is the most informative. Follow-up will continue to be done via text, email, and phone calls with a goal to attain the largest longitudinal prospective study of its kind.

This study has several limitations. First, the enrollment process changed in the early portion of the study for some centers. While this did not affect the overall number of positive PPVs and allowed for better accrual for these institutions, it meant that the actual denominator was not provided creating an artificially high reported rate of PPV. However, the rate of PPVs is similar to that previously published. There were 80 patients who did not have a PPV checked at the time of the operation and were removed. This was recognized early as an issue and there were several mechanisms put in place to increase compliance including taping a reminder to the laparoscopic monitor, marking the operating room white board, placing a reminder card in the laparoscopic operating room pack, and including the study as part of the surgical time out. We saw improvement as the study progressed. Another limitation is that while overall follow-up rate was 80%, the average single-year follow-up rates were, as mentioned, between 40–50%. While this may mean some patients were potentially lost to follow-up, they were only lost in this period of evaluation. We will continue to attempt contact for the allotted 18 years. While it is possible that some hernias were missed, or patients had a hernia repaired elsewhere, the number of such patients would be low based on what we know from our present results and would not likely affect the overall message of this study.

## Conclusions

Finding a PPV at the time of pyloromyotomy was common but the need for hernia repair is rare to date. Long-term longitudinal follow-up of this cohort into adulthood will delineate the subsequent natural history.

**Type of Study**

Prospective Observational Study.

**Source of Funding**

None.

**Declarations of Competing Interest**

The authors report no conflicts of interest.

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