

## Original Article



# Hypertrophic Pyloric Stenosis: 10 Years' Experience with Standard Open and Laparoscopic Approach

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### Conflict of Interest

The authors have no financial conflicts of interest.

## ABSTRACT

**Purpose:** Hypertrophic pyloric stenosis (HPS) is the most common cause of gastric obstruction in newborns. Extra-mucosal pyloromyotomy can be performed through a small laparotomy or laparoscopy. The aim of this study was to compare the two surgical techniques. We also analyzed the incidence of HPS in infants in the last 10 years in relation to the demographic trend of our province.

**Methods:** We analyzed all the cases of HPS treated at our Unit between January 2010 and December 2019. The data were obtained from operating systems. Data about the demographic trends, in particular, the number of births and the population residing in the province of Verona from 2010 to 2019, were also retrieved.

**Results:** During the study period, 60 patients were treated for HPS and met the inclusion criteria. Of these, 56 males and 4 females with an average age of 38±14 days at surgery were included. No differences were found in terms of the duration of surgery, post-operative complications, duration of hospitalization, and weight at the time of surgery. The only statistically significant data was the chlorine level in cases with and without post-operative vomiting (97±3.5 vs. 102±3.3 mmol/L,  $p<0.05$ ). There was a lower incidence of HPS from 2014 to 2019; however, there was no significant evidence regarding the correlation between this and the reduced birth rate recorded in the province of Verona during the same period.

**Conclusion:** Although laparoscopic pyloromyotomy is a highly complex procedure, it is a feasible alternative to the classic open technique.

**Keywords:** Pyloric stenosis, hypertrophic; Methods; Laparoscopy

## INTRODUCTION

Hypertrophic pyloric stenosis (HPS) is characterized by a narrowing of the pyloric canal resulting from the hypertrophy of the muscles that form the pylorus.

It was first described in 1717 by Blair during a post-mortem study of a newborn baby [1]. In 1888 Hirschsprung provided the first detailed description of HPS, explaining it as a form of congenital involution of the fetal pylorus [2,3]; he coined it angeborener pylorusstenose

(congenital pylorostic stenosis). In 1908 Dufour and Fredet suggested a surgical splitting of the hypertrophic pyloric muscle up to the submucosa and suturing in the transverse direction of the muscle itself to treat the condition [4-6]. This technique was modified in 1912 by Ramstedt, who skipped the transverse suture following the muscle splitting up to the submucosa, thus laying the foundation for the current surgical correction [7].

Several different co-factors and causes for the condition have been suggested; however, there is no consensus so far [1-11], and both the standard open or minimally invasive surgical techniques are accepted.

The purpose of the study was to analyze cases of HPS treated at Woman and Child Hospital University of Verona using the traditional open and laparoscopic technique and compare them in terms of the duration of surgery, intra- and post-operative complications, resumption of feeding, and duration of hospitalization. We also analyze the incidence of HPS in infants in the last 10 years in relation to the demographic trend of the population in our region.

## MATERIALS AND METHODS

Since April 2017, a new Woman and Child Hospital was built, and a single pediatric ward was created. This was a retrospective survey conducted in a region. An internal review board approved the study (PFL-05-2020).

A database of medical records of all children admitted to our tertiary center was created in 2010. A retrospective study was conducted analyzing all cases of HPS treated at our unit from January 2010 to December 2019. The data were obtained from the OPERA, ORMAWEB, and GECOS operating systems. All patients with the diagnosis of HPS who underwent pyloromyotomy with the traditional or laparoscopic technique were included. The exclusion criteria were as follows: patients lost to follow-up, patients with pyloric stenosis not caused by classical muscular hypertrophy (e.g., incomplete membrane), patients with incorrect diagnosis, and patients from other hospitals (late or wrong diagnosis because many radiologist reported wrong parameters).

The following data were extracted: age and weight at the time of surgery, sex, hematochemical values before surgery (sodium, potassium, chlorine), and ultrasound data (transverse diameter of the pylorus, pyloric length, and pyloric muscle thickness). Among the surgical data, the durations of the open technique vs. laparoscopic technique surgeries and the intra- and post-operative complications were considered. The occurrence of complications such as the need for a nasogastric tube, episodes of post-operative vomiting, start of re-feeding, and length of hospitalization was evaluated postoperatively. Data on the demographic trend of the population living in the province of Verona from 2010 to 2019 was also obtained, particularly, the number of births within the province and their change over the year.

### Statistical analysis

The patient data were entered into an electronic database. The Student's t-test was used to compare continuous variable, and the chi-square test was used to compare categorical variables for bivariate analysis. A *p*-value less than 0.05 was considered as significant.

## RESULTS

During the study period, 63 patients with a diagnosis of HPS were treated; one patient was excluded because she was registered in the ORMAWEB operating system with the code corresponding to the pathology, but pyloromyotomy was not performed. Two patients were excluded because they were transferred from other hospitals (late diagnosis more than 10 days after hospitalization).

Of the 60 patients included in the study, 56 were male and 4 female, with the average age at surgery being  $38 \pm 14$  days. The distribution of cases by year and the distribution by sex are shown in **Table 1**.

### Ultrasound data

All patients underwent an ultrasound scan at the time of admission for the evaluation of gastric distension and the measurements of the pyloric canal. However, on analyzing the ultrasound reports, it was noted that all three parameters, namely the pyloric canal length and transverse diameter and thickness of the pyloric muscle, were evaluated and reported only in 45% of the cases. In 38.3% of cases, only two of these parameters were evaluated and reported, namely the pyloric length and pyloric muscle thickness. In two patients, only the pyloric length and transverse diameter were reported. The ultrasound reports of six patients could not be acquired, and the report of one patient reported only data related to gastrectasia ( $p < 0.05$ ).

A comparison of the average pyloric length before and after the year of transfer to a new Woman and Child Hospital (April 2017), showed that the average length before 2017 was  $19.6 \pm 2.6$  mm, while that after April 2017 was  $18.7 \pm 1.6$  mm ( $p < 0.05$ ). This indicates that since 2017, patients with shorter pyloric lengths have undergone surgery.

In the year 2014, during which the number of surgical patients was statistically higher compared to other years ( $n=14$ ,  $p < 0.05$ ), the pyloric diameter was not larger compared to that in the other years ( $19.7 \pm 3.4$  mm in 2014;  $19.4 \pm 2.4$  mm in the other years,  $p > 0.05$ ).

### Surgical aspects

Since 2010 there has been a decrease in the use of the open technique with a relative increase in the use of the minimally invasive technique, and this change has been especially evident after 2014. There were 30 cases using the open technique vs. 7 using the laparoscopic technique during the period 2010-2014 ( $p < 0.05$ ) and 4 cases using the open technique vs. 19 using the laparoscopic technique in the period 2015-2019 ( $p < 0.05$ ).

**Table 1.** Patient distribution

Year	Total cases	Male	Female
2010	5	5	-
2011	4	3	1
2012	8	7	1
2013	6	6	-
2014	14	13	1
2015	3	3	-
2016	6	6	-
2017	5	4	1
2018	5	5	-
2019	4	4	-

Comparison of the duration of surgery showed that the average duration with the open technique was  $39.9 \pm 14.4$  minutes, while that with the laparoscopic technique was  $45.6 \pm 16.4$  minutes. There was no statistically significant difference in the duration between the two surgical techniques ( $p > 0.05$ ). In the laparoscopic technique, there was no difference in the duration of the procedure performed by different surgeons (3 senior surgeons); however, an increase in the learning curve was observed, with a progressive decrease in the duration of surgery.

### Intra- and post-operative complications

With respect to the intra-operative complications, a case of punctiform perforation of the mucosa (treated with suture during surgery) was observed in the laparoscopic group, and two cases of duodenal perforation were observed in the open technique group in 2011 ( $p > 0.05$ ).

Regarding post-operative complications, one patient treated with the laparoscopic technique developed a surgical site infection and one patient treated with the open technique developed a subocclusion. In both groups, there were no cases of incomplete myotomy or the need for re-intervention ( $p > 0.05$ ).

### Post-operative period: clinical/radiological evaluations (Table 2)

Resumption of feeding occurred in a gradual manner according to our protocol, which provides a first meal comprising 15 mL of 5% glucose followed by a mixed meal comprising 15 mL of 5% glucose and 15 mL milk after 3 hours. Subsequently, milk is fed every 3 hours, increasing the amount by 15 mL each time until the normal dietary regimen is reached. The timing of the resumption of feeding could not be compared due to the differences in the protocol at the discretion of the operating surgeon; the resumption of feeding varied from 3 to 24 hours after surgery in both groups.

During the period following the introduction of the laparoscopic technique (from 2014), 3 patients undergoing the open technique and 4 undergoing the laparoscopic technique had an episode of vomiting after the resumption of feeding, which resolved spontaneously ( $p > 0.05$ ).

There was no correlation between the diameter of the pylorus and episodes of post-operative vomiting. Comparing the hemato-chemical values in patients with postoperative vomiting episodes, there was no significant difference in natremia before surgery between patients who underwent surgery with the open technique (132 mmol/L) and those who underwent surgery with the laparoscopic technique ( $133 \pm 2.6$  mmol/L) ( $p > 0.05$ ). The only statistically significant difference was the low level of chlorine associated with post-operative vomiting,

**Table 2.** Clinical and surgical data of the patients

Variable	Open technique	Laparoscopic technique	p-value
Cases (male/female)	31/3	25/1	>0.05
Weight (g)	3,673±639	4,121.25±968	>0.05
Post-operative vomiting	3	4	>0.05
Hospitalization (d)	3.5 (1–5)	3.2 (2–5)	>0.05
Pre-operative sodium level (mmol/L)	132	133±2.6	>0.05
Pre-operative chlorine level (mmol/L), post-operative vomiting (+)/(-)	97±3.5 mmol/L vs. 102±3.3 mmol/L		<0.05
Operative time (min)	39.9±14.4	45.6±16.4	>0.05
Intraoperative complications	Perforation: 2	Perforation: 1	>0.05
Post-operative complications	Subocclusion: 1	Skin infection: 1	>0.05

Values are presented as number only, mean±standard deviation or mean (range).

Chlorine and post-operative vomiting: 97±3.5 mmol/L vs. 102±3.3 mmol/L in those with and without post-operative vomiting.

**Table 3.** Incidence per year

Year	Nativity	Case
2010	9,244	5 (0.05)
2011	8,894	4 (0.04)
2012	8,604	8 (0.09)
2013	8,201	6 (0.07)
2014	8,184	14 (0.17)
2015	7,984	3 (0.03)
2016	7,773	6 (0.07)
2017	7,561	5 (0.06)
2018	7,363	5 (0.06)
2019	7,136	4 (0.05)

Values are presented as number only or number (%).

regardless of the technique used, with the levels being  $97\pm 3.5$  mmol/L vs.  $102\pm 3.3$  mmol/L in patients with and without episodes of post-operative vomiting, respectively ( $p < 0.05$ ).

Correlating the weight with the intervention, there were no significant differences between the groups treated with the open vs. laparoscopic techniques, nor any significant differences in the post-operative clinical course ( $3,673\pm 639$  g vs.  $4,121.25\pm 968$  g,  $p > 0.05$ ).

During the study, the improvement of laparoscopic skills was associated to a decrease of surgical time (from 65 to 25 minutes) and a progressive decrease in the duration of hospitalization (from 4 to 2 days) was noted.

The duration of hospitalization was comparable in the two groups, with an average stay of 3.2 days in the laparoscopic group (2–5 days) and 3.5 days in the open technique group (1–5 days) ( $p > 0.05$ ). Patients who required a longer hospital stay showed a greater incidence of dehydration and a longer duration of symptoms at the time of hospitalization.

**Table 3** shows both the birth rate and the cases per year; in addition, with a progressive decrease in birth rates, a decrease in the incidence of HPS was reported.

## DISCUSSION

There have been numerous changes in the treatment of HPS over the years, from the first gastroenteroanastomosis performed in 1898 to pyloroplasty in 1902, and finally, the extramucosal myotomy in 1911, performed by Ramstedt in the right upper abdominal quadrant. In 1986, Tan and Bianchi introduced the supra-umbilical crescent incision along the folds of the umbilical scar itself and approached the peritoneum through the fascia of the abdominal muscles to limit the esthetic damage caused by the incision suggested by Ramstedt. Both intra- and postoperative complications were similar to those with the classic approach, and the esthetic result was excellent [11-17].

Several studies have compared the two surgical techniques, initially observing a higher percentage of complications such as perforation and incomplete myotomy in patients operated on with the minimally invasive technique [16,17].

Subsequently, with an experience in performing the technique, a decrease in the incidence of major complications and reduction in the duration of post-operative hospitalization, post-

operative pain, and time until the resumption of feeding was observed. Other studies have supported the laparoscopic technique as a safe and effective method for the management of patients with HPS since it is associated with a shorter duration of hospitalization and reduced likelihood of complications [17].

The experience of our unit indicates that both are valid surgical techniques, with no significant differences in the duration of surgery, major or minor complications, time to resumption of feeding, and duration of hospitalization.

From the clinical point of view, the analysis of chlorine values at the time of diagnosis showed that patients who presented in a state of hypochloremia showed a higher rate of post-operative vomiting, while patients with normal hematochemical values of tests did not show such episodes. This might be related to a more severe initial clinical presentation and/or a diagnostic delay of the disease. However, the weight at the time of diagnosis had no influence on the post-operative clinical course.

Since 2017, the year of transfer of the Pediatric Surgery Unit to the new Woman and Child Hospital, the average pyloric length on ultrasound examination at the time of admission was shorter compared to that in the years before 2017. This might be due to the segregation of services in a single center that serves as a reference point and reduces the dispersion of patients to different hospitals, thus ensuring early diagnosis and treatment.

As for the epidemiological variations of the disease over the last decade, studies conducted in Germany, Scotland, and most recently in New Zealand have reported a decrease in the number of cases. All studies, however, report that the reasons for this reduction in the incidence are unknown [18-20].

In line with that in the previous literature, there was a lower incidence of HPS cases from 2014 to 2019 at our unit; however, there was no significant evidence about the progressive reduction in the birth rate recorded in our province during the study period (according to the data: 9,244 newborns in 2010 decreased to 7,136 in 2019) [21].

Therefore, the reduction in the incidence of HPS could be related to a possible reduction in the risk factors related to nutrition, i.e., artificial breastfeeding. It has been demonstrated that artificial breastfeeding could be a predisposing factor for the onset of the disease, unlike exclusive breastfeeding. In our province, there are now three hospitals recognized as Baby-Friendly Hospitals (recognized by the United Nations Children's Fund [UNICEF]). The specific objective of the project is that all pregnant women and mothers are protected from the marketing of breast milk substitutes and are informed about breastfeeding and nutrition in early childhood. This might have led to a decrease in the incidence of HPS, since our center is the only reference center for the treatment of HPS.

We conclude that there are no differences between the traditional technique and the laparoscopic technique in terms of the duration of surgery, major or minor complications, time to resumption of feeding, and duration of hospitalization. Hypochloremia at the time of diagnosis can affect the post-operative clinical course, with more episodes of vomiting seen in patients with low chlorine levels than in patients with normal levels. Although laparoscopic pyloromyotomy is a highly complex surgery, is a valid alternative to the classic open technique, with identical clinical results and better esthetic results.

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