Minimal access surgery in children: Implementation of an innovating technique
Oomen, M.W.N.

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Laparoscopic pyloromyotomy, the tail of the learning curve

M.W. Oomen¹, R.Bakx¹, M.H.W.A.Wijnen², B.Peeters³,
D.Boersma¹, H.A.Heij¹.

¹Pediatric Surgical Center of Amsterdam, VU Medical Centre/Academic Medical Center, Amsterdam. The Netherlands ²Department of Pediatric Surgery, Radboud Nijmegen Medical Center, Nijmegen. ³Department of Pediatrics, Academic Medical Center, Amsterdam.
Abstract

The debate whether laparoscopic pyloromyotomy (LP) is superior to open pyloromyotomy (OP) remains actual. A recent review showed no benefit between the LP or OP but in the studied RCT’s the learning curve was not addressed. Comparing LP including the learning curve with OP after the learning curve is questionable. In previous research, the learning curve of LP was analyzed. It was concluded that the plateau was reached after 35 procedures with a steep decrease in complications when comparing before and after 35 procedures.

Aim: To retrospectively analyse the results obtained in HPS patients after the learning curve in LP has been reached. The results will be compared with results of OP in HPS patients in the same period.

Methods: A retrospective analysis in 106 OP and 57 LP was performed from September 2008 until June 2012.

Results: The overall complication rate in the OP group was significantly higher than in the LP group (18% vs 3.5%, p=0.012). Also there is a higher major complication rate in the OP group (10.4% vs 1.7%, p=0.045). The median time to operate was with 28.5 min in OP and 30.0 min in LP (n.s.) whereas the LOS was two days in both groups (n.s.)

Conclusion: In this study a further decline in overall and major complications after the learning curve is seen in the LP group; the tail of the learning curve. The debate whether LP is superior to OP is not finished as long as it is not clear whether the minimally invasive operation is beyond the initial or tail of the learning curve.
**Background**

The debate whether laparoscopic pyloromyotomy is superior to open pyloromyotomy (OP) is still actual. With a frequency of 1-3/1000 live birth hypertrophic pyloric stenosis (HPS) is a relative frequent occurring pathology in the daily practice of the pediatric surgeon. In a training hospital HPS is a condition that is suitable for the teaching of minimally invasive pediatric surgical skills.

Few studies on the surgical outcomes of open (OP) versus laparoscopic pyloromyotomy (LP) in the treatment of hypertrophic pyloric stenosis (HPS) have been published \(^1,2,3\). In a systematic review and meta-analysis it was shown that when focusing on major complications there is no significant difference between the two procedures \(^4\). However, when a novel surgical approach is introduced it is always accompanied with a learning curve. In laparoscopic pyloromyotomy this has been acknowledged and some publications mention the initial learning curve and pitfalls \(^5,6\). The RCT’s analyzed in the systematic review may contain a learning curve effect since the influence of the learning curve in the LP group in the different RCT’s was not addressed. Comparing OP after learning curve and LP with learning curve is questionable.

In previous research from our institute, the learning curve in laparoscopic pyloromyotomy was analyzed \(^7\). The plateau of the learning curve was reached after 35 procedures. The complication rate between OP (21.5%) and LP (21.1%) was similar in both groups. However, a significant reduction in complications was seen between the two laparoscopic groups (31.5% versus 11.4%, \(p=0.041\)) This decline in complications crossed the number of complications in the open pyloromyotomy group \(^7\).

We hypothesize that in LP for HPS after the learning curve there is a persistent or even further improvement in the postoperative complication rate to reach a plateau (= tail).

**Aim**

To retrospectively analyse the results obtained in HPS patients after the learning curve in LP has been reached. The results will be compared with results of OP in HPS patients in the same period. Primary endpoint is the rate of complications; secondary endpoints are operation time and length of stay.

**Methods**

Data were analyzed retrospectively. The study was started after the period where the initial learning curve was accomplished, from September 2008 to June 2012. All the data were collected from children that were operated for HPS, laparoscopically or open, in the Academic Medical Center and the Vrije Universiteit Medical Center in Amsterdam, the Netherlands during this period. There were 136 boys and 27 girls.
The LP was considered as established in the hospital and operations were all carried out by or supervised by the author (MO) or one other new staff surgeon trained in a center of excellence for minimal invasive pediatric surgery where the learning curve was completed. Primary endpoint was postoperative complication rate. Overall complication rate was scored and the major complications were scored separately. Major complications were perforation of the mucosa, incomplete pyloromyotomy or any other reason to reoperate or readmit the patient. Secondary endpoints were operating time and length of stay. Parents were informed about the different types of procedures. It was explained that LP was a relatively new technique with unproven advantages over OP. Type of approach was determined by the surgeon’s preference. Preoperative parameters including sex, age at admission, and age at operation were collected from all patients. The peri- and postoperative data studied in both groups were operating time, hospital stay, the number and nature of complications, and the consequences of these complications. Furthermore, the number of conversions and their indications were counted. The data were analyzed statistically using SPSS version 19.0 (SPSS, Chicago, IL, USA) and the chi-square test. Significance was defined as a p value of 0.05 or less.

Preoperative care
In patients who were admitted for suspected HPS diagnose was made by ultrasound or physical examination after feeding showing a peristaltic wave over the stomach. Before the operation, all the infants had correction of the hypochloremic metabolic alkalosis. All the patients were under general anesthesia. The umbilicus and the abdomen were thoroughly cleansed with chlorhexidine or iodine two times, and a sterile field was created.

Open pyloromyotomy
A semicircular incision was made in the supraumbilical skinfold following the contours of the umbilicus. The skin, subcutaneous tissues, and fascia were undermined with diathermy dissection. The fascia was opened. Luxation of the stomach with the pylorus was followed by an incision in the serosa of the pylorus. The muscle was split down to the mucosa. The stomach was replaced intraabdominally. The linea alba was closed with Vicryl sutures, and the cutis was approximated with Monocryl. The wound was closed with Steristrips.

Laparoscopic pyloromyotomy
A small incision was made in the subumbilical region, through which a 5-mm trocar was introduced. A 3-mm trocar was inserted through the abdominal wall at the right upper quadrant under direct vision so the duodenum could be grasped. A disposable laparoscopic knife was introduced in the epigastric region. The avascular part of the pylorus was identified, and the serosa was incised. The knife was pulled back, and the laparoscopic spreader was used for the pyloromyotomy. The stomach was filled with air to determine
whether perforations had occurred. After removal of the instruments, the incisions were closed.

Postoperative care
In all cases, a standard postoperative feeding regimen was started for both groups. At 6 h after the operation, a full feeding ad libitum regimen was administered. Discharge followed when the infant tolerated full feeding. The babies were reviewed at an outpatient follow-up visit after 2 or 3 weeks unless postoperative complications occurred.

Results
Preoperative data
The OP group consisted of 89 boys and 17 girls (n=106), and in the LP group there were 47 boys and 10 girls (n=57). The median age at the date of the operation was 4.4 weeks (range 1.8 – 10.1 weeks) in the OP group and 4.7 weeks (range 2.7 – 14.6 weeks) in the LP group. These data do not differ significantly.

Perioperative data
The median operating times were not significantly different between the OP (28.5 min, range 8 - 102) and the LP (30.0 min, range 18 – 100, p = ns) group.
In the group of surgeons that operated the LP this was done by staff surgeons in 68% whereas in the OP group this was 47%.

Postoperative data
The median hospital stay after surgery was 2.0 days (range 1 – 11 days) for the OP patients and 2.0 days (range 1- 6 days, p= ns) for the LP patients. The overall postoperative

<table>
<thead>
<tr>
<th>Table 1. Overall complications</th>
<th>OP n (%)</th>
<th>LP n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No complications</td>
<td>87(82)</td>
<td>55(96.5)</td>
</tr>
<tr>
<td>Perforation</td>
<td>1(1)</td>
<td>0</td>
</tr>
<tr>
<td>Wound infection</td>
<td>5(4.7)</td>
<td>0</td>
</tr>
<tr>
<td>Fascia dehiscence</td>
<td>5(4.7)</td>
<td>0</td>
</tr>
<tr>
<td>Delayed passage</td>
<td>3(2.8)</td>
<td>1(1.7)</td>
</tr>
<tr>
<td>Serosal lesion</td>
<td>3 (2.8)</td>
<td></td>
</tr>
<tr>
<td>Incomplete pyloromyotomy</td>
<td>1(1)</td>
<td></td>
</tr>
<tr>
<td>Iatrogenic skin lesion</td>
<td>1(1)</td>
<td></td>
</tr>
<tr>
<td>Postop.bleeding</td>
<td></td>
<td>1(1.7)</td>
</tr>
</tbody>
</table>
complication rate was significantly different between the OP group 18% (18/106) and the LP group 3.5% (2/57) $p=0.012$. The overall postoperative complications are shown in Table 1.

The complication in the LP group was one postoperative bleeding that needed reintervention and ended with a laparotomy. The bleeding focus was on one trocart site and on the pyloromyotomy site at the stomach, both controlled surgically and with administrating of coagulation products. After haematological analysis it was confirmed that the patient had a temporary vitamin K insufficiency although this was administrated before surgery. Also there was one patient with delayed passage that resolved spontaneously.

In the OP group of the 18 complications six patients needed reintervention, five of them because of wound related complications and one because of incomplete pyloromyotomy for which the patient was treated with pneumodilatation that caused a perforation and ended in a laparotomy. The patient was given a central venous line and stayed a couple of days in the ICU but recovered later completely. The five wound related complications were fascial dehiscence requiring surgery. In five patients wound infections were treated with antibiotics and/or drainage for which two were readmitted in the hospital. Further there were three patients with a serosal injury during surgery. In one patient a mucosal injury during surgery was recognized and closed. In 3 patients a delayed passage occurred for which one was readmitted and observed. The other two were treated expectatively and resolved spontaneously.

Separate from the overall complications also the major complications were analyzed. The major postoperative complications are shown in Table 2.

When analyzing the major complications there is a significant difference in favour of LP. In OP there were 10.4% major complications and in LP 1.7% ($p=0.045$).

This difference in primary operating surgeon in overall and major complications showed that in OP 50% of the complications were done by a staff surgeon. In LP the complications were all present when a staff surgeon was the primary surgeon.

### Table 2. Major complications

<table>
<thead>
<tr>
<th></th>
<th>OP n (%)</th>
<th>LP n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No complications</td>
<td>95(89.6)</td>
<td>56(98.3)</td>
</tr>
<tr>
<td>Perforation</td>
<td>1(1)</td>
<td>0</td>
</tr>
<tr>
<td>Wound infection, readmittance/intervention</td>
<td>3(2.8)</td>
<td>0</td>
</tr>
<tr>
<td>Fascia dehiscence</td>
<td>5(4.7)</td>
<td>0</td>
</tr>
<tr>
<td>Delayed passage, readmittance</td>
<td>1(1)</td>
<td>0</td>
</tr>
<tr>
<td>Incomplete pyloromyotomy</td>
<td>1(1)</td>
<td>0</td>
</tr>
<tr>
<td>Postop. bleeding</td>
<td>1(1.7)</td>
<td>0</td>
</tr>
</tbody>
</table>
Discussion

In this study, the overall complication rate in the OP group was significantly higher than in the LP group (18% vs 3.5%, \( p=0.012 \)). Also there is a higher major complication rate in the OP group (10.4% vs 1.7%, \( p=0.045 \)). There was no difference in median operation time or median postoperative length of stay between the OP and the LP group.

Overall complications

When compared with previous results from our institution concerning the initial learning curve the overall complication rate in the LP is lower (3.5% versus 21.1%), while the complication rate remains more or less consistent in the OP groups (18% vs 21.5%) \(^7\).

There was a decrease in median operation time from 33 to 30 min. in the OP and in the LP group from 40 to 30 min. A decline in postoperative length of stay from 3 to 2 days in the OP was seen while it did not change (2 days) in the LP group \(^7\). The improvement in LOS in the OP can possibly be explained by the introducing of fast track surgery with the implementation of the LS \(^8\).

As shown before, there was a sharp decrease in complications once the learning curve was achieved (31.5% versus 11.4%). Compared with the second group (11.4% complications), the current complication rate in the LP showed a further decrease to 3.5%. This indicates that there is still an improvement after the initial learning curve concerning overall complications. This could confirm the findings of Voitk \(^9\) et al where there still was a detectable improvement that persisted after 200 laparoscopic cholecystectomies when evaluating the results of 500 cases. The complications reached a plateau, the tail of the learning curve.

Major complications

In a review focusing on major complications 4.9% were detected in the LP (n=247) group and 2.0% in the OP (n=255) group \(^4\).

Our LP has a low complication rate with 1.7% (1/56) but on the other hand our OP complication rate remains high with 10.4% (11/106). A reason of our low LP complication rate might be the dedication and the limited number of the laparoscopic surgeons in this study. When not performing the operation self they would teach and coach the procedure to fellows and residents.

This comparison of open and minimal access procedures in a retrospective study is prone to flaws. No difference in patient groups between OP and LP was detected. Since the institutional learning curve for OP has reached a plateau many years ago, residents in (paediatric) surgery are more likely to be trained in this procedure than in LP. In time, a small group of expert minimally invasive surgeons gained increasing experience in LP and thereby improved their performance.
A distinction has to be made between the learning curve of the individual trainee and the learning curve of the teaching group or institution. Since knowledge and skills are to a certain degree transferable, individual trainees can profit from the experience gained by the teachers. That has always been the case in open surgery and is now confirmed in minimal access surgery as well.

We mentioned that the group of surgeons that operated the LP in 68% was done by staff surgeons whereas in the OP group this was 47%. This difference may explain the further reduction of complications after LP, whereas the complications after OP remained at the same level. But 50% of the overall and major complications in OP occurred in patients operated by staff surgeons as primary surgeon.

Nevertheless the access is different in nature between OP and LP. The surgical difference is in fact that LP is avoiding a median laparotomy through a relative small skin incision. If the operation does not contain a laparotomy a fascial dehiscence is not possible and the manipulation of the skin is not prone for a wound infection and the manipulation of the stomach and pylorus is not prone to serosal lesions. But these assumed advances of LP over OP still have to be proven.

In conclusion is the debate whether LS is superior to OP not justified when it is not clear whether the minimal invasive operation is beyond the initial or tail of the learning curve and thus cannot be compared with the open approach.

In the future more learning curves should be identified and, when possible because of volume, it should contain also the tail of the learning curve. Only then a good randomized controlled study is meaningful.
References


