Minimal access surgery in children: Implementation of an innovating technique

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Learning curves in pediatric laparoscopy, how many is enough? The Amsterdam experience in laparoscopic pyloromyotomy

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Abstract

Objective: Few studies have been published regarding the surgical outcomes of open (OP) versus laparoscopic pyloromyotomy (LP) in the treatment of hypertrophic pyloric stenosis. The question arises how many laparoscopic procedures are required to pass the learning curve and which technique is better in terms of postoperative complications. The aim of this study was to evaluate and quantify the learning curve at our centre for the laparoscopic technique. A second goal of this study was to evaluate the preoperative and postoperative data of OP compared with LP for infantile hypertrophic pyloric stenosis.

Method: A retrospective analysis was performed in 229 patients with an infantile hypertrophic pyloric stenosis. Between January 2002 and September 2008, 158 infants underwent OP compared with 71 infants where an LP was performed.

Results: There was a significant difference in median operating time between the OP (33 min) and LP (40 min) group. Median hospital stay after surgery in OP patients was 3 days and in LP patients 2 days (p=0.002). The postoperative complication rate was not significantly different between the OP group (21.5%) and the LP group (21.1%, p=.947). In the first 35 LP-procedures, complications were seen in 31.5% of the patients, while this rate decreased to 11.4% in the second 35 LP-procedures (p=0.041). There were two perforations and three conversions in the first LP group, in the second LP group one perforation was observed.

Conclusion: There was a significant decrease in number of complications between the first group of the LP patients and the second group of LP patients quantifying the learning curve. Not only the complication rate was lower in the second LP group, but there was also a decrease in severe complications. This indicates that the learning curve in our series for the laparoscopic pyloromyotomy involved 35 procedures.
Introduction

A common cause of vomiting after feeds in the first few weeks of life is infantile hypertrophic pyloric stenosis (HPS). HPS is characterized by hypertrophy and hyperplasia of the circular muscle layer of the pylorus, with stenosis of the pylorus channel, causing gastric outlet obstruction, gastric distension and retrograde peristalsis in the stomach, which can be seen by physical examination after feeding. As a consequence, dehydration and hypochloremic metabolic alkalosis will exist. No clear pathophysiologic sequence or etiology has been described, although there seems to be a relation between maternal Bendectin use in the first trimester and infantile hypertrophic pyloric stenosis. The incidence of HPS is approximately 1 to 3 per 1000 live births. HPS is seen more often in male, with a male-to-female ratio of 4:1 Everett.

The surgical treatment of choice in the last century has been the technique described by Ramstedt in 1912, who introduced the longitudinal splitting of the seromuscular layer of the pylorus without suturing, which is defined as “pyloromyotomy”. It relieves the constriction and allows normal passage of stomach contents into the duodenum. The operation traditionally has been performed through a classical right upper quadrant transverse (RUQ) incision. Although effective at providing excellent exposure of the pylorus, this method results in an abdominal scar that grows with the patient, often become quite significant with time. There are several other approaches currently advocated for pyloromyotomy. In 1986, Tan and Bianchi described a new technique in which the pyloromyotomy was performed through a supraumbilical skin fold incision. This approach achieves excellent cosmetic outcome with an apparently unscarred abdomen. Alain et al. introduced in 1991 the laparoscopic approach. Since then a few centers have reported their outcomes of the OP compared with the LP. The potential advantages of the LP have been ascribed as shorter hospital stay, improved cosmesis, shorter postoperative recovery and less postoperative pain.

The question arises if the LP is a better operation technique for HPS and is therefore superior over the open approach. Two prospective, randomized controlled trials have compared a laparoscopic with an open pyloromyotomy group for hypertrophic pyloric stenosis. Leclair et al. showed that laparoscopic pyloromyotomy has a similar complication rate compared with the open umbilical approach, but may expose patients to a risk of inadequate pyloromyotomy. However, in the study of St Peter et al. the benefits of laparoscopic pyloromyotomy are described as less postoperative pain, reduced postoperative emesis and a fewer number of complications. This study reported no difference in operating time between open and laparoscopic pyloromyotomy. This finding is not supported by Leclair et al. They showed that the duration of operation was longer in the laparoscopic group. Overall, there are contradictory conclusions with regard to the superiority of the laparoscopic procedure.
Another issue with regard to LP is the existence of a learning curve. As is known from many laparoscopic procedures like colonic resections, it takes quite some procedures before the technique is safely performed. Kramer et al.\(^\text{14}\) showed a decrease in operating time in children who underwent laparoscopic extra mucosal pyloromyotomy for hypertrophic pyloric stenosis and found a positive learning curve. The first operations required over 30 minutes on average. After some years of experience with the laparoscopic approach the operations lasted an average of 16 minutes. Another study also showed a steep learning curve in laparoscopic operations with a decrease in operating time after about thirty cases\(^\text{15}\).

The aim of this study was to evaluate and quantify the learning curve at our center for the laparoscopic technique. A second goal of this study was to evaluate the preoperative and postoperative data of OP compared with LP for infantile hypertrophic pyloric stenosis.

**Patients and methods**

A retrospective study was performed of 229 patients with an infantile hypertrophic pyloric stenosis. From January 2002 to September 2008, these patients (196 males, 33 females) were operated in the Academic Medical Center and Vrije Universiteit Medical Center in Amsterdam, the Netherlands. 158 (69\%) infants underwent a standard open pyloromyotomy via a circumbilical incision\(^\text{4}\). In 71 (31.0 \%) infants a laparoscopic pyloromyotomy was performed. The laparoscopic pyloromyotomy was introduced by one surgeon (MO) who had been trained during residency in another clinic. Half of the procedures were performed by this single surgeon. A total of four different surgeons performed the remaining 35 procedures of which the large majority was supervised by the initiating surgeon.

Parents were informed about the different types of procedures and were offered LP for their child if wanted. It was explained that LP was a relatively new technique of which the advantages over OP are not proven. Parents were allowed to choose the type of operation performed.

Of all patients, preoperative parameters as sex, age at admission, and age at operation were collected. 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 and indication for conversions was counted. Data were analyzed statistically using SPSS Version 14.0 and the chi-square test. Significance was defined as \(P\) value \(\leq 0.05\).

**Preoperative care**

The diagnosis hypertrophic pyloric stenosis was made by ultrasound or by physical examination after feeding showing peristaltic wave over the stomach. Before operation,
all infants had correction of the hypochloremic metabolic alkalosis. All 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. Prophylactic antibiotics were administered if indicated.

**Surgical techniques**

*Open pyloromyotomy*

A semi-circular incision was made in the supraumbilical skin fold following the contours of the umbilicus. The skin, subcutaneous tissues and fascia were undermined with diathermy dissection. The fascia is opened. Luxation of the stomach with the pylorus is followed by an incision in the serosa of the pylorus. Splitting of the muscle was done down to the mucosa. The stomach was replaced intra-abdominal. 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, where a 5-mm trochar was introduced. A 3-mm trochar 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 see if perforations had been occurred. After removal of instruments the incisions were closed.

**Postoperative care**

In all cases, a standard postoperative feeding regimen was commenced for both groups. Six hours after the operation full feeding ad libitum regimen were administered. Discharge followed when tolerating full feeding. Babies were reviewed at outpatient follow-up after two or three weeks, unless postoperative complications occurred.

**Results**

**Preoperative data**

There were 133 boys in the open pyloromyotomy group versus 63 boys in the laparoscopic group. Twenty-five girls underwent an OP versus eight girls who underwent a LP. In the OP group (n=158) median age at date of operation was 4.4 (range 1.3 – 24.4) weeks. Median age at date of operation was 4.7 (range 1.7 – 46.3) weeks in the LP group (n=71). This difference is not significant. Demographic details are shown in Table 1.
Per operative data
There was a significant difference in median operating time between the OP (33 min) and LP (40 min) group (p=0.000).

Postoperative data
Median hospital stay after surgery in OP patients was 3 days and in LP patients 2 days (p=0.002). The median total length of hospitalization was 5 days in the OP group versus 4 days in the LP group (p=0.048).

The postoperative complication rate was not significantly different between the OP group (21.5%) and the LP group (21.1%, p=.947). Postoperative complications are shown in Table 2.

Table 1. Main results

<table>
<thead>
<tr>
<th></th>
<th>Open (n=158)</th>
<th>Laparoscopic (n=71)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex ratio (M:F)</td>
<td>133:25</td>
<td>63:08</td>
<td>ns</td>
</tr>
<tr>
<td>Age at operation (weeks)</td>
<td>4.4 (1.3 – 24.4)</td>
<td>4.7 (1.7 – 46.3)</td>
<td>ns</td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>33</td>
<td>40</td>
<td>0.000</td>
</tr>
<tr>
<td>Hospital stay after surgery (days)</td>
<td>3</td>
<td>2</td>
<td>0.002</td>
</tr>
<tr>
<td>Total length of stay (days)</td>
<td>5</td>
<td>4</td>
<td>0.048</td>
</tr>
<tr>
<td>Postoperative complication rate (%)</td>
<td>21.5</td>
<td>21.1</td>
<td>0.947</td>
</tr>
</tbody>
</table>

Values are median (range).

Table 2. Postoperative complications

<table>
<thead>
<tr>
<th></th>
<th>OP</th>
<th>LP</th>
</tr>
</thead>
<tbody>
<tr>
<td>No complications</td>
<td>124 (78.5 %)</td>
<td>56 (78.9%)</td>
</tr>
<tr>
<td>Perforation</td>
<td>2 (1.3%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>9 (5.7%)</td>
<td>2 (2.8%)</td>
</tr>
<tr>
<td>Dehiscence of fascia</td>
<td>12 (7.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Delayed passage</td>
<td>2 (1.3%)</td>
<td>2 (2.8%)</td>
</tr>
<tr>
<td>Injury to the duodenum</td>
<td>2 (1.3%)</td>
<td>0</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>2 (1.3%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Abscess</td>
<td>3 (1.9%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Other complications</td>
<td>2 (1.2%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Conversion to OP</td>
<td>3 (4.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>158</strong></td>
<td><strong>71</strong></td>
</tr>
</tbody>
</table>
Among the LP patients the complication rate was analyzed in groups of ten patients to gain information concerning the learning curve. There seems to be a trend in reduction of postoperative complications in the LP group after some experience with this technique. The results are shown in Figure 1.

The LP patients have been split in two groups to analyze if there are differences in complications rates and difference in severity of complications. The first LP group consists of the first thirty-five LP patients. The next thirty-five LP patients belong to the second group. In the first 35 LP-procedures, complications were seen in 31.5% of the patients, while this rate decreased to 11.4% in the second 35 LP-procedures (p=0.041). Among the complications in the first group there were two perforations, requiring reoperation and three conversions. In the second LP group only one perforation was observed, which was recognized preoperatively and the procedure was converted. Median operating time was respectively 42 and 40 minutes in the first and second LP group.

Discussion

In this study, the learning curve after introduction of LP was analyzed by comparing the number of complications in the first half of the LP procedures with the second half of the LP procedures. This study showed a significant decrease in number of complications between the first group of the LP patients and the second group of LP patients. Not only the complication rate was lower in the second LP group, but there was also a decrease in severe complications. This indicates that the learning curve for the laparoscopic pyloromyotomy in our series involved 35 procedures.
Chapter 5

So far LP is not a better technique in terms of postoperative complications in this series in comparison with OP patients. However, there seems to be a trend in reduction of postoperative complications in the LP group after thirty-five procedures. Therefore, the first thirty-five patients might reflect the learning curve with a reduction in complications in the last thirty-five patients. A complication rate of 20% was reported in ten laparoscopic operations performed in 2005 when we started to do LP. The next ten infants who underwent LP had a complication rate of 50%. After some experience with the laparoscopic approach the average was declined to 20% and even to 10% after seventy operations. There seems to be a trend to fewer complications, although we cannot ensure this benefit. It might be expected that the reduction in complications can be sustained and a reduction in postoperative complications might be possible. This reduction might justify the LP, but has to further be investigated by means of a randomized controlled clinical trial. One study in the Netherlands 13 reported a learning curve in children who underwent laparoscopic extra mucosal pyloromyotomy for hypertrophic pyloric stenosis, although they reported data from mean operating time. The study of Adibe et al 16 showed an institutional learning curve when the laparoscopic pyloromyotomy was introduced as reflected by slightly higher rates of mucosal injury and incomplete pyloromyotomy.

Next to that a significant difference in median operating time and hospital stay was seen between the OP and LP patients, where a shorter hospital stay was reported for LP patients. The decline in complication rate seen in infants who underwent LP emphasizes the need for more follow-up of this group of patients to see whether this positive learning curve is maintained. Further research by means of a randomized clinical trial is needed to justify LP as the standard of care.

Introducing a new technique requires careful attention to the procedure and information towards the patient and his/her parents. In recent years, the use of minimal invasive surgical procedures has gained increased popularity, not only in pediatric surgery but also in adult surgery. These techniques are usually adopted before evidence of safety have been fully established. When a new technique is introduced, the surgeon will find him/herself gaining proficiency and experience on suitable patients and preferably under supervision of an experienced colleague. Hence the surgeon embarks on a ‘learning curve’ 17. Laparoscopic pyloromyotomy has gained popularity for the last decade with the advancement of laparoscopic technology and development of instrumentation suitable for use in infants. Where a surgeon embarks on any learning curve, it is necessary to inform the patient of any uncertainty regarding risks and outcomes associated with the procedure and ensure that the patient fully understands that the procedure is new. The laparoscopic pyloromyotomy was introduced in our clinic by a surgeon trained in another hospital. All parents were informed about the novelty of the technique and were offered a choice between two techniques. Informed consent was obtained as in every other procedure.
performed in our institution. Nevertheless, it is important for surgeons to reflect on their own competence to perform any novel technique in order to avoid unnecessary harm to patients.

Conclusion

A significant decrease in number and severity of complications was seen between the first and second group of the LP patients, indicating that the learning curve in our series for the laparoscopic pyloromyotomy involved 35 procedures. Between the OP and LP patients, there was no difference in postoperative complications, but a significant difference in median operating time and hospital stay was seen. Further research by means of a solid randomized clinical trial or a meta-analysis of the available randomized clinical trials is needed to justify LP as the standard of care.
Chapter 5

References


