Minimal access surgery in children: Implementation of an innovating technique
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Summary, conclusions, discussion and future perspectives
Summary

Minimally invasive surgery (MIS) is performed in many hospitals and new projects are started worldwide to implement MIS. The lack of proper procedures for implementation of MIS and inconsistent analysis of the outcome in general surgery was criticised by the Netherlands Health Care Inspectorate. With the increasing acceptance of MIS in paediatric surgery there is need for a study on various aspects of implementation in this patient group. This thesis presents the findings, which can be applied at the introduction of this new technique.

In Part I of this thesis the available literature concerning the implementation and use of new endoscopic techniques and its indications has been analysed.

The International Pediatric Endosurgery Group (IPEG) is the biggest and most important forum for paediatric MIS in the world. To encourage and support standards of training and practice, several guidelines based on the best available evidence are written by the Clinical & Practice Guidelines Committee of IPEG. Chapter 1 is a review of best available evidence on which mediastinal masses can be biopsied safely by MIS. Minimal invasive diagnostic procedures concerning mediastinal lesions are safe and effective in any anatomical place. (Level III, Grade C recommendation).

In addition, an analysis to obtain evidence for MIS in the treatment of benign lesions shows that Benign lesions can be resected by MIS safely. With MIS there is a decrease in length of stay, chest tube duration, blood loss and it is cosmetically superior over thoracotomy. (Level II, Grade C recommendation).

For malignant lesions thoracoscopic approach is only recommended in neurogenic tumours. (Level II, Grade C recommendation).

To assess the results of the implementation of an innovative technique the literature was also evaluated on available comparative studies between a minimally invasive and a traditional open procedure. Esophageal atresia is seen as one of the cornerstones of the success of paediatric surgery. After the introduction of the first thoracoscopic repair of EA-TEF successfully ¹ more centres started the procedure. A systematic review to evaluate differences in outcomes between the open and minimally invasive approach of EA-TEF is presented in chapter 2. There was no clear benefit for the open nor for the thoracoscopic correction of esophageal atresia in terms of duration of operation, duration of postoperative ventilation, length of stay and complications. However none of these retrospective studies reviewed, pay attention to the learning curve of the thoracoscopic procedure. Recently the first attempt was made to define a learning-curve in EA-TEF ². Results could very well be different when the MIS approach is compared with the open
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approach when it is beyond the learning-curve. Therefore, a randomized controlled trial in which the factor of the learning curve is ruled out, is required. Further analysis of the results should also elucidate possible long term complications.

In chapter 3 a study is presented on a more frequently occurring condition, hypertrophic pyloric stenosis (HPS). After the introduction in 1992 of the laparoscopic pyloromyotomy (LP) several systematic reviews between open pyloromyotomy via a circumbilical incision (OP) and LP have been performed without clear advantages towards LP or OP. However, the outcome parameters analysed in these reviews are often not relevant from a clinical point of view. Therefore a systematic review is presented focussing on major complications of surgical treatment of HPS which bears clinical relevance. The presented results show no clear benefit of laparoscopic correction over the open pyloromyotomy when focusing on the primary endpoint of major complications eg incomplete pyloromyotomy, perforation, and need for reoperation. One of the secondary outcomes, time to full feed, was found to be significantly shorter in the laparoscopic group, but this is measured in hours and therefore seems barely clinically significant. None of the studies describe the implementation of a learning curve of LP. This aspect is absent in the available literature and the outcomes might well be different if the LP had been performed by surgeons who had completed their learning curves.

A RCT comparing OP and LP after the completion of the learning curve of LP should be performed.

In the RCT’s comparing OP and LP in HPS the primary outcomes and methodological design are sometimes debatable. The methodological set up needs to be flawless. Therefore chapter 4 presents a letter to the editor commenting on a RCT of Siddiqui 3. In this study two flaws are criticised, at first the randomization was not blinded but by date, however 30% more laparoscopic approaches were performed compared with the open approach which is not explained. And second we disagree with the authors final conclusion that “with clearly superior cosmetic results one can easily make the argument for laparoscopic approach” as the comparison between the right upper quadrant incision and laparoscopic approach is debatable. The authors did not perform the circumbilical approach for OP as it was not routinely practiced however it is mentioned that the circumbilical approach provides superior cosmetic outcome as well 4. The conclusion that laparoscopic approach has clearly superior cosmetic results seems not justified as the comparison should be done between LP and the circumbilical open pyloromyotomy.
In PART II the implementation of MIS for thoracoscopic lobectomy, laparoscopic pyloromyotomy & laparoscopic splenectomy in our center is described and evaluated.

In chapter 5 the question is studied as to how many laparoscopic procedures are required for a surgeon to complete the learning curve. A retrospective analysis was performed in 229 patients with infantile hypertrophic pyloric stenosis, 158 infants underwent OP and 71 infants LP. When comparing the complications per group, there were no differences between the OP (21.5%) and the implemented LP (21.1%). However the complications were analysed for subgroups, it was found that in the first 35 LP patients the complication rate was 31.5%, this rate decreased to 11.4% (p=0.041) during the next 35 LP procedures. The learning curve was thus defined as 35 procedures.

After the initial learning curve has been identified, chapter 6, presents an investigation whether the decline in complications described in chapter five remains the same or further reduction could be achieved. A retrospective analysis of another cohort of 106 OP and 57 LP was done. 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). Still a further decline in overall and major complications in favor of laparoscopic pyloromyotomy could be seen.

The learning curve of OP also has to be taken into account, as this procedure was more often performed by residents (51%), than LP (32%). However in OP there were 50% complications in the operations performed by staff members.

The debate whether LP is superior to OP is not finished as long as the learning curves are not accounted for in the analysis because minimally invasive and the open operation have been performed by surgeons in the learning curve.

Chapter five and six justify a randomized controlled trial between laparoscopic and open pyloromyotomy by dedicated surgeons in LP and OP.

In chapter 7 the implementation of laparoscopic splenectomy was studied, with the assumption that increased risk of portal vein thrombosis (PVT) was related to the duration of the operation due to the stasis in portal blood flow during the prolonged pneumoperitoneum.

The aim of this study was to evaluate the occurrence of PVT after LS and compare it with that of OS in a pediatric cohort, and to establish if the learning curve and duration of pneumoperitoneum of LS influenced this occurrence. A retrospective cohort of 76 patients splenectomized for benign hematological disease was analyzed, 24 after OS and 52 after LS. Postoperative US was performed following six OS and 40 LS. Two symptomatic PVT could be detected with ultrasound. In both patients also a concomitant laparoscopic cholecystectomy was performed. No significant decrease in operating time in relation to the experience of the surgeons could be detected.
These data show that the prolonged duration of operation is related to the implementation of laparoscopic splenectomy. There is a low risk of PVT after LP, that appears to be associated with concomitant cholecystectomy. Implementing LS is safe in patients with benign haematological disease.

In chapter 8 the implementation of a demanding minimally invasive operation, thoracoscopic lobectomy (TL), by means of the master-apprentice-model (MAM) is described. The results of TL were also compared with those of open lobectomy (OL) from our institution to assess if continuation of TL is legitimate. Thirteen TL patients and 17 OL patients were retrospectively compared. Indications were congenital pulmonary airway malformations and sequestration of the lung.

Operation time was longer in the TL group (median 173 minutes TL vs 143 OL) and length of stay in the TL group was shorter (median 3 days TL vs median 5 days OL). Duration of chest tube drainage was shorter in the TL group (2 TL versus 3 OL days). There were two complications in the TL group and seven in the OL group, but the two groups were not in all aspects comparable as the open group had more symptomatic patients (42%) than the thoracoscopic group (8%).

Implementation of thoracoscopic lobectomies using the Master Apprentice Model is safe and the obtained results justify the continuation of TL. MAM could be the method of choice in demanding minimally invasive operations. In a recent publication about the learning curve of thoracoscopic repair of EA-TEF it was also recommended that centers with the ambition to start up a program for this procedure to do so under guidance of experienced pediatric endoscopic surgeons to avoid an extended learning curve.

Conclusions

When assessing the implementation of MIS as a new surgical approach, available guidelines can help to find the best evidence. In esophageal atresia and hypertrophic pyloric stenosis comparative studies between open approach and MIS show no results in favour of either, but they do not mention the learning curve which could affect the results.

In hypertrophic pyloric stenosis the initial learning curve is identified and consists of 35 procedures. A further improvement in decreasing complications is reached after completion of the initial learning curve, the tail of the learning curve.

The learning curve in laparoscopic splenectomy, as has been described by Cusick, should contain 20 LS. This however could not be detected in our implementation of laparoscopic splenectomy for benign haematological disease, apparently we are still in it. However follow-up by ultrasonography showed a low risk of occurrence of PVT and justifies continuation of this procedure.
When implementing a demanding operation in a rare pathology as in thoracoscopic lobectomy the master-apprentice model is a safe model. This collaboration is an example of how to deal with threats in implementing advanced MIS. The results are encouraging and support continuation of this approach for paediatric lung resections.

**Discussion and Future perspectives**

When a minimally invasive operation is introduced, particularly in children this process should be accompanied by guidelines and regulations and by an ethical approval mandated by professional associations on a national basis.

Implementation of a minimally invasive operation requires identification of a learning curve which should be completed for patient safety reasons. The patient can then benefit from it in terms of quicker recovery, less pain, better cosmesis and perhaps less complications. If this is not done properly minimally invasive surgery (MIS) can be a threat. The challenge is to identify more learning curves and safe methods for implementation. The definition of the learning curve follows mostly from the scoring of outcome parameters, like postoperative complications and procedural parameters, like duration of operation or stay in hospital. The comparison with the open procedure can be done after a quantified number of procedures or after a certain period in time.

The most important criterium is the safety of a new technique assessed by outcome parameters like postoperative complications and morbidity. The procedural parameter, duration of operation, as indicator of the learning curve follows if the postoperative complication rate is not significantly different between the open and minimal invasive technique. Operation time only is not an adequate parameter in this respect.

RCT’s comparing traditional open procedures and minimal invasive procedures should only be performed after learning curves have been completed. Further research should identify new learning curves like in minimally invasive repair of esophageal atresia and thoracoscopic lobectomy. Regarding the systemic effects of MIS, it is already known that it alters the immune system of the patient and contributes to the attenuation of the trauma response to surgery. More research should be done to identify effects of the pneumoperitoneum and pneumothorax on the circulation and cerebral perfusion.

**Suggested future research**

In all projects it is essential that studies should be performed after completion of the learning curves (both for the MIS and the open approach), which implies that both types of operations are performed by dedicated teams.

A randomized controlled trial comparing circumbilical open pyloromyotomy with laparoscopic pyloromyotomy after completion of the learning curve.
Identifying aspects of the continuous blood flow during laparoscopic cholecystectomy in the portal vein that could elucidate a possible relationship between portal vein thrombosis and laparoscopic splenectomy with concomitant cholecystectomy.

A multicenter study to analyze the effect of prophylactic low molecular heparin when performing laparoscopic splenectomy with concomitant cholecystectomy.

A randomized controlled trial comparing open versus thoracoscopic esophageal atresia with TEF.

Future

With the further expected application of paediatric endoscopic surgery there is a potential increase of patient safety concerns that will result in a more critical relationship between the patient and their relatives and the (paediatric) surgeon. In addition, the world wide financial crisis will put health care insurance companies and hospital economists in a position that they will seek for more arguments before investing in new expensive surgical equipment. And the health care inspectorate demands more efforts from the surgical societies to improve their results and diminish their complications.

Asking for improvements, the health care inspectorate, at least in the Dutch context, will demand volume and numbers will play an important role now and even more in the future. Health care insurance companies will be following this and financial issues in time of crisis will play an increasing role. In this coming era therefore the training of surgeons will demand more learning curves to identify the desired volume.

Concerning the problem of volume in paediatric surgery one can wonder if it is justified to start or continue doing a specific procedure minimal invasively. Collaboration between several surgical centres can provide sufficient exposure and will increase skills and knowledge by sharing experience, especially in low volume high complex operations like esophageal atresia and thoracoscopic lobectomy.

Next to that a further implementation of the training in MIS of residents and fellows should be set up. An educational system in which all the aspects of MIS in children are included should be developed. Throughout a structured curriculum there should be separate modules which should be examined and learning curves which should be completed, leading eventually to a certification. This certification should be identified first in national professional associations.

Besides clinically benefits for the patient and educational benefits, collaboration will provide a platform for data collection and research. In the Netherlands the European Paediatric Surgical Audit (EPSA) was recently started (www.clinicalaudit.nl/psa/).
web-based database gives the opportunity for all the paediatric surgical centres to give input in defined surgical neonatal pathologies as for example gastroschisis, omphaloceles, oesophageal atresia. In the future this could also include a specific minimal invasive section. Output would be nationwide and could compete with bigger volume studies from abroad. Also collaboration in existing international platforms can be very fruitful as in the International Pediatric Endosurgery Group (IPEG) which has a long term research program (www.ipeg.org).

By collaboration the industry and technical universities can be inspired to go for new improvements such as in ergonomics. Ergonomics, as proven in robotics in which the surgeon, performing his physically demanding MIS, is better of physically and can maintain and teach longer his skills 10.

Taking a break during long duration minimally invasive operations appears to improve the surgeons’ performance 11. Many aspects of MIS still have to be investigated in the context of the surgeons’ health as minimal invasive surgery is more demanding than open surgery 12. Injury and eventually early retirement of a certified and trained paediatric surgeon with minimal invasive skills would be a loss for both the patient and society in terms of quality and costs, not mentioning the personal disaster of the surgeon.
References


