Teaching and quality control in fetoscopic surgery

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SUMMARY

Learning curve and current practice

The concept of a "learning curve" is being used increasingly in surgical training and education to denote the process of gaining knowledge and improving skills. An often arising question in all types of surgery is the actual number of procedures an individual operator has to perform to achieve and maintain satisfactory outcome results. This is even truer for complex and rare interventions, such as fetoscopic surgery. Fetoscopic surgery is a surgical technique that is used to treat fetus(es) that are still inside the pregnant uterus. The most commonly performed procedure is laser surgery for twin-twin transfusion syndrome.

Twin-twin transfusion syndrome (TTTS) is one of the most common major complications of monochorionic (MC) twin pregnancies and carries a high risk of perinatal mortality and morbidity. Fetoscopic laser coagulation is the treatment of choice offered in approximately 100 specialized centers around the world. TTTS is rare and fetoscopic laser treatment is complex. With an increasing number of centers offering this procedure there is concern that, at least temporarily, less favorable outcomes will be seen because of limited experience in new centers and learning curve effects.

In **chapter 1** of this thesis we used the cumulative sum analysis to assess the learning curves and monitor ongoing performance of four operators performing fetoscopic laser therapy. This study shows an increase in survival rates with growing operator experience. The number of procedures required to reach an adequate level of performance ranged between 26 and 35 surgeries. The minimal individual variation in learning profiles that we found may be explained by the "group" learning effect, by influence of general expertise and exchange of experience.

Fetoscopic laser surgery was first performed in a few centers in the United States and Europe. These pioneer centers have made several modifications to the technique, making it difficult to compare results between centers. In **chapter 2** we conducted an international survey and took an important first step in the process of developing evidence-based international guidelines, by evaluating differences between international fetal centers in their treatment of TTTS. Considerable variations were found in patient characteristics, instrumentation and techniques, which appeared to be, at least partially, related to the volume of patients treated and geographical circumstances of the centers.

In **chapter 3** we reviewed the early years of practice compared to current practice. Since the first publications on fetoscopic laser surgery, survival rates have increased from 35% survival of both twins to 65%, with a consistent mean gestational age of 32 weeks. The evolution of the laser technique is likely to have significantly impacted this. Learning curve effects and improved early neonatal care may be other attributing factors. Even though we showed a significant increase in neonatal survival in 25 years, results are still far from optimal. We see challenges in improving the treatment of TTTS to increase survival of both twins and in prolonging pregnancies beyond 34 weeks of gestation.

Challenges in monochorionic pregnancies

Some MC pregnancies are more challenging than others. Fetoscopic laser surgery may then either not be considered as the first treatment of choice or may fail due to technical limitations in identifying anastomoses. Identification of those challenging subgroups is important to determine the best management options.

In **chapter 4** we focused on antenatal surgical interventions in monoamniotic (MA) pregnancies. Compared with complicated diamniotic cases, MA pregnancies carry additional risks. We studied MA pregnancies complicated by TTTS, twin reversed arterial perfusion, discordant anomalies, or request for reduction. We investigated relevant technical aspects of several fetal surgical interventions in complicated MA pregnancies and compared our experience with data obtained by a systematic review of the literature. We concluded that these complex procedures in this rare and highly complicated group of pregnancies, can lead to good outcome in the majority of cases, when performed in highly specialized fetal treatment centers. In case of a single intended survivor, our results suggest improved pregnancy outcomes in cases treated with cord transection (e.g. cutting the cord of the affected twin to prevent entanglement). Considering the rarity and complexity of these pregnancies, it remains crucial to individualize each case when determining the timing and type of intervention.
As it is an invasive procedure, perioperative complications of laser surgery itself increase the risk of adverse outcome. One of these complications is unintentional perforation of the intertwin dividing membranes, thereby creating an iatrogenic monoamniotic twin (iMAT) pregnancy. If iMAT is suspected, pregnancies are often more closely monitored, hospitalization after viability is considered and a preterm, elective Cesarean section is scheduled between 32 and 34 weeks' gestation to prevent complications related to cord entanglement.

In **chapter 5** we investigated the incidence of iMAT after laser surgery for TTTS and compared management and perinatal outcomes of suspected iMAT cases with those of twins with intact intertwin membranes. Patients with iMAT were more likely to deliver prematurely, and this was associated with increased neonatal morbidity. Moreover, iMAT may serve as an indicator for technically difficult procedures.

Another group in which laser therapy can be more difficult includes triplet pregnancies. Because a MC twin pair can be part of any other high-order multiple pregnancy, survival rates of MC triplets are often confused with dichorionic (DC) triplets, with one pair of MC twins affected by TTTS and one singleton. This situation is different to MC triplets that share a single placenta with three fetuses and therefore all three, instead of two fetuses, are connected by vascular anastomoses.
In **chapter 6** we compared the perinatal outcomes of all MC and DC triplets with TTTS treated at our center and reported in the literature in the last two decades. Perinatal morbidity and mortality in MC triplets with TTTS was higher and gestational age at birth earlier than in DC triplets. The data demonstrate that fetoscopic laser coagulation in DC triplet pregnancies complicated by TTTS is a feasible treatment option with increasing survival rates and more advanced gestational age at birth.
Model for training laser therapy Knowing that laser therapy is a complex procedure and there is an increased need for training, the final part of this thesis is dedicated to development of a training curriculum for this procedure. The SILICONE project: **SI**mulator for **L**aser therapy and **I**dentification of **C**ritical steps of **O**peration: **N**ew **E**ducation program; consists of three parts:
Part 1: Development of an evaluation instrument for fetoscopic laser surgery.
Part 2: Validation of this instrument.
Part 3: Validation of a training curriculum based on the instrument.

A first essential step towards a training curriculum was determining the applicable items to assess. In **chapter 7** we used the Delphi methodology to achieve expert consensus regarding the substeps that are considered essential in performing laser surgery for TTTS. The majority of fetal surgery experts participated. We produced a list of substeps deemed essential. Items were ranked in order of importance. This study provides a first step towards an authority-based training curriculum and evaluation tool for laser surgery for TTTS.
In the second part of the project we assessed the reliability and construct validity of the evaluation instrument in the context of fetoscopic operating room performance.

(**chapter 8**) We developed a silicone simulator for laser therapy and asked experts and novices to perform the laser procedure on the simulator. The assignment was evaluated by two independent observers using the evaluation instrument. An acceptable level of inter observer reliability was demonstrated. The instrument effectively distinguished between performance of experts and novices.

In order to evaluate whether simulator training could be attributable to gain and retain skills in fetal therapy, in the third part of the project we performed a prospective randomized controlled trial and assessed a comprehensive training curriculum (based on the essential steps defined in part 1) for fetoscopic laser surgery. (**chapter 9**) Novices who participated in the curriculum showed better performances during an ex vivo assignment on the high fidelity simulator for laser therapy for TTTS, compared to novice without training. Using the same simulator, expert benchmark levels for proficiency were set.