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IMPLEMENTATION OF ROBOTIC SURGERY IN A PEDIATRIC HOSPITAL: LESSONS LEARNED

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Abstract:	<p>ABSTRACT</p> <p>Background: Since the late 1980's, Minimally Invasive Surgery (MIS) has been one of the fastest growing approaches for surgical procedures. However, its development has reached a plateau. One of the reasons is the difficulty to operate on more complex cases, such as neonatal procedures. Some experts report outstanding outcomes for complex operations, but not all surgeons may be able to achieve the same results. Is Robotic Surgery (RS) a solution?</p> <p>Methods: To answer this question, we reviewed the current indications of RS for the pediatric population and the steps needed to incorporate the Robotic Surgical System in a children's hospital. We reported our experience and presented our first results as well as the encountered problems.</p> <p>Results: After a year and a half of experience with RS, several lessons were learned: 1) The current Robotic Surgical System cannot be considered a replacement to conventional MIS yet; 2) Docking is less time consuming than expected; 3) Post-operative pain is significantly decreased; 4) The absence of haptic feedback is still a matter of concern; 5) Costs can be afforded by sharing the RS with adult surgeons.</p> <p>Conclusions: Based on our experience, the advantages seem to outweigh the drawbacks as it encourages team-building and increases overall comfort for the surgeon. However, the current literature fails to prove that RS gives better results for pediatric patients. New advances in technology will probably help to overcome the encountered difficulties as well as the high costs.</p>

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IMPLEMENTATION OF ROBOTICSURGERY IN A PEDIATRIC HOSPITAL:

LESSONS LEARNED

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DISCLOSURE STATEMENT

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ABSTRACT

Background: Since the late 1980's, Minimally Invasive Surgery (MIS) has been one of the fastest growing approaches for surgical procedures. However, its development has reached a plateau. One of the reasons is the difficulty to operate on more complex cases, such as neonatal procedures. Some experts report outstanding outcomes for complex operations, but not all surgeons may be able to achieve the same results. Is Robotic Surgery (RS) a solution?

Methods: To answer this question, we reviewed the current indications of RS for the pediatric population and the steps needed to incorporate the Robotic Surgical System in a children's hospital. We reported our experience and presented our first results as well as the encountered problems.

Results: After a year and a half of experience with RS, several lessons were learned: 1) The current Robotic Surgical System cannot be considered a replacement to conventional MIS yet; 2) Docking is less time consuming than expected; 3) Post-operative pain is significantly decreased; 4) The absence of haptic feedback is still a matter of concern; 5) Costs can be afforded by sharing the RS with adult surgeons.

Conclusions: Based on our experience, the advantages seem to outweigh the drawbacks as it encourages team-building and increases overall comfort for the surgeon. However, the current literature fails to prove that RS gives better results for pediatric patients. New advances in technology will probably help to overcome the encountered difficulties as well as the high costs.

INTRODUCTION

Since its implementation in the late 1980's Minimally Invasive Surgery (MIS) has proven its feasibility and safety in the adult population when compared to the standard open approach. It has since become apparent that it can be superior to open surgery when applied to selected patients and pathologies. Despite the steep learning curve, conventional MIS (laparoscopy, thoracoscopy and retroperitoneoscopy) offers several advantages: 1) It has been shown to reduce post-operative pain; 2) It may shorten the length of hospital stay (LOS); and 3) It has better cosmetic results. In Pediatric Surgery however, there is no such evidence of superiority over the open approach (1) and MIS can only be considered feasible and safe in children when performed by experienced surgeons (2). The limitations of conventional MIS become more apparent when applied to the little patient. In particular the decrease in dexterity, the limited degrees of freedom, two-dimensional view, and the lack of depth perception make MIS challenging in the pediatric population. These limitations can be overcome with training and experience but some operations are still difficult to perform, even for highly skilled surgeons. In order to understand where we stand today in terms of indications for conventional MIS surgery, a few considerations have to be made: 1) The majority of general pediatric surgery cases may be accomplished with a minimally invasive approach (i.e. appendicitis, cholecystectomy, gastroesophageal reflux); 2) More complex operations such as lung lobectomy, nephrectomy or pyeloplasty, can be successfully performed. However, extensive training is required which is why they are mainly reserved to experts in the field; 3) Some operations are extremely challenging even for highly skilled MIS surgeons; this is particularly the case for oncological and neonatal surgery due to the narrow operative spaces and the low caseload; 4) Many of the instruments used in pediatric MIS are identical to those used for adult patients, and are clearly too big to be functional on children. In

addition, the combination of financial constraints and low demand makes it difficult to encourage the Surgical Industry to develop smaller tools for our field (3). Our team feels that after 20 years of exciting progress in pediatric MIS, a plateau has been reached due to the reasons listed above. Could Robotic Surgery (RS) be a solution?

To date RS has been largely adopted, especially for urological, gynecological and colorectal procedures. However, evidence-based studies showing better results compared with laparoscopy and open surgery are still limited (4, 5). Currently, the most performed robotic procedure is prostatectomy. While it showed similar outcomes as compared to open retropubic prostatectomy (6), randomized controlled studies and meta-analysis in gynecologic and colorectal surgery favored RS. This was due to better outcomes in terms of operative time, conversion rate, and LOS (4, 5, 7). Unfortunately, the application of RS in pediatric surgery is still controversial. With this review, we aim to evaluate how the RS technology can impact a pediatric hospital and report our experience with the implementation of a Robotic Surgical Program.

IMPLEMENTATION OF A ROBOTIC PROGRAM AT HOPITAL UNIVERSITAIRE DES ENFANTS REINE FABIOLA (HUDERF)

In 2012, the growing perception that the refinement of pediatric MIS was reaching a plateau led us to believe that the robotic system would have been the next step in surgical development. The rationales that compelled us to implement a Da Vinci Si Robotic System in our hospital were the following:

1. We were looking for a new technology that could have taken over conventional MIS, overcoming its limits, especially for technically challenging procedures. We felt that RS

would have been the next step in surgical development, helping surgeons to improve their skills and to increase the quality of MIS surgery.

2. We felt that robotic surgery would have been an incentive for the administration of our hospital, a third level Pediatric Center, to invest more in minimally invasive technologies.
3. To ensure the best results for a surgical workforce, team-building is of paramount importance. The team is urged to work more efficiently, in an effort to deliver the desired results. Team-building in the operating room (OR) helps to foster better and open communication among the team. We believed that RS, more than any other type of approach, would have given a huge contribute to team-building in our Surgical Department.
4. The robot signals technological advancement and innovation. Other than being a marketing product to increase attractivity outside the hospital, it increases morale among the people working inside the institution.
5. Ultimately, Single Incision Surgery is something that we have always wanted to attempt but, with very few exceptions, it was impossible to achieve with conventional MIS as the instruments were specifically developed for adult patients (8).

HUDERF BUSINESS PLAN

Once the administration of our institution approved the proposal to purchase the Da Vinci robotic system, we finally obtained the implementation of a Da Vinci Si model in August 2015. The initial investment was entirely supported by our children’s hospital. Throughout the years, we cut down on costs through grants and fundraisings.

At our institution, the children's hospital owns the robot. To help cover the costs the adult surgeons are allowed to perform robotic procedures in the pediatric OR, however, the pediatric surgeons maintain control over its scheduling and use. This is a different scenario compared to many other hospitals around the globe. There are three main advantages for our arrangement: 1) The centralization of the robotic system facilitates more efficient scheduling for robotic cases; 2) Incentivizes pediatric surgeons to adopt RS more frequently and to perform more challenging procedures; 3) Sharing the robot with adult surgeons is still feasible and helps to cut down on expenses. The annual costs are partly compensated by a 1,500 € fee paid by the adult hospital for each adult patient operated with the robot. Besides, as adult surgeons use 8 mm instruments and pediatric surgeons 5 mm instruments, each hospital is responsible for purchasing their own tools. Ultimately, our business coordinators simulated a plan to cover the overall expenses and calculated a minimum number of patients to be operated over a 5-year period that reached a plateau of 120-150 pediatric operations per year: 1st year, 30 cases; 2nd year, 60 cases; 3rd year, 100 cases; 4th year, 120 cases; 5th year, 120-150 cases.

PRELIMINARY RESULTS

During the first year, we almost achieved our business goal by operating on 24 children in ten months. The global number of pediatric patients who underwent robotic procedures during the first two years are summarized in Table 1. Extra costs due to the "built-in obsolescence" of robotic instruments were also recorded (Table 2). Overall, we encountered four complications. The first one was an iliac artery spasm after a bilateral Lich-Gregoir procedure. Most probably, the spasm was due to patient's positioning — this complication has been extensively documented during an open approach. However, iliac artery spasm can also be due to

compression of the artery by a 5 mm instruments when the trocar is too close to the groin. The patient recovered uneventfully a few hours later and received a subcutaneous anticoagulation prophylaxis. A second complication was a ureteral necrosis after robotic excision of a rhabdomyosarcoma of the groin, which was infiltrating the ureter. With the robot the tumor was easily dissected, but part of the infiltrated ureter became necrotic. This is a complication that has been documented with both conventional MIS and open approach. Unfortunately, due to the extent of the necrosis, we were not able to repair the ureter robotically. An open ureteral reimplantation with psoas bladder hitch was necessary. A third complication occurred during a pyeloplasty. We had to convert to an open approach because the pelvis was completely hidden into the kidney making presentation even impossible after “conversion” to a laparoscopic approach. The last but most important complication was a bile duct injury during a cholecystectomy. The patient had an anatomic variation of the cystic duct which had a parallel course with the common hepatic duct. The bile duct was immediately repaired robotically and stented. The patient was discharged twelve days later. After an extensive discussion of this case at our morbidity and mortality multidisciplinary meeting, we concluded that the wrong orientation of the camera, which was rotated upside down during the dissection, contributed to the adverse event. This complication had a negative impact on our robotic program which was suspended for few months. We finally restarted the program in April 2017.

DISCUSSION

Many criticisms were raised more than 20 years ago when MIS was introduced in pediatric surgery, including difficult tissue manipulation in narrow spaces, discrepancy between the size of the child and that of available instruments, and higher costs compared with traditional open surgery. Nowadays, RS is experiencing the same hurdles and skepticisms. Although many

studies regarding economic aspects related to the use of RS in the adult population have been reported, this issue has not yet been adequately examined in pediatric patients. At present, although it is difficult to define both applicability and reproducibility of RS in children, most surgeons proved to appreciate the change from classic open laparotomic/thoracotomic surgery to RS, and the possibility to overcome some major limits of laparoscopy (9-11). In addition, it has also been proved how easy it is to shift from laparoscopy to RS (12). Certain anatomic structures such as the deep pelvis can be technically demanding when approached with conventional laparoscopy due to very narrow working spaces. This is the case of restorative proctectomy with J-pouch ileo-rectal anastomosis or esophagogastric disconnection. RS seemingly offers advantages over traditional minimally invasive surgery, such as three-dimensional vision, greater magnification, operator-controlled camera movement, improved dexterity, motion scaling, tremor filtration, and removal of the fulcrum effect, allowing for better and more precise dissections. Similarly, rectal dissection can be easily carried down to the levator ani with minimal traumatism of perirectal structures with RS. Furthermore, RS proved to be particularly suitable for oncologic surgery, given the reduced need for mobilization and manipulation of tissues together with a sharper dissection permitted by the increased degrees of freedom of robotic arms.

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee has compared RAS with conventional MIS in the adult population in different surgical areas (foregut, colorectal, hepatobiliary, and pancreatic surgery), analyzing safety, efficacy, and costs. Although the authors found RS to be as safe and effective as conventional MIS, they underlined that the increased costs must be taken into maximal consideration when resorting to such approaches. In addition, another downside of RS

is linked to the Intuitive Surgical, Inc. monopoly. Using a clever business model, Intuitive bought out all of its tele-surgery competitors and closed the market to other companies. The consequence is a lack of competition with incredibly high selling prices. The “built-in obsolescence” of each instrument is the paradigm of this business model. According to the Intuitive 2015 annual report, “a programmed memory chip inside each instrument is designed to prevent the instrument from being used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure”. On the other hand, Intuitive Surgical, Inc. brought some criticism to the SAGES assessment in terms of modality of comparison between robotic and laparoscopic surgery, adoption of exclusion criteria for analyzed studies, and modality of cost comparison. Of note, one of the key points raised was that RS should be compared with open surgery rather than conventional MIS, given the wider number of procedures that are amenable with the RS approach (13). We agree on that and we suggest that in certain instances RS should represent the true alternative to open surgery. This is one of the most intriguing take-home messages that underlines how RS allows surgeons to apply MIS concepts to surgical procedures that are usually performed through laparotomy/thoracotomy.

Our preliminary experience turned out to be extremely positive, confirming that the involved staff members are very keen in investing in high-level technology that extended the horizon of the applicability of MIS. The Da Vinci Robotic System is a tool that offers an MIS approach to many pediatric pathologies, in particular those who require complex reconstructive surgery. Although cost-effectiveness is still a matter of debate, a number of pediatric patients would surely benefit from this highly innovative approach. Even simple operations can be used as a “gateway” procedure to RS with the intent to progress to more complex procedures.

Gastroesophageal reflux surgery is a good example. Although the robot will never prove its superiority over conventional MIS, a recent status evaluation by Chaussy et al. confirms that fundoplication is one of the most performed procedures with robotic assistance in children (14). In addition, due to its versatility, an increasing number of RE-DO surgeries are being performed with the robot (15).

Overall, we have learned a few valuable lessons from our experience:

1. The prohibitive cost of the robot is probably the most important reason why pediatric surgeons have not embraced this technology as readily as their adult colleagues. A recent analysis by Mahida et al. compared hospitalization costs of robotic, laparoscopic and open procedures. Not surprisingly, the authors demonstrated that general costs of robotic surgery were higher than non-robotic operations (16). We are cognizant of the higher costs and we have estimated that for each operation the added cost range between 800 € and 1,200 €. Most of this extra cost is due to the “build-in obsolescence” of the instruments. However, cost sharing with our adult colleagues has enabled us to adopt this technology.
2. The need for accessory MIS instruments is seldom reported in articles comparing costs between MIS and RS. However, robotic procedures in children are oftentimes impossible to be performed without the aid of an additional trocar — to retract, aspirate, irrigate or clip tissues.
3. Patient’s size does not appear to affect surgical success. A recent comparative study by Ballouhey et al. reported same outcomes in children weighing less and more than 15 kg (17). However, proper port placement is critical when using the 5 mm instruments. They

need a wider workspace due to their lower endowrist dexterity as compared to the 8 mm ones (18).

4. Team training was faster than expected. Docking was learned quickly by the nurses, largely due to preoperative drawing of patient's positioning — docking time was roughly 30 min after the initial five procedures. We performed a total colectomy for Hirschsprung's disease, repositioning the robot 3 times during the operation (left side, right side, and pelvic positions), in less than 170 min.
5. Pediatric surgical caseload is low. Therefore, "gateway" procedures such as Palomo for varicocele are critical to improve the learning process and to attempt more challenging operations.
6. The preliminary results of an ongoing study showed that in case of proper docking and port positioning there was minimal postoperative pain. This is leading us to push the envelope and to attempt Single Site Surgery in the near future.
7. Working without haptic feedback is a new experience for a traditionally trained surgeon. However, despite the lack of tactile sensation, the markedly enhanced three-dimensional view and instrument dexterity offer significant advantages for complex pediatric procedures.

What should we expect in the future for pediatric RS?

- Development of smaller instruments with higher degrees of freedom.
- Development of new and cheaper robotic surgical systems, as many patents are about to expire leading to a market expansion.
- Application of haptic technology to the new robotic systems.
- Accredited training programs and certifications in Robotic Pediatric Surgery.

When all the expectations listed above are fulfilled, RS will most likely take over conventional pediatric MIS and allow for more complex procedures, such as neonatal (3), cancer (19) and fetal surgery (20). Furthermore, new promising technologies such as virtual and augmented reality, 3D reconstruction and printing, and intra-abdominal mini-robots will soon be at our fingertips (21, 22). It is our responsibility to stay tuned as we witness ongoing developments in this fascinating technology-driven field of research.

CONCLUSION

Obviously, implementing a robotic program in a children's hospital is not an easy game. This is mainly due to the fact that the advantages of the current robotic system are still debatable. Based on our experience, the benefits seem to outweigh the drawbacks in terms of teambuilding, attractivity and comfort for the surgeon. However, the current literature fails to prove that RS gives better results for pediatric patients. New advances in technology will probably help to overcome the encountered difficulties as well as the high costs.

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TABLES AND FIGURES

Table 1: Type, number of cases, and complications (Nov 2015 – Oct 2017)

TYPE OF OPERATION	NUMBER OF CASES	COMPLICATIONS
NISSEN and TOUPET	11	0
CHOLECYSTECTOMY	12	1 main duct section directly repaired
LICH-GREGOIR (1 duplication)	5 ureters / 3 patients	1 iliac artery spasm
SPLENECTOMY	3	0
PYELOPLASTY	6	1 conversion to conventional MIS than to open
ABDOMINAL TUMORS	2	1 ureteral necrosis
COLOPROCTECTOMY + 70 cm of small bowel resection (Hirschsprung)	1	0
COLO-RECTAL ANASTOMOSIS (after Hartmann)	1	0
PALOMO (varicocele)	2	0
total	43	

Table 2: Extra cost due to built-in obsolescence of the RAS instruments

Pyeloplasty	1121.57 euro
Lich Gregoir	1121.57 euro
Nissen/Toupet	945.79 euro
Cholecystectomy	867.57 euro