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INTRODUCTION

Prostate cancer is the most common cancer, excluding skin cancer, and the second leading cause of cancer-related death in men in the United States (1). After PSA approval by FDA in 1986, the incidence of prostate cancer had steeply increased; rates peaked in white men in 1992 (237.8 per 100,000 men) and in African American men in 1993 (343.1 per 100,000 men). The increased rate of new diagnosis had been associated to a disease downward stage migration, particularly in early 90s; since 1995 stage migration has slowed but continues to decrease significantly (2). However, since the early 1990s prostate cancer incidence is declining and the estimated incidence for 2008 has been 186,320 (1).

The gold standard treatment for organ confined prostate cancer is radical prostatectomy. It has been demonstrated to provide cancer specific survival benefit compared to conservative management in a prospective randomized trial demonstrating a reduction of disease-specific mortality, overall mortality, and the risks of metastasis and local progression (3).

Nevertheless, despite well established cancer control, perioperative impact and functional results are matter of concern for the patients and their treating physicians. Alternative approaches have been developed in the past years in order to perceive the best chances to maintain an adequate cancer cure, minimizing side effects. A minimally invasive laparoscopic approach has been proposed in 1992 by Schuessler (4) first, and then standardized by Curto et al in 1997 (5). Despite the promising perioperative and functional results, laparoscopic prostatectomy had a limited diffusion, particularly in the USA, being a technically demanding procedure. The use of 2D vision and the reduced degrees of freedom of the laparoscopic instruments required a steep learning curve for mastering the procedure and various reports indicate that proficiency to perform LRP in 4 hours requires at least 40 to 60 cases (6, 7).

A further step toward the diffusion of the minimally invasive approach to prostatectomy was due to the introduction of new technologies in the surgical field. A robotic master-slave system (da Vinci™, Intuitive Surgical, Sunnyvale, CA, USA) was used by Binder in May 2000 for the first robotic assisted laparoscopic prostatectomy (8). The da Vinci system, even though it does not satisfy the common definition of surgical robot (*computer-controlled manipulator with artificial sensing that can be reprogrammed to move and position tools to carry out a range of surgical tasks*) (9), is commonly defined 'da Vinci robot' and consequently the surgical procedures performed with such tool are commonly defined robotic procedures. The 3D vision, instrument with 7 degrees of freedom, motion downscaling, anti tremor filter and ergonomic surgical position due to the operative console are the most relevant advantages of this instrument.

The easier learning curve has been attractive for most of the urologists, particularly laparoscopic naïve. According to Ahlering et al, only 10 cases are sufficient to perform a robotic prostatectomy with satisfying results within four hours (10). These advantages have been allowing a widespread diffusion of the da Vinci system worldwide. From 766 da Vinci prostatectomy in 2002 to more than 48.000 in 2007 have been performed, according to the intuitive surgical. About 1100 da Vinci has been placed so far in the world; of these more than 800 in USA (11).

Our aim has been to review the key elements that substantially contribute to raise a successful robotic program.

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PROGRAM DESIGN

BUSINESS PLAN DEVELOPMENT

The establishment of an economic model is crucial for a robotic program. An accurate due diligence is important to establish the economic boundaries that each institution has to deal with; the development of the business plan requires an evaluation of the direct costs (such as buying the robotic system) and of the associated material, staff recruitment and/or staff training. Possible operating room (OR) modifications could be necessary to support the console and the other equipment; a further necessary action is the recruitment of a leading surgeon or his development.

A further key element is the evaluation of the growth potential; for this particular purpose, a thorough market analysis will help to estimate the impact of the new program on the institution. A study of the population and the competition, the analysis of reimbursements and payers are additional aspects that conclude the evaluation.

One of the key steps to pursue a successful robotic program is the surgical volume. It is strictly connected to the learning curve and to the quality of outcomes. According to the experience of the Ohio state university, three to five cases per week during the initiation of the program are necessary to obtain continuity in the learning curve. Authors report a significant increase in surgical volume since the introduction of the robotic program, from 40 to 350 cases per year within five years (12). Furthermore, the establishment of an economic model is crucial for a robotic program. Activity-based costing and management (ABC) or alternative models seem appropriate approaches to develop a business plan related to robotic surgery.

ABC is a costing model that identifies activities in an organization and assigns the cost of each activity resource to all products and services according to the actual consumption by each: it assigns more indirect costs (overhead) into direct costs. In this way an organization can establish the true cost of its individual products and services for the purposes of identifying and eliminating those which are unprofitable and lowering the prices of those which are overpriced.

PURCHASE OF ROBOTIC SYSTEM

The da Vinci robotic system has a significant cost associated with its purchase. The cost of the robot is approximatel $1.2–1.7 million USD depending upon the type of system purchased. In addition there is a per case disposable fee for the robotic instruments of approximately $200 per instrument used. There is also a maintenance contract of $100,000 USD yearly per system (11).

In order to make a cost analysis and therefore to check the economic feasibility of the purchase of a da Vinci system, we need to evaluate the following items:

1) the cost of the surgery,
2) the reimbursement (according to the different health systems).

The cost of surgery can be evaluated with an analysis of the variable costs and the fixed costs. Variable costs are related to all those activities that are necessary to produce the surgical performance (such as disposable tools, medications etc.). Fixed costs are represented by the overall OR time dedicated to robotics and the purchase of the system. It is clear that a high surgical volume center can have an impact in terms of variable costs reduction; hence, the best chance to increase surgical volume and therefore to reduce costs is to share the use of the da Vinci system with our surgical teams, as gynecologists, general surgeons and other specialties.

INITIATION OF THE PROGRAM

The beginning of any robotic program can be challenging as multiple members of the team are learning the technology and their own personal roles on the team. Notwithstanding the robotic learning curve could be considered less challenging than laparoscopic one in terms of surgical procedure, there are many aspects that beyond the surgical act need to be developed at the beginning of the experience. Robotic docking and undocking, use of disposable instruments, assisting at the bedside far from the console: all the different people involved in the robotic program have their own learning curve; therefore it is of major importance to define which robotic procedures need to be performed at the beginning, since the main goal of a robotic team is to standardize the procedure as soon as possible.

Administrative staff

Beside the clinical team, a dedicated robotic program manager is necessary to coordinate administrative staff, to bridge the gap between clinicians and marketing, website management, patients' education and other crucial applications.

This way, the clinician can be more concentrated on surgical works and the program manager could accurately monitor the growth and all the other collateral activities.

IMPLEMENTATION

The operating room (OR)

Starting a robotic surgery program implies an organizing effort that has to be evaluated.

A dedicated OR for robotic surgery is advisable; compared to a traditional OR, a robotic OR has to be projected according to further necessities:

- Space limitations due to the presence of a surgical console, a surgical cart and the da Vinci
- The potential need for multiple assistants used in addition to the regular OR staff, particularly at the beginning of the learning curve.
- The need of keeping a specific stock required by the short life of many disposable instruments and

the need of extra instruments in case of possible malfunctioning.
– Large OR (about 60 m^2) with LCD screens and appropriate technological controls are advisable.

The robotic team

The leading surgeon

A leading surgeon to spearhead the program and work out the "kinks" is essential to the start up. This individual would oversee the clinical aspect of the program and plan the strategy for scaling the learning curve and then growing the program. Mastering the robotic approach is crucial. For a new robotic center, considering the widespread diffusion of robotic surgery, there is the need to start the program effectively, tackling the learning curve.

The role of the leading surgeon is not just performing the procedure but also to coordinate and to take care of the team and its training. A surgeon who starts a robotic program should involve other colleagues to promote the development of common scientific programs, to share the costs increasing overall surgical volume and to raise the visibility of the facility and therefore patients' recruitment. Surgical proficiency and ability to communicate and to create scientific network are essential skills to run a program.

For the classically trained surgeon the challenge of standard laparoscopy is often overwhelming, whereas transferring the surgical skills in the robotic environment is easier. Patel et al report a learning curve of 20 – 25 cases (13), in line with other experiences (14); and this is confirmed also for laparoscopic naïve surgeons (10).

Unless the surgeon starting the new program is already experienced, he needs to have the determination to undergo a proper training.

The keys to train leading surgeons are based on improving their knowledge of the da Vinci system with lab exercises on cadavers or porcine models; the next steps are case observations and video based learning and, it is advisable to perform the first procedures with a proctor.

Following a complete training, patient selection is the key. The leading surgeon, possibly discussing with the anesthesiologist, should select the appropriate patients. Body mass index, prostate volume and morphology, comorbidities and preoperative sexual function need to be carefully evaluated at the beginning of a surgical experience.

The operating room nursing staff

Contrary to traditional open surgery, robotic surgery implies that the leading surgeon does not have direct contact with the patient being completely immersed in the console and the scrub nurse (SN) and physician assistant (PA) are the only ones in direct contact with the patient. A complete understanding of the procedure and the surgical steps is crucial. The scrub nurse should coordinate with the PA during the entire procedure, providing sutures, instruments and helping taking care of the camera.

A scarce coordination between PA and SN can cause significant delays and difficulties during the procedure.

The surgical physician assistant

The physician assistant has one of the most important roles in the OR robotic team.

Most of the programs start with two surgeons working together, but with more experience and in order to reduce costs, the bedside surgeon can be easily substituted, in the US, by a surgical PA. The PA, at the bedside, needs to have a perfect coordination with the leading surgeon and the scrub nurse: a complete knowledge of the anatomy and the surgical operation are mandatory to provide adequate tractions, to expose the surgical field according to the surgeon's preferences, to position vascular clips and also vascular clamps. Furthermore, the surgical PA has a role in training further PA and also resident physician to learn how to assist at bedside.

Surgical fellows and residents

Training programs with "hands on" experience for fellows and residents have been recently developed for robotic surgery. Adequate teaching programs allow for an effective increase of fellows' experience with no impact on patients' outcome (15).

Robotic training for residents does provide a challenge for the supervising surgeon, due to use of a remote console and lack of haptic feedback. Nevertheless is crucial to provide an adequate foundation of robotic principles in trainees.

MAINTENANCE

Data collection

Starting a new surgical program should suggest a frequent update and audit regarding efficiency, outcomes and patient satisfaction. In addition, it is advisable to present and share a new experience with colleagues during meetings and scientific events or reporting it as peer reviewed papers in order to improve quality and to share knowledge and findings. An appropriate and prospective data collection is mandatory. A simple, easy to read database should include all the information; validated self administered questionnaires should be used as evaluation methods and strict follow up should be carried out particularly for oncological diseases.

Outcomes should be monitored regularly, in order to constantly monitor the outcome of the new surgical approach. A comparison with the previous adopted technique will be useful to evaluate possible advantages due to the advent of the new technique (16). Clinically it is also helpful to record each of the early cases and review them with the team to evaluate progress and plan a common approach to the procedure. A complete collection of video recorded surgical procedures is mandatory for surgical audits and for training of fellows and residents.

Monitoring the economic feasibility

A previously reported econominc feasibility study at an academic institution (12) concluded that the cost of medical and surgical supplies, including the cost of instruments accounted for 45% of total average direct cost and approximately one-third of average total cost. Operating room services and therefore, duration of OR utilization accounted for almost 30% of total average direct cost and 35% of the total cost per procedure, respectively. Projecting an increase in the number of procedures performed per year from 100 to 500 reduced costs by around 18%, based on the cost of the robot, and maximal change in costs was seen in increasing volumes from 20 to 100 cases per year.

Training and education

Once the program is launched, maintenance implies the enlargement of the surgical staff. Residents and fellows are involved in surgical activities with the supervision of a PA and primary clinician, beginning their surgical activity as bedside assistants, after an initial experience watching at least 20 cases.

It is noteworthy that surgical procedures performed using a camera have many advantages in terms of training. The video monitors and recorders allow the trainee to watch the procedure with the same field of vision as the operator and it is easier to create a complete video data base that can be used for further and future training.

Growth

All the aspects involved in the robotic program need to be checked periodically. Together with the program manager, the leading surgeon needs to assess the economic sustainability of the program; a breakdown of all parameters allows for an accurate check of materials and waste assessment. Considering the elevated costs, a reduction in OR time is one of the most important items to be checked to increase the economic feasibility of the project.

Obviously, the most important thing is the clinical evaluation. Matching databases and literature to compare the results of the new technique with the gold standard procedures and with other groups performing robotic programs can help monitor surgical quality.

Only if the auto-assessment reveals satisfactory outcomes, a further increase of the activity with new investments in terms of materials (another robot) and / or HR (surgeons, PA etc.) can be considered.

Nevertheless, an accurate market analysis needs to be renewed before the investment occurs, to match the chance of offering much more surgical volume and the real necessity of this increase.

CONCLUSIONS

According to the literature, robotic surgery has a less steep learning curve when compared to laparoscopy; particularly for a procedure such as radical prostatectomy. Building a successful robotic program means taking into account many details such as economics, organization and teaching. The keys for success are directly related to the infrastructure supporting the program, coordination of team work and careful review of outcomes.

To create, maintain and grow a robotic program, it is of utmost importance to build a complete and accurate strategy from the beginning. The risk-benefits analysis, the business plan and the leading surgeon are key factors for success.

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