Saudi Urological Association consensus guidelines on the use of robotic surgery in urology

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Abstract Over the past three decades, minimally invasive robotic technology has evolved substantially in urological practice, replacing many open procedures and becoming part of routine clinical practice. The Health Sector Transformation Program for the Kingdom's Vision 2030 aims to restructure the health sector and optimize its status and prospects as an effective and integrated ecosystem centered on the patient's health. Therefore, this consensus seeks to endorse the clinical practice guidelines for robotic surgery (RS) in the KSA, highlighting its effectiveness, safety, and favorable outcomes compared to open and laparoscopic surgeries in certain procedures when used by trained surgeons in well-structured RS programs.

Keywords: Consensus, robot, robot surgery, Saudi vision, training

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INTRODUCTION

Minimally invasive surgery (MIS) provides superior results to open surgery, leading to shorter recovery and reduced blood loss and perioperative complications.[1] Minimally invasive robotic technology has evolved in urological practice over the previous three decades. Currently, it is replacing open surgical procedures and has incorporated into everyday clinical practice. Starting in this century, robotic surgical devices are routinely used in different minimally invasive surgical procedures, including urology. As they evolve and become less expensive, robotic devices will become more frequently utilized and widely disseminated in all surgical procedures.

Over the last decade, robotic surgery (RS) has been successfully adopted worldwide for complex oncological procedures affecting the prostate, kidney, and urinary bladder.[2-4] Surgical robots help surgeons perform robotic MIS after a relatively short learning curve.[5,6] The three-dimensional (3D) magnified vision of robots with EndoWrist® technology (Intuitive Surgical Inc., Sunnyvale, CA, USA) has made dissection and suturing

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easier, especially with improved depth perception and precision with intuitive movement. Furthermore, it offers higher quality, more efficient surgery and allows surgeons to reach difficult locations in the body with a scope and fine instruments. In addition, it offers improved ergonomics that save the surgeon from occupational damage and injury. Nevertheless, the lack of tactile sense, longer operative times, and relatively higher cost may impact the widespread acceptance of robotic approaches.[7,8]

According to the company that makes the da Vinci Surgical System (Intuitive Surgical Inc.), the Surgical Robots Market exceeded 4.6 billion USD in 2020, with 570,00 da Vinci procedures performed worldwide in 2014. There were 4271 systems installed worldwide in September 2017, including 65% in the USA, 17% in Europe, 13% in Asia, and 5% in other areas. Between 2021 and 2031, the global surgical robotics market is predicted to grow, increasing from $5.46 billion in 2020 to USD 16.77 billion by 2031.[9] Moreover, the worldwide surgical robotics market is expected to witness immense growth over the prediction period due to the increasing prevalence of geriatric populations with chronic disorders, thus improving policies and funding.

ROBOTIC SURGERY IN SAUDI ARABIA

The Kingdom of Saudi Arabia is a good model to describe RS in the Middle East since it had the first surgical robot installed in 2003.[10] There are 16 surgical robots in Saudi Arabia, putting the kingdom at the top among owners of surgical robots in the Middle East. These 11 Xi and 5 Si robots installed in governmental hospitals, may limit the awareness of these services. This has translated to the fact that more than 90% of prostate and kidney cancer cases are managed by surgical robots in major and academic hospitals. This is consistent with the trend in most countries that have obtained this technology over the past 20 years. Acquiring surgical robots in private hospitals is expected to significantly influence the robotic caseload, especially by increasing the number of certified fellowship-trained robotic surgeons returning to their home country. Notably, RS is now the standard approach to dealing with many urological malignancies in most residency programs where urology trainees are trained in the USA, Canada, and Europe. This is supported by the progressive and significantly increased number of RSs performed within the past 5 years. This number is expected to substantially improve with increased awareness, optimized referral patterns among urologists, and coverage of the technique by medical insurance.

Asker *et al*. described trends in partial nephrectomy management at King Abdullah International Medical Research Center, Riyadh, and compared the MIS with the open surgery approaches. Robotic-assisted procedures were significantly associated with shorter operative time, lower blood loss, and longer hospital stay than open surgical techniques.[11] In addition, robotic techniques are significantly associated with shorter ischemia time, lower Clavien grades of complications, and less deterioration of long-term renal function over 6–12 months. The experience of robotic partial nephrectomy of 101 cases in Saudi Arabia showed similar outcomes to international centers of excellence.[12]

Recently, Azhar and his colleagues presented the first multinational experience in robot-assisted radical prostatectomy (RARP) in 207 patients. The authors confirmed the safety and efficacy of RARP by fellowship-trained experts in Saudi Arabia, where their outcomes were promising and comparable to those of international centers with the higher caseload.[13]

The Saudi Urological Association (SUA) Guidelines recommended robotic excision, preferably by partial nephrectomy, in all cases of localized disease and those with a solitary kidney, bilateral tumors, familial renal cell cancer, or renal insufficiency (evidence level1).[14] Similarly, the SUA recommended robotic radical cystectomy with extended lymphadenectomy as an alternative MIS for invasive bladder cancer.[15]

SURGEON TRAINING AND CREDENTIALING

Before clinical use, surgeons and support teams should undergo adequate technical training in surgical robots, including basic and advanced techniques, to develop good proficiency. After obtaining competence, the chief of service or the institutional board determines a period of provisional privileges and monitors performance through institutional quality assurance procedures. Periodic renewal of these privileges would depend on continuing medical education and relevant meetings and courses attendance. Furthermore, virtual reality simulators may help robotic surgeons to become familiar with different complex devices before clinical use, especially in emergencies. Moreover, surgeons should be aware of how to use the robot for specific surgeries and how to manage system failure. Adding the knowledge to an existing robotic clinical skill will significantly improve the quality of required learning.

CLINICAL APPLICATIONS

In comparison with conventional open or laparoscopic surgery, RS has the clinical advantages of better visualization of the operative field with 3D imaging and improved ergonomics for surgeons with well-stabilized instruments in the surgical field, especially in complex reconstructive processes. Being the earliest to be performed by robot, radical prostatectomy (RARP) is the most common robotic-assisted urological procedure to date. RARP has 5%–7% Clavien grade I–II and 4% Clavien grade III–IV complications,[15] with a 0.1%–0.2% mortality rate.[16] A recent meta-analysis showed significantly lower readmission and reoperation rates after RARP,[17] with a 22.4% biochemical recurrence rate at 10 years postoperatively and recurrence-free, metastasis-free, and cancer-specific survival rates of 73.1%, 97.5%, and 98.8%, respectively.[18] In addition, the potency recovery rates of 54%–90% and 63%–94% after 12 and 24 months, respectively, following RARP were faster than those following open RP.[19]

RA partial nephrectomy (RAPN) is feasible for large and complex hilar tumors,[20] with comparable adverse events to open PN, with a median ischemia time of 18.8 min and a 2.2% positive surgical margin rate. Intra- and postoperative complications were 2.6% and 13%, respectively, including 3.6% Clavien grade III-IV complications.[21,22] The recurrence-free and cancer-specific survival rates were 89.9% and 99%, respectively, at 5 years.[23] Ischemia and operating time, estimated blood loss, use of hemostatic agents, and length of hospital stay were significantly better with RAPN than with the laparoscopic approach.[24]

RA radical cystectomy (RARC) with urinary diversion is a safe, effective, and technically feasible alternative to open RC (ORC). RARC is associated with a longer operative time but has significantly fewer adverse events and blood loss, lower transfusion rates, and a shorter length of hospital stay. In addition, RARC is significantly associated with increased lymph node yield, with positive surgical margin rates comparable to ORC[1] and readmission rates (27% vs. 25.5%).[3,25] A < 1% difference in 2-year progression-free survival was reported between RARC and ORC, with comparable complication rates of 67% and 69%, respectively.[26] Lymph node yield expected to improve with previous experience in RARP,[27] with 48% overall complications, including 19% Clavien Grades III–V and a 4.2% mortality rate.[28] Robot-assisted intracorporeal urinary diversion is also feasible,[29] with 100% overall and recurrence-free survival at 2 years.[30] In a recent randomized clinical study, patients with nonmetastatic bladder cancer undergoing RARC with intracorporeal diversion were associated with significantly increased days alive and out of hospital over 90 days compared with those undergoing ORC.[31]

Similarly, robotic-assisted adrenalectomy (RAA) is safe and effective for benign adrenal masses, with a wide operative time of 98–234 min, a hospital stay of 1.1–6.4 days, estimated blood loss of 50–576 mL, and laparoscopic or open conversion rates of 0 = 40%.[30,32] Brunaud and associates reported that RAA was two times more costly than the laparoscopic approach, with a 10% perioperative complication rate,[33] while Giulianotti *et al.* reported a 2.4% postoperative complication rate and 2.4% mortality rate.[34] RAA was comparable with laparoscopic adrenalectomy in terms of length of hospital stay, complications, and conversion rates.[35] RS's clinical applications have extended to include different urological procedures at academic and experienced centers [Table 1].

ROBOTIC SURGERY IN THE INTERNATIONAL GUIDELINES

The European Urological Association (EUA) recommended using RARP for localized prostate cancer to achieve better

Table 1: Approved list of procedures that can be performed robotically by trained surgeons

Prostate
Radical prostatectomy
Simple prostatectomy
Kidney/adrenal
Partial nephrectomy
Radical nephrectomy
Pyeloplasty
Nephroureterectomy with or without excision of the bladder cuff
Extended pyelolithotomy (staghorn or multiple stones)
Renal cyst decortication/excision
Donor nephrectomy
Nephropexy
Management of chyluria
Adrenalectomy
Ureter
Ureteroneocystostomy
Ureteroureterostomy
Ureterectomy and reimplantation
Ureterolithotomy and ureterolysis
Ureterolympholysis
Ureteric stump excision
Ureteral hernia repair
Ureteropyelostomy and ureterocalicostomy
Bladder
Radical cystectomy with intra/extracorporeal urinary diversion
Partial cystectomy
Diverticulectomy
Anterior pelvic exenteration
Female urology
Vesicovaginal fistula repair
Vesico-uterine fistula repair
Ureterovaginal fistula repair
Sacrocolpopexy
Bladder neck suspension
Pediatric urology
Pyeloplasty
Ureteric reimplantation
Partial nephrectomy
Catheterizable channel creation (mitrofanoff procedure)
Excision of utricle

early continence and potency rates.[36] The EUA guidelines also recommended using surgical robots for partial and radical nephrectomy, if technically feasible. RARC with intra- or extracorporeal urinary diversion is a feasible and safe approach with comparable perioperative and long-term complications to ORC with an equivalent yield of lymphadenectomy and oncological efficacy.[36]

The Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) recommended RS in several urological procedures.[36] Robotics may offer advantages not only for RP but also for cystectomy, pyeloplasty, ureteral reimplantation, and partial, complete, and donor nephrectomy. Furthermore, bladder tumor resection may be performed robotically with few postoperative adverse events.[37]

COST-BENEFIT ANALYSIS OF ROBOTIC SURGERY

Cost-effectiveness analysis in healthcare examines both the costs and the outcomes of alternative surgical interventions. The cost of a surgical robot includes capital acquisition, use of instruments, expenses of team training, operating room setup time, and equipment repair and maintenance. RS should be appropriately compared to alternative surgical options, such as open, laparoscopic, or minimally invasive techniques.

The capital acquisition cost will vary across different institutions. It may include the capital purchase cost, donations, marketing programs, institutional technology investment decisions, and allocation of investment, while depreciation could be assessed on a per case basis.[37] Multidisciplinary teams may be included in the initial analysis, and the utilization of different robotic instruments may vary in other cases. A significant part of the yearly cost would include the cost of servicing, maintenance, and repair of these complex devices. This cost is estimated to be 10% of the capital acquisition cost each year,[36] which will reduce with future device development. Operating room time may include room setup time, time for draping and docking the robot, procedure time, and room turnover time, which are improved by sufficient team training, appropriate patient selection, and surgical team experience.

Most of the reported surgical robotic injuries result from human error secondary to inappropriate training on the device's safe use rather than device-specific issues. The 0.38% device failure rate was not associated with significant patient injury.[38,39] However, these adverse events will significantly influence the cost of care. Currently, robotic procedures performed by experts have comparable complication rates with alternative surgical techniques.

The length of stay (LOS) would affect the overall cost outside the operating room, where decreased LOS may counterbalance the increased operating room expenses associated with all forms of MIS. Postoperative pain, intraoperative bleeding, and perioperative adverse events have influenced the LOS. Therefore, RS should be compared to alternative techniques based on a given procedure, where it may appropriately compare to either MIS or open techniques.

GENERAL BENEFITS

Surgical robots create a highly effective therapeutic system for performing complex surgical procedures due to excellent visualization, platform stability, tremor reduction, motion scaling, and articulating end effectors. Furthermore, enhancements in precision may help surgeons perform a variety of advanced MIS procedures, especially for patients in whom conventional laparoscopic techniques cannot be performed. Compared to patients undergoing open surgery, RS reduced the readmission rate by 52% and cut blood clot risk by 77% with shorter hospital stays and faster recovery.[31]

ERGONOMICS

The surgeon's ergonomics of RS is better than that of the standard endoscopic procedures. Open and laparoscopic approaches are physically strenuous and may be associated with surgeon morbidity. However, robotic conducted procedures are generally more ergonomic for the surgeon, who sits comfortably in an ergonomically designed workstation.[37] These ergonomic differences will be magnified for lengthy procedures.

LEARNING CURVE AND TRAINING

Technically, complex surgical tasks are time-consuming and present a substantial learning curve. The additional degrees of freedom offered by articulated-arm robots may facilitate such complex procedures and reduce technical skill acquisition time.[37] Moreover, surgeons may easily access difficult anatomic regions, potentially speeding up the introduction and clinical adoption of new MIS techniques.

RETURN TO USUAL ACTIVITY AND SICK LEAVE

Sick leave length is an important parameter that indirectly measures the ability of patients to return to work after a surgical procedure. As RS may have better patient outcomes than open or standard minimally invasive procedures, it can lead to shorter sick leave and quicker return to work than open surgical procedures.[40] This may represent indirect cost benefits of the robotic-assisted procedure, which should be considered in cost analysis studies comparing RS to open surgery.

SUMMARY

Since its introduction, RS has extended to almost all aspects of urological surgical fields and has become the standard of care for many complex reconstructive procedures. With increasing caseloads and diversity of cases, RS continues to grow in the Middle East, specifically in the KSA, which owns 16 surgical robots, putting it at the top of the list of owners of surgical robots in the Middle East, especially with the increasing number of certified robotic surgeons returning to their home country.[41,42] The number of RSs performed within the past 5 years in the KSA has progressively increased, and Saudi urologists consider RSs to be the standard of care for RP, pyeloplasty, and PN.[37] This would be significantly further improved with increased awareness, acceptance of modern technology, coverage of the technique by medical insurance, and increased referral patterns among urologists.

The utilization of RS should be associated with decreasing costs to health-care systems and improved clinical outcomes. Therefore, this technology should be more affordable, especially because it promotes an earlier postoperative return to work and daily activities than other surgical procedures.

Key points

- RS has extended to almost all aspects of urologic surgical fields and has become the standard of care for many complex reconstructive procedures
- RS has the advantages of reduced blood loss and perioperative complications and improved perioperative outcomes compared to open surgery, especially in complex reconstructive processes, including RP, RN or PN, RC, and adrenalectomy
- KSA represents a good model for the description of RS in the Middle East, since it has 16 surgical robots, with increasing numbers of certified robotic surgeons returning to their home country
- The international guidelines and the SUA Guidelines recommended RS for most complex oncological and reconstructive procedures
- The Board of Governors of the SAGES recommended RS with its substantial advantages over conventional MIS in several urological procedures
- RS has cost-effectiveness, with better patient outcomes and less morbidity, which leads to shorter sick leave and quicker return to work, and thus should be regarded as an indirect cost-benefit of the procedure
- RS creates a highly effective therapeutic system for performing surgical procedures, even in patients who could not undergo conventional laparoscopic surgeries
- The progressively increased number of robotic-assisted procedures performed within the past 5 years in KSA would support the use of the approach
- Increased awareness, acceptance of modern technology, and its incorporation in the health insurance plan in Saudi Arabia would represent a cornerstone and play a crucial role in making this technology available for everyone in the Kingdom.

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Conflicts of interest
There are no conflicts of interest.

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