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“ΕΛΑΧΙΣΤΑ ΕΠΕΜΒΑΤΙΚΗ ΧΕΙΡΟΥΡΓΙΚΗ, ΡΟΜΠΟΤΙΚΗ
ΧΕΙΡΟΥΡΓΙΚΗ ΚΑΙ ΤΗΛΕΧΕΙΡΟΥΡΓΙΚΗ”**

**ΕΘΝΙΚΟ ΚΑΙ ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ**

ΔΙΠΛΩΜΑΤΙΚΗ ΕΡΓΑΣΙΑ

ΘΕΜΑ:

**CHANGE OF PRACTICE PATTERNS IN UROLOGY WITH THE
INTRODUCTION OF THE DA VINCI SURGICAL SYSTEM:
RESULTS FROM A GREEK NATIONAL HOSPITAL**

ΜΕΤΑΠΤΥΧΙΑΚΟΣ ΦΟΙΤΗΤΗΣ:

ΔΕΛΗΓΙΑΝΝΗΣ ΔΗΜΗΤΡΙΟΣ

ΕΙΔΙΚΕΥΟΜΕΝΟΣ ΟΥΡΟΛΟΓΟΣ

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ΤΗΝ ΑΞΙΟΛΟΓΗΣΗ ΤΗΣ ΔΙΠΛΩΜΑΤΙΚΗΣ ΕΡΓΑΣΙΑΣ
Του Μεταπτυχιακού Φοιτητή Δεληγιάννη Δημητρίου

Εξεταστική Επιτροπή

- Ευάγγελος Φελέκουρας, Αναπλ. Καθηγητής Χειρουργικής, **Επιβλέπων**
- Χρήστος Π. Τσιγκρής, Καθηγητής Χειρουργικής & Επιστημονικός Υπεύθυνος
του Π.Μ.Σ
- Θεόδωρος Διαμαντής, Καθηγητής Χειρουργικής

Η Τριμελής Εξεταστική Επιτροπή η οποία ορίστηκε από την ΓΣΕΣ της Ιατρικής Σχολής του Παν. Αθηνών Συνεδρίαση της.....^{ης} 20.... για την αξιολόγηση και εξέταση του υποψηφίου κ. Δεληγιάννη Δημητρίου, συνεδρίασε σήμερα .../.../....

Η Επιτροπή διαπίστωσε ότι η Διπλωματική Εργασία του Κυρίου Δεληγιάννη Δημητρίου με
τίτλο: Change of Practice Patterns in Urology with the Introduction of the Da Vinci Surgical System: Results From A Greek National Hospital είναι πρωτότυπη, επιστημονικά και τεχνικά άρτια και η βιβλιογραφική πληροφορία ολοκληρωμένη και εμπειριστατωμένη.

Η εξεταστική επιτροπή αφού έλαβε υπ' όψιν το περιεχόμενο της εργασίας και τη συμβολή της στην επιστήμη, με ψήφους προτείνει την απονομή του Μεταπτυχιακού Διπλώματος Ειδίκευσης (Master's Degree), στον παραπάνω Μεταπτυχιακό Φοιτητή.

Στην ψηφοφορία για την βαθμολογία ο υποψήφιος έλαβε για τον βαθμό «ΑΡΙΣΤΑ» ψήφους, για τον βαθμό «ΛΙΑΝ ΚΑΛΩΣ» ψήφους, και για τον βαθμό «ΚΑΛΩΣ» ψήφους Κατά συνέπεια, απονέμεται ο βαθμός «.....».

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| • Χρήστος Π. Τσιγκρής, | (Υπογραφή) _____ |
| • Θεόδωρος Διαμαντής, | (Υπογραφή) _____ |

ΕΥΧΑΡΙΣΤΙΕΣ

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CONTENTS

	Page
Introduction	6
 Part 1st	
 1. Robotic Surgery	9
1.1 Definitions – Basics of surgical robots	9
1.2 History of surgical robots	11
1.3 History of robotic surgery	14
1.4 Da Vinci Surgical System	15
1.5 Applications	20
1.6 Advantages - Disadvantages	22
1.6.1 Advantages	22
1.6.2 Disadvantages	23
1.7 Future application for robotics	24
 2. Robotic assistance in Urology	26
2.1 History of robotics in Urology	26
2.2 Robot-assisted radical prostatectomy (RARP)	27
2.3 Robot - assisted cystectomy (RARC)	32
2.4 Robot - assisted nephrectomy	34
2.4.1 Robot - assisted radical nephrectomy (RAN)	34
2.4.2 Robot - assisted partial nephrectomy (RPN)	36
2.5 Robot - assisted pyeloplasty (RLPP)	42
2.6 Other robotic applications in urological procedures	43

Part 2nd

Purpose	46
Materials and Methods	47
Results	48
Tables and Figures	52
Discussion	57
Conclusions	61
Abstract in Greek - ΠΕΡΙΛΗΨΗ	62
Abstract in English	64
References	65

Introduction

The first use of surgical robotic assistance in urology was in 1989 when Davies et al used the PROBOT during transurethral prostate resection [3,6]. In 2000, Binder et al performed the first robot-assisted RP. FDA clearance for the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) in prostate surgery was granted in 2001 [7,11].

Since then, there is increasing patient and surgeon interest in minimally-invasive techniques, particularly with the use of the DVS. Urology has seen a dramatic clinical expansion and explosion of RAS and especially its greatest application with RP. Nevertheless, the robotic evolution of surgical care has been tempered by increased costs, lack of institutional support and funding and a shortage of surgeons with specialized training [2]. As with any novel approach a period for acquiring competence and proficiency was required.

As robot-assisted radical prostatectomy (RARP) is currently becoming the golden standard procedure, the majority of the procedures are urological, while cardiac, gynecological and general surgeons also using the DVS in practice [1].

Since the first reports, robot-assisted surgery (RAS) has become a fundamental part of urologic surgery with initial enthusiasm changing to a broad acceptance [22]. There is an increasing adoption of RAS, especially in urological procedures, with RARP being the most commonly carried out robotic procedure worldwide, with increasing numbers performed each year [1,5].

Robot-assisted radical nephrectomy (RAN) is showing also an increasing development in robotic urologic surgery [2]. The robot has also allowed non-experienced surgeons the ability to successfully perform robot-assisted laparoscopic pyeloplasty (RLPP) with excellent results [3,4]. Other procedures also performed are partial nephrectomy and cystectomy.

There is limited knowledge about how the diffusion of robotics has influenced urological individual practice patterns in Greece. The first da Vinci Surgical System (DVS) in a public hospital in Greece was installed in July of 2008 at “Laiko” Hospital in Athens. There are seven more installed in Greece, all based in private

hospitals. Most procedures currently being carried out are urological with general surgeons also using the system, mostly for bariatric procedures. Urologists have been quick to embrace this novel technology and RARP is the most commonly carried out robotic procedure, followed by RLPP, RAN and robot-assisted nephroureterectomy (RALNU). This is extremely interesting taking into account the fact that Greece is suffering from economic crisis and funding is under austerity measures proposed by the International Monetary Fund (IMF) [23].

Using retrospective case log data from “Laiko” Hospital, in this study we seek to determine practice patterns in open and robotic urologic surgery in Greece since the installation of the DVS. This study examined contemporary trends in a public hospital in Greece and the relationship between robot acquisition and changes in the total procedural volume.

PART 1st

1. Robotic Surgery

1.1 Definitions – Basics of surgical robots

The concept of having an apparatus to aid or augment what is possible with the human hand is not new.

The word “robot” is derived from the Czech word *robota* meaning “work” or “forced labor” and was introduced by the writer Karel Capek.

Isaac Asimov coined the term robotics, although the definition of a robot is quite varied. At 1942 he published the three robotics laws. Mechanics, electronics and informatics advances at XXth century developed robots to be able to do very complex self governing works.

Critical elements of a robot include [3]:

- (1) Programmability (a robot is a computer)
- (2) Flexibility (the robot must be able to operate a range of programs in a variety of ways)
- (3) Mechanical capability (a robot is a machine to interact with the environment).

Thus, most robots are computerized systems with mechanical capabilities.

With respect to surgical robots, there are those that are shared control (robot is primarily an assistant, such as camera holder), telesurgical, and supervisory controlled [27].

A surgical robot has been defined as ‘a computer-controlled manipulator with artificial sensing that can be reprogrammed to move and position tools to carry out a range of surgical tasks [1,30]. Strictly speaking, the current popular surgical ‘robots’ do not satisfy this definition and some authors have suggested the term ‘computer-assisted surgery’ which more accurately describes the current generation of robotic devices [31].

Surgical robots are divided into three categories:

- (1) Active systems: These systems have artificial intelligence that allows them to perform a procedure autonomously under the supervision of the surgeon.

- (2) Semi-active systems: These systems have an automatic and a surgeon-guided component.
- (3) Master-slave systems: The surgeon operates the robot directly from a remote console or a workstation. There is not any autonomous component in these systems. An example of this system is the da Vinci surgical robot currently in use (Table 1).

Table 1: Categories of surgical robots

Active systems	Semi-active systems	Master- slave systems
Probot (TURP)	Mechanical guide for biopsy (neurosurgery)	AESOP
PAKY (Percutaneous renal access)		ZEUS
		Da Vinci

Robotic surgery has its own place within the following concepts [28]:

- (1) Computer assisted surgery (CAS)
- (2) Computer integrated surgery (CIS)
- (3) Surgical automation
- (4) Surgical system integration
- (5) Artificial intelligence (AI)

According to the latter, telesurgery could be divided into the following main categories:

- CAS,
- Robotic system-assistant
- Robotic system-surgeon,
- Robotic surgery.

1.2 History of surgical robots

Over the past decade, the imagination of patients and surgeons alike has been captured by the arrival of robot-assisted surgery. Robotic surgery is a reality, beginning from the roots in the ancient world more than 4000 years ago up to the modern robotics, with a history of only 29 years old.

The desire to design automatic machines imitating humans started at around 400 a.C.. Archytas of Tarentum, Heron of Alexandria, Hsieh-Fec, Al-Jahari, Bacon, Turriano, Leonardo da Vinci, Vaucanson o von Kempelen were robot inventors [29].

The world's first surgical robot, 'Arthrobot' was born in 1983 and was designed to assist orthopaedic procedures [32].

The first use of surgical robotic assistance was in 1985 at the Memorial Medical Center, Long Beach, CA, USA when Kwoh et al utilized a modified industrial robot to aid in drilling and biopsies during computed tomography-guided stereotactic brain surgery [3,33]. This robot was the PUMA 560 (Unimate, New Jersey, US).

This was followed in 1988 by ROBODOC (Integrated Surgical Systems, Sacramento, CA, US), a system used in total hip arthroplasty to allow precise preoperative planning, and to mill out precise fittings in the femur for hip replacement. This system helped the surgeon mill a hole in the femur and produced cavities that were 10 times more accurate than could be achieved by manual reaming. This was the first commercially available surgical robotic system. It gained Food and Drug Administration (FDA) approval in the United States in 1998 for total hip arthroplasty and in 2003 for total knee arthroplasty.

In more recent years several computer-based navigation systems have been introduced to aid in the total knee replacement procedure [36]. A similar proposition to ROBODOC entered clinical use in Germany a few years later: the Computer Assisted Surgical Planning and Robotics (CASPAR) system active robot. CASPAR was an industrial PUMA robot adopted for total hip and knee arthroplasty and for anterior ligament repair [42]. The first use of this system was in March 200 in the Kassel Orthopaedic Centre, Germany.

The pioneers were Wickham et al. from Guy's Hospital and Imperial College, London, who used the PROBOT in the late 1980s [1]. The PROBOT used a robotic frame, which guided a rotating blade to complete transurethral resection of the prostate (TURP). Initial studies on prostate shaped potatoes were followed by clinical trials in patients to show safety and feasibility of the technology. This was a truly autonomous device satisfying the definitions outlined.

Other urological robots have included the percutaneous renal access robot, PAKY (Percutaneous Access to the Kidney) - RCM, which showed superior accuracy but longer operating times when compared to humans.

Computer Motion, Inc (Santa Barbara [CA], US) was the original leading medical robots supplier. In 1993, released AESOP (Automated Endoscopic System for Optimal Positioning), which was a laparoscopic manipulator [1,32]. This was the first surgical robot approved by the FDA [3,37]. Specifically, it was a robotic arm to assist in laparoscopic camera holding and positioning. It held the laparoscope under voice or pedal control and provided steadier images with fewer instrument collisions than a human assistant [34]. They enabled the concept of solo-surgery, dispensing with the need for surgical assistants [35]. Aesop has assisted in more than 45,000 minimally invasive surgical procedures and is a standard tool for urologists performing laparoscopic prostatectomy. However, although several units remain in clinical use in Australia, the AESOP has not been in commercial production since a corporate merger between Computer Motion Inc and Intuitive Surgical in 2003 (Figure 1.1).



Figure 1.1 The AESOP

The CyberKnife (Accuray, Sunnyvale [CA], US) was introduced in 1994 for stereotactic radiosurgery in neurosurgery [32]. It uses radiation to treat a tumor whilst minimizing radiation to the adjacent tissues.

Other attempts to use an active robot to place in lock a jig or fixture in position, through which a surgical tool can be inserted by the surgeon, were made. Brainlab (Germany), developed Vectorbot and Zimmer (USA) developed Bone Resection Instrument Guidance by the Intelligent Manipulator (BRIGIT) [42]. Both programmes were halted before commercialization.

The most important year is 1998 which is a significant landmark. Integrated Surgical Systems bought from the SRI (Stanford Research Institute), the Green Telepresence Surgery System and introduced the da Vinci Surgical System as Intuitive Surgical Inc (Sunnyvale [CA], US). In the same year Computer Motion Inc introduced the ZEUS Robotic Surgical System [32].

This development was a result of US military attempting to remove surgeons from the battlefield, since the 1960s. There was when the concept of ‘telepresence’ was born and the master-slave platform developed, which also intrigued the National Aeronautics and Space Administration (NASA). Consequently, the United States Department of Defense, NASA and SRI worked on the development of the master-slave systems, which eventually led to the formation of the da Vinci and the ZEUS systems [3].

ZEUS was designed for cardiac procedures, but was diversified for use by urologists, gynecologists and general surgeons [3,38]. This system utilized an AESOP arm for camera control and two robotics arms with four degrees of freedom for tissue manipulations (Figure 1.2).

In 2003, as mentioned above, there was a corporate merger of Computer Motion Inc with Intuitive Surgical. Since then, the ZEUS system is no longer commercially available with the da Vinci surgical system being currently the only available telerobotic surgical system and Intuitive being the sole producer of surgical devices [39,40].

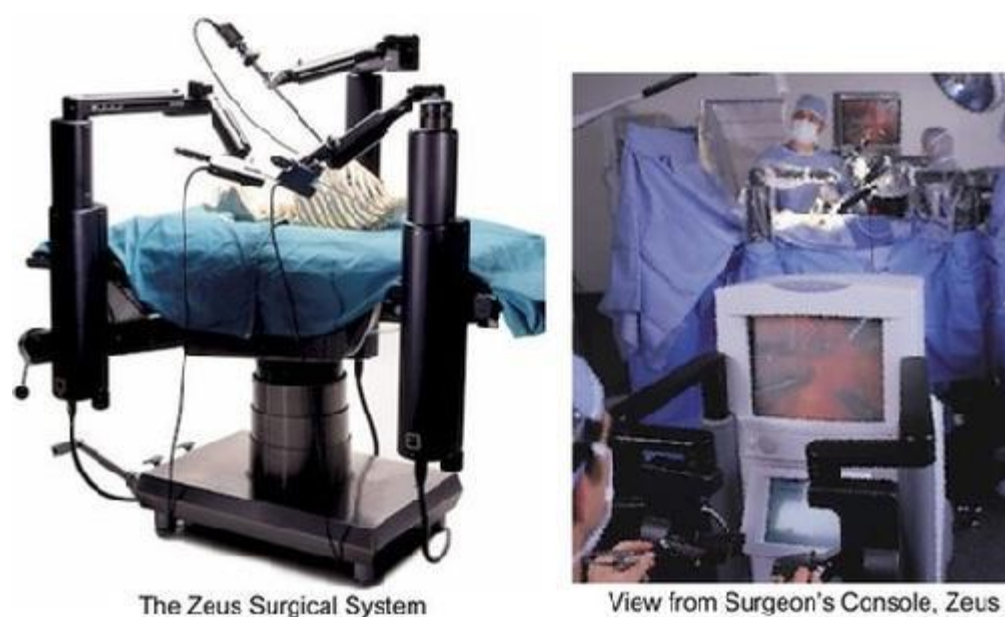


Figure 1.2 The ZEUS surgical system

1.3 History of robotic surgery

Since the first use of robotics in a surgical operation in 1985, technology has developed, with numerous surgical robots being developed and utilized over the years.

The timeline of the robotic surgery is presented in table 2.

Table 2: Robotic Surgery Timeline

1985 →	First surgical robot utilization : Kwoh :Neurosurgery
1989 →	First urologic robot : Probot : Davies : TURP
1993 →	First commercially available robot approved by the FDA : AESOP
1997 →	First robot-assisted laparoscopic cholecystectomy: Cardiere : Belgium [43]
1998 →	First da Vinci robot assisted heart bypass : Germany [41]
2000 →	FDA approval for the da Vinci for use in laparoscopic procedures
2001 →	First robot-assisted radical prostatectomy (RARP) : Binder et al
2001 →	FDA approval for the use of the da Vinci in prostate surgery

1.4 Da Vinci Surgical System

The name ‘da Vinci’ stems for the 15th century inventor, painter, philosopher and Renaissance man: da Vinci is widely known for advancing the study of human anatomy. He studied a lot human anatomy, participated in many autopsies and produced many extremely detailed anatomical drawings. He was also extremely interested in mechanics and automation. He developed a number of mannequins including a mechanical knight.

His study of human anatomy led to the design of the first known robot in history.

This design was known as ‘Leonardo’s Robot’ and was created around 1495, but was rediscovered in the 1950s (Figure 1.3).



Figure 1.3 The first human robot by Leonardo da Vinci: ‘Leonardo’s Robot’

As mentioned above, the da Vinci surgical system (DVS) (Intuitive Surgical Inc, CA, US) gradually evolved in the mid-1990s from a research project involving the US Department of Defense and the SRI. It was introduced in 1999 and following the merger of Intuitive with the Computer Motion Inc in 2003, it is currently the only commercially available surgical robot.

The first reported da Vinci robotic surgical procedure was a robot-assisted heart bypass which took place in Germany in 1998 [32,41].

The device gained FDA approval for use in general laparoscopic surgery (gallbladder diseases and reflux) in July 2000 [32].

The first reported robot-assisted radical prostatectomy (RARP) took place in Paris, France by Binder et al [32,44].

The FDA approval for urological procedures, and particularly for prostate surgery, came in 2001. After initially embarking into cardiothoracic surgery, the system found broad acceptance by the urological community.

The da Vinci surgical system is a master-slave rather than a true autonomous robot. The surgeon sits at a console remote from the patient, controlling three or four robotics arms, which are docked through laparoscopic ports.

The system has three components:

(1) *Console:* The surgeon sits comfortably at the console, while viewing a high definition, 3D image from the stereoscopic endoscope at 10 x magnification. The surgeon's thumb and forefinger control the movements of the robotic arms.

Foot pedals allow control of diathermy and the camera.

The system translates the surgeon's hand, wrist and fingers movements into precise, real-time movements of surgical instruments, with elimination of the tremor (Figure 1.4).



Figure 1.4 The console of the da Vinci surgical system

(2) *Patient-side cart:* It consists of one arm to control the high-definition 3-D endoscope (camera) and two or three arms to hold the operating instruments. The vision system has two camera control units and two lights sources that isolate and synchronize the image and project a stereoscopic image on the surgeon's console (Figure 1.5-1.6).



Figure 1.5 The 3-D vision system



Figure 1.6 The 3-D endoscope (camera)

The endowrist instruments which are mounted on the arms are designed with seven degrees of motion freedom, a range of movements even greater than the human wrist (Figure 1.7).



Figure 1.7 The Endowrist system – 7 degrees of freedom

(3) *Image-processing / insufflation stack*: It contains the camera-control units for the 3-D imaging system, image recording devices, a laparoscopic insufflators and a monitor for 2-D vision for the assistants.

The first generation of the da Vinci surgical system ceased production in 2007. The current systems are the da Vinci S, the Si, the Xi (model IS4000), the S-TransOral Robotic Surgery (TORS), the SP (model SP999) and the Single-Site (Figure 1.8).

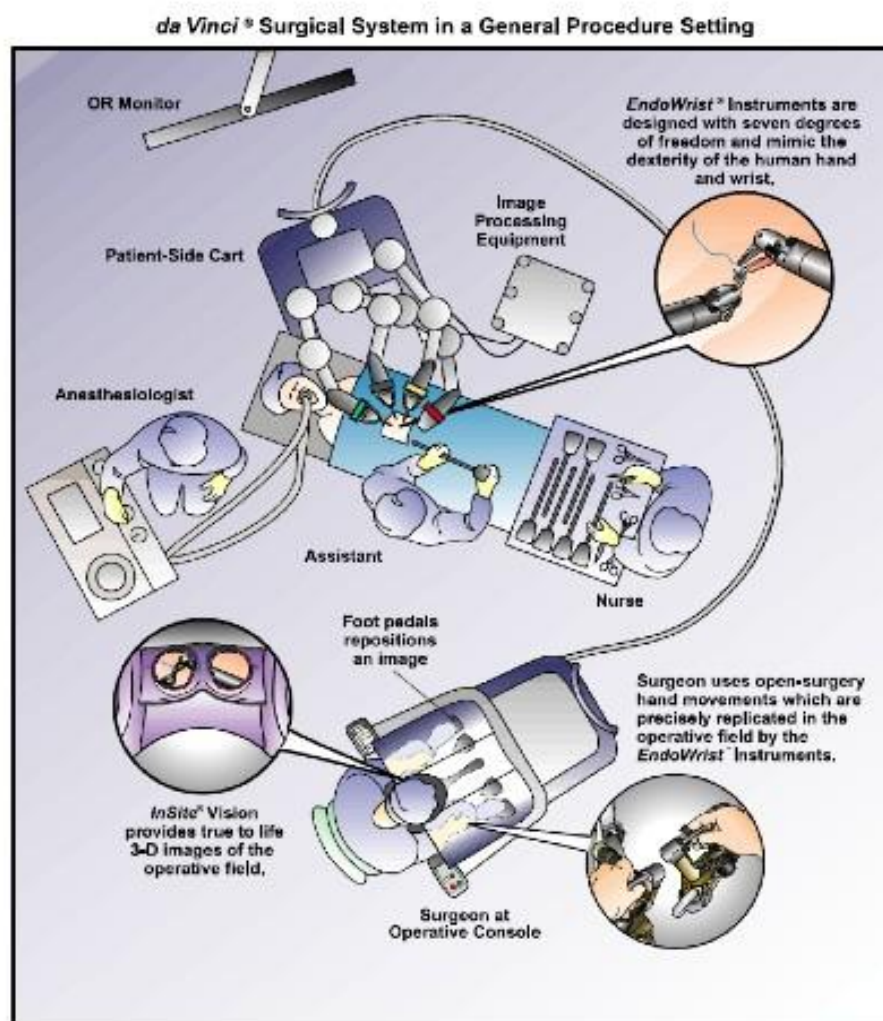


Figure 1.8 The setting of the da Vinci surgical system in an operating theatre

1.5 Applications

One of the first surgical uses of the robot was in orthopaedics, neurosurgery and cardiac surgery. However, it was the use in urology and particularly in prostate surgery, which led to widespread popularity [32,46]. The da Vinci Surgical System is also used in other surgical specialties including general surgery, gynaecology and head and neck surgery.

The main applications of the da Vinci surgical system and the robotic surgery, which have gained FDA approval, are:

- (1) *Urology*: Radical prostatectomy, cystectomy, nephrectomy, partial nephrectomy, pyeloplasty.
- (2) *Gynaecology*: Hysterectomy, myomectomy, sacrocolpopexy, oophorectomy, ovarian cystectomy, resection of endometriosis and lymphadenectomy.
- (3) *General Surgery*: Colorectal, bariatric surgery, Heller myotomy, fundoplication and hepatobiliary surgery
- (4) *Cardio-thoracic Surgery* : Thoracoscopic procedures, mediastinotomy for coronary anastomosis during cardiac revascularization
- (5) *Head – Neck Surgery* : Thyroid surgery, trans-oral otolaryngology procedures, neurosurgery

The da Vinci System is the most widely utilized surgical robot worldwide. Intuitive Surgical Inc in their 2010 Annual Report states that they have an installed base of 2,966 da Vinci Surgical Systems, including 2,083 in the U.S., 476 in Europe, 159 in Japan and 248 in the rest of the world. It is estimated that by the end of 2013, surgeons using the da Vinci System completed approximately 523,000 surgical procedures of various types in hospitals throughout the world, compared to approximately 450,000 and 359,000 procedures performed in 2012 and 2011, respectively. [60].

Since 1998, there have been over 4000 peer-reviewed publications in various surgical specialties regarding the da Vinci System, of which 46% refer to urology, 17% to cardiothoracic operations, 13% to general surgery, 8% to gynaecology, 7% to general topics about surgery outcomes and trends, 4% to pediatric surgery, and 2% to otorhinolaryngology [32,47].

Intuitive Surgical Inc in their 2010 Annual Report, states that over 70% of the overall procedures carried out worldwide are prostatectomy and hysterectomy. Other procedures are still less common, with gynaecology showing the highest growth rate [11,48].

Despite the increasing popularity of robotic surgery, except in RARP, there is no unequivocal evidence to show its superiority over traditional laparoscopic surgery in

other surgical procedures [32]. Additionally, it is the good marketing of Intuitive Surgical Inc that has led to a rapid increase of robotic prostatectomies worldwide [11]. The market share of RARP compared to laparoscopic and open is estimated as exceeding 80% in the USA, according to the manufacturer of the DVS [48].

1.6 Advantages – Disadvantages

1.6.1 Advantages

The main advantages of the da Vinci Surgical System, compared to standard laparoscopic approach, are [3,45] :

- ✓ The three dimensional image which is superior to the two dimensional of the laparoscopic surgery.
- ✓ The enhanced magnification provided which is very helpful for better visualization of the surgery field.
- ✓ Articulation of the instruments at the wrist. It seems that the Endowrist technology is that makes the device such a remarkable piece of technology [1]. The seven degrees of freedom mimics human hand and improves on the four degrees of freedom seen in standard laparoscopic surgery.
- ✓ Human tremor is almost eliminated making surgeon's movements more precise [3,38].
- ✓ Improved surgeon ergonomics. The surgeon operates from a rather comfortable place remote from the patient. As Eric Hanly and Marc Talamini wrote in the American Journal of Surgery in 2004: ‘‘The view is spectacular, the movements are intuitive and during a case with long operative time the chair is like first class seat in a transcontinental flight..!!’’

It also seems that the learning curve is shorter for robotic compared with laparoscopic surgery, as the Detroit group has demonstrated [51].

The robotic system overcomes the limitations of the standard laparoscopic approach and allows for precise dissection in a confined space with excellent vision and better ergonomics for the surgeon, as mentioned above.

Furthermore, the robotic procedures achieve all the associated benefits of conventional laparoscopic procedures, as they are included in minimally invasive surgery. Across different specialties, the majority of robotic surgeries have been associated with [32,49] :

- ✓ Decreased blood loss- lower transfusion rate
- ✓ Decreased length of hospital stay
- ✓ Decreased postoperative pain-need for analgesia
- ✓ Decreased in-hospital morbidity and mostly mortality [50]
- ✓ Smaller wound-less wound complications-better cosmetic result
- ✓ Faster mobilization of the patient and return to everyday activities-work

1.6.2 Disadvantages

The main disadvantages of the da Vinci Surgical System, compared to standard laparoscopic approach [52], are:

- ✓ Lack of tactile feedback, which can lead to difficulty with inadvertent tissue injury [3,45]
- ✓ Longer operation time, due to longer time to set up the system
- ✓ Need for trained personnel (dedicated nurse) and dedicated operating room, since the machine is bulky and needs storage space
- ✓ Reliance on the tableside assistant
- ✓ There are not any real advantages compared to laparoscopic surgery
- ✓ Most important of all being the *significant increased cost*.

The robot itself costs about \$1,3-\$1,5 million, with yearly maintenance fee of \$100,000, of about 10% of the initial purchase, and a recurring cost of \$400 to \$1200 per case for disposable instrumentation, depending upon the procedure [16]. An analysis of new technology and health care costs of 20 different robot-assisted surgeries, showed that the use of the robot added 13% (US \$ 3200) to the total average cost of a procedure in 2007 [54]. In another analysis of 643 cases, Bolenz et al reported that the robotic approach is 1.5 times more expensive than the open approach, based on an average of 126 patients per year. The main difference was seen in surgical supply cost that was ten times higher. When considering purchase and maintenance costs for the robot, the burden increased by \$2,698 per patient [11,57]. It has been proposed that open radical prostatectomy (RRP) has a cost advantage of around \$1,700 per case compared to RARP [55]. Scales et al., used a model and calculated that RARP could reach equivalence of RRP, if surgical volume was 10 cases per week and become profitable if 14 cases per week were performed [56].

1.7 Future application for robotics

Laparoscopic single-site surgery (LESS) and natural orifice trans-luminal endoscopic surgery (NOTES) are novel techniques that have the potential to further minimize the invasiveness and morbidity of surgery [32]. LESS has yet to become widespread in surgery but is gaining ground in the robotics arena.

LESS is the general term for all surgical procedures performed by one single skin incision for the introduction of camera and instruments, with or without an additional port of 15 mm [72]. The advantages offered by this approach are still in discussion and not yet proven. The superior cosmetic outcome offered by LESS seems to be the main advantage and the primary reason for using this technology [79,80].

The first report on LESS in urology for human patients was in 2007 by Raman et al., who performed three LESS nephrectomies using a single trans-umbilical incision [81].

Various trocar settings have been used to minimize the reduction of instrument triangulation, which is the main limitation of LESS. Most studies have used a single-port system with three or four instrument channels. Another approach is a single-incision triangulated umbilical surgery with straight instruments [72].

In 2009, the first robot-assisted LESS (R-LESS) was reported by Kaouk et al. [82], who later reported the use of R-LESS in 13 % of cases in a multi-institutional analysis in 2011 of 1076 LESS cases [83].

The most widely adopted LESS operations in urology are simple and radical nephrectomies. The feasibility and safety of this minimally invasive technique have been well documented.

When performed by experienced surgeons in selected cases, LESS surgery is considered safe with conversion and complication rates similar to those obtained with a multi-port laparoscopic approach.

However, the technical difficulty of these procedures is increased with the need for specialized instruments. Challenges with LESS surgery include adjusting to the necessary curved instruments and the limited range of motion. Florescent-sensitive cameras are a recent innovation which may provide functional intra-operative imaging. Even tough, it is thought that LESS is going to minimize complications and improve outcomes [32,59].

The master-slave systems and improved telecommunication technology have made telesurgery a reality. In 2001, a New York to France (Strasbourg) cholecystectomy was performed with a 200-millisecond delay from the controls in New York to the instruments in France, by Lindburgh [3,58].

An experienced surgeon can mentor a less experienced one through a procedure. An expert surgeon may operate on any patient at a compatible center anywhere in the world. Also, surgery would be possible in remote areas in need such as the battlefield and outer space [3].

2. Robotic assistance in Urology

2.1 History of robotics in Urology

After the introduction of the term Minimally Invasive Surgery (MIS), the term was coined by John E.A. Wickham, who vigorously promoted this type of surgery.

Wickham was the urologist surgeon who developed the PROBOT in the late 1980s at the Guy's Hospital and Imperial College, London.

The first use of surgical robotic assistance in urology was in 1989 when Davies et al used the PROBOT during transurethral prostate resection (TURP), indicating a dramatic potential reduction of TURP times from one hour to five minutes [42]. Initial studies on prostate-shaped potatoes were followed up by clinical trials in patients to show safety and feasibility of the technology. This was a truly autonomous device. However, convincing advantages over conventional TURP were not shown and the PROBOT did not reach commercial production.

The first laparoscopic radical prostatectomy was performed in 1991.

In 2000, Binder et al performed the first robot-assisted radical prostatectomy (RARP), closely followed by other European centers [66].

In 2001, FDA clearance for the DVS in prostate surgery was granted [7,11]. Binder and Kramer published the first series of robotic-assisted laparoscopic prostatectomy (RARP) completed in 10 patients in 2001 [66]. Since that time, very few procedures have seen more dramatic clinical expansion than RARP.

Urology has long been adoptive to advances in technology. It is not surprising that soon after robotic technology was first applied to medical science, it was embraced by the urology community. Robotic surgery has applications in many aspects of urological surgery. This is especially true in RARP, where the initial reports by Menon et al [61] led to an exponential growth of robotic surgery in clinically localized prostate cancer. More recently, there has been an increasing number of robotic renal surgeries and robotic cystectomy in centers of excellence [32].

2.2 Robot-assisted radical prostatectomy (RARP)

Prostate cancer is the second most common solid organ malignancy in men in the world, the first in the US and the second leading cause of cancer death, with a world age-standardized rate of 28 per 100,000 males [62].

Radical prostatectomy (RP) is a standard treatment option for localized carcinoma of the prostate, with a demonstrated survival advantage when compared with watchful waiting in the randomized controlled trial SPCG-4 (Scandinavian Prostate Cancer Group Study No 4) [63].

Hugh Hampton Young first described the perineal prostatectomy over 100 years ago in 1905 [75]. Subsequently, the first retropubic radical prostatectomy (RRP) was performed by Millin in 1947 [76]. Walsh and Donker first introduced the anatomic nerve-sparing technique for RRP in 1982 [67,68]. However, open RP is associated with high morbidity rates.

More recently, in 1997, Schuessler et al introduced laparoscopic RP with the aim of reducing morbidity, with many undeniable advantages when compared with open RP [65]. Nevertheless, the technical demands of laparoscopic RP and the steep learning curve prevented its widespread use by the average urologist, since it did not offer any advantages over open RP.

The introduction of the DVS was the breakthrough in minimally invasive surgery for RP. From the initial descriptions in 2000, robot-assisted radical prostatectomy has overtaken open RP as the most common surgical approach for RP and is estimated to account for approximately 80% of all RP procedures in the US [64].

Menon et al from the Vattikuti Urology Institute in Detroit, US, are responsible for the explosion and popularization of RARP [32]. This technique offers all the advantages of minimally invasive laparoscopic prostatectomy with added advantages of shorter learning curve and improved ergonomics, leading to the widespread use and acceptance.

Various approaches for RARP have been described. The approach could be either transperitoneal or extraperitoneal. For the transperitoneal technique, the initial dissection can proceed: either (a) anteriorly, through the retropubic space and the

bladder neck or (b) posteriorly, with dissection of the seminal vesicles and through the plane between the prostate and rectum.

It seems that posterior dissection has several advantages. It improves the working space, which allows for better visualization of the structures to be dissected and thereby limits the amount of traction exerted and the total thermal energy delivered. It also provides a safer posterior bladder neck transaction later on in the procedure.

The main steps in the posterior technique for RARP are the following [69]:

1. Posterior dissection, division of vas deferens and exposure of the seminal vesicles
2. Retzius space dissection and endopelvic fascia dissection: anterior prostatic fat dissection
3. Dorsal vein complex ligation
4. Bladder neck transaction
5. Athermal nerve sparing technique and vascular pedicle control
6. Continuous vesico-urethral anastomosis, with posterior bladder neck reconstruction

Regardless of technique, the patient must be placed in a steep Trendelenburg position in order to displace the bowels cranially (Figure 2.1).

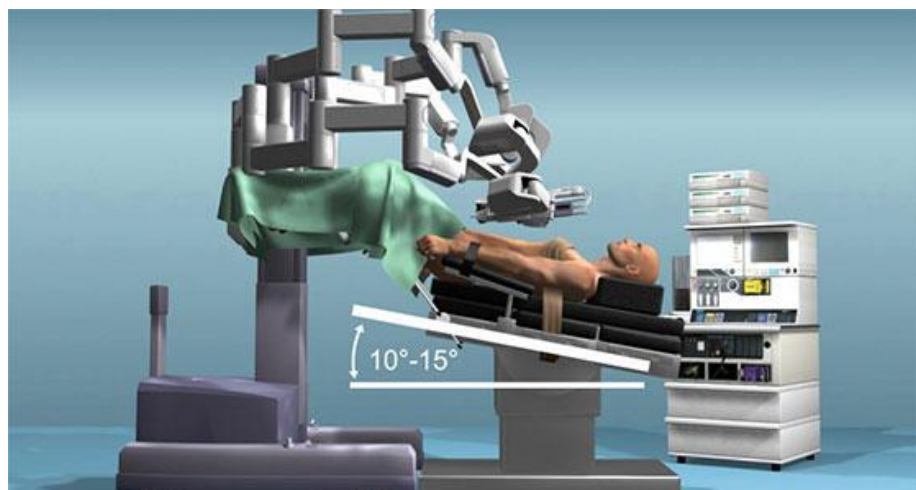


Figure 2.1 Patient's positioning in RARP

Figures 2.2 and 2.3 show the placement of the trocars for RARP.

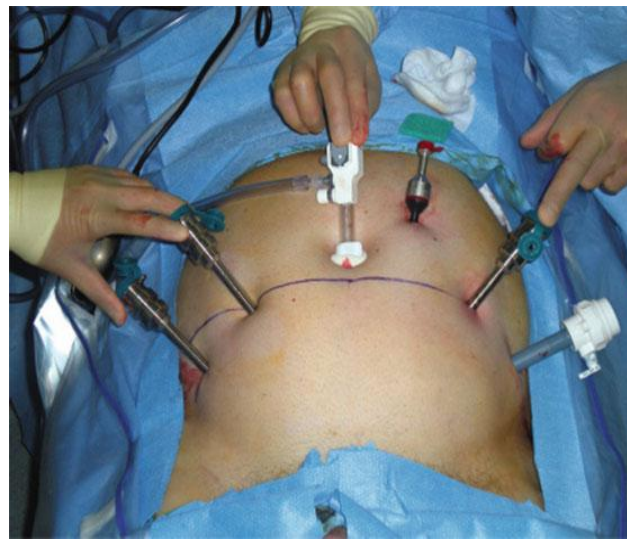


Figure 2.2 Placement of the trocars for RARP

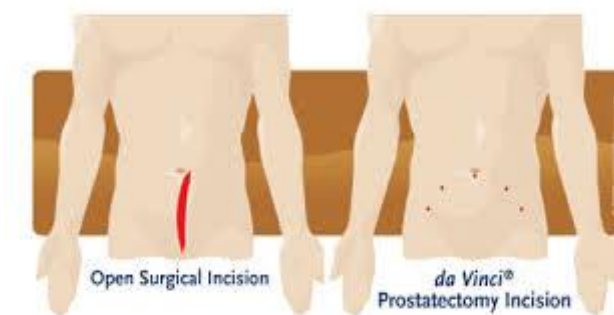


Figure 2.3 Open and Robot-assisted radical prostatectomy: incisions

The operation is fundamentally no different than open or laparoscopic RP, with goals of trifecta: complete remove of the cancer (prostate, seminal vesicles), preservation of urinary continence and return of sexual function (Figure 2.4).

A variety of surgical techniques have been employed in an attempt to improve early return of continence after RARP, including: bladder neck (BN) preservation, intussusception of the BN, puboprosthetic ligament sparing, sling construction,

incorporation of the striate urethral sphincter to the anastomosis, and tubularization of the BN [39].

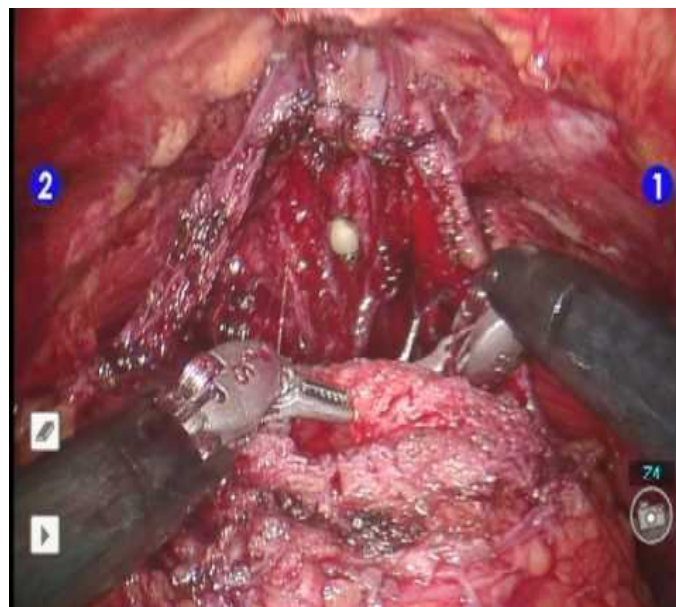


Figure 2.4 RARP with preservation of the neurovascular bundles

Many of these reconstruction techniques for RARP have been based on the posterior reconstruction described by Rocco and colleagues in 2001 [70].

In posterior reconstruction, the posterior rhabdosphincter is joined to the posterior Denonvilliers' fascia and fixed to the bladder wall 1-2 cm cranially, prior to completing the anastomosis.

The anterior fixation stitch or urethropexy can be performed either prior to or after the anastomosis, with Campenni et al. demonstrating an increase in continence as measured by leak-point pressures [71].

There are many studies showing the relative benefits of RARP compared with open RP regarding perioperative outcomes and complications, namely by Ahlering et al [12], Menon et al. [13], Rocco et al., Farnham et al. [15].

The main advantages of RARP are [77]:

- Decreased blood loss [24]
- Decreased blood transfusion [24]

- Shorter hospitalization
- Less pain, as Krambeck et al. demonstrated [78]

Novara, Ficarra et al. demonstrated in a systematic review [24] that RARP showed lower overall complications rates, with mean value of about 9 % and lower prevalence of specific surgical complications, such as lymphocele/lymphorrhea, urine leak, and reoperation.

After open RP, continence rates 1 year after surgery are expected to be ≥ 90 %. Most single institution series of RARP report comparable results, with ≥ 93 % (4-13 %) of men being continent 12 months after surgery (LE 2a) [27].

A cumulative analyses by Ficarra et al. [25], showed a statistically significant advantage in favor of RARP in comparison with both open and laparoscopic RP in terms of 12-month urinary continence recovery (LE 3b). It seems that posterior reconstruction, with or without anterior reconstruction, is associated with a small advantage in urinary continence recovery 1 month after the surgery.

Overall rates of potency after open RP approach 70 %, but are largely dependent on baseline function and age [27]. Nerve-sparing RARP is associated with an incidence of 12- and 24- month erectile dysfunction ranging from 10 % to 46 % and from 6 % to 37 % respectively.

An update of systematic reviews of the literature [26], showed, for the first time, significant advantages in favor of RARP in comparison to open RP, in terms of 12-month potency rates (LE 2a-3b). Taking into account, however, that potency rates are influenced by numerous factors, including patient characteristics, nerve sparing extension and techniques, definition of potency and methods used to collect data (LE 2a).

Most of the studies comparing oncological outcomes between RARP, open and laparoscopic RP, reported equivalent or lower positive surgical margins (PSM) rates for RARP than for the other two approaches (72). The two currently available prospective randomized studies (LE 2b) that compare RARP with laparoscopic RP, found no difference in PSMs between the two surgical groups [73,74]. Long-term

PSA-free survival of patients treated with RARP as documented for up to 5 years is comparable to other RP approaches (LE 3b) [72]. In two large robotic series, the risk of PSM was 4 % and 13 % in pT2 and 34 % and 35 % in pT3 (Badani et al. 2007; Patel et al., 2008).

2.3 Robot - assisted cystectomy (RARC)

Radical cystectomy and pelvic lymph node dissection are the gold standard treatment options for muscle-invasive or for high-risk/refractory noninvasive urothelial carcinoma of the bladder. When performed to men, it includes cystoprostatectomy and when performed to women anterior pelvic exenteration, including always removal of pelvic lymph nodes [27]. However, this procedure is associated with high morbidity of up to 50 % and mortality of up to 5 %, even in centers of excellence [84].

In an effort to further decrease the morbidity of open radical cystectomy (ORC), minimally invasive laparoscopic and robot-assisted laparoscopic RC were developed [85].

Similar to laparoscopic radical prostatectomy, laparoscopic cystectomy was reported to be feasible early in the evolution of laparoscopy (1992) but was infrequently performed due to technical challenges and limitations in instrumentation, prolonged operative time, and need for complex reconstruction. With increasing laparoscopic skills and experience with radical prostatectomy, more reports of laparoscopic cystectomy emerged and the operation developed over the past decade.

Case series at expert centers showed that when compared with open surgery, laparoscopic cystectomy resulted in a lower morbidity rate with significantly lower blood loss and transfusion rates, less pain and shorter hospitalization time [32,86].

Nevertheless, it remains a difficult operation given the need for meticulous cancer excision, extended lymphadenectomy in all cases, and urinary tract reconstruction.

Robot-assisted radical cystectomy was introduced as an attempt to offset the high technical skill required for laparoscopic RC, and was first performed in 2003 by Beecken et al. [87].

The indications for RARC are the same as those for ORC contemplated in the European Association of Urology Guidelines.

During RARC, in men, along with the bladder and the surrounding perivesical tissues, the prostate and the seminal vesicles are removed, while in women, the ovaries, fallopian tubes, and uterus may be removed [88].

The feasibility of pelvic lymph node dissection during RARC as well as the adequacy of nodal yield has been a matter of concern. A prospective maintained but retrospectively analyzed study based on the International Cystectomy Consortium database concluded that the rates of lymphadenectomy at RARC for advanced bladder cancer are similar to those of ORC series [90]. Another randomized, prospective trial by Nix et al. showed equivalence in node counts with a mean of 18 nodes removed in the open group and 19 nodes in the robotic group [89].

During RARC, ileal conduit or orthotopic bladder substitution can be performed with intracorporeal or extracorporeal techniques [88]. Intracorporeal construction of urinary diversion with or without robotic assistance has been tested in small series only. It is very challenging with the current equipment available and is still considered an experimental technique. While, in the European Association of Urology Guidelines, laparoscopic cystectomy, with or without robotic assistance, and pelvic lymphadenectomy with extracorporeal construction of urinary diversion are considered an option for surgical treatment (LE3) [88].

Currently, high levels of clinical evidence of the benefits of RARC are lacking in peer-reviewed literature, since most series are single-institution, non-randomized case series [88,89].

A recent retrospective analysis [91] on consecutive series of patients undergoing RC (100 RARCs and 100 ORC) with curative intent over a 4-year period suggests that in RARC the perioperative oncological outcomes are comparable with ORC, and RARC has lower overall and major complication (Clavien \geq 3) rates (35 % vs 57 %; P=0.001

and 10 % vs 22 %; $P=0.019$, respectively), less blood loss, and shorter hospitalization time versus ORC. Similar findings, regarding less blood loss, reduced morbidity, improved convalescence, and earlier initiation of adjuvant systemic therapies, were reported by Yu et al. in a recent population-based study comparing 224 RARCs with 1444 ORC cases [92].

The only prospective randomized controlled noninferiority study [89] that compared RARC to ORC demonstrated lower mean blood loss (575 vs 258 ml), lower analgesic requirements and earlier return to bowel function (4.3 vs 3.2 days), in favor of the robotic group.

The authors in a study comparing postoperative complications in 104 RARCs versus 83 ORCs [94], concluded that RARC is an independent predictor of fewer overall and major complications, with a 17 % major complications rate in patients undergoing RARC compared with a 31 % complication rate observed in ORC patients.

Another recent collaborative review [93] seems to indicate that in patients with bladder cancer $\leq pT2$, laparoscopic and robot-assisted RC achieve comparable, acceptable positive surgical margins to ORC.

Cumulatively, it is supported that RARC can achieve a similar oncologic surgical quality to ORC, and that this depends more on the surgeon performing the surgery than the technology used [72]. Furthermore, it seems that RARC is a feasible and safe approach with perioperative and long-term complications comparable to PRC (LE 1b).

2.4 Robot – assisted nephrectomy

2.4.1 Robot – assisted radical nephrectomy (RAN)

The gold standard of treatment for large renal tumors was once open radical nephrectomy (ORN) with demonstrable good long-term oncologic outcomes [88]. The management of renal tumors has evolved over the past decades, with the advent of laparoscopic techniques as well as the application of ablative technologies. Since the first laparoscopic nephrectomy (LRN) in 1991[102], a shift toward minimally invasive renal surgery has presented and subsequent data have proven that equivalent cancer control is achieved by the laparoscopic technique [27].

The introduction of the da Vinci surgical system was accompanied by potential advantages of robotic assistance for performing a radical nephrectomy, which are: a magnified 3-D high-definition vision and the movements of the Endowrist system that can facilitate a safe and precise dissection and ligation of the renal hilum. Consequently, RAN can be used as training during learning curve for acquiring expertise for more complex renal surgery, such as a partial nephrectomy [103]. Nevertheless, RAN has some undeniable disadvantages in terms of high cost, the set-up time, need for training in its use, lack of tactile feedback which is very important with regard to the renal hilum, and the need for an experienced laparoscopic assistant [88]. So, although RAN was introduced in 2000, the main limitations of the approach have slowed its widespread adoption.

RAN can be performed either by a trans-peritoneal or a retroperitoneal approach and robot-assisted donor nephrectomy are considered safe procedures as evidenced by the few published cohorts on the subject [72].

In the European Association of Urology Guidelines, LRN is the standard of care for patients with T2 tumors and smaller renal masses not treatable by nephron-sparing techniques [104]. The same principles as those for LRN seem to apply for RAN.

Complications rates for RAN have been reported up to 18 %, which is similar to the reported rates for LRN [105].

There are limited data with regard to comparison of RAN to LRN, with cohorts of < 50 patients [72]. Similar perioperative outcomes were reported in most of the comparative studies (LE 3).

One of these studies [105], presented no difference between the two groups in terms of blood loss, need for blood transfusion, analgesic requirements, hospital stay, and

convalescence time. The mean operating time was significantly longer with the use of the robot. The authors concluded in their study, that there were no extraordinary benefits of RAN observed over LRN for localized renal tumors.

Another study compared radical nephrectomy performed open, laparoscopic, hand-assisted laparoscopic or with robot-assisted approach [107]. No difference in terms of perioperative complications were reported between the methods. While blood loss, postoperative narcotic doses, and hospitalization were significantly higher in the open group, the median operative time was significantly longer for RAN.

Taking into account the fact that in RAN the operative time is prolonged due to the time necessary for robot docking and the learning curve is longer, without any advantages over LRN, it seems that robotic assistance may be considered a technical overtreatment for renal tumors [72]. Murphy and Dasgupta in an article of them [106], regarding treatment of small renal tumors with robotic assistance, concluded that RAN is unlikely to enter standard practice.

As mentioned above, it can still be a useful training setting for robot-assisted partial nephrectomy.

2.4.2 Robot – assisted partial nephrectomy (RPN)

In the recent decade, there has been a stage and size migration of renal tumors. The incidence of small renal tumors has increased by 3, 7 % per year [32]. Data from more than 2000 patients who underwent radical nephrectomy at Memorial Sloan Kettering Cancer Center from 1989 to 2005 showed that the operation was an independent factor for the development of new-onset chronic kidney disease [108].

Furthermore, recent publications have suggested that greater efforts should be made to spare as much normal renal parenchyma as possible and that partial nephrectomy should be performed more often [109].

According to the current European Association of Urology Guidelines on renal cell cancer, nephron-sparing surgery, if feasible, is the standard procedure for solitary renal tumors measuring up to 7 cm, \leq T1b [72]. It seems that partial nephrectomy for renal tumors measuring less than 4 cm, and probably up to 7 cm, has many benefits over radical nephrectomy, which are: avoidance of overtreatment of benign lesions which account for the 20 % of small renal masses, further treatment options available if contralateral kidney recurrence occurs, better quality of life and decreased overall mortality [110].

However, open partial nephrectomy has been viewed as a difficult operation because of patient morbidity, expectation of significant bleeding, and concerns surrounding surgical margins. The morbidity is associated with the following: the muscle-cutting flank incision may involve removal of the 12th rib, leading to flank bulge, pain, paraesthesia, and hernia formation. All these factors are relevant in the discussion of laparoscopic partial nephrectomy, in order to reduce the morbidity associated with the open procedure.

The first laparoscopic partial nephrectomy was reported in 1993, but the acceptance and dissemination were relatively slow, given the technical skills required to ensure complete tumor excision and adequate hemostasis.

Laparoscopic partial nephrectomy offers the advantages of shorter hospital stay, decreased blood loss, and a shorter operating time versus the open procedure. Large series from highly experienced surgeons, confirm the oncologic adequacy of the procedure as well as the safety and low risk of complications [27].

However, concerns still surrounded renal injury given the increased warm ischemic time required for the procedure, most often performed without renal hypothermia. Furthermore there are more post-operative urological complications and increased number of subsequent procedures. Thus, the procedure is not routinely performed in many centers due to its prolonged learning curve and the surgical expertise required, and hand assistance was initially proposed as an aid to perform the operation and reduce the warm ischemia time.

Robot-assisted partial nephrectomy (RPN) was first reported by Gettman et al. in 2004 [111], and seems to bridge the gap between open and laparoscopic partial nephrectomy. The use of the robotic assistance allows magnified stereoscopic visualization and the use of articulated robotic instruments under precise control. It has facilitated the technical performance of partial nephrectomies by simplifying and speeding up two important parts of the procedure: dissection of the renal parenchyma and suturing after tumor resection. After positioning the patient and setting up the trocars (Figure 2.5), one of the techniques for RPN described by Wang et al., include the following [114]:

- ✓ Reflection of colon - Division of colorenal ligaments
- ✓ Elevation of the lower pole - Identification of the ureter
- ✓ Dissection of hilum - Release of Gerota's fascia
- ✓ Placement of bulldog clamps
- ✓ Excision of mass (Figure 2.6)
- ✓ Closure of collecting system and base of resection site – closure of renal capsule

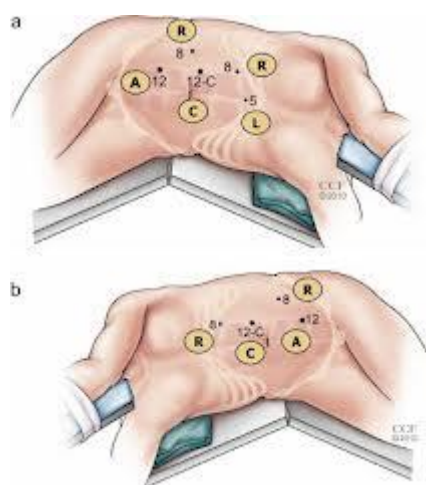


Figure 2.5 Positioning of the patient – trocar set up for RPN



Figure 2.6 Excision of the tumor in a RPN

Since RPN introduction, there has been a steady increase in the number of procedures performed, with more than 300 cases reported between 2005 and 2010 [88]. It is becoming the technique of choice for most stage T1a renal tumors, where the technology and expertise are available.

New technologies have been developed and tested to obtain hemostasis, including the use of hemostatic agents, thermal energy devices, and novel sutures and suturing aids. In addition, selective clamping of the renal artery or emission/early release of vascular occlusion has been performed to reduce the potential for renal injury. Most agree that the availability of the robot permits surgeons with less experience with laparoscopy to perform the procedure and shortens the learning curve for the operation.

Since the initial series of RPN reported by Gettman et al., numerous publications have compared RPN to LPN (Table 3).

Table 1 – The outcomes of selected studies on robot-assisted partial nephrectomy compared with laparoscopic partial nephrectomy

Study	N LPN RPN	OR time LPN RPN	EBL LPN RPN	TF rate LPN RPN	W-ischaemia LPN RPN	Complications LPN RPN	Hospital stay LPN RPN	Study design	LE
Aron et al. [19]	12	256	300	NA	22	NA	4.4	Retrospective, matched pair	3
Benway et al. [20]	12	242	329		23		4.7	Retrospective	3
	118	174	196	2	28.4	12	2.7		
	129	189	155	1	19.7	11	2.4		
Deane et al. [21]	11	289	198	NA	35	0	3.1	Retrospective	3
	11	228	115		32	1	2.0		
DeLong et al. [22]	15	253	NA	NA	39.9	NA	NA	Retrospective	3
	13	352			29.7				
Jeong et al. [23]	26	139	208	1	17	NA	5.3	Retrospective	3
	31	169	198	1	20		5.2		
Kural et al. [24]	20	226	387	2	35	2	4.2	Retrospective	3
	11	185	286	0	27	1	3.9		
Williams et al. [25]	59	221	146.3	NA	18.5	–	2.71	Prospective, single surgeon	3
Wang et al. [26]	27	233	179.6		28.0		2.51	Comparative, retrospective	3
	62	156	173	1	25	8	2.9		
Ellison et al. [27]	40	140	136	2	19	6	2.5	Retrospective	3
	108	162	400	–	19.3	–	2.2		
	108	215	368		24.9		2.7		
Pierorazio et al. [28]	102	192	245.1	–	18	–	NA	Retrospective	3
	48	152	122.4		14.1				
Seo et al. [29]	14	117	264.1	–	36.4	–	5.3	Retrospective	3
	13	153	283.6		35.3		6.2		
Long et al. [15]	182	240.7	325.0	14.3%	23.2	5.5%	1.36	Retrospective	3
	199	196.9	280.2	12.1%	22.4	3.0%	2.21		

EBL = estimated blood loss; LE = level of evidence; LPN = laparoscopic partial nephrectomy; N = nephrectomy; NA = not available; OR time = operating time; RPN = robotic partial nephrectomy; TF = transfusion rate; W-ischaemia = warm ischaemia time.

Table 3 Comparison of the outcomes of RPN and LPN in selected studies

Wang et al. [113] in a large, contemporary single surgeon study found no difference in the techniques with respect to blood loss and positive surgical margins; however, the robotic approach had advantages of shorter operative and warm ischemia time as well as length of hospitalization.

Over the last years numerous studies have compared RPN to LPN and have shown that RPN seems to be a safe and viable alternative to laparoscopic partial nephrectomy (LPN), providing equivalent early oncological outcomes and comparable morbidity to a traditional LPN, as was reported by Benway et al. in 2009 [112]. Moreover, RPN appears to offer additional advantages over LPN, such as [112]:

- Decreased hospital stay
- Less intra-operative blood loss
- Shorter warm ischemic time averaging less than 20 minutes.

In addition, increasing tumor complexity appears to have less impact on operative parameters for RPN than to LPN, suggesting that RPN may be superior to LPN for the treatment of more endophytic or centrally located renal masses.

A recently published systemic meta-analysis on RPN versus LPN incorporating data from 717 patients (313 RPN vs 404 LPN) reported a significantly lower warm ischemia time in the RPN arm. There were no significant differences between the two groups in all other examined perioperative parameters.

Currently, RPN has become a safe and efficient option in treatment of renal mass. Numerous studies showed that in the hands of an expert surgeon dealing with other robotic procedures, RPN is a safe, minimally-invasive procedure requiring a short learning curve to reach satisfying results in terms of blood loss, warm ischemia time and complication rates. Additionally, short-term analysis of functional and oncological outcomes shows comparable results to the widely accepted LPN procedure [114]. Though, long-term data are required to confirm cancer control equivalent to radical nephrectomy and open partial nephrectomy and preservation of renal function.

RPN has now overtaken LPN in the US as the minimally invasive approach of choice for partial nephrectomy, as demonstrated by the results from the Nationwide Inpatient Sample (NIS) [22] (Figure 2.7).

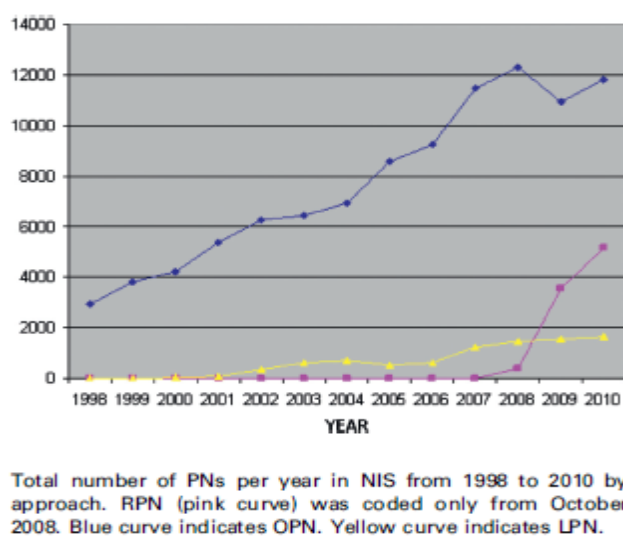


Figure 2.7 Practice patterns in partial nephrectomy in the US

2.5 Robot – assisted pyeloplasty (RLPP)

The management of ureteropelvic junction (UPJ) obstruction has evolved and various approaches have been attempted, including traditional open surgery, endoscopic, and laparoscopic or robot-assisted.

The open operation options include dismembered, flap, and incisional - intubated types, based on the specific ureteral anatomy, size of the renal pelvis, and the presence or absence of a crossing renal vessel [27].

All these techniques have been applied using either laparoscopy or robotic assistance, with most centers using the Heinz-Anderson or the Y-V pyeloplasty technique. The results should be compared with the gold standard of open procedures, with contemporary series reporting success in > 90 % of cases.

The first laparoscopic pyeloplasty (LPP) performed to an adult was reported in 1993, and the technique performed was the dismembered pyeloplasty, as it has been described for open procedures. Since then, larger series of LPP have been reported with success rate with regard to the management of the UPJ obstruction being > 90 % [27]. Currently the laparoscopic approach is being considered by most of the urologists as the gold standard procedure for the management of cases of adult UPJ obstruction. However, the laparoscopic procedure was mostly performed by experienced surgeons at academic referral centers given the low incidence of condition and technical challenges of the complex reconstruction, including cutting of the dilated pelvis and ureter and subsequent suturing.

Robotic assistance can significantly aid reconstructive surgery, such as pyeloplasty, due to delicate robotic arm maneuverability, three-dimensional vision, and tremor control, thus making easier the tailoring of the pelvis and ureter, and the suturing of the anastomosis.

The initial experience of robot-assisted laparoscopic pyeloplasty (RLPP) dates back to 1999 and followed the standard technique described for laparoscopic pyeloplasty [95]. The first reported RLPP was in 2002.

Currently, most of the literature regarding robotic pyeloplasty is in pediatric patients.

In the adult population, it seems that RLPP has comparable results with conventional laparoscopic pyeloplasty, in terms of operative time, perioperative outcomes, and success rates [96,97]. Usually, less time needed for suturing in RLPP is reported.

Complications for both techniques are rare.

A meta-analysis of comparative studies of RLPP and LPP retrieved only eight studies valid enough for consideration. It was concluded that both techniques had no major differences with regard to operation time, postoperative urine leakage, and success rate [98].

The success rate in terms of short-term resolution of the UPJ obstruction being > 95 %; many of these series have included cases of secondary UPJ obstruction after failed prior treatment, such as endopyelotomy [99].

Hemal et al. [100], reported advantages of RLPP over LPP, in 60 patients, which included faster operative time, less blood loss, and shorter hospitalization (2 vs 3.5 days), with similar success rates (97 % for robotic vs 100 % for laparoscopic).

In another study, Mufarrij et al. [101] reported the combined robotic pyeloplasty experience in 140 patients from three medical centers. The mean operative time was 217 minutes with length of hospital stay 2.1 days. The success rate as demonstrated on the first follow-up imaging study was 96 % and the complication rate was 10 %.

2.6 Other robotic applications in urological procedures

The da Vinci surgical system is also being used to assist other urological procedures than those already mentioned, such as:

- ureteric reimplantation

- appendicovesicostomy
- augmentation enterocystoplasty
- adrenalectomy
- sacrocolpopexy
- radical nephroureterectomy

Robot-assisted laparoscopic nephroureterectomy (RALNU) is a relatively new procedure with promising early results. It is currently used as a minimally-invasive alternative technique to the open procedure, which is considered the standard of treatment for upper urinary tract urothelial cell carcinomas (UUT-UCCs) with excision of the bladder cuff, regardless of the location of the tumor (LE 3). [88].

It has to be mentioned that RALNU is not mentioned as an option in the European Association of Urology Guidelines on UUT-UCCs.

RALNU was first described by the retroperitoneal route by Rose et al. in 2006 [116].

RALNU is associated with decreased morbidity for the patient and is characterized by all those advantages that the DVS provides over a standard laparoscopic procedure, and thus has the potential for a more widespread adoption by urologists.

Despite the documented benefits of minimally invasive RALNU in perioperative morbidity, the oncological equivalence of this procedure to the open one remains to be completely established even if overall, in the last decade, numerous studies have demonstrated oncological equivalence for laparoscopic and open procedures [117].

Murphy et al. [106] concluded in his article about RALNU, that it is technical feasible with short-term oncologic outcomes being encouraging, but there are no prospective comparisons with conventional laparoscopic approach.

PART 2nd

Purpose

The first use of surgical robotic assistance in urology was in 1989 and the official introduction of the da Vinci surgical system (DVS) for prostate surgery was in 2001[7,11].

Since then urology has seen a dramatic clinical explosion of robot-assisted surgery (RAS) across the globe and especially its greatest application with robot-assisted radical prostatectomy (RARP). RARP is the most commonly robot-assisted procedure performed worldwide, with increasing numbers each year. This is attributed to the undeniable benefits of RAS compared to open procedures for the patients [3], and patients' increasing interest for the novel technology.

The first and only DVS in a Greek public hospital was installed in July of 2008 at “Laiko” Hospital in Athens.

There are numerous studies examining the change of practice patterns and the trends after the introduction of the DVS in urology, all of these held in financially-advanced countries. None of these have examined the institutional status regarding RAS in a country being in economic crisis, with austerity measures and under the International Monetary Fund guidance (IMF).

The purpose of the present study is to determine the attitudinal change for urologic surgery in Greece since the introduction of the DVS. It is very interesting to look at whether the Greek urologists have embraced this novel technology despite lack of funds and cost cuts at National Health System (NHS) level. Furthermore, we describe the relationship between the introduction and uptake of RAS and the change in the total volume of procedures performed.

Materials and Methods

Data

For our study we obtained annualized case log data on urologic procedures between 2008-when the DVS was installed- and 2013, from “Laiko” Hospital in Athens , Greece.

We identified six urologic surgeons who performed the procedures, two of whom were RAS – dedicated surgeons with specialized training.

Surgeons provided self-descriptive information including age, specialization, practice patterns and training in urologic laparoscopy – robotics.

The procedures that were pooled and analyzed -open and robot-assisted respectively- are: prostatectomy, nephrectomy, nephroureterectomy and pyeloplasty. Patient characteristics were not recorded or analyzed at this instance.

Methods

We used summary statistics to describe current practice patterns, after stratifying the surgical procedures with regard to the following variables:

- (A) The surgeon who performed the procedure (dedicated RAS or not)
- (B) Open or robot-assisted surgery
- (C) The type of procedure: prostatectomy, nephrectomy, nephroureterectomy and pyeloplasty.

We analyzed trends in open and RAS in each type of procedure. Especially in prostatectomy and pyeloplasty, where a large attitudinal change seemed to exist.

We also analyzed trends regarding each surgeon separately.

Furthermore, we sought to determine the relationship between the introduction of RAS and change in total volume of procedures performed at “Laiko” Hospital.

The robotic group included a small number of traditional laparoscopic cases, given the limits in coding and thus identification of them.

Results

1578 of the urological procedures that were performed at “Laiko” Hospital in Athens, Greece, between 2008 and 2013, of whom 1342 (85%) were open and 236 RAS (15 %), were pooled and studied. These procedures were prostatectomy, open and RAS (RRP – RARP), nephrectomy, open and RAS (ORN-RAN), nephroureterectomy, open and RAS (ONUT – RALNU) and pyeloplasty, open and RAS (OPyel – RLPP), respectively.

We identified six surgeons. All urologists were male (100 %), two of them, surgeons A and B, were RAS – dedicated surgeons, two of them, surgeons C and D, performed exclusively open procedures and the other two, surgeons E and F, performed mostly open procedures and rather occasionally RAS. Table 1 shows the characteristics of the urologic surgeons in our study.

Surgeons A and B were 50 and 48 years old respectively, having specialized training in laparoscopy and in urologic robotics. They performed 199 RAS of a total of 236 robot-assisted procedures between 2008 and 2013 (84 %). Surgeons C and D were 57 and 56 years old respectively, without specialized training and performed exclusively open procedures. Surgeons E and F were 59 and 45 years old respectively and performed the remaining 37 RAS (16 %), having basic training in robotics and having the RAS-dedicated surgeons as actors-proctors.

A large increase in the number of urological procedures done robot-assisted during the 6-year study period was recorded. In 2008, urologists performed 198 open procedures and 14 RAS, which is 7 % of the total procedural volume. This percentage gradually increased to 9 % in 2009, 11 % in 2010, and 18 % in 2012. In 2013, which was the last year studied, 235 open procedures and 96 RAS were performed, with RAS being 30 % of the total procedural volume. There was an almost 6-fold increase in RAS from 2008 to 2013, but also an increase by 56 % in the total procedural volume.

Though, we observed that there was a clear downward trend in RAS in 2010-2011. This is attributed to the beginning of the dept crisis era in Greece and the introduction of the International Monetary Fund (IMF). In fact, the DVS was not operating for a

major period from 2010 to 2011, due to lack of funds for yearly maintenance and supply of disposal instrumentation. Even though this adverse conjuncture, there was a large increase in the number of RAS performed during the 6-year study period. Furthermore, we observed that after the introduction of the DVS at “Laiko” Hospital and especially after 2012 when it was in use again, there was a significant increase in the total number of procedures performed by the six high-volume surgeons, from 212 procedures in 2008 to 331 in 2013.

Figures 1 and 2 show the relationship between open, RAS procedures and the total procedural volume from 2008 to 2013.

Type of procedure

When stratifying the procedures by type, we observed a noticeable change both in the annual proportion of prostatectomies and pyeloplasties performed using the robot-assisted method and in the total volume, from 2008 to 2013.

(A) Prostatectomy:

Figure 3 shows the evolution of radical prostatectomy (RP) performed open and robot-assisted, from 2008 to 2013. In 2008 urologists in “Laiko” Hospital, performed a total of 94 RP, two of them being RAS (2 %). In 2013 they performed 124 RP, 57 of them being RAS, which is 46% of the total volume of procedures and 67 open, which is 54% of the total procedural volume.

We observed a dramatic increase both in the total number of RP during the 6-year study period and in the number of RAS. Thus in 2013 there was a 27-fold increase in RARP and the number of RARP was almost equal to that of open RP.

Figure 4 shows, the increase in the total number of RP’s performed at “Laiko” Hospital after the introduction of the DVS and especially after 2012, when it was in broad use again. We recorded that the increase is attributed mostly to the two RAS-dedicated surgeons and consequently to the RARP’s they performed, since the other

surgeons and especially those performing exclusively open procedures kept almost steady the number of procedures they performed reaching a plateau.

(B) Pyeloplasty:

Figure 5 shows the attitudinal change in pyeloplasty from 2008 to 2013 in “Laiko” Hospital with the use of the DVS. In 2008, only two pyeloplasties were performed, both with the robot-assisted method. In 2010, pyeloplasties were done more often with the robot-assisted method rather than open, while in 2013 eight out of nine procedures performed were robot-assisted (89 %).

Figure 6 shows the trend in radical nephrectomy and nephroureterectomy during this period.

(C) RAS – dedicated surgeons

Figure 7 shows the procedures performed by the two RAS – dedicated surgeons, A and B, from 2008 to 2013. A large increase in the number of RAS done and a trend towards minimally-invasive techniques was identified. They gradually decreased the number of open procedures and increased the number of RAS performed and consequently in 2013, they performed more RAS than open procedures. Furthermore, the two RAS-dedicated surgeons increased the total procedural volume performed from 86 procedures in 2008 to 145 in 2013, with 13% of them being RAS in 2008 and 57% in 2013. The introduction and use of the DVS, especially by the two RAS-dedicated surgeons, resulted in more patient seeking treatment at “Laiko” Hospital in order to undergo RAS and consequently as the numbers of RAS increased, the total procedural volume increased also.

The annual proportion of procedures done by surgeon A increased by almost 70 %, with a large increase in the number of RAS, during the 6-year study period. The percentage of RAS cases he performed increased from 13% in 2008 to 72% in 2013. At the same time there was a 20-fold increase in the number of RARP, especially after 2012 and an increase in the total volume of radical prostatectomies by 36 %, as Figure 8 shows. This result was also notable with nephroureterectomy and pyeloplasty.

Surgeon B increased his RAS cases from 12% in 2008 to 39% in 2013. He decreased the number of open RP, increased the number of RARP by 10-fold and the total number of RPs by 50 %. This result was not noticeable with NUT and pyeloplasty.

Tables and Figures

	Surgeons					
	A	B	C	D	E	F
Male / female	M	M	M	M	M	M
Age	50	48	57	56	59	45
Basic training in RAS	Yes	Yes	No	No	Yes	Yes
Laparoscopy training	Yes	Yes	No	No	No	No
RAS cases performed	135	64	0	1	29	7

Table 1: Surgeons' characteristics

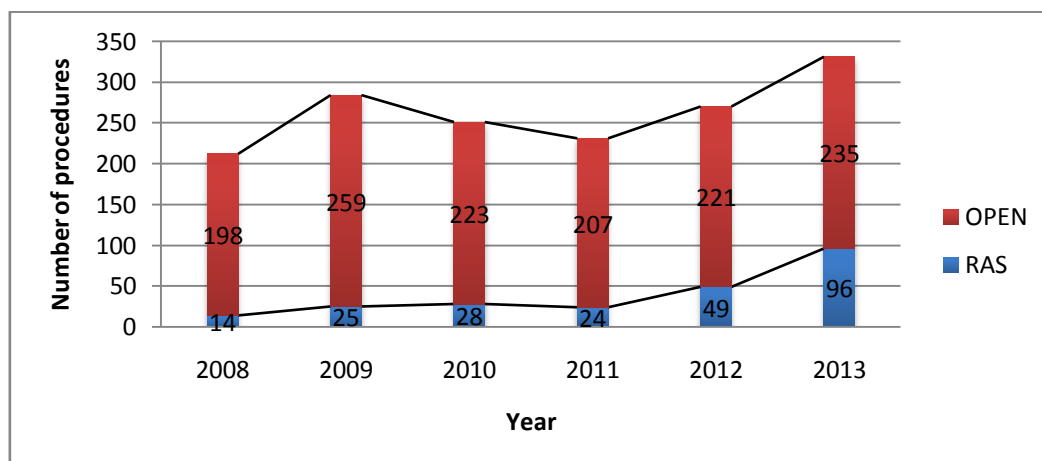


Figure 1: RAS compared to open and total procedural volume from 2008 to 2013

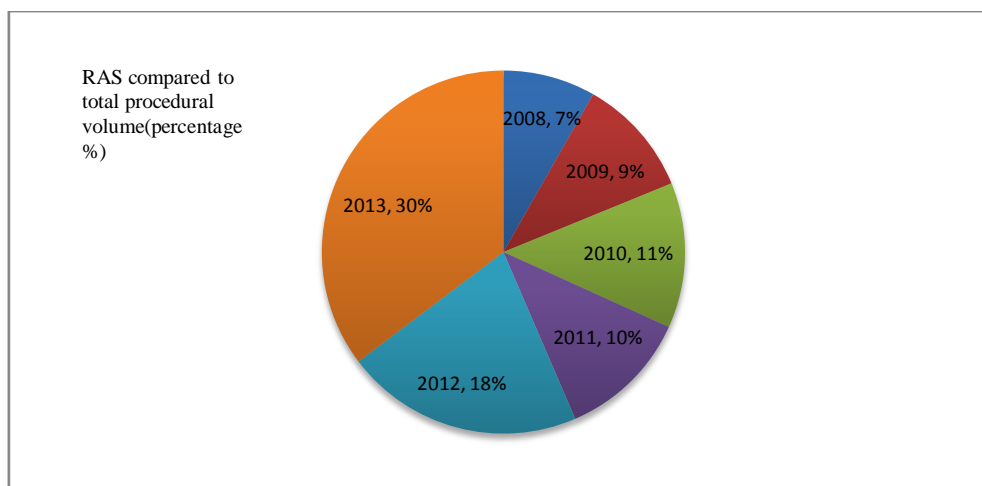


Figure 2: RAS compared to total procedural volume each year
- 2008: 7%, 2010: 11%, 2013: 30%

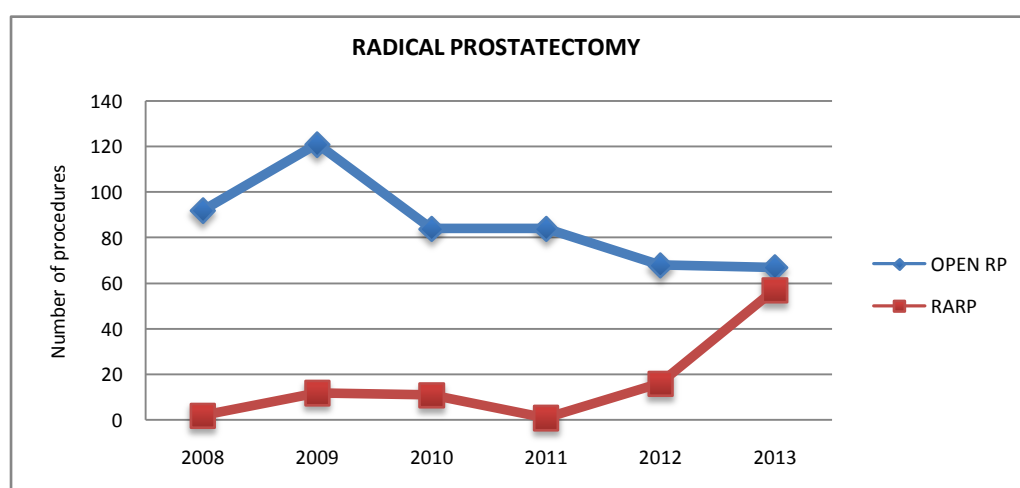


Figure 3: The evolution of open and robot-assisted radical prostatectomy

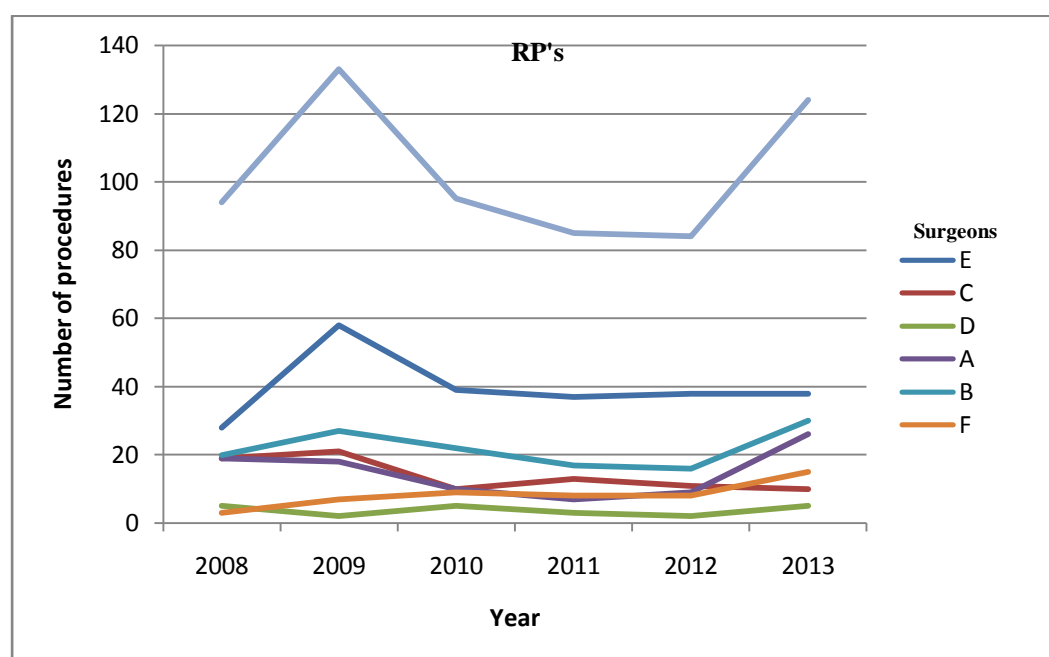


Figure 4: Radical prostatectomies performed both open and RAS by the six surgeons from 2008 to 2013

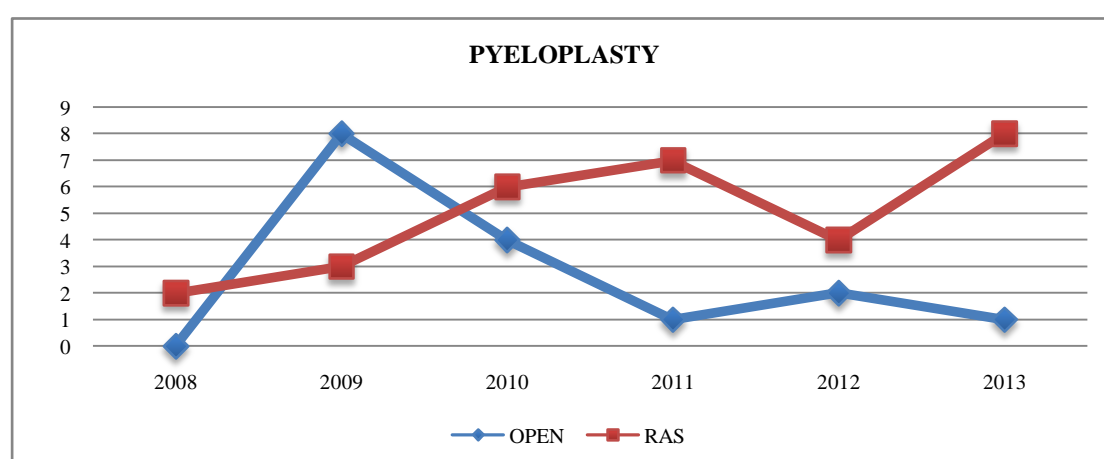


Figure 5: Evolution in the numbers of open and RAS pyeloplasty

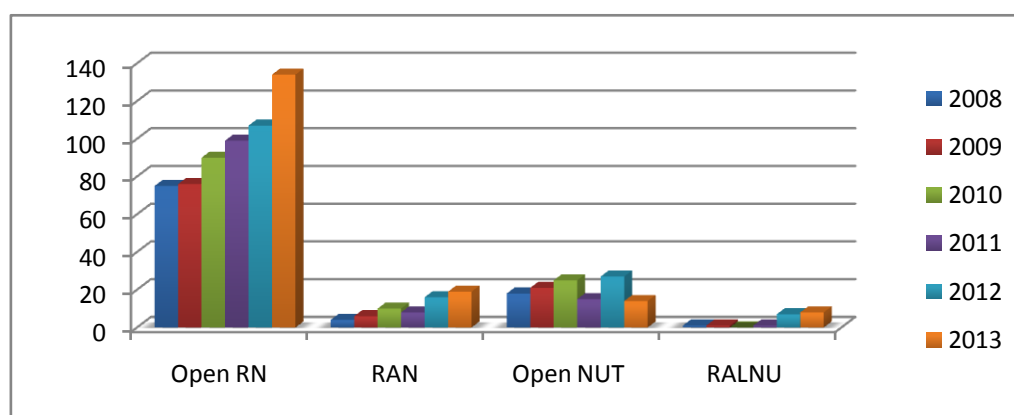


Figure 6: Practice patterns in nephrectomy and nephroureterectomy in “Laiko” Hospital during the study period

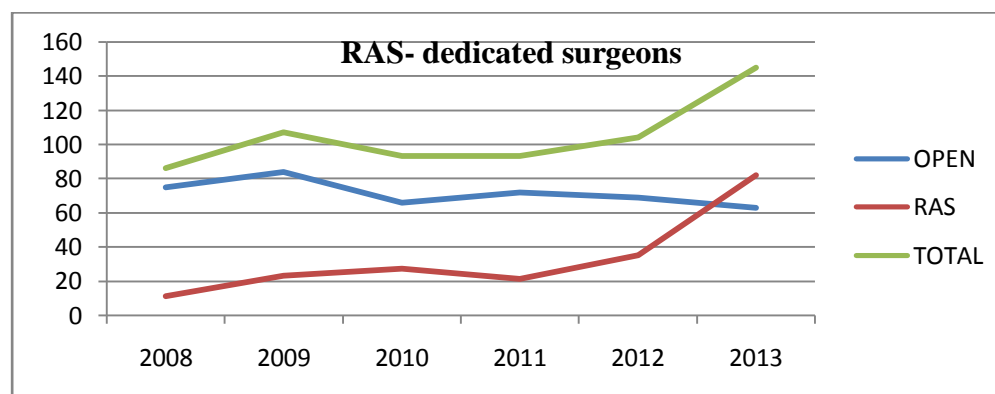


Figure 7: Procedures done open and RAS by the 2 RAS dedicated surgeons and the comparison with the total procedural volume

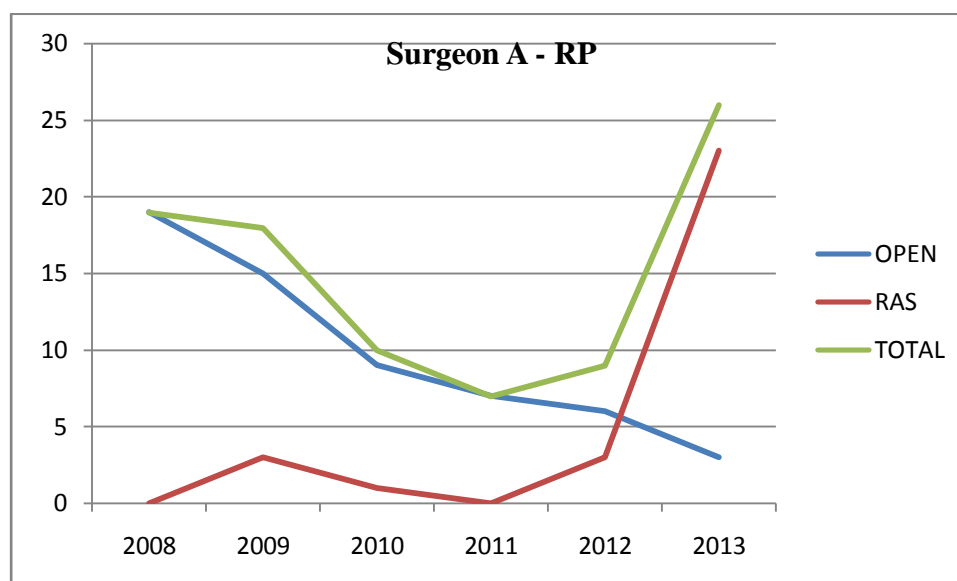


Figure 8: Surgeons' A practice patterns regarding radical prostatectomy

Discussion

Other studies have previously examined practice patterns in minimally invasive surgery. Namely, one survey of urologists in the Midwest United States in 2003 regarding laparoscopic surgery [2,17], a study in 2012 in the US about current trends in RARP [9] and a survey in 2014 about urologic laparoscopy in Germany, Austria and Switzerland [18]. All of these studies were held in financially-advanced countries.

Thus one of the major advantages of the present study is that it gives us the first results of the use of the DVS, in a country in debt crisis with major economic obstacles, with austerity measures and funding being under the IMF guidance [23].

Comparative studies have suggested RAS to have proven benefits compared to open procedures [3]. Most important of them being decreased blood loss, decreased postoperative pain, shorter hospital stay and faster recovery. Others advantages are also suggested, such as smaller wound and less wound complications, improved psychological status and faster mobilization of the patient, which is associated with decreased probability of others post-operative complications.

A limited number of studies on the DVS have proven the benefit of this approach, especially about RARP, including postoperative pain, decreased blood loss and shorter hospital stay [11,12,13]. For instance, Farnham et al have demonstrated in a large single-surgeon prospective trial that RARP was associated with less blood loss, high postoperative hematocrit and lower blood transfusion rates than open RP [3,15,]. Furthermore, decreased blood loss, fastest recovery of urinary incontinence and more effective nerve-sparing technique, are the most important advantages of RARP [24,25,26]. No difference in terms of oncologic outcomes has been reported [11,14].

The most important drawbacks of the DVS is the substantial cost, its long setup time and mostly longer operation [3,16]. The robot itself costs about \$1,3-\$1,5 million, with yearly maintenance fee of \$100,000, and a recurring cost of \$400 to \$1200 per case for disposable instrumentation, depending upon the procedure [16]. This is even

more important in Public health systems in countries under economical crisis and austerity measures.

RARP remains the most commonly performed RAS with increasing numbers performed each year. While 1500 RARP were performed in the United States in 2000, that number increased to 8000 in 2004 and 50000 in 2007 [2,8]. In 2010, 67 % of RP were done robotically in the U.S. with a substantial increase in the total number of procedures performed [9]. The most commonly reported estimates stem from SEER (Surveillance, Epidemiology and End Results)-Medicare are not current [9]. In the SEER-Medicare cohort the minimally invasive RP rate increased from 9 % in 2003 to 42 % in 2006 [9,19]. Indeed, most urologists declare RARP to be the gold standard for prostatectomy [2]. It has surpassed open RP, despite the lack of prospective evidence showing its oncologic advantages or cost-effectiveness [9,14].

Robot-assisted nephrectomy is a more recent development of robotic urologic surgery [2], but the technical advantages over the standard laparoscopic procedure are less evident than those of RP. It is unclear whether RAN will ultimately be adopted in the same fashion as RARP, but the impact will likely not be inconsequential [10]. Other procedures such as partial nephrectomy (PN), cystectomy and pyeloplasty are increasingly performed with robotic assistance. It is interesting that robot-assisted PN seems to have now supplanted laparoscopic PN as the most common minimally invasive approach for PN [21].

Greek citizens had the opportunity to have free access to the DVS via public health services after installation of the system at “Laiko” Hospital in Athens, a public hospital in July 2008. Our analysis of case log data from “Laiko” Hospital provides insight into contemporary practice patterns of Greek urologists, regarding robot-assisted surgery.

The most important study finding is the substantial increase in the number of RAS in this 6-year period. As well, an increase in the total volume of procedures done during this period and after the introduction of the DVS was also observed. We found that RAS – dedicated urologists who performed RAS and especially RARP had a higher

annual volume than those who performed only open procedures. Based on these finding and those of others [9,19,20], it appears that the uptake of robotics has contributed to the centralization of urological procedures (mostly RP) in the hands of higher volume surgeons. Indeed, surgeons who performed RAS in our study had a higher volume and a greater absolute number of procedures. They gradually decreased the number of open procedures and increased the number of RAS performed and consequently increased the total procedural volume performed.

Urologists with specialized training in laparoscopy and robotics in urology were dedicated to perform RAS. However, other surgeons who had basic training in robotics also performed RAS depending probably on the affiliation with the academic hospital, the existence of the DVS and the existing surgical skills, having the RAS-dedicated surgeons as actors-proctors.

Significant factors that contributed to the prevalence of RAS in urology in “Laiko” Hospital, as mentioned by previous similar studies [18], were:

- Use of trained personnel (nurse, anesthesiologist)
- Structured training programs (in cooperation with Karolinska University Hospital, Stockholm , Sweden)
- Dedicated operating room
- Organized surgery schedule exclusively for RAS.

The benefits of RAS for the patients are proven and undeniable, especially for RARP. There is also increasing interest and desire from the patients to have a robot-assisted surgery after the introduction of the DVS. In order to keep in touch with the novel technology and patients’ selection for minimally invasive techniques, urologists at “Laiko” Hospital switched towards RAS in line with developed countries worldwide. As a result and due to the broad use of the DVS in urologic surgery, an increasing number of patients are turning to the Greek national health system, seeking treatment mostly for RP.

The effort made in “Laiko” Hospital and the results are being highlighted by the fact that over the last years the adverse conjuncture of debt crisis in Greece has led to

dramatic changes in health care system [23]. It has to be mentioned, that the operation of the DVS was suspended for almost 1 year from 2010 to 2011. Even though, the study suggests that RAS has become a surgical standard in urology in the Greek national health system (NHS), especially for procedures such as radical prostatectomy.

Due to austerity measures, a very few resources were available for public health in Greece and consequently, surgeons at “Laiko” Hospital had to encounter with two situations: On the one hand, significant deficiencies in supply of essential disposable materials such as gauze, alcohol and syringes for daily use. On the other hand, the university setting and the educational-academic character of the Hospital. So, despite cost cuts they transferred funds in order to keep in touch with technology and sustain in use the DVS, a particularly high-cost system.

A limitation of this study is its retrospective design. Moreover it is a purely descriptive study, lacking any clinical or pathological data that would provide valuable clinical information. Selection bias could be considered the specific types of procedures pooled and examined, not including the whole armamentarium of urologic surgery. The number of procedures done open and RAS are rather small.

However, this study highlights the development of robot-assisted surgery in a public hospital in a country at dept crisis under the IMF guidance. Therefore it could be a stepping stone for a cost-effectiveness analysis of the DVS in the context of public National Health System hospitals.

Conclusions

Robot- assisted surgery using the DVS has integrated into the minimally invasive armamentarium for urologic surgery in Greece at public hospital level, in line with developed countries worldwide. Its greatest application is seen in radical prostatectomy and pyeloplasty. There is attitudinal change towards RAS, which is combined with an increase in the total volume of procedures performed, which is mostly attributed to the experience gradually gained, the undeniable benefits for the patients and patients' desire.

Surgeon characteristics and practice patterns have a clear role in the type of the procedure performed. RAS-dedicated surgeons have dramatically increased both the number of RAS and the total procedural volume performed. The avocation with minimally invasive techniques is causing increasing numbers of patients seeking treatment in a public hospital, a reference center for robotics.

The significant recession and debt crisis in Greece this period highlights the value of this study, showing the increasing use of RAS despite the ongoing debate over the usefulness and cost-effectiveness, in a country with austerity measures and where funding is under the International Monetary Fund guidance. Despite cost cuts and due to the academic character of the hospital, Greek urologists managed to transfer funds in order to keep in use the DVS. Further studies regarding the cost and the overall advantages for a public hospital at NHS level, are needed.

Abstract in Greek - ΠΕΡΙΛΗΨΗ

Σκοπός: Να καθοριστεί η αλλαγή της χειρουργικής νοοτροπίας στην Ουρολογία μετά την εισαγωγή του ρομποτικού συστήματος da Vinci (DVS). Περιγράφουμε τις σύγχρονες τάσεις σε επίπεδο δημοσίου νοσοκομείου, ενώ η χώρα βρίσκεται σε οικονομική κρίση υπό το Διεθνές Νομισματικό Ταμείο (ΔΝΤ).

Υλικό και Μέθοδοι: Μελετήσαμε αναδρομικά, τα δεδομένα καταγραφής ουρολογικών χειρουργικών επεμβάσεων από το Γενικό Νοσοκομείο Αθηνών (ΓΝΑ) 'Λαϊκό', σε ετήσια βάση, από το 2008 (εγκατάσταση του DVS) έως και το 2013. Εκτιμήσαμε χρησιμοποιώντας συνοπτικά στατιστικά στοιχεία, τις τάσεις σχετικά με τις ρομποτικά-υποβοηθούμενες επεμβάσεις (PYE) και την σχέση τους με την αλλαγή στο συνολικό αριθμό επεμβάσεων που πραγματοποιήθηκαν.

Αποτελέσματα: Μελετήθηκαν 1578 από τις ουρολογικές επεμβάσεις που πραγματοποιήθηκαν στο ΓΝΑ 'Λαϊκό', από έξι χειρουργούς κατά την 6-χρονη περίοδο μελέτης, 1342 (85%) από τις οποίες έγιναν ανοικτά και 96 (15%) έγιναν PYE. Παρατηρήσαμε αύξηση κατά έξι φορές στον αριθμό των PYE που πραγματοποιήθηκαν, από 7 % επί του συνολικού αριθμού επεμβάσεων (14/212) το 2008 σε 30 % (96/328) το 2013, κατά κύριο λόγο από δύο χειρουργούς αφοσιωμένους στις PYE. Όσον αφορά την ριζική προστατεκτομή, το 2008 το 2% έγινε ρομποτικά-υποβοηθούμενα και το 98% ανοικτά, ενώ το 2013 το 46% και το 54% αντιστοίχως. Η πυελοπλαστική γινόταν πιο συχνά με ρομποτική υποβοήθηση ήδη από το 2010. Οι αφοσιωμένοι χειρουργοί στις PYE αύξησαν τον αριθμό των PYE αλλά και το συνολικό αριθμό επεμβάσεων που πραγματοποίησαν. Από 86 επεμβάσεις το 2008 σε 145 το 2013, με το 57% από αυτές να είναι PYE το 2013 σε σύγκριση με ποσοστό 13% το 2008.

Συμπεράσματα: Η ρομποτικά-υποβοηθούμενη χειρουργική έχει ενσωματωθεί στο οπλοστάσιο του Έλληνα ουρολόγου χειρουργού σε επίπεδο δημοσίου νοσοκομείου. Η εξομοίωση με το DVS σχετίζεται επίσης με αύξηση του συνολικού αριθμού επεμβάσεων που πραγματοποιούνται, κυρίως την ριζική προστατεκτομή, παρόλη την έντονη διαμάχη περί της χρησιμότητας και της σχέσης κόστους-

αποτελεσματικότητας, σε περίοδο οικονομικής κρίσης και αυστηρών μέτρων λιτότητας.

Abstract in English

Purpose: To determine the attitudinal change for urologic surgery in Greece since the introduction of the da Vinci Surgical System (DVS). We describe contemporary trends at public hospital level – the initial Greek experience, while at the same time Greece is in economic crisis and funding is under austerity measures.

Materials and Methods: We retrospectively analyzed annualized case log data on urologic procedures, between 2008 (installation of the DVS) and 2013, from “Laiko” Hospital in Athens. We evaluated, using summary statistics, trends and institutional status regarding robot- assisted surgery (RAS). We also analyzed the relationship between the introduction of RAS and change in total volume of procedures performed.

Results: 1578 of the urological procedures that were performed at “Laiko” Hospital by six surgeons during this 6 -year period, 1342(85%) open and 236 RAS (15 %), were pooled and studied. We observed a 6-fold increase in the number of RAS performed, from 7% of the total procedural volume (14/212) in 2008 to 30% (96/331) in 2013, particularly from the two RAS –dedicated surgeons. For radical prostatectomy, in 2008 2% were robot-assisted and 98% open while in 2013, 46% and 54% respectively. Pyeloplasty was performed more often using the robot-assisted method since 2010. RAS-dedicated surgeons increased both RAS and the total number of procedures they performed. From 86 in 2008 to 145 in 2013, with 57 % of them being RAS in 2013 as compared to 13 % in 2008.

Conclusions: Robot-assisted surgery has integrated into the armamentarium for urologic surgery in Greece at national hospital level. Surgical robot acquisition is also associated with increased volume of procedures, especially prostatectomy, despite the ongoing debate over the usefulness and cost-effectiveness, during economic crisis and International Monetary Fund (IFN) era.

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