ENDOUROLOGY
Invited Review

Robotic surgery and malpractice

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Cite this article as: Usluoğulları FH, Tıplamaz S, Yaycı N. Robotic surgery and malpractice. Turk J Urol 2017; 43(4): 425-8.

ABSTRACT

Robotic surgery has undergone exponential growth since the last two decades. Employment of new technologies in surgery creates many ethical challenges concerning the advantages and disadvantages different from conventional surgery, ensuring safety of the new technology, giving permission to surgeons for using new technology, the way of informing patients before undergoing a new technology or technique, and the responsibilities of surgeons, firms and hospitals to the patients etc. In this review, robotic surgery was discussed from malpractice perspective.

Keywords: Competency; malpractice; robotic surgery.

Introduction

The term *Robot* was firstly mentioned in Karel Čapek's book written in the year 1920 entitled *R.U.R. - Rossum's Universal Robots*. Halid Fahri translated this book into *Ottoman Turkish* as *R.U.R. Suni Adamlar Fabrikası (The factory of Universal Artificial Human Beings)* and it was published in ottoman Turkish in the year 1927 by the government printing office.[1] Then this terminology was begun to be used in the whole world.[2]

The concept of automation in robots dates back to 2500 years ago, while modern robots have been developed in 1960s. The cornerstone of the first robotic surgery is the robot PUMA560 developed by Victor Scheinmann in the year 1978.[3] In the year 1985, using PUMA 200 version of this robot and under the guidance of computed tomography brain biopsy was performed.[4] In the year 1997 prototype of Vinci Robotic Surgery System was introduced, and in the year 2000 it was the first robot approved by FDA (US Food and Drug Association) to be used in surgical interventions.[3]

A total of 1.745 million robotic surgeries were realized between the years 2000-2013 in the USA. In the USA, a database called The Manufacturer and User Facility Device Experience ("MAUDE") has been formulated. The reports concerning the adverse results suspiciously caused by the medical devices are sent to this database (The establishment which uses these devices, the manufacturing firm, and distributors are compelled to send these reports). According to this databank between 2000, and 2013 10.624 unwanted outcomes (death, injury, breakdowns, and other unclassified) related to robotic devices have been reported. For each robotic surgical procedure unwanted outcomes were detected at rate of <0.6 percent. From the year 2006 on, annual number of reports have increased 32-fold, and in the year 2013 number of deaths (n=58), and injured patients (n=938), and cases of malfunction (n=4124) skyrocketed. Number of annual robotic surgeries performed increased 10-fold relative to the previous year. Between the years 2004, and 2011 on an average of every 100.000 procedures 550 (CI: 95% 410-700 cases) unwanted outcomes occurred, and climbed to 1000 events per 100.000 procedures in the year 2013. Rates of injuries, and death toll have not changed much from 2007 on (median, 83.4/100.000 procedures, 95% CI: 74.2-92.7). A total of 10.624 unwanted out-

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Submitted: 15.05.2017

Accepted: 07.08.2017

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Available online at www.turkishjournalofurology.com

Turk J Urol 2017; 43(4): 425-8
DOI:10.5152/tud.2017.59013

comes were reported for gynecological (n=3.194; 30.1%), and urological (n=1.565; 14.7%) procedures. Data specific to urological procedures are shown in Table 1.[5,6]

Its use, and advantages

Together with advances in technology robotic surgery has become a routinely applied day surgery, and its popularity has increased incrementally. In many centers, its use rapidly increased in surgical branches mainly in urologic surgery, followed by gynecology, general surgery, pediatric surgery, thoracic surgery and orthopedics.[7] Contrary to 2-dimensional images provided by laparoscopic systems, robotic surgery gives the impression of 3-dimensional image, and depth to surgeons accustomed to open surgery. It provides surgical comfort in areas where manual manipulation, and manoeuvres are challenging. Since robotic system does not fatigue, it provides an advantage of procedural continuity, and the risk of hand tremors is eliminated.[2] In addition, its other other advantages include shorter anesthesia time, decreased postoperative pain, and hospital stay, lower risk of cardiovascular complications, rapid recovery which gives the patient the chance of rapidly returning to his/her normal daily activities.

Components of malpractice

Whether it relates to the lawsuits concerning the civil or criminal court, classically malpractice requires demonstration of four main components.

1. Within the frame of standard criteria of care, the surgeon should have the task of providing medical care for this patient in question,
2. The surgeon has a negligence in his/her task of because of inadvertency,
3. The patient should suffer from this outcome,
4. A cause-effect relationship should exist between the harmful outcome, and erroneous practice of the surgeon.[8,9]

Naturally, these principles are also valid for robotic surgery, and in case of dispute each parameter should be evaluated based on individual case.

Legal aspect

Robotic surgery has opened new horizons in surgical medicine. It is a very new field of surgery, and the cases have not been followed up for an adequate period of time. Besides, new applications, and techniques are still being developed. All of these issues naturally have brought the legal problems on to agenda. Informing the patient, his consent, indication, surgical instruments used, technical infrastructure, complications developed during the procedure, switching to open surgery appear to give rise to legal problems.

Qualification/authorization certificate

Nowadays, most of the actively practicing surgeons completed their specialization training without receiving training in robotic surgery. This condition raises priorly the problem of qualification and authorization for the surgeons practicing robotic surgery. As is the case with newly developed technologies, a universally accepted qualification, and autorization certification system is not available yet.[10,11]

Indeed, receival of a certificate for the implementation of specified training, protects the surgeon in case of an indictment. Although some attempts so as to provide general solutions to these issues in the fields of urology, and gynecology have been made, a relevant general system has not been established excluding in-service principles, and rules developed by individual hospitals *per se*. During the process of establishing such a system, analysis of the historical development of laparoscopy which is the previous version of robotic surgery will be a guiding principle.

When the laparoscopy was introduced firstly, the surgeons had to learn this new method where 3-dimensional visualization, and tactile perception were not possible. Therefore, the surgeons developed laparoscopic simulators, and laparoscopic training boxes so as to learn this new unfamiliar method without compromising patient's safety. From the year 2009 on American Surgery Board demanded from all graduates of general surgery a document which certifies that they successfully completed simulation-based approved, and standardized The Fundamentals of

Table 1. Data on adverse outcomes observed in urology

	Death, n (%)	Injury, n (%)	Breakdowns, n (%)	Other, n (%)		Total
Adverse outcomes	30 (2%)	272 (17%)	902 (58%)	361 (23%)		1.565 (100%)
	Prostatectomy	**Nephrectomy**	**Cystectomy**	**Pyeloplasty**	**Other**	
Type of surgery	1,291 (82%)	138 (9%)	48 (3%)	31 (2%)	57 (4%)	
	Conversion to another surgical procedure			**Scheduling reoperation day**		
Procedures performed	212 (13.5%)			148 (9%)		

Laparoscopic Surgery (FLS) training module which is designed to teach principles of physiology, basic medicine, and technical skills required for basic laparoscopic surgery.[12] In the field of robotic surgery it seems to be impossible to reach a consensus on the scope, duration, number of cases performed which should be covered by a training intended to a give a certificate of authorization to applicants. Up to establishment of such an accepted certificate of authorization, each institute, and hospital should specify structured in-service training program for the surgeon who will practice robotic surgery and also the minimal criteria to be met by each surgical procedure.

When evaluating competency of the surgeon, his/her familiarity with the instrument and equipment used, duration of practice in robotic surgery, duration of entire surgery, estimated blood loss, complications, number of conversions to open surgery, appropriate patient choice, and compliance with general safety rules should be taken into consideration.[13]

In a case where intestinal perforation developed during robot-assisted cholecystectomy, lawsuit was filed against the surgeon because of inappropriate use of the robotic device, and the claimant charged the hospital for its failure to certify its surgeon. In the USA it is compulsory for the gynecologists without any experience in robotic surgery to complete robotic surgery certification program offered by the manufacturing firm before using Da Vinci surgical system.[14] However in our country an official regulation on bestowing an authorization/certification document is not available.

Notification and consent

Giving consent to a surgeon who is known to have inadequate experience in robotic surgery is a very critical issue. As you all know, during learning process of new technologies, each surgeon passes a period of learning curve. Concerning the cases realized during this period very important problems can be confronted. How one can speak of lack of training, and experience of the surgeon concerning the cases realized during this process? Who will supervise the surgeon, and how can the degree of responsibility assumed by the supervisor, and the surgeon be determined if a claim is filed. One should be prepared to face these inconveniences.

In a case who developed bilateral ureteral injury during robotic hysterectomy which was repaired subsequently, a claim was filed because of inappropriate notification. The patient claimed that if he had known that the surgeon had not sufficient training, and experience before, then she would not consent to robotic hysterectomy.[14]

Indication

Therefore, using open, laparoscopic or robotic surgery for the realization of a specific operation should be carefully considered, in other words the indication of robotic surgery should be based on well-established criteria.[15] Before offering the patient the alternative of robotic surgery, as an issue of critical importance, robotic surgery should be at least as effective as open surgery, even if not relatively better.[7]

Surgical superiority of this mechanical system in some surgical interventions as prostatectomy is indisputable, however presently clear-cut data about long-term recurrence rates of tumor surgery have not been available yet because of time constraints.[16]

In conclusion,

1. As is valid for every new technological application, very comprehensive, and detailed information should be provided, and especially indication should be carefully established.
2. Although a generally accepted procedure on authorization/certification does not exist applicants of robotic surgery should take necessary measures which will make them and the hospital feel safe.
3. During the period of learning-curve surgeons should feel themselselves safe and be especially attentive about practicing safe procedures under supervision.
4. One should not forget that during these cases which are performed using advanced technology one may confront complications which will be hard to attribute to human or instrument –related causes.

Peer-review: This manuscript was prepared by the invitation of the Editorial Board and its scientific evaluation was carried out by the Editorial Board.

Author Contributions: Concept – N.Y., F.H.U.; Design – N.Y., F.H.U.; Supervision – N.Y., S.T.; Resources – F.H.U., S.T.; Materials – F.H.U.; Data Collection and/or Processing – F.H.U.; Analysis and/or Interpretation – F.H.U., S.T.; Literature Search – F.H.U.; Writing Manuscript – F.H.U.; Critical Review – S.T., F.H.U.; Other – F.H.U.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

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