Integrated HTA and FMECA methodology for the evaluation of robotic surgery

Integrated HTA and FMECA Methodology for the Evaluation of Robotic Surgery

R. Miniati[1], F. Dori[1], F. Frosini[1], P. Avezzano[1], S. Grillone[1], E. Iadanza[1], S. Vezzosi[2], A. Belardinelli[2]

[1]Department of Information Engineering, University of Florence, Florence, Italy
[2]Careggi Teaching Hospital, Florence, Italy

Abstract— **Robotic surgery has been strongly improved since the beginning of the twenty-first century and chased important level of technical and clinical performances. Within the robotic area, the most worldwide used surgical robot is the da Vinci® system made by Intuitive Surgical Inc.**

The aim of this study was to evaluate at the hospital scale the robotic surgery (Hospital –Based Health Technology Assessment) in comparison to the open and laparoscopic procedures yet combining a FMECA analysis to accurately assess all those aspects involving patient and staff safety.

The total number of robotic procedures directly observed by the surgical department and reported in the following study was 44, including 28 urology interventions and 16 general surgeries. The study confirmed clinical benefits carried out with the robot but bigger complexity in managing the whole surgical system in terms of structural needs, staff and technology.

For the future, further steps regard the necessity to dispose of a wider number of robotic procedures in order to strength the analysis reliability and complete the socio-economic assessment with medium and long terms observation. Finally a new FMECA application will be essential to monitor the real effects of the suggested actions on the evaluated risks according to the already known and new failure modes.

Keywords— **Robotic Surgery, HTA, FMECA, Risk Analysis**

I. INTRODUCTION

Robotic surgery has been strongly improved since the beginning of the twenty-first century and chased important level of technical and clinical performances allowing a worldwide spread of robotic systems and becoming a standard procedure for surgeries till the point to start replacing some traditional laparoscopy interventions.

The aim of this study was to evaluate, at the hospital scale, the robotic surgery (Hospital –Based Health Technology Assessment) in comparison to the open and laparoscopic procedures yet combining a FMECA analysis to accurately assess all those aspects involving patient and staff safety in a wider domain of surgical process and system by also including external elements besides the robotic technology such as structural aspects, environmental issues and organizational procedures.

The paper is structured as follows: first, define robotic surgery state of art through a literature research and in-hospital process analysis; secondly, select a specific set of proper indicators for the technology evaluation and next, as third step, collect hospital data for the calculation of the above indicators. In the next section of the paper, the results coming from the HTA are reported by focusing on the comparison amongst the different techniques (robotics, laparoscopy and open surgeries) including the outcomes of the FMECA application as well. Conclusions and possible further developments close the paper.

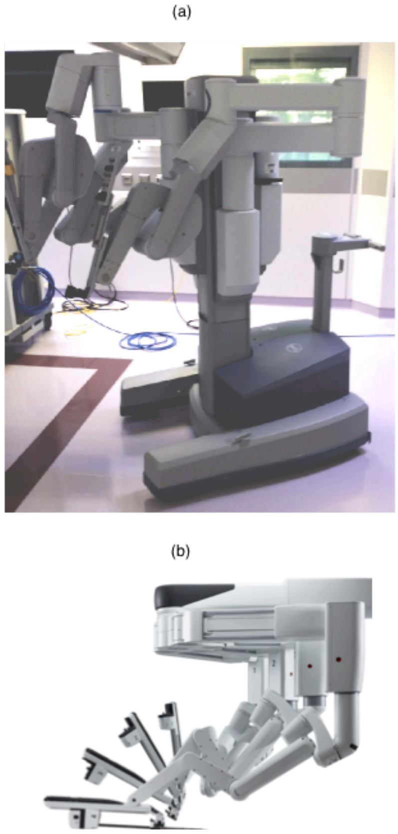
II. METHODS

A. *State of art and process analysis*

Many HTA studies on robotic surgery compare the robotic system with other surgical techniques such as open and/or laparoscopy. Within the robotic area, the most used surgical robot is the da Vinci® made by Intuitive Surgical Inc. The latest version currently available is new model da Vinci® Xi (see Figures 1 (b)), which updates the previous model da Vinci® Si (see Figures 1 (a)). The most significant differences amongst surgeries approaches (i.e. traditional laparoscopy, open and robotics) were seen within the intra-operative phase. Due to the presence of more actions for the technology management, the robot system resulted to be more complex for the surgical process including additional phases for docking, setup and undocking.

The analyzed phases included setup, trocars positioning, docking, undocking and console time [1-7]. The literature analysis [2-7] was a result of a systematic review carried out in Pubmed and Direct Science and showed, with respect to the robot system, that both setup and docking times depend on the type of procedure and on the team experience. Both phases are strongly user-dependent and it has been proved how experienced surgeons are significantly faster. It's also been shown a short learning curve. For the setup, the mean values range between 17- 22 minutes, while the average time of docking is 5-16 min. (ca. 8% of the whole mean operative time). For the laparoscopy setup, the rates significantly decrease till a mean value of 8 minutes [4].

Figure 1. Front view of the main body belonging to the: (a) In-hospital surgical robot da Vinci® Si model; (b) Surgical robot da Vinci® Xi model [http://www.palexmedical.com].



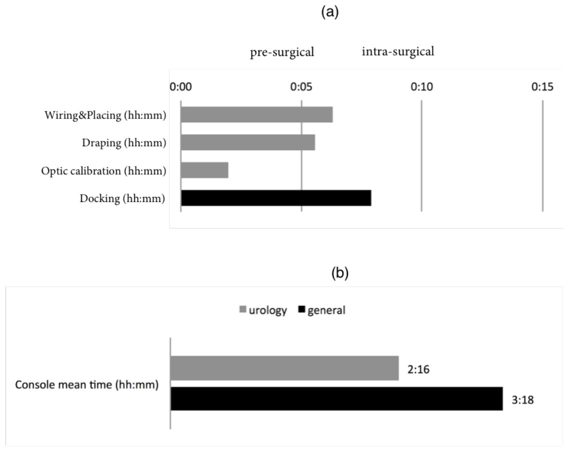
B. HB-HTA and FMECA

For the assessment of the robotic systems, It was chosen to consider the following four areas of evaluation and, from a specific literature research, obtaining the main assessment criteria and Key Performance Indicators (KPIs) to be applied [8-10], belonging to the following area of interest: Process, Clinical, Economic and Safety. The FMECA application was mainly focused on safety issues related to only robotic system. The most relevant indices selected to compare the different surgical processes are as follows:

Process - 'room occupation mean time', ‘anesthesia mean time’ and 'mean time of intervention;' Clinical - 'mean hospital staying', 're-intervention rate', 'transfusion rate', 'mean number of blood sacs per patient', 'intra- and post-operative mortality rates’, ‘patient mean age’, 'ICU mean staying’, ‘ICU utilization rate', 'conversion-to-open rate;' Economics – ‘general cost of the operating room', 'mean cost of hospitalization' and 'ICU mean cost.’

The risk analysis is an important tool for identifying, assessing and reducing work-related risks. The FMECA application, one of the most used and established risk analysis techniques [11], can be done at the level of product design, process implementation and technology assessment. It consists of identifying and assess the risk associated to all the phases composing the process by defining the potential failure modes (e.g. malfunctions, defects, errors), estimating the expected risk (RPN) and listing the possible actions/interventions essential for risk reduction. Once defined, it is necessary as last step, to check whether and how those actions would impact the current failure modes or add new ones.

Figure 2. Mean times concerning different surgical phases carried out with the robotic system referred to (a) setup and docking phase; (b) console time within the surgical phase.

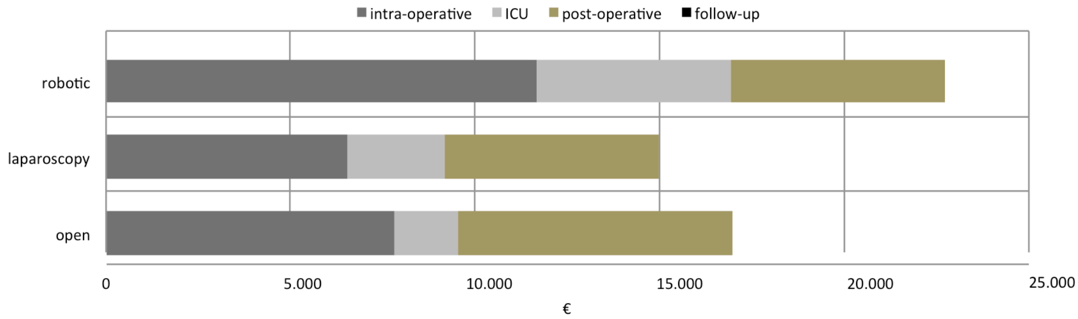


For each type of action aiming to reduce the risk, a qualitative cost estimation (low, medium or high cost action) has been associated in order to provide the decision makers a general cost assessment for safety improvement within the robotic surgical process. Most of the suggested ‘organizational changes’ were considered at zero cost while ‘technological and structural interventions’ are usually defined as high cost actions [12].

III. Results

According to the current state of art, robotic surgery has longer surgical times than the open technique, while it can be comparable to laparoscopy. The robotic approach seems performing better than the open technique with regard to the bleeding, post-operative complications and hospitalization length. They are comparable when considering oncological results. More difficult is comparing robotic system to laparoscopy since clinical benefits depend on the specific surgical procedure.

Figure 3. Cost comparison amongst different procedures in general surgery (robot, laparoscopy and open) categorized per care phase: surgery, ICU, post-surgery and follow-up.

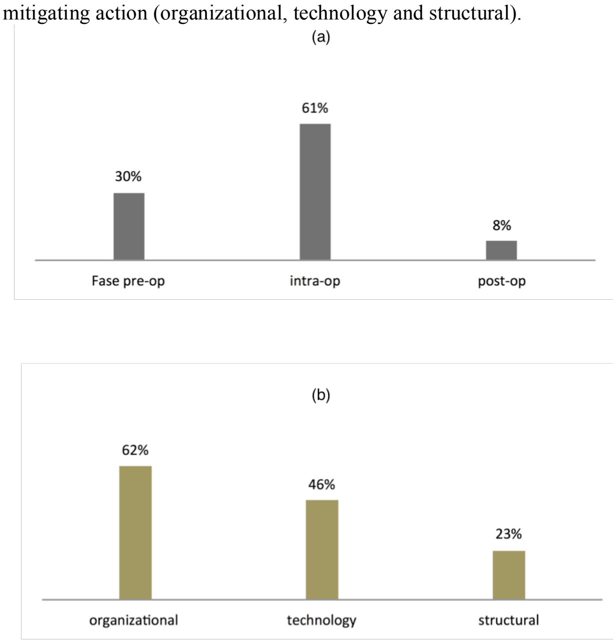


Finally, although the direct cost of robotic procedures are much higher than the ones with the other surgical techniques, especially in the intra-operative phase, strengths for the robot can be found in better ergonomics and higher level of precision permitted by surgical instruments. Moving to the hospital data collection carried out, the total number of robotic procedures directly observed by the surgical department and reported in the following study was 44, 28 urology interventions and 16 general surgeries. A shown in figure 2(a), the mean setup time for urology is divided into further three sub-phases regarding the robotic arms: placing, wiring&draping and optic calibration. The docking phase is included in the surgical time (mean time of 7 minutes for urology) weighting a mean value of 4% of the whole surgical time. As reported in figure 2(b), the console time (effective use of the robot) within the surgical period results in a mean weight of 77% for urology (low variance: 68% -86%) and 61% for general surgery (high variance: 31% -91%).

The economic costs have been summarized into three main voices: Intra-operative, ICU and post-operative. The intra-operative cost includes: (1) a mean cost (common to all procedures) deriving by direct and indirect costs for disposables and general technology usage, personnel/staff and supporting services such as sterilization and anesthesia; (2) direct cost related to specific robotic accessories dependent to each different surgical procedure. See figure 3 for an overview of the general surgery cost assessment. It was obtained by weighting the specific costs for each procedure to the number of procedures. The follow-up cost wasn't taken into consideration because of the lack of data.

The robotic system had the highest values for both the intra-operative (due to higher costs for accessories) and the ICU costs, while for the post-operative, open surgery had the highest one, with laparoscopy and robotic showing similar values. Laparoscopy showed the highest transfusion rate (11.1%) while robotic surgery had the highest 'conversion-to-open' rate with 4.5% (laparoscopy at 3.1%). Finally, the mean standard deviation for all robotic procedures was much lower compared to laparoscopy and/or open. Regarding the safety aspects analyzed by FMECA, figure 4(a) shows the risk distribution on the different activities in relation to different stages of the surgical process: pre-, intra- and post- operative. Intra-operative has been evaluated as the most critical phase by providing the highest RPN values and covering the 61% of the total number of failure modes. Moreover, as reported in figure 4(b), considering all the failure modes with unacceptable risk, it is interesting to notice how the most recurrent type of action was the organizational one (e.g. Consecutively planning of surgically homogeneous procedures, specific training to the team).

Figure 4. Failure modes categorization according to (a) clinical path: (pre-, intra- and post-operative); (b) type of suggested mitigating action (organizational, technology and structural).



Conclusions

The study was carried out in a privileged hospital environment with the benefit of centralizing different specialties for robotic surgery (i.e. Urology, General) and so allowing a direct comparison with the traditional techniques (i.e. Open and Laparoscopy). The study confirmed clinical benefits carried out with the robot but bigger complexity in managing the whole surgical system in terms of structural needs, staff and technology. These management skills (setup, docking and failure modes) are strongly dependent to the experience of the team while the clinical duration of different robotic surgeries showed less variability amongst experienced surgeons (all with robotic experience) than when comparing laparoscopy or open surgeries.

For the future it is essential to collect more data (given the current small number of robotic interventions observed in this study) in order to carry out more reliable analysis and complete the socio-economic assessment with data belonging to medium and long terms observation.

Finally, regarding the FMECA a new application will be essential to monitor the real effects of the suggested actions on the evaluated risks for both the already known and the new ones.

Acknowledgments

The authors would like to express their sincere gratitude to the Careggi Head Director, Dr. Monica Calamai for the support and interest showed in the study. The authors would like to say thank you also to the clinical departments involved during the data collection and especially to Prof. Marco Carini, Dr. Andrea Coratti, Dr. Giuseppe Chiaramonti, Dr. Maurizio Moroni. and Dr. Grazia Gentilini.

Conflict of Interest

The authors declare that they have no conflict of interest.

References

1. Associazione italiana di oncologia medica, Linee guida Carcinoma della prostata, Edizione 2013.
2. Iranmanesh P, Morel P, Wagner OJ, Inan I, Pugin F, Hagen ME, Set-up and docking of the da Vinci® surgical system: prospective analysis of initial experience, Int J Med Robotics Comput Assist Surg 2010; 6: 57-60.
3. Iranmanesh P, Morel P, Buchs NC, Pugin F, Volonte F, Seshadri U, Kreaden US, Hagen ME, Docking of the da Vinci® Si Surgical System with single-site technology, Int J Med Robotics Comput Assist Surg, 2013;9:12-16.
4. Breitenstein S, Nocito A, Puhan M, Held U, Weber M, and Clavien PA, Robotic-assisted Versus Laparoscopic colecystectomy: Outcome and Cost Analyses of a Case-matched Control Study, Ann Surg, 2008;247:987-993.
5. Giulianotti PC, Coratti A, Angelini M, Sbrana F, Cecconi S, Balestracci T, Caraviglios G, Robotics in General Surgery: Personal Experience in a Large Community Hospital, Arch Surg, 2003;138:777-784.
6. Thiel DD, Francis P, Heckman MG, Winfield HN, Prospective Evaluation of Factors Affecting Operating Time in a Residency/Fellowship Training Program Incorporating Robot-Assisted Laparoscopic Prostatectomy, Journal Of Endourology, 2008;22:1331-1338.
7. Link RE, Bhayani SB, Kavoussi LR, A Prospective Comparison of Robotic and Laparoscopic Pyeloplasty, Annals of Surgery, 2006;243:486-491.
8. Roberto Miniati, Fabrizio Dori, Ernesto Iadanza, Mario M. Fregonara. Health technology management: A database analysis as support of technology managers in hospital Technology and Health Care 19 (2011) 445-454
9. Roberto Miniati, Francesco Frosini, Giulio Cecconi, Fabrizio Dori, and Guido Biffi Gentili. Development of sustainable models for technology evaluation in hospital Technology and Health Care 22 (2014) 729–739
10. R. Miniati, F. Dori, G. Cecconi, F. Frosini, F. Saccà, G. Biffi Gentili, F. Petrucci, S. Franchi, R. Gusinu. Hospital Based Economic Assessment of Robotic Surgery Proceeding from the XIII Mediterranean Conference on Medical and Biological Engineering and Computing (2013), Seville, Spain
11. Italian Norm CEI EN 60812 Analysis Techniques for System Reliability - Procedure for Failure Mode and Effects Analysis (FMEA) – 2006-10-01
12. R. Miniati, F. Dori, G. Cecconi,, R. Gusinu, F. Niccolini and G. Biffi Gentili. HTA decision support system for sustainable business continuity management in hospitals. the case of surgical activity at the University Hospital in Florence. Technology and Health Care 21 (2013) 49-61.

Use macro [author address] to enter the address of the corresponding author:

Author: Roberto Miniati
Institute: Department of Information Engineering -University of Florence
Street: Via Santa Marta 3 50039
City: Florence
Country: Italy
Email: roberto.miniati@unifi.it