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INTRODUCTION OF ROBOT-ASSISTED SURGERY AT UNIVERSITY HOSPITAL CENTRE SPLIT

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ABSTRACT

Robot-assisted surgery is becoming a widely accepted method, especially as it expands indications for minimally invasive surgical procedures. This technology enhances accuracy, safety, and improves treatment outcomes, as it is associated with reduced blood loss, decreased morbidity, and accelerated recovery.

For the safe and successful introduction of robot-assisted surgery into a hospital, especially if it involves a new and first robotic system in the country, several interconnected prerequisites need to be fulfilled. First of all, it is necessary to have secured funds and the cooperation and support of the Ministry of Health. In particular project, funds are secured from EU funds. Additionally, it is necessary to have a consensus of the hospital's directorate and the heads of the organizational units within the hospital. The hospital must have a developed program for minimally invasive surgery and a large number of surgical procedures. Finally, the support and cooperation from the Agency for Medicinal Products and Medical Devices, equipment manufacturers and hospital specialist services are required. This program has been developing at University Hospital Split for about two years and the first surgical procedures were performed on March 11, 2024.

Keywords: robot-assisted surgery, University Hospital Centre Split

INTRODUCTION

As part of the National Recovery and Resilience Plan 2021-2026 (NRRP), a total of EUR 12,000,000.00 has been secured for University Hospital Split (UH Split). Of these funds, EUR 9,954,210.63 has been secured for the investment C5.1. R5-I1 Digital integration of operating rooms and robotic surgery at UH Split (EUR 1,990,842.63 from the state budget and EUR 7,963,368.50 from the NRRP). The cost of introducing robot-assisted surgical procedures at UH Split amounted to EUR 5,688,667.63 [1].

The application for this project stated that this investment would improve the quality of healthcare, monitor outcomes and extend the lives of patients, especially those with malignant diseases. The digitalization and integration of operating rooms will optimize the planning, documentation, storage, the exchange of data about patients and the types and methods of surgical treatments. Robotic surgery will increase the number of minimally invasive surgeries performed using this most advanced method of surgical treatment, improve treatment outcomes, reduce complications, and increase patient's chances of recovery [1].

As part of this investment, the HUGO™ RAS System, manufactured by Medtronic, USA (Hugo), along with the necessary supporting equipment and instruments for performing robot-assisted surgical procedures, was acquired [2,3].

Hugo consists of a surgical console with a special device for training and simulation, 4 surgical robotic arms and an endoscopic tower. Using appropriate cables, the robotic arm and the surgical console are connected to the endoscopic column, which together form a unique system for performing robot-assisted surgical procedures [2].

This is one of the most advanced devices of its kind in Croatia and this part of Europe. The Clinical Hospital Centre Split thus becomes a hospital where robot-assisted surgical operations will be performed, with the possibility to develop into an international educational center for robotic surgery [2].

METHODS

Successful implementation of the project for introducing robot-assisted surgery in the hospital requires initiating a series of procedures and meeting a number of conditions:

1. a sufficient number of educated and trained specialists from various fields
2. collaboration and consensus among leading experts and hospital management, as well as other involved departments
3. collaboration and consensus with the Ministry of Health

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4. securing funding for consumable materials
5. collaboration with the regulatory body (HALMED)
6. collaboration with the equipment manufacturer
7. availability of appropriate technology
8. available and well-developed education for performing surgical operations

Ad 1. Sufficient number of educated and trained specialists from various fields

At UH Split, minimally invasive surgery holds an important and irreplaceable position. At the Clinic for Surgery, all surgeons perform minimally invasive procedures. In the field of abdominal surgery, all gallbladder and appendix surgeries are performed laparoscopically, along with numerous other surgeries such as hernia, colon, bile duct, stomach, spleen, liver surgeries and more. In addition, pioneering procedures in Croatia and the entire region (this part of Europe), such as transvaginal and transanal operations, were performed at the Clinic for Surgery. In thoracic surgery, a large number of different thoracoscopic and mediastinoscopic operations are performed, some of which were performed for the first time both in Croatia and this part of Europe. Also, at the Clinic for Surgery, advanced endoscopic surgery courses are performed. Similarly, at the Clinics for Pediatric Surgery, Urology and Gynecology, a large number of advanced minimally invasive surgical procedures are performed.

Ad 2. Collaboration and consensus among leading experts and hospital management, as well as other involved departments

For the implementation of such a complex project the consensus among leading clinical experts and hospital management is necessary. Consensus must exist in the commitment to the project and in defining the hospital's needs. Finally, close cooperation is needed between departments of technical services, European funds, procurement and others.

Ad 3. Collaboration and consensus with the Ministry of Health

This project is of strategic interest for the entire Republic of Croatia, so the involvement of the Ministry of health was necessary from the beginning. Consensus in the project's implementation is crucial from the initial application for EU funding to the project's completion (adhering to deadlines, integrating into clinical practice, monitoring outcomes, etc.).

Ad 4. Ensuring methods of covering the costs of consumable materials

Robot-assisted surgery is associated with increased costs for consumable materials per surgical procedure. Therefore, during the project implementation, it was insisted on procuring a sufficient quantity of instruments and other consumables. At the very beginning of the project, contact was established with the Croatian Health Insurance Fund (HZZO) to find a way to cover the increased costs of robot-assisted surgeries. The temporary solution is for HZZO to cover the additional cost of consumables, with the ultimate goal being to achieve a separate coding for all robot-assisted operations.

Ad 5. Collaboration with the regulatory body (HALMED)

At the project's inception, it was necessary to clarify with regulators what are the essential requirements and whether there are any barriers to introducing new and previously unknown technology to the Croatian market. This information was crucial, especially for the equipment manufacturers, to ensure that entering the Croatian market would not incur additional costs or require compliance with regulatory demands. Fortunately, since the equipment is already present in the EU and approved by EU regulators, no additional alignment was necessary. Additionally, thanks to our positive laws and regulations, there was no need for translation of accompanying documentation or user interfaces into the Croatian language, which was of utmost importance to equipment manufacturers.

Ad 6. Collaboration with the equipment manufacturer

When introducing new technology, collaboration with the equipment manufacturer is necessary. This collaboration involves exchanging information with all manufacturers to fulfill predetermined needs and expectations. Manufacturer's technical departments and the hospital are required to determine all the use cases in a particular hospital in regards to access paths for the equipment, as well as the all prerequirements to integrate the device into the hospital's energy and IT systems.

Ad 7. Availability of appropriate technology

This technology is of strategic interest not only to manufacturers and hospitals but also to the wider community. Manufacturers have their strategic plans, which often do not include smaller countries like the Republic of Croatia. Fortunately, through the wholehearted efforts of all involved parties in the process, it was possible to influence manufacturer's strategies. Today, thanks to this project, all currently relevant technology in the field of robot-assisted surgery is available in the Republic of Croatia. Thus, in a unique way, this project led to the complete opening and integration of the Republic of Croatia into the world's elite society of robot-assisted surgery.

Ad 8. Available and well-developed education and procedures for performing initial surgical procedures

After the system arrived at the hospital, appropriate education began, as it was a contractual obligation of the equipment supplier. Initially, training started on the simulator, which is an integral part of the process. The next step were practices in the operating room, setting up and dismantling the robotic arms, placing trocars on models and sterile covering of robotic arms. The most crucial part of the team's education (two surgeons and instrument nurse) took place at the Orsi Academy in Ghent, Belgium, in the duration of 4 days. After the introductory and theoretical part, the core of the training consisted of exercises with the robot: setting up and removing trocars and robotic arms; eliminating of defects and malfunctions during procedures; handling emergencies; operating on tissue models, pigs, and cadavers. An essential part of the final training and the beginning of surgical procedures was the presence of necessary technical staff and proctors for the initial period of performing surgical procedures [4].

RESULTS

The HUGO™ RAS System has been installed and is fully functional at UH Split. The first supervised surgeries under proctor's supervision were performed on March 11, 2024.

From March 11, 2024, when the first surgery was performed, to March 20, 2024, a total of 6 patients were operated. There were 5 males and 1 female, with an average age of 56.7 years (range 33-73 years). Three cholecystectomies were performed due to chronic calculous cholecystitis and 3 hernioplasties (2 bilateral).

The average docking time of the system was 22.5 minutes (range 15-35 minutes).

The average duration of cholecystectomy surgeries ranged from 50-60 minutes and for hernioplasties, it ranged from 30-80 minutes (bilateral hernia).

During surgery, in the immediate and later postoperative period, there were no complications.

All patients were part of the day surgery program and were discharged from the hospital within 24 hours of admission.

DISCUSSION

For the successful implementation of robot-assisted procedures in a hospital, it is necessary to fulfill a series of prerequisites, especially if such a system is being introduced for the first time in the entire country.

Robot-assisted surgical procedures can certainly be introduced in hospitals where minimally invasive surgery is well-developed, with sufficiently skilled staff and a high volume of surgical procedures. Based on our modest experience, the setup time and performance of surgical procedures may be slightly longer initially, but surgeries can be safely performed without complications even during the initial period of the system implementation.

CONCLUSION

The successful introduction and application of the robot-assisted surgery system at UH Split have opened the way for the introduction of such systems in other hospitals in the Republic of Croatia. After UH Split's initial engagement over several years, just a few months after introducing this system in our hospital, another robotic system has already been installed in Croatia and one public procurement process is being carried out. There are also indications of the introduction of several more systems in different hospitals, with the potential of the healthcare system in the Republic of Croatia for introducing up to 8 such or similar systems.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.