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Reliability of robotic system during general surgical procedures in a university hospital

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Failure;
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Abstract

BACKGROUND: Data concerning the reliability of robotic systems are scarce, especially for general surgery. The aim of this study was to assess the incidence and consequences of robotic malfunction in a teaching institution.

METHODS: From January 2006 to September 2012, 526 consecutive robotic general surgical procedures were performed. All failures were prospectively recorded in a computerized database and reviewed retrospectively.

RESULTS: Robotic malfunctions occurred in 18 cases (3.4%). These dysfunctions concerned the robotic instruments in 9 cases, the robotic arms in 4 cases, the surgical console in 3 cases, and the optical system in 2 cases. Two malfunctions were considered critical, and 1 led to a laparoscopic conversion (conversion rate due to malfunction, .2%). Overall, there were more dysfunctions at the beginning of the study period (2006 to 2010) than more recently (2011 to 2012) (4.2% vs 2.6%, $P = .35$).

CONCLUSIONS: The robotic system malfunction rate was low. Most malfunctions could be resolved during surgery, allowing the procedures to be completed safely. With increased experience, the system malfunction rate seems to be reduced.

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Since the introduction of robotics for general surgery, many reports have shown not only the feasibility but also the safety of this approach, even in advanced cases.[1,2] Pancreatic and liver resections, for example, have been performed with encouraging results using a robotic approach,[3–6] although they are considered to be rather demanding laparoscopic procedures. In terms of safety, no specific risk factors for morbidity after robotic general surgery have been reported, with the exception of a multiquadrant approach.[2] Otherwise, the risk factors for complications are similar to those already reported for open or laparoscopic surgery.[2,7]

Clearly, this new technology has significant advantages, such as 3-dimensional vision, tremor filtration, stability, and increased maneuverability, that can overcome the technical limitations of standard laparoscopy. However, the potential technical advantages of the robotic approach are delivered through sophisticated engineering that is significantly more complex in both hardware and software than laparoscopic instruments. Additionally, the da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, CA) is an entire system solution for surgery instead of a set of instruments. Therefore, by its nature, the robotic system might be more prone to dysfunction than a simpler surgical solution. Additionally,

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for the first time, the operating surgeon is not at the patient's side during a robotic procedure. Thus, he or she needs to trust the robotic system, the assistant surgeon, and the scrub team. Several centers have evaluated the risk for malfunction of the system, especially for urology,[8–13] gynecology,[14] and pediatric surgery,[15] but for general surgery, the data remain relatively scarce.[16,17] Some groups have reported interesting results, with malfunction rates ranging from 2.4 to 4.5%.[10,18]

As a teaching institution, we started our robotic program in 2006 and were immediately concerned with the safety of the system. The aim of this study was thus to assess the incidence and consequences of robotic malfunction.

Methods

From January 2006 to September 2012, 526 consecutive robotic general surgical procedures were prospectively recorded and constitute our study population. The different surgical procedures are summarized in Table 1.

During the study period, 3 different robotic systems were used consecutively. The first da Vinci Surgical System was introduced in January 2006. It was the first version of the system. Then in May 2008, the system was upgraded to the da Vinci S System, and finally, in April 2010, the last version, the da Vinci Si System, was acquired as well. Actually, 2 different systems (the S and Si) are currently used and shared at our hospital in a multidisciplinary program.[19–30]

All procedures were performed by various experienced surgeons. The same dedicated scrub nurses were in charge of the draping and setup of the robot as well as intraoperative assistance during the procedure.

Table 1 Types of robotic general surgical procedures

Procedure	n
Bariatric surgery	327
Roux-en-Y gastric bypass	320
Sleeve gastrectomy	6
Removal of gastric banding	1
Upper gastrointestinal surgery	50
Nissen fundoplication	40
Heller myotomy	3
Partial gastrectomy	7
Colorectal surgery	40
Right colectomy	7
Sigmoidectomy	14
Low anterior resection	8
Abdominoperineal amputation	2
Rectopexy	7
Transanal endoscopic microsurgery	2
Hepatobiliary and pancreatic surgery	107
Cholecystectomy*	97
Minor hepatectomy	9
Distal pancreatectomy	1
Others	2
Total	526

*Including 75 single-site cholecystectomies.

A system failure was defined as any deviation from the standard and normal course of the robotic procedure and due to the system itself. All these failures were prospectively recorded in a computerized database and reviewed retrospectively. The type of malfunction, the consequences, and how it was managed were recorded as well. Robotic malfunctions were categorized as related to robotic arms, robotic instruments, optical or video systems, or the surgical console. Instrument malfunctions were subclassified according to the type of instrument.

Statistical analysis

The results of parametric and nonparametric data analysis are expressed as mean ± SD and median (range), respectively. GraphPad (GraphPad Software, La Jolla CA) was used for all statistical analyses. Confidence intervals were set at 95%. Two-sided P values $\leq .05$ were considered statistically significant. Comparisons between both groups were determined using Fisher's exact test for discrete variables and Student's t test for continuous variables.

Results

During the study period, a total of 526 robotic cases were performed in the Division of General Surgery. There was a continuous increase in the number of robotic procedures performed (Fig. 1). Robotic malfunctions occurred in 18 cases (3.4%). These failures were related to malfunctions of robotic instruments in 9 cases (Table 2). The harmonic scalpel was concerned in all these cases and required instrument replacement. The tip of the instrument (Fig. 2) was the origin of the malfunctions in all cases. Excluding these 9 malfunctions of instruments, the rate of "pure system failures" was 1.7%. Concerning the robotic arms, we recorded 4 cases of malfunction due to malpositioning of the adapter between the robotic arm and the instrument. Repositioning the adapter resolved the dysfunction in all cases. The optical system was the root of malfunctions in 2 cases. One led to a laparoscopic conversion because of light source failure. The surgical console had 1 major and 2 minor malfunctions. In 1 case, the system froze and stopped working during a gastric bypass. The system was shut down and rebooted successfully. The procedure was finished without additional problems thereafter. The 2 minor dysfunctions were caused by a problem with the audio control. The procedures were still performed robotically.

None of the recorded failures led to adverse patient consequences. Only 1 conversion to laparoscopy was required because of the light source problem, which led to a conversion rate because of system malfunction of .2%.

All malfunctions were directly related to the robotic system, except 1, which occurred with the Standard or the S

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