Safety Model for the Introduction of Robotic Surgery in Gynecology

Modelo de segurança para a introdução da cirurgia robótica em ginecologia

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Abstract

Objective   To analyze the perioperative results and safety of performing gynecological surgeries using robot-assisted laparoscopy during implementation of the technique in a community hospital over a 6-year period.

Methods   This was a retrospective observational study in which the medical records of 274 patients who underwent robotic surgery from September 2008 to December 2014 were analyzed. We evaluated age, body mass index (BMI), diagnosis, procedures performed, American Society of Anesthesiologists (ASA) classification, the presence of a proctor (experienced surgeon with at least 20 robotic cases), operative time, transfusion rate, perioperative complications, conversion rate, length of stay, referral to the intensive care unit (ICU), and mortality. We compared transfusion rate, perioperative complications and conversion rate between procedures performed by experienced and beginner robotic surgeons assisted by an experienced proctor.
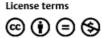
Results   During the observed period, 3 experienced robotic surgeons performed 187 surgeries, while 87 surgeries were performed by 20 less experienced teams, always with the assistance of a proctor. The median patient age was 38 years, and the median BMI was 23.3 kg/m^2. The most frequent diagnosis was endometriosis (57%) and the great majority of the patients were classified as ASA I or ASA II (99.6%). The median operative time was 225 minutes, and the median length of stay was 2 days. We observed a 5.8% transfusion rate, 0.8% rate of perioperative complications, 1.1% conversion rate to laparoscopy or laparotomy, no patients referred to ICU, and no deaths. There were no differences in transfusion, complications and conversion rates between experienced robotic surgeons and beginner robotic surgeons assisted by an experienced proctor.

Conclusion   In our casuistic, robot-assisted laparoscopy demonstrated to be a safe technique for gynecological surgeries, and the presence of an experienced proctor was considered a highlight in the safety model adopted for the introduction of the robotic gynecological surgery in a high-volume hospital and, mainly, for its extension among several surgical teams, assuring patient safety.

Keywords
► robotics
► robotic surgical procedures/adverse effects
► gynecologic surgical procedures/methods
► endometriosis/surgery
► gynecology

Resumo

Objetivo   Analisar os resultados perioperatórios e a segurança da realização de cirurgias ginecológicas por laparoscopia robô-assistida durante a implementação da técnica num hospital comunitário ao longo de 6 anos.

Métodos   Este foi um estudo retrospectivo observacional, com análise dos prontuários de 274 pacientes que se submeteram à cirurgia robótica de setembro de 2008 a dezembro de 2014. Avaliamos idade, índice de massa corpórea (IMC), diagnóstico, procedimentos realizados, classificação da Sociedade Americana de Anestesiologia (ASA), presença de um preceptor (cirurgião experiente, com pelo menos 20 casos robóticos), tempo cirúrgico, taxa de transfusão, complicações perioperatórias, taxa de conversão, tempo de internação, encaminhamento para Unidade de Terapia Intensiva (UTI) e mortalidade. Comparamos taxa de transfusão, complicações perioperatórias e taxa de conversão entre procedimentos realizados por cirurgiões experientes com a técnica e cirurgiões iniciantes na robótica, sempre assistidos por um preceptor experiente.

Resultados   Durante o período observado, 3 cirurgiões experientes realizaram 187 cirurgias, enquanto que 87 cirurgias foram realizadas por 20 equipes menos experientes, sempre com a presença de um preceptor. A mediana da idade foi 38 anos, e a mediana do IMC foi 23,3 kg/m^2. O diagnóstico mais frequente foi endometriose (57%) e a grande maioria das pacientes foi classificada como ASA I ou ASA II (99,6%). O tempo de cirurgia teve uma mediana de 225 minutos, e o tempo de permanência hospitalar teve uma mediana de 2 dias. Observamos 5,8% de taxa de transfusão, 0,8% de taxa de complicações perioperatórias, 1,1% de taxa de conversão para laparoscopia ou laparotomia e não houve pacientes encaminhadas à UTI, nem óbitos. Não houve diferença nos índices de transfusão, complicações e conversão entre cirurgiões experientes e cirurgiões iniciantes na robótica, assistidos por um preceptor experiente.

Conclusão   Em nossa casuística, a laparoscopia robô-assistida demonstrou ser uma técnica segura para cirurgias ginecológicas, e a presença de um preceptor experiente foi considerada um ponto de destaque no modelo de segurança adotado para a introdução da cirurgia robótica em ginecologia num hospital de grande volume e, principalmente, na sua expansão entre diversas equipes cirúrgicas, mantendo a segurança das pacientes.

Palavras-chave

► robótica
► procedimentos cirúrgicos robóticos/ efeitos adversos
► procedimentos cirúrgicos em ginecologia/métodos
► endometriose/ cirurgia
► ginecologia

Introduction

In the 1990s, laparoscopy, previously relegated to diagnostic procedures, gained prominence in surgeries on the female reproductive system.[1] The evolution from open surgery to laparoscopy brought benefits for patients, and robotics represents a technological advancement in minimally invasive surgery.[1] The word robot refers to compulsory or mandatory work, and the term was created and first used by Karel Capek in 1920, in his play *Rossum Universal Robots.* The Robotics Institute of America defines a robot as a machine that has a human form of performing tasks, possibly with more precise skills.[2]

Robotic surgery models emerged in the 1980s at the request of the United States Army, which sought alternatives for the surgical treatment of soldiers wounded on the battlefield.[3] Robotic systems were continually created until the development of the da Vinci System (Intuitive Surgical, Sunnyvale, California, USA), which is now widely used for procedures in different specialties, including gynecology.[4] In

Brazil, the Hospital Israelita Albert Einstein (HIAE) has pioneered the practice of robot-assisted laparoscopy in several specialties, including gynecology, and has performed a growing number of procedures since 2008.

Studies have compared the perioperative results of conventional, laparoscopic, and robotic surgeries in the field of gynecology, including benign and malignant surgeries, mainly hysterectomies.[5,6] The disadvantages of conventional surgery over laparoscopy are clear in terms of abdominal incisions, length of stay, greater need for postoperative analgesia, and higher complication rates.[5–7] On the other hand, when robot-assisted laparoscopy is compared with conventional laparoscopy, it would be expected that complex procedures become safer and more reproducible, as certain difficulties would be overcome. These include limitations on instruments range of motion, two-dimensional vision, tremor, ability to perform laparoscopic sutures, the need for an assistant to hold the camera, and a steep learning curve in the laparoscopy.[4,7]

Robot-assisted laparoscopy can be used in many gynecological procedures, including myomectomies, hysterectomies,

adnexal surgeries, treatment of endometriosis, sacrocolpopexies, tubal reanastomosis, and oncological surgeries, including pelvic and para-aortic lymphadenectomies.[8–13] However, technological implementation in a surgical environment, especially when it involves several or many teams, with different levels of training and skills, is a great challenge and responsibility because patient safety can never be put at risk, otherwise the use of those tools should be strongly discouraged. Proctors in our hospital are designated by a multidisciplinary surgical committee. They need to be experienced in laparoscopy and recognized as proficient in robotics, with a minimum of 20 robotics cases (usually more than that). Those proctors have the function of supporting other less experienced teams throughout the surgery and handling the robot, with the role of intervening and even performing some steps of the procedure, if necessary. At the end, they evaluate the surgeons' skills in the different tasks of operations. It is also the proctor who formally enables other surgeons to perform procedures on their own after proven proficiency, thus ensuring good surgical results while always prioritizing patient safety.

The objective of this study was to analyze the perioperative results and safety of performing gynecological surgeries using robot-assisted laparoscopy during implementation of the technique over a 6-year period, considering procedures performed with and without a proctor.

Methods

This retrospective, observational and cross-sectional study was approved by the Institutional Medical Ethics Committee, CAAE: 38045414.7.0000.0071. We analyzed the medical records of 274 patients who underwent gynecological surgeries for benign or malignant diseases at the Hospital Israelita Albert Einstein (HIAE), São Paulo, Brazil, from September 2008 to December 2014. Patients with surgical indication for the treatment of gynecological diseases were included, and patients with non-gynecological procedures were excluded, even if there was a gynecological procedure for them as well.

The study considered each patient age, BMI, ASA classification, and diagnosis. We evaluated the procedures performed, operative time, length of stay, perioperative complications, blood transfusion, conversions (laparoscopy or laparotomy), transfer to the intensive care unit, and mortality. The data were descriptively analyzed using absolute frequency and percentages for qualitative variables and averages, standard deviations, or medians and quartiles for quantitative variables. The median was selected in cases of asymmetric sample distribution. The analyses were performed using SPSS statistical program, version 17.0 (SPSS Inc., Chicago, USA) to compare complications, transfusion rate and surgical conversion between experienced robotic surgeons without proctor and beginner robotic surgeons with proctor assistance.

Results

The number of surgeries was found to have increased over the course of the study period, with 16 (5.8%) surgeries in 2009, 22 (8.0%) in 2010, 45 (16.4%) in 2011, 38 (13.9%) in 2012, 63 (23%) in 2013, and 87 (31.8%) in 2014. In 2008, three (1.1%) surgeries were performed from September to December. Three teams performed the procedures in 187 patients (68.2%), with a mean of 62.33 cases per surgeon (range: 27–126). Twenty teams still in their initial robotics learning curve were responsible for 87 cases (31.8%), with a mean of 4.35 cases per surgeon (range: 1–14), always with the participation of a proctor.

The patients were aged 20 to 84 years, with a median age of 38 years, and the BMI range was 16 to 46.7 kg/m^2, with a median of 23.3 kg/m^2. In the surgical risk evaluation, only one patient had a preoperative ASA score of III (0.4%). The others were classified as ASA I or ASA II, indicating low clinical-surgical risk. The following preoperative diagnoses were found: endometriosis, uterine myoma, endometrial cancer, adenomyosis, and benign ovarian tumor. The following procedures were performed: ovarian cystectomy, treatment of intestinal endometriosis, hysterectomy, treatment of deep endometriosis (other than intestinal), myomectomy, oophorectomy, lymphadenectomy and sacrocolpopexy. The most frequent diagnosis was endometriosis, which occurred in 192 patients (70.1%). The most frequent procedures were ovarian cystectomy (22%) and treatment of intestinal endometriosis (20%) (►Tables 1 and 2).

The diagnoses were included in the study as individual occurrences, given that each patient might have more than one diagnosis at the time of surgical decision. The same was considered for the procedures performed, as different procedures could be necessary during a single patient surgery. The operative time was 55 to 600 minutes, with a median

Table 1 Distribution of surgeries by the preoperative diagnosis ($n = 338$)

Diagnosis	n (%)
Endometriosis	193 (57)
Uterine myoma	120 (35.5)
Endometrial cancer	10 (3)
Adenomyosis	10 (3)
Benign ovarian tumor	5 (1.5)

Table 2 Distribution of procedures performed ($n = 501$)

Procedures	n (%)
Ovarian cystectomy	110 (22)
Treatment of intestinal endometriosis	101 (20)
Hysterectomy	89 (17.8)
Treatment of deep endometriosis (other than intestinal)	85 (17)
Myomectomy	66 (13.2)
Oophorectomy	40 (8)
Lymphadenectomy	9 (1.8)
Sacrocolpopexy	1 (0.2)

time of 225 minutes (interquartile range [IQR]: 150–280 minute). The postoperative length of stay was 0.5 to 12 days, with a median time of 2 days (IQR: 2–3 days). Transfusions were required in 5.8% of the surgeries (1–3 red blood cell concentrates). There were complications in 2.6% of the surgeries and conversion to laparotomy or laparoscopy in 1.1% of the cases. There were no transfers to the ICU and no deaths (►Table 3). There were no differences in complication rates between the group of surgeons with less experience in robotics (who were always assisted by a proctor) and the group of more experienced surgeons (►Table 4).

Discussion

A 2010 review showed that robotic surgery has gradually become a frequent choice, and this modality has demonstrated good results in terms of reducing trauma and shortening the length of stay, with fewer complications, as

Table 3 Distribution of surgeries by parameters analyzed in the case series (n = 274)

Distribution of surgeries	
Operative time	Minutes
Median (IQR)	225 (150–280)
Minimum–Maximum	55–600
Postoperative length of stay	Days
Median (IQR)	2 (2–3)
Minimum–Maximum	0.5–12
Need for transfusion	n (%)
No	258 (94.2)
Yes	16 (5.8)
Amount transfused	n (%)
None	258 (94.2)
1	7 (2.6)
2	7 (2.6)
3	2 (0.7)
Description of perioperative complications	n (%)
No complications	272 (99.2)
Ureteral reconstruction due to ureteral injury	1 (0.4)
Colonic fistula, with colostomy performed	1 (0.4)
Surgical conversion (laparoscopy/laparotomy)	n (%)
No conversion	271 (98.9)
Laparoscopy	2 (0.7)
Laparotomy	1 (0.4)
Intra-hospital mortality/Transfer to ICU	n (%)
None	0 (0)

Abbreviation: IQR, interquartile range.

Table 4 Comparison of complication, conversion and transfusion rates between surgeries performed with and without proctor (n = 274)

Variables	Without proctor	With proctor
Need for transfusion n (%)		
No	177 (94.7)	81 (93.1)
Yes	10 (5.3)	6 (6.9)
$p_1 = 0.611$		
Complications n (%)		
No	186 (99.5)	86 (98.9)
Yes	1 (0.5) colonic fistula requiring colostomy	1 (1.1) ureter injury requiring reconstruction
$p_2 = 0.535$		
Surgical conversion n (%) (laparoscopy/laparotomy)		
No	185 (98.9)	86 (98.9)
Yes	2 (1.1) laparoscopy	1 (1.1) laparotomy
$p_2 > 0.999$		

p_1, chi-squared test; p_2, Fisher exact test.

evidenced by the extent to which it has been more present in several specialties every day.[14] Although most gynecological procedures could be done by robotics, and this technology has been recently made available in more than 30 hospitals in Brazil, the number of procedures is still low even in those hospitals, demonstrating the difficulty in qualifying a good number of surgeons to use this technology safely and effectively.

In this study, we focused on safety-related outcomes, evaluating two distinct groups of surgeons: 20 with little experience in robotics (mean: 4.35 cases per surgeon; range: 1–14) and 3 experienced robotic surgeons (mean: 62.33 cases per surgeon; range: 27–126). The results demonstrated low rates of complications, transfusion and conversion, even when surgeons less experienced in robotics did the procedures, always assisted by an experienced proctor. However, we emphasize that our results have limitations related to study design, because it is retrospective and observational, with convenience sample, since we could not perform sample size analysis and may not have adequately identified confounding factors.

In a 2009 retrospective study that compared robotic surgery to laparoscopy for hysterectomy, the operative time was found to be like those reported in our casuistic. There were no statistically significant differences in operative time, blood loss or length of stay, and conversion to laparoscopy was not required.[15] Reynolds and Advincula[16] and Hanssens et al[17] have shown that the time required for robotic surgery exceeds that for laparoscopy, though these results vary according to the surgeons' experience.

Fastrez et al,[18] in a multicenter study with a group of 37 robot-assisted pelvic lymphadenectomies, reported that one patient had an aortic injury requiring conversion to laparotomy

and one patient had a ureteral lesion treated without conversion. In the nine lymphadenectomies performed at HIAE, none of these complications were observed, a result which reflects the safety of this kind of approach for this procedure.

At the hospital evaluated herein, 66 myomectomies were performed through minimally invasive robot-assisted approach between 2008 and 2014 and no conversions were required. This result is compatible with the data from Cheng et al,[19] in which 21 robotic myomectomies were performed between 2010 and 2012 with no conversions were required either.

In 2015, Corrado et al[20] compared different surgical approaches for the treatment of endometrial cancer and showed that the group who underwent robotic surgery had a 1.4% rate of conversion to laparotomy and a 2.7% rate of conversion to laparoscopy, comparable to the rate observed at HIAE for all robotic gynecological surgeries between 2008 and 2014 (1.1%). The same authors reported a 1.4% blood transfusion rate, slightly lower than the 5.8% observed in the current study.[20]

Although we had only one case of sacrocolpopexy, a systematic review conducted in 2016 by Pan et al,[21] showed that the robotic approach is as safe as laparoscopy for performing the procedure, as there are no statistical differences between the two approaches in either complication rates or operative time. One of the biggest challenges of minimally invasive gynecological surgery is the difficulty in performing this type of approach on morbidly obese patients.[22] Being aware of this issue, minimally invasive surgeries must be introduced slowly and safely to those patients. Our casuistic had three patients with BMI $> 40 \text{ kg/m}^2$, with no complications at all.

Conclusion

Robot-assisted laparoscopy in gynecological surgeries has been shown to be safe, with the presence of a proctor being critical for a successful transition for less experienced teams. This study demonstrates the safety of the model here presented for the introduction of robotic gynecological surgery into the hospital practice, but the rapid development in robot-assisted surgery calls for long-term prospective randomized controlled trials.

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