Early Experience of Robotic Hysterectomy for Treatment of Benign Uterine Disease

Experiência inicial da histerectomia robótica no tratamento da patologia uterina benigna

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Abstract

Objectives To demonstrate the initial experience of robotic hysterectomy to treat benign uterine disease at a university hospital in Brazil.

Methods A cross-sectional study was conducted to review data from the first twenty patients undergoing robotic hysterectomy at our hospital. The surgeries were performed from November 2013 to August 2014, all of them by the same surgeon. The patients were reviewed for preoperative characteristics, including age, body mass index (BMI), indications for the hysterectomy and previous surgeries. Data of operative times, complications, postoperative pain and length of hospital stay were also collected.

Results The total operating room time was 252.9 minutes, while the operative time was 180.7 minutes and the console time was 136.6 minutes. Docking time was 4.2 minutes, and the average undocking time was 1.9 minutes. There was a strong correlation between the operative time and the patient's BMI ($r = 0.670$; $p = 0.001$). The console time had significant correlation with the uterine weight and the patient's BMI ($r = 0.468$; $p = 0.037$). A learning curve was observed during docking and undocking times.

Conclusion Despite its high cost, the robotic surgery is gaining more space in gynecological surgery. By the results obtained in our hospital, this surgical proposal proved to be feasible and safe. Our initial experience demonstrated a learning curve in some ways.

Keywords
- ► robotic hysterectomy
- ► gynecological surgery
- ► da vinci
- ► learning curve

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Resumo

Objetivos O presente projeto visa à documentação da experiência inicial do Hospital de Clínicas de Porto Alegre na realização da histerectomia robótica.

Métodos Um estudo transversal foi realizado a fim de revisar dados das primeiras vinte pacientes submetidas à histerectomia robótica em nosso hospital. As cirurgias foram realizadas no período de novembro de 2013 a agosto de 2014, e todas tiveram o mesmo cirurgião. Foram analisadas características pré-operatórias, incluindo idade, índice de massa corporal, cirurgias prévias abdominais, paridade, indicação da histerectomia. Dados referentes aos tempos operatórios, complicações, dor pós-operatória e tempo de internação pós-operatória também foram coletados.

Resultados O tempo de sala total foi de 252,9 minutos, enquanto o tempo cirúrgico total foi 180,7 minutos, e o tempo de console foi 136,6 minutos. O tempo médio de *docking* foi 4,2 minutos; e o tempo médio de *undocking* foi 1,9 minutos. Foi observada forte correlação entre o tempo cirúrgico total e o índice de massa corporal da paciente ($r = 0{,}670$; $p = 0{,}001$). O tempo de console teve correlação significativa com o peso uterino e com o índice de massa corporal das pacientes ($r = 0{,}468$; $p = 0{,}037$). Foi observada curva de aprendizado nos tempos de *docking* e *undocking*.

Conclusão Apesar do alto custo, a robótica vem ganhando espaço na cirurgia ginecológica. Pelos resultados obtidos no nosso hospital, a proposta provou ser factível e segura. Nossa experiência inicial demonstrou curva de aprendizado em alguns aspectos.

Palavras-Chave
- ► histerectomia robótica
- ► cirurgia ginecológica
- ► da vinci
- ► curva de aprendizado

Introduction

Despite many non-surgical treatments for uterine conditions, hysterectomy is still a common surgical procedure. It is estimated that 20–30% of women are to undergo this surgical procedure until they reach the age of 60.[1,2] In the United States, hysterectomy is the second most performed gynecological surgery, preceded only by cesarean section.[3]

The frequency of this intervention varies in different countries, and it is higher in the United States and Australia when compared with Europe. In 2012, $\sim$ 109,000 hysterectomies were performed by the Sistema Único de Saúde (SUS – the Brazilian Unified Healthcare System) in Brazil.[4] According to data from 2010 from the Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística, IBGE), the occurrence of hysterectomies due to all possible causes was of 143/100,000 women,[5] a rate that has been growing every year.

The pathway choice is part of the surgical procedure, and several factors can influence the path of hysterectomy, including the size and shape of the vagina and uterus, accessibility, the presence of extra-uterine disease, needs for concomitant procedures, the training and experience of the surgeon, the technology available at the hospital, the resources, and even patient preference.[6]

Over the past 25 years, many efforts have been made to reduce the number of abdominal hysterectomies, like the development of the technology for minimally invasive surgeries.[7,8] The minimally invasive approach advantages are widely known, and consist of smaller incisions, leading to less postoperative pain, quick recovery and return to activities, and less surgical morbidity.[9,10]

Robotic surgery developed by the Intuitive Surgical Systems Incorporations™ (Sunnyvale, CA, US) present several advantages when compared with laparoscopy, such as three-dimensional vision, EndoWrist™ (Intuitive Surgical Systems Incorporations™, Sunnyvale, CA, US) technology (which makes it possible to mimic the movements of the human hand), and better ergonomics. Some clinical outcomes, such as lower blood loss, less postoperative pain, earlier hospital discharge and improvement of postoperative quality of life are also observed in these procedures. In 2001, robotic surgery was approved by the Food and Drug Administration (FDA) to be used in urological procedures; the approval was later extended to thoracic surgery and cardiac surgery.[11]

The first robotic hysterectomy was performed in 1998,[12] but only in April 2005 the FDA approved the release of the Da Vinci System™ (Intuitive Surgical Systems Incorporations™, Sunnyvale, CA, US) for use in gynecological procedures. This system is based on preliminary safety data observed during myomectomies and hysterectomies performed at the University of Michigan.[13] After the FDA approval, the adoption of robotics in gynecological surgeries spread worldwide.

In Brazil, this technology was first used in urological procedures in March 2008. Currently, 16 robots are being used in Brazil, with an individual implementation cost of approximately US$ 2 million. In 2012, $\sim$ 600 procedures were conducted in Brazil using this technology, whereas in the world, the number of these surgeries reached 450,000 during the same period.

This project is the documentation of the initial clinical use and experience of robotic hysterectomy procedures for the treatment of benign uterine pathologies in the Hospital de Clínicas de Porto Alegre.

Methods

In order to conduct this cross-sectional study, data from the first twenty patients undergoing robotic hysterectomy at Hospital de Clínicas de Porto Alegre were analyzed. The surgeries were performed by the same surgeon from November 2013 to August 2014.

Patients that underwent surgery were selected at the gynecological clinic based on their clinical history of benign uterine pathologies, such as fibroids or abnormal uterine bleeding. The indication for surgical procedure was made by an experienced physician, based in the classic indications for hysterectomy, like vaginal bleeding that didn't respond to hormonal treatments, or the presence of symptomatic fibroids, diagnosed by vaginal ultrasound. There were selected patients who would be candidates for a minimally invasive approach, such as laparoscopy.

The patients were admitted at the hospital on the day of the procedure, or the day before, when it was necessary to control clinical comorbidities. In the operating room they underwent general anesthesia after the administration of perioperative antibiotics. All the patients were submitted to the same anesthetic procedures. For deep venous thrombosis prophylaxis, lower extremity sequential compression devices and elastic stockings were used. All procedures were performed in the lithotomy position, and the patient's arms were tucked at the side to minimize the patient's position shifting and prevent nerve injury. After bladder catheterization with a Foley catheter, the uterine manipulator was inserted (Edlo™, Exaltech Ind. Com. Eireli, Porto Alegre, Brazil, or Storz™, Karl Storz GmbH & Co. KG, Tuttlingen, Germany), and a suture was placed at the cervix to facilitate uterine extraction. After an adequate pneumoperitoneum using a Veress needle, a 12-mm trocar was inserted 3–5 cm above the umbilicus for the camera placement. Three robotic 8-mm trocars were placed in the abdomen of the patient, at least 10 cm apart, with the lower port slightly above the anterior superior iliac spine and the upper port triangulated between the umbilical port and the lower port. The right-sided port was placed parallel to the lower left-sided port. A 10-mm accessory trocar was also placed in the upper left quadrant of the abdomen (cephalad and to the right of the camera trocar), allowing bedside surgical assistance.

After this initial preparation, the patients were placed in a steep Trendelenburg position, and the docking was performed. In the first two cases the docking was used between the legs of the patient, and in all subsequent surgeries side docking was used for better uterine manipulation. The console time was initiated after the docking of the robot. All the material utilized during surgery (Monopolar EndoWrist Scissors, bipolar Forcips Maryland, ProGrasp Forcips, Endowrist Needle Driver and SutureCut Needle Driver) was provided by Intuitive Surgical Systems Incorporation, Sunnyvale, CA, US. All hysterectomies were performed entirely with robotic assistance. After the removal of the uterus (in some cases vaginal morcellation was required), the suture of the vaginal cuff was robotically performed using a simple continuous suture. For the vaginal cuff suture, an EndoWrist™ Needle Driver and a SutureCut™ Needle Driver (Intuitive Surgical Systems Incorporations™, Sunnyvale, CA, US) were used. After hemostasis, patients were deflated followed by robotic system undocking. Finally, the umbilical aponeurosis puncture and skin were sutured.

The surgical team consisted of the console surgeon, a bedside assistant, and a second assistant sitting between the legs of the patient, who performed the uterine manipulation. In order to better evaluate the learning curve of the robotic procedures performed at the hospital, the surgery team was kept the same, and the first eight cases were supervised by a proctor.

During the procedures, all the surgical times were registered, including: total operating room time – the difference between the patient's times of entry and exit from the operating room; operative time – from the first incision in the skin to the end of skin suture; patient positioning time – defined as the time to fix the patient on the surgical table on the Trendelenburg position; docking time – the time of coupling the robotic system in the patient, beginning exactly with the first command to push the robot and ending after the insertion of the robotic clamps to enable surgery; console time – the time for the surgeon to perform the surgery using the joystick, including vaginal cuff closure; undocking time – defined as time of the removal of the robotic system from the patient; and closing time – the time to undo the pneumoperitoneum and suture the abdominal wall.

All the data collection and analysis of the robotic surgery were approved by the Ethics Committee of the Institution (CAAE 38510914.0.0000.5327), followed by the application of the informed consent form. In addition to the collection of surgical times, the surgeries were ordered chronologically, and the patient's records were analyzed for the following parameters: age, body mass index (BMI), parity, number of cesareans and previous abdominal surgeries, hysterectomy indication, pathological data, uterine weight, bleeding during surgery and postoperative complications. The blood loss during surgery was quantified by the liquid that was collected by the vacuum aspirator, subtracting the amount of saline that was used during the procedure. The time of postoperative recovery, defined as the difference in hours between the end time of the surgery to the time of hospital discharge, was also registered.

Data regarding postoperative pain were also collected, including the degree of pain using the Visual Analog Scale for Pain (VAS Pain, which is already used routinely in our hospital wards) in the first 24 hours after surgery, and the use of opioid analgesics during the first 24 hours of the patient's hospitalization. The number of patients who complained of pain in the first 24 hours after surgery was also counted, and they were divided into three groups according to the VAS Pain: mild pain (VAS Pain 1–3), moderate pain (VAS Pain 4–7) and severe pain (VAS Pain 8–10).

Statistical Analysis

Statistical analyses were performed using the SPSS program version 22 (SPSS Inc., Chicago, IL, US). The patient's preoperative, operative and postoperative parameters were represented by mean, standard deviations (SDs) and percentages. Pearson's coefficient was used to study the correlation between surgical time and uterine weight; surgical time and BMI; and surgical time and surgery number. Spearman's coefficient was used to represent the correlation between the time and the number of previous abdominal surgeries, and for the analysis of the learning curve. A p value < 0.05 was considered statistically significant.

Results

The average age of the 20 patients was 44.9 years. The mean BMI was 30.9 kg/m^2, with a range of 22.9–44.32 kg/m^2. In our study, the most common surgical indications were abnormal uterine bleeding and fibroids, and 45% of the analyzed patients had both conditions at the time of surgical indication. Of the 20 patients, 65% had undergone previous abdominal surgery, and among them, 50% of patients had already been submitted to 2 previous surgeries. In addition, 50% of patients had undergone caesarean section. Preoperative data are displayed in ►**Table 1**.

The average total operating room time was 252.9 ($\pm$ 46.5) minutes, while for the operative time and console time it was 180.7 and 136.6 minutes respectively. In addition to that, the average docking time was 4.2 minutes, and the average undocking time was 1.9 minutes. The average uterine weight was 205.9 g. The time of postoperative recovery was 25.2 hours. No conversion was observed.

There was no correlation between the operative time and the uterine weight, or between the operative time and the number of previous abdominal surgeries. However, a strong correlation was observed between the operative time and the patient's BMI ($r = 0.670$; $p = 0.001$; ►**Fig. 1**).

Table 1 Preoperative and postoperative data

Patient characteristics	Robotic Hysterectomy ($n = 20$)
Age (years) – mean ± SD	44.9 ± 5.3
BMI (kg/m^2) – mean ± SD	30.9 ± 6.4
Previous abdominal surgeries – n (%)	13 (65.0)
Number of previous abdominal surgeries – median	2.0
Cesarean section – n (%)	10 (50.0)
Number of cesarean sections – median	0.5
Indication – n (%)	
Abnormal uterine bleeding	10 (50.0)
Fibroids	1 (5.0)
Abnormal uterine bleeding + fibroids	9 (45.0)
Patients with pain in the first 24h – n (%)	
Yes	12 (60.0)
No	8 (40.0)
Patients with pain in the first 24h – n (%)	
Mild VAS Pain < 3	4 (20.0)
Moderate VAS Pain 4–7	9 (45.0)
Severe VAS Pain > 7	5 (25.0)
Use of morphine – n (%)	4 (20.0)

Abbreviations: BMI, body mass index; SD, standard deviation; VAS Pain, visual analog scale for pain.

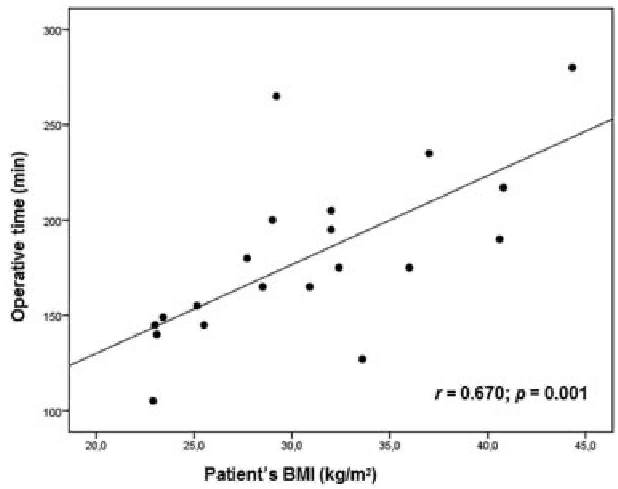

Fig. 1 A strong correlation was observed between the operative time and the patient's BMI ($r = 0.670$; $p = 0.001$).

In an attempt to associate the increase of the operative time with the patient's characteristics, analyses of the console time and of the patient's clinical history information were performed. The console time summarizes the main surgeon's time, excluding the docking and undocking times and the time of abdominal puncture and suture. For these analyses, a moderate correlation between the console time and the uterine weight ($r = 0.468$; $p = 0.037$) was observed. Despite that, a strong correlation between the console time and the BMI ($r = 0.618$; $p = 0.004$) was also observed. No significant association was observed between the console time and the number of previous abdominal surgeries.

Data of surgical time were chronologically analyzed to establish the learning curve. There was no correlation between the operative time and the number of surgeries (►**Fig. 2A**), even after adjustment for BMI ($r_{partial}$ = -0.285; $p = 0.237$; data not shown). No significant association between the console time and the number of surgeries (r_s = -0.245; $p = 0.298$) was observed (►**Fig. 2B**). However, there was an inverse correlation between the docking time and the number of surgeries (r = -0.568; $p = 0.009$–►**Fig. 2C**), and between the undocking time and the number of surgeries (r = -0.861; $p < 0.001$–►**Fig. 2D**).

Antibiotic therapy with metronidazole indicated by vaginal discharge was administrated in two patients in the early postoperative period. Despite that, no other complications were reported.

Data related to postoperative pain were evaluated. Eight patients (40%) showed no record of pain in the first 24 hours after surgery. Additional morphine administration was required for pain control in 4 patients (20%).

Discussion

The first publication regarding the use of robotics in gynecology was released in 2002, when Diaz-Arrastia et al[12]

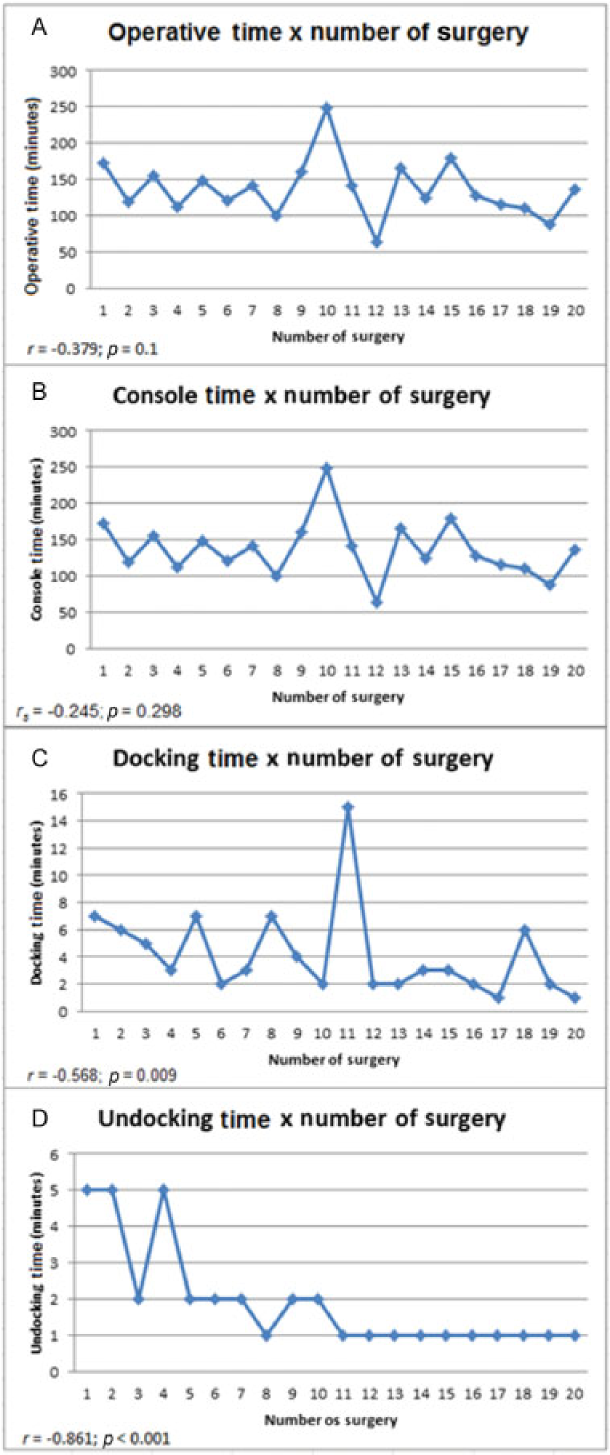

Fig. 2 Learning curve for the operative (A), console (B), docking (C) and undocking (D) times. There was no correlation between the operative time and the number of surgeries (A). No significant association between the console time and the number of surgeries (r_s = -0.245; p = 0.298) was observed (B). However, there was an inverse correlation between the docking time and the number of surgeries (r = -0.568; p = 0.009–Figure 2C) and between the undocking time and the number of surgeries (r = -0.861; $p < 0.001$–Figure 2D).

published satisfactory results about 11 patients that had undergone robotic surgery. In this publication the patients were between 22–77 years old, and the operative time ranged from 4.5 to 10 hours. Patients submitted to the robotic procedure progressed well and showed good post-operative recovery.[12]

However, FDA approval for the use of robotics in gynecology only happened after a publication of a research group from the University of Michigan, which refers to the follow-up of 16 patients that underwent robotic hysterectomies and myomectomies. The mean operative time mentioned in this publication was 242 minutes (range: 170 to 432 minutes).[13]

The data obtained in our study, derived from a small number of patients selected in a non-probabilistic manner, demonstrated a prolonged operative time, with an average of 180.7 minutes. Other studies with a limited number of patients also reported an extended operative time (192 minutes and 200 minutes).[14,15] A lower operative time was shown by Payne and Dauterive,[16] who conducted the first comparative study between laparoscopic and robotic surgeries for the treatment of benign uterine diseases. In their study, a retrospective analysis of 200 patients who had undergone hysterectomy (100 patients by laparoscopy and 100 patients by robotic surgery) was performed. The average operative time in the robotic surgery group was 119.4 minutes, while, in the laparoscopic group it was 92 minutes. In the same study, when a comparison was made between the operative time of laparoscopy and the last 25 cases treated with robotic surgery, a smaller operative time was found in the robotic surgery group.

A prolonged operative time was expected in our study, and it can be attributed mainly to the combination of abdominal puncture, console time and docking time. In an attempt to find the characteristics of the patient that are involved with the increment in surgical time, a strong correlation between the patient's BMI and the total surgical time ($r = 0.670$; $p = 0.001$) was observed: the most obese patients had higher surgical times. These results for robotic hysterectomy are in accordance with another study, in which patients classified as morbidly obese showed higher operative times than those who were not (BMI < 35).[17]

No correlation between uterine weight and operative time has been shown in the literature.[18,19] In agreement to that, no correlation between the total operative time and the uterine weight, or between the total operative time and the number of previous abdominal surgeries was observed in the present study.

The console time, which in our study showed an average of 136.6 minutes, presented a strong correlation with the patient's BMI ($r = 0.618$; $p = 0.004$) and a moderate correlation with the uterine weight ($r = 0.468$; $p = 0.037$), and it might have suffered the influence of such parameters, since patients with a higher BMI had an increased surgical time, as well as patients with a larger uterus. The console time was not analyzed separately in any other studies.

Regarding docking time data, which in the present study presented an average of 4.2 minutes, they are lower when compared with other studies.[20] This is probably related to the presence of a trained surgeon, who collaborated on the preparation of the patient, punctures and docking time in our surgeries.

Only one patient had significant bleeding in our series (150 mL). This finding differs from the description of the first cases in other hospitals. Different studies have already reported an intraoperative bleeding of ~ 50–1500 mL,[12] and 96 mL average, ranging from 50 to 300 mL.[13]

Postoperative complications are common after such procedures, and have been describe in other studies. Reynolds and Advincula[13] reported thermal intestinal injury, pneumonia, abdominal wall cellulitis and vaginal cuff hematoma. On the other hand, in our study, only two patients required orally antibiotic administration for the treatment of vaginal discharge. Unlike the literature, in which conversion rates ranging from 1.8[21] to 10% are shown,[15] no conversion was observed in our study.

Data regarding the learning curve of our group has shown that we have gained experience in some of the analyzed parameters. The data of the surgical times were correlated with the number of performed surgeries in chronological order. Operative time and console time had no significant association with the number of surgeries. There was an inverse correlation between the docking time and the number of surgeries, as well as between the undocking time and the number of surgeries. A learning curve was observed in some studies, as the one performed by Lenihan et al,[21] which estimated a learning curve for the use of robotics for the surgical treatment of benign gynecological diseases, collecting data of two surgeons. In 2 years, they performed 113 surgeries. The surgical time for hysterectomies stabilized at 95 minutes after 50 operated cases.

By the results obtained in our hospital, this surgical proposal proved to be feasible and safe. Nevertheless, we still have the drawback of the cost as an obstacle to overcome. Despite this obstacle, robotic surgery is gaining more space in the clinical practice. Comparison studies are being conducted to compare the robotic surgery to other techniques already implemented in our gynecological practice.

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