



First 200 Robotic General Surgery Cases in a Community Hospital: A Retrospective Cohort Study

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Abstract

Background and Objectives: A retrospective series and learning curve of the first 101 robotic general surgery cases from a single surgeon in a small community hospital has been previously reported. This study serves as a continuation and offers a more detailed statistical analysis while demonstrating the efficacy and safety of a general surgery robotics program in a community hospital with quality assessment measures.

Methods: Measurements included total operative time, console time, conversion rates, complications, surgical site infections, surgical site occurrences, length of stay, and patient demographics. Descriptive statistics were included for all variables. Linear regression was used to test the hypothesis of a learning curve, reflected by a decrease in console time with experience.

Results: Between March 2014 and February 2017, 200 robotic general surgery cases were performed by a single surgeon in a 266-bed community hospital, including laparoscopic cholecystectomies; ventral, incisional, and umbilical hernia repairs; colorectal; foregut and bariatric; inguinal hernia repairs; and miscellaneous procedures. One hundred and ninety-eight of the cases (99%) were completed robotically. Thirteen patients were readmitted within 30 days, and 21 had complications (11%). There were no mortalities, and all complications were resolved positively. The mean operative and console times of all 200 cases were 214.8 and 105.7 minutes, respectively. Decreased console time was significantly associated with increasing case load, even after controlling for surgery type.

Conclusion: With increased operative volume, general surgeons who utilize the robotic platform can improve operative outcomes, decrease operative times and perform increasingly complicated procedures while maintaining low complication rates.

Keywords: Community hospital; General surgery; Robotic surgery; Learning experience; Outcomes

Introduction

The da Vinci Surgical System (Intuitive Surgical, Inc. Sunnyvale, California, USA) was approved by the U.S. Food and Drug Administration (FDA) in 2000, with early applications for heart surgery, cholecystectomy, and Nissen fundoplication [1,2]. Within general surgery, applications have expanded to colorectal surgery, abdominal wall reconstruction, and bariatric surgery.

While opposition to the use of robotic technology in general surgery has slowly decreased, there is some resistance based on concerns regarding an overuse of resources. Proponents of the robotic platform cite enhanced visualization, improved instrument dexterity, and increased surgeon control as advantages [3]. The use of the da Vinci surgical system for single site cholecystectomy was first reported in large American and European academic medical centers in 2011 [4,5]. Since this time, many groups have shown single site cholecystectomy to have minimal complications and good outcomes [6,7].

Reductions in postoperative pain, complication rates, and recovery time served as the foundation for the transition from open to laparoscopic ventral hernia repair, which was first performed in 1992 [8,9]. The advent of the robotic platform offered the same advantages as the laparoscopic technique, with some studies showing the additional benefit of a greater decrease in pain by avoiding trans-fascial sutures, and a greater ease of mesh implantation [10,11]. Most inguinal hernias still continue to be repaired open rather than laparoscopically [12]. Several single surgeon reports exist

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documenting successful robotic inguinal hernia repair [6,13,14].

After the first reports of telerobotic-assisted laparoscopic colectomies in 2001 [15] robotic colorectal surgery has been shown to have efficacy similar to that of conventional laparoscopy [16]. The robotic technology has potentially augmented benefits in rectal and oncologic surgery secondary to fine visualization and enhanced dexterity crucial to the efficacious manipulation in small operative fields where precision with tissue manipulation is crucial [17,18].

Regarding foregut and bariatric surgery, the first reported robot-assisted bariatric procedure, gastric banding, occurred in 1998 [19]. Since then, robotic systems have also been applied to sleeve gastrectomy and Roux-en-Y gastric bypass [20]. Robotic Nissen fundoplication has a positive role in repair of hiatal hernia and surgical management of gastroesophageal reflux disease. Although a 2013 meta-analysis on robotic and laparoscopic Nissen fundoplication found no significant difference in outcomes, a review article reports a general consensus from 16 published papers supporting the use of robotics for complex surgeries or redo procedures [21,22]. The first major reports on the successful implementation of robotic technology in the surgical management of achalasia presented no instances of esophageal perforation with robotic Heller myotomy compared to an incidence rate of 5% to 10% with laparoscopic Heller myotomy [23-25].

Aim and Objectives

In 2016, we described the outcomes of the first robotic general surgery case series in an American community-based, non-tertiary hospital performed by a single surgeon [6]. The present paper is a follow-up study. We have further examined our minimally invasive robotic surgery program with the primary aim to evaluate for safety in terms of review of complications. Our secondary objective was to test for an improvement over time in key surgical outcomes to demonstrate that robotic general surgery can be successfully implemented in a community hospital with appropriate training of the surgeon and the surgical team. With increasing number of cases, both in volume and complexity, the surgeon and the team gain valuable experience that contributes to better outcomes. The previous retrospective review series of 101 cases suggests that this experience may lead to a decrease in console time; the present paper tests this hypothesis.

Materials and Methods

Under approval from the Capital Regional Medical Center Institutional Review Board, we performed a single-center retrospective chart review and analysis of the first 200 robot-assisted general surgery cases completed by a single surgeon in a 266-bed acute care community hospital. Electronic medical records and operative logs were reviewed corresponding to the surgeon's first 139 cases completed with the da Vinci S system from March of 2014 to August of 2015, and 61 cases completed with the da Vinci Si system from August 2015 to February 2017. There was no exclusion criteria. The data is being reported utilizing the Strengthening The Reporting Of Cohort Studies in Surgery (STROCSS) criteria [26].

Surgical technique

The first 139 surgeries in this retrospective series were performed using the da Vinci S surgical system, which consists of four components: the patient-side cart, the EndoWrist instruments, the surgeon console, and the vision system. The patient-side cart at the side of the operating table is composed of three or four robotic arms,

one which holds the camera system. The remaining robot arms can be fitted with various surgical EndoWrist instruments mounted to trocars to enable the surgeon to dissect, cut, retract, clamp, and suture with a broader range of motion as compared to open and laparoscopic surgery. In addition to the expected duties, the surgical first assistant at the bedside is tasked with exchanging the surgical instruments at the surgeon's request. The surgeon console includes a binocular stereoscopic viewer that delivers images from the two 5 mm cameras docked on one of the arms of the patient-side cart, producing a 3-dimensional image with up to 10x magnification. The surgeon controls the robot from the master controls mounted to the surgeon console. The 5 mm cameras also relay information to a processing center displaying the surgeon's view on a high-definition screen within the operating room to the benefit of the first assistant [27].

The remaining 61 surgeries in this report were performed using the da Vinci Si surgical system. The overall set-up is similar to that of the S system, but it is important to note new features such as the motorized patient-side cart, a one-piece sterile drape, and the ability to have a single-site configuration feature introduced to increase the efficiency of the system [27]. Both the da Vinci S surgical system and the da Vinci Si surgical system have been shown to be safe surgical options across many surgical specialties including general surgery [1-25,28-32].

Data analysis

SAS version 9.4 (SAS Institute, Cary, North Carolina, USA) was used for statistical analysis. Descriptive statistics are provided on demographic and other clinical variables, such as length of hospital stay. Means, medians, standard deviations, quartiles, and ranges are provided for continuous variables, and frequencies are provided for categorical variables. Safety was measured using complication rates, readmissions, and 30 day morbidity, noting how they compare to standards of rates for laparoscopic surgery. For hernias, recurrence was examined. Linear regression models were fit for console time using backward selection with case number, surgical type (described below) and American Society of Anesthesiologists (ASA) physical status classification as potential covariates. To test the hypothesis that console time decreases with increasing experience, we examined the magnitude and significance of the coefficient for case number, using a two-sided test at the Bonferroni-adjusted 5% level.

Results

Between March 2014 and February 2017, 200 robotic general surgery cases were performed by the first author of this paper at Capital Regional Medical Center in Tallahassee, Florida, USA. The data collected were analyzed after the cases were divided into the following 6 groups by type of surgery performed. Group A: Cholecystectomy (n=28), Group B: Ventral, Incisional, Umbilical Hernia (n=60), Group C: Colorectal (n=28), Group D: Gastric, Esophageal, Bariatric (n=21), Group E: Inguinal Hernia (n=45), Group H: Multiple Procedures (n=18). Surgery types are similar to our previous report with a few exceptions [6]. In this report, we have combined foregut and bariatric procedures into a single group (group D). Surgeries that included multiple procedures, e.g., cholecystectomy and umbilical hernia repair performed during the same operation, were categorized into a separate group (group H).

Descriptive statistics are provided in (Tables 1 and 2) for continuous and categorical variables, respectively. The patients averaged 53 years of age and were evenly matched by gender. The

Table 1: Surgical times and patient continuous measurements.

Variable	N	Mean	SD	Median	Min	Lower Quartile	Upper Quartile	Max
Age (years)	200	52.7	16.9	53	19	39	65.5	88
BMI (kg/m ²)	198	31.6	8.7	30	15.7	25.8	35.1	80.1
Operative Time (min)	200	214.8	90.3	188.5	74	151.5	248.5	722
Cut to Close Time (min)	200	158.9	91.1	133.5	41	97.5	193	677
Console Time (min)	183	105.7	66.6	85	29	62	126	525
EBL (mL)	200	28.7	65.8	20	5	10	20	700
Hospital Stay (days)	200	1.5	2.3	1	0	0	2	14

BMI: Body Mass Index calculated as kg/m²; **EBL:** Estimated Blood Loss; **0:** Outpatient procedure; **Operative time:** the total amount of time the patient was in the operating room; **Cut to close:** the amount of time from the first incision to the last suture tie; **Console time:** the amount of time the surgeon was seated at the surgeon console operating the robot.

Table 2: Frequencies of adverse events and categorical patient demographics.

Variable	Count	Percent
Male	100	50
Female	100	50
ASA Class I	11	6
ASA Class II	94	47
ASA Class III	88	44
ASA Class IV	7	4
Group A: Cholecystectomy	28	14
Group B: Ventral, incisional, Umbilical Hernia	60	30
Group C: Colorectal	28	14
Group D: Gastric, Esophageal, Bariatric	21	11
Group E: Inguinal hernia	45	23
Group H: Multiple Procedures	18	9
Complications	21	11
Convert to open	2	1
Readmission (30 days)	13	7
30 day morbidity	19	10
SSI	3	2
SSO	5	3
Transfusions	4	2
Recurrence	10	8

ASA: American Society of Anesthesiologists (ASA) physical status classification; **SSI:** Surgical Site Infection; **SSO:** Surgical Site Occurrences (i.e., seroma, hematoma).

mean Body Mass Index (BMI) of the patients was 31.6 kg/m². Most patients (over 90%) were in the ASA II or III classification.

Robotic surgery times ranged from 74 minutes to 722 minutes, including 41 minutes to 677 from cut to close, and 29 minutes to 525 minutes on the console. The mean (standard deviation) robotic surgery times for all cases irrespective of category were 214.8 (90.3) minutes for total operative time, 158.9 (91.1) minutes for cut to close and 105.7 (66.6) minutes of surgeon console time. The median robotic surgery times were 188.5 minutes for total operative time, 133.5 minutes for cut to close and 85 minutes of surgeon console time.

Surgical outcomes were positive. Of the 200 procedures, 198 were completed robotically. Nearly half (96 patients, or 48%) of surgeries were outpatient, over three-quarters required no more than two days in the hospital, and over 90% required no more than 4 days. Overall, there was a complication rate of 11% (21 complications), including

Table 3: Regression parameters: denoting the average console time for each surgery group and decrease in console with increasing patient number.

Variable	Estimate	Standard Error	P-value
Intercept	93	11.3	<0.0001
N	-0.3	0.07	0.0002
Group B	23.5	12.4	0.06
Group C	140.4	15.2	<0.0001
Group D	74.3	15.4	<0.0001
Group E	14.5	12.9	0.3
Group H	20.9	16.4	0.2

Estimate: the expected change in console time for a unit change in one variable, holding all others constant; **Intercept:** the expected console time when all variables are equal to zero. While the intercept is not always readily interpretable, in this case, the intercept corresponds to the expected console time for the hypothetical first patient, assuming that the patient had a surgery type in Group A; **N:** patient number; **Group A:** Cholecystectomy; **Group B:** Ventral, Incisional, Umbilical Hernias; **Group C:** Colorectal; **Group D:** Gastric, Esophageal, Bariatric; **Group E:** Inguinal Hernias; **Group H:** Multiple Procedures.

conversion to open, re-admission within 30 days, 30 day morbidity, Surgical Site Infections (SSI), Surgical Site Occurrence (SSO), blood transfusions, and recurrence if applicable. Overall, 13 patients were readmitted to the hospital within 30 days. There were no mortalities in any of the groups, and all complications were resolved on follow-up with good outcomes.

The linear regression parameter estimates modeling the console times adjusted for surgery group and patient number are provided in (Table 3). The estimates in Table 3 for groups B-H denote the expected difference between a surgery in that group compared to a hypothetical surgery in Group A conducted at the same time. ASA class was not included because it was not associated with console time after adjusting for surgery group and patient number. On the other hand, surgery group was strongly associated with console time (p <0.0001). Cholecystectomy (group A), the reference group, took the shortest time on average, and Colorectal (group C) took the most console time, followed by Gastric/Esophageal/Bariatric (group D). Console times were similar for groups B, E, and H, all of which involve hernia procedures. After adjusting for surgery group, console time was also associated with case load; average console time dropped by 0.3 minutes per case over the course of the study (p=0.0002). Similar results (not shown) held for total operative time and cut to close time, even though only the surgeon at the console was constant for all procedures; operating room teams varied throughout the study. The model demonstrated that surgical time decreased over time, as the surgeon gained experience and grew more proficient at the reported robotic procedures.

Group A: Cholecystectomy

This group consisted of 28 robot assisted cholecystectomies performed from March 2014 through February 2017. Twenty-one of these were completed using the multi-port technique on 6 male and 15 female patients with a mean age of 45.8 years. The mean BMI was 32.4. The mean total operation time was 174.1 minutes with a mean console time for the multi-port cholecystectomies of 79.2 minutes. There were 3 complications in this group, occurring in the 2nd, 6th and 17th multi-port laparoscopic cholecystectomy. One was due to a superficial accidental thermal injury to the gastric wall serosa in the setting of a fixed stomach related to a PEG tube. The serosal injury was easily repaired intraoperatively with a gastrorrhaphy performed with the robotic technology. Also in this group, a port-site superficial SSI occurred. Two readmissions occurred with one patient requiring a blood transfusion. The aforementioned complications were seen early, during the first year of this surgeon's robotic experience. All cases were successfully completed robotically.

The remaining 7 cases were completed using the da Vinci Si single site instruments on 1 male and 6 female patients with a mean age of 43.3 years. The mean BMI was 32.0. The mean total operation time was 143.4 minutes with a mean console time for the single site cholecystectomies of 60.1 minutes, a reduction of 6.4 minutes from the surgeon's mean console time for multi-port cholecystectomy. All 7 cases were completed successfully with no complications or conversions to open. There were no transfusions and all patients were discharged home the same day. There were no post-operative SSOs or SSIs. One patient was admitted within a 30 day time period post-operatively for community-acquired pneumonia.

Group B: Ventral, Incisional, Umbilical Hernias

This group consisted of 60 ventral abdominal wall, incisional and umbilical hernia repairs which were all successfully completed robotically; of note, over 50% of these cases incorporated component separations and/or enterolysis. The patient group was comprised of 22 males and 38 females with an average age of 52.1 years. The mean BMI was 34.0. The mean total operation time was 214.5 minutes with a mean console time of 91.6 minutes; the console time was not available for 6 of these cases. There were 3 complications in this group caused by a port site hernia in the 3rd case of this group, a port site seroma in the 5th case of this group, and one port site SSI in the 30th case of this group. There was one patient who required a blood transfusion. Average length of stay was 1.5 days with 20 patients able to go home the same day. Four operations were performed for repair of hernia recurrences after previous repair by the first author.

Group C: Colorectal

Twenty-eight cases comprise this group and range from colostomy reversal to hemi-colectomy. Specifically there were 20 left/sigmoid colectomies, 6 right colectomies, and 2 colostomy reversals. This patient group was comprised of 10 males and 18 females with a mean age of 55.1 years and mean BMI of 33.04. The mean total operation time was 348.4 minutes with a mean surgeon console time of 204.4 minutes. The console time was not recorded for 6 of these cases. There were 8 complications-case 3, 8, 13, 17, 18, 24, 24, 26-within the group. Of these, 5 occurred while performing sigmoid colectomy, an advanced procedure the surgeon began to perform with increased frequency after case 101. Only 1 case required conversion to open secondary to need for extensive enterolysis which was early in the first 6 months of the study. There was 1 patient who required a blood transfusion. The average length of stay was 5.5 days (range 2-14 days).

There were 3 post-operative SSOs, no SSIs, and 5 readmissions for a urinary tract infection, abdominal pain, and suspected pulmonary embolism; four of these patients were ASA class IV at the time of operation.

Group D: Gastric, Esophageal, Bariatric

Twenty-one cases comprise this group. For the purpose of ensuring sufficient sample size for the linear model, which is required to answer the primary hypothesis, esophageal, gastric, and bariatric procedures were combined into a single group. Procedures performed include 1 Nissen fundoplication, 2 Heller myotomies, 1 gastrocutaneous fistula resection, 10 para-esophageal hernia repairs, 3 sleeve gastrectomies, and 1 Roux-en-Y gastric bypass. There were 5 males and 16 females with a mean age of 50.4 years. The mean BMI was 33.5. The mean total operation time was 258.3 minutes with a mean surgeon console time of 137.9 minutes. There were 3 complications in this group, one of which occurred in a Heller myotomy with hiatal hernia repair and Dor fundoplication that required a subsequent POEM procedure for recurrent achalasia in the setting of a sigmoid esophagus in a 21-year-old male patient with end-stage achalasia.

The robotic Roux-en-Y gastric bypass, case 188 of this 200 case series, was the first robotic bariatric operation performed by the surgeon and the first one of its kind in the history of the city. Overall, the case went well. There was continued abdominal pain from adhesions that was treated 3 months later with laparoscopic enterolysis. After pain resolution, the patient's course was satisfactory and her BMI 6 months status-post surgery had decreased from 41.3 to 32.6. The patient denied any signs or symptoms of gastroesophageal reflux disease, which was a secondary reason to perform a gastric bypass in her case, given her BMI. There was 1 patient who required a blood transfusion. The average length of stay was 2.5 days (range 1-6 days); 1 patient stayed in the hospital for an extra day because of lack of transportation. There was 1 post-operative SSO which occurred in case 101 of 200, zero SSI, and 1 readmission. No case required conversion to open.

Group E: Inguinal Hernias

Forty-five cases comprise this group with 40 of the patients being male and 5 female. The mean age was 52.9 years and the mean BMI was 27. The mean total operation time was 161.18 minutes with a mean surgeon console time of 84.4 minutes; 3 data points were missing for surgeon console time. Five cases were performed for recurrent inguinal hernias. There were 4 complications which occurred in cases 2,111,417 of the group. No patients required a blood transfusion. The majority of these cases, 39, were performed as outpatient procedures; the remaining 6 cases had an average length of stay of 2.7 days (range 1-6 days). There was 1 post-operative SSI, no SSOs, and 2 readmissions. No case required conversion to open.

Group H: Multiple Procedures

This group includes 18 cases where the surgeon completed multiple procedures during one operation. The decision was made to keep this group separate to better document the console times and the progression of the surgeon's learning experience. The procedure most often performed was repair of inguinal hernia associated with repair of ventral and/or umbilical hernia. Two female patients and 16 male patients comprise this group. The mean age was 57.9 years with a mean BMI of 30.3. The mean total operation time was 166.1 minutes with a mean surgeon console time of 84.6 minutes; one data point was not recorded for surgeon console time. Of the 18 cases, 15

were performed as outpatient. Length of stay was 1 day for a patient who underwent robotic bilateral inguinal and umbilical hernia repair, 4 days for cholecystectomy with enterolysis and ventral hernia repair, and 5 days for a patient with BMI of 60 who underwent partial colectomy and umbilical hernia repair. No case required conversion to open. There were no complications, SSIs, SSOs, or readmissions.

Discussion

This retrospective review of the first 200 robotic general surgery cases by a single surgeon in a small community hospital without the resources that would normally be available in a large academic center shows that, with outcomes comparable to those found in laparoscopy [28], a robotics program can be safely implemented in a community hospital setting. This study does not intend to show that robotic surgery is superior to laparoscopy, nor does it suggest that a robotics program should be implemented at all community hospitals. What it hopes to express is that with a surgical team that is motivated and willing to undergo proper training, a robotics program can be safely and effectively implemented. The opponents to robotics in general surgery express concerns that the increased operative time results in significantly more post-operative complications [29]. Robotics in general surgery might still be in its early stages with a relative paucity of data regarding peri-operative outcomes; as such, this position is understandable. This criticism underscores the need for more studies on robotic general surgery outcomes and the benefit of implementing robotics programs, with well-trained surgical teams, in community hospitals.

A well-trained surgical team is of utmost importance in all robotics programs and is especially essential in a general surgery program housed within a non-academic center in which the surgeon assumes responsibility for arranging training and learning experiences for the surgical team [30]. Training for the surgical team included a robotics basics course, an advanced colorectal course, and several case observations for foregut and bariatrics where the surgeon took his first assistants and surgical technologists to learn from robotic surgery experts in other cities and states. The early inexperience of the team resulted in many confounders for total operative time and docking time; thus, for the purposes of this review, we focused on console time to better capture the surgeon's growth and improvement.

The surgeon's learning progress on the reported surgical procedures flowed as follows: cholecystectomy, inguinal hernia, umbilical, ventral, incisional, colorectal, foregut, bariatric. This progression highlights measurable improvement from minimal case difficulty to highly complex cases. Within the subgroups, there is also a linear progression whereby cases completed early in the surgeon's experience required more time than those that came later. In general, the console time decreased with each additional procedure. We utilized a linear regression model to investigate the effect of console time with each additional procedure, controlling for surgical case type. With each additional case, console time decreased by an average of 0.3 minutes ($p=0.0002$), indicating that the surgeon and surgical team indeed improved with experience.

There were a few items missing from our data. In particular, surgeon console times were missing for 17 cases: 2 from group A, 6 from group B and C, 2 from group E, and 1 from group H. Missing data is a common challenge, especially in retrospective studies. The proportion of missing data in the present study is below 10%, a threshold above which statistical analyses are likely to be biased [31].

The surgical team attained intimate knowledge of the requisite training required of the first assistants, surgical technologists, and nursing staff, in addition to the surgeon to successfully implement a robotic general surgery program in a community hospital. Another valuable lesson highlighted in the literature review and throughout our cases is that, although the robotic technology has been typically supported for complex surgeries such as foregut and colorectal procedures, or bariatric revisions, it could also be applied to a large variety of cases that have been traditionally performed laparoscopically with comparable benefits to patients. The most efficient and safest way to acquire the knowledge and skills required to perform complex robotic procedures is to undergo extensive model training followed by application of the technology to less complex cases, which when completed successfully, build the team's confidence and abilities for the most complex operations.

After an extensive review of the literature, to our knowledge, no other surgeon or group to date has reported a robotic general surgery learning experience encompassing this variety of procedures in any other American non-academic, small community hospital environment. Since this retrospective review series of 200 robotic general surgery cases was completed, other publications by the first author of this study have supported the observations described in this paper, both with statistical and clinical significance [32,33].

Conclusion

With increasing case volume while utilizing the robotic platform, and with systematic training for the surgeon and the surgical team, it is possible to show progression by decreasing operative time while maintaining low complication rates in a successful robotic general surgery program in a community hospital. The robotic technology can be applied to complex and routine general surgery procedures while achieving results comparable to those of laparoscopy.

Limitations

As this study is a retrospective review of a single surgeon's operative experience, limitations arise due to the sample size. For example, the small number of cases per category renders the team unable to statistically test for the presence of learning curves for safety outcomes. Another limitation lies within the nature of the rotating surgical team; if all 200 of the cases in this study were performed by this single surgeon and a non-rotating surgical staff for the duration, it would eliminate the confounding factors inherent in rotating teams. As with all retrospective studies, there are missing data points, but the proportion of patients with the main outcomes missing was small.

Future

We hope that our results may serve as a platform for other multi-procedural studies and provide evidence to support the feasibility of a general surgery robotics program in similar, small community hospitals.

Disclosures

Dr. Oviedo has no conflicts of interest or financial ties to disclose. Dr. Brownstein has no conflicts of interest or financial ties to disclose. Dr. Smith has no conflicts of interest or financial ties to disclose. Dr. Robertson has no conflicts of interest or financial ties to disclose. Dr. Nair-Collins has no conflicts of interest or financial ties to disclose.

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