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The current status of robotic surgery for endometrial cancer in Japan

Tomoko Gota*, Kensuke Tomio, Taichi Kurose, Risa Saito, Ryoken Nara, Sohmi Kin, Minami Hoshiba, Yuri Ogata, Misao Nakanishi, Maya Takamoto, Miyuki Sadatsuki, Hajime Oishi

Department of Obstetrics and Gynecology, Center Hospital of the National Center for Global Health and Medicine, Tokyo, Japan.

Abstract: The da Vinci® surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA) was approved in 2009 by the Japanese Ministry of Health, Labor, and Welfare. In gynecology, robotic surgery for hysterectomy for benign indications and early-stage endometrial cancer has been covered by National Health Insurance since 2018. In a context where the da Vinci surgical system has prevailed in urology departments in Japan, gynecological robotic surgery has spread rapidly once it was covered by insurance. Although minimally invasive gynecologic surgery (minimally invasive surgery, or MIS) in Japan has a specific context, there are several problems with its safety, surgeon education, and cost in Japan. To maximize the many advantages of robotic surgery, its effectiveness needs to be carefully evaluated and this new technology needs to be safely incorporated in practice.

***Keywords*:** endometrial cancer, robotic surgery, minimally invasive surgery

Introduction

The da Vinci S, Si, and Xi surgical systems were respectively approved by Japanese Ministry of Health, Labor, and Welfare in 2009, 2012 and 2015, and their use has rapidly spread in urology. The da Vinci provides the surgeon with an enlarged three-dimensional view and motion scaling, it eliminates instrument tremors, and it allows the performance of accurate surgical procedures with articulated arms. The short learning curve in also a merit of robotic surgery (*1,2*). The pelvic cavity is deep and narrow. In spite of these advantages of robotic surgery at that site, the problem of high costs has prevented robotic surgery from becoming standard treatment. Nevertheless, 12 new procedures were covered by National Health Insurance in Japan in April 2018. Hysterectomy for benign indications and early-stage endometrial cancer has been approved in gynecology. Since 2018, facilities have increasingly adopted a robotic approach to gynecological disease.

The current article reviews the current status of, problems with, and prospects of robotic surgery for patients with endometrial cancer in Japan.

The history of minimally invasive gynecologic surgery in Japan

The da Vinci surgical system was first introduced in Asia at Keio University in March 2000. Robot-assisted hysterectomy was first performed in Japan in March 2009 at Tokyo Medical University Hospital. Although the gynecological organs that are locate in the deep and narrow pelvic cavity are ideal for a robotic approach, high costs and the lack of evidence indicating the superiority of robotic surgery initially prevented the da Vinci system from being approved by the Japanese Ministry of Health, Labor, and Welfare.

In contrast, MIS was greatly needed for young female patients, and the small number of Japanese patients was suitable for a laparoscopic approach. In Japan, gynecological laparoscopic surgery was initially performed for benign indications by clinicians in reproductive medicine and endocrinology, and most gynecologic oncologists preferred open surgery to laparoscopic surgery. As a result, the introduction of MIS for gynecological malignancies was delayed.

The LAP2 study was a multicenter randomized controlled trial, the results of which were published in 2012 (*3*). The LAP2 study indicated the feasibility and inferiority of oncologic outcomes of MIS for patients with early-stage endometrial cancer compared to conventional laparotomy. According to that study, the estimated hazard ratio for the 3-year recurrence rate was 1.14 (95% CI = 0.92 to 1.46), and the estimated 5-year overall survival rate was 89.9% in each group. After the LAP2 study, laparoscopic surgery for patients with stage IA endometrial cancer was covered by National Health Insurance in 2014, and it has gradually spread to many facilities. The Japan Gynecologic and Obstetric Endoscopy Database (JOE-D) indicated that gynecologic laparoscopic surgeries increased from 56,233 in 2014 to 80,678 in 2016. Moreover,

laparoscopic surgeries for gynecological malignancy increased approximately 1.8-fold (from 1,898 to 3,490 cases) from 2014 to 2016 (*4*). Thus, laparoscopic surgery had already become the standard treatment in gynecology departments in Japan, while robotic surgery was adopted slowly and in limited instances.

However, that situation changed after 12 new procedures were covered by Japan's National Health Insurance in April 2018. In gynecology, hysterectomy for benign uterine disease and endometrial cancer was covered. In April 2020, robot-assisted sacrocolpopexy for pelvic organ prolapse was added to the list. Since the da Vinci surgical systems were already installed in urology at many facilities, robotic gynecological surgery has spread rapidly over the past few years. There are now approximately 350 da Vinci surgical systems installed in Japan, which is nearly half of the number in Asia.

Education in robotic surgery

The Japan Society of Gynecologic Robotic Surgery (JSGRS) was established in January 2019, and the JSGRS instituted the trainer system in order to safely introduce robotic surgery. Trainers need practical experience as well as knowledge of the three different da Vinci systems: Si, X, and Xi. The demand for trainers is increasing, and the lack of trainers is a problem in Japan.

Current status of and problems with MIS for patients with endometrial cancer

The number of patients with endometrial cancer has increased in Japan, and the Japan Society of Obstetrics and Gynecology (JSOG) reported that there were 11,230 patients with endometrial cancer in 2018 (*5*). Endometrial cancer was diagnosed in its early stages in most of those patients, and the demand for MIS has also been increasing. According to a survey by the Japan Society for Endoscopic Surgery (JSES), the usage of laparoscopic surgery for endometrial cancer increased from 210 in 2011 to 4,045 in 2019 (Figure 1), respectively accounting for 0.67% and 4.68% of gynecological endoscopic surgeries (*6*).

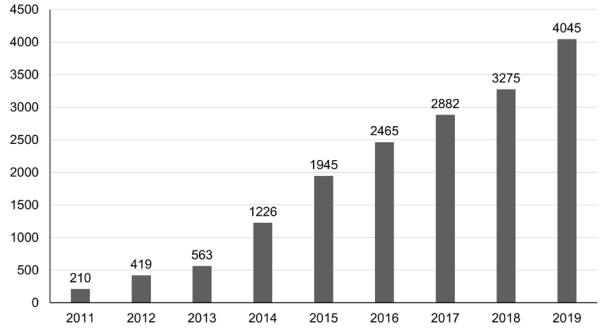

Figure 1. The number of laparoscopic surgeries for endometrial cancer in Japan. Data adapted from (*6*).

A point worth noting is that the rate of discrepancy between preoperative and postoperative staging varies between 6.8% and 41.2%. A high rate of upstaging has been reported at some medium-volume facilities (*7-12*). Lymphadenectomy for low-risk disease was omitted from the Japanese treatment guidelines for neoplasms of the uterine corpus, which was updated by the Japan Society of Gynecologic Oncology (JSGO) in 2018. In contrast, pelvic and para-aortic lymphadenectomy were performed in 91.5% of patients undergoing a laparoscopy and in 95.8% of those undergoing a laparotomy in the LAP2 study (*3*).

There is a possibility that preoperative underdiagnosis, differences in surgical techniques, and differences in the treatment results of high-volume centers and low- to mid-volume center may affect oncologic outcomes. Further studies of the clinical prognosis of MIS need to be conducted in patients with endometrial cancer nationwide. Precise enrollment of MIS candidates is essential for accurate preoperative diagnosis.

Robotic hysterectomy for endometrial cancer

A few randomized controlled trials (RCTs) have assessed the clinical outcomes of robotic surgery for gynecological malignancies, and to the extent known no RCTs have reported the oncologic outcomes of robotic surgery alone. Initial concern about robotic surgery limited its cost effectiveness, but recent studies have reported that the cost of robotic surgery is similar to or less than that of a laparotomy specifically for oncologic indications (*13-16*). Operating time has also been a disadvantage of robotic surgery compared to conventional laparoscopic surgery, but this might be solved by a surgical team with sufficient experience (*17-19*). Moreover, several studies have indicated that robot-assisted hysterectomy yields favorable outcomes in terms of the rate of conversion, intraoperative blood loss, the duration of hospitalization, and complications compared to laparoscopic hysterectomy (*17-18,20*). Retrospective Japanese studies of robotic surgery for endometrial cancer have indicated similar favorable perioperative outcomes even in the early phase (Table 1). In a retrospective study at a single institution, the selection criteria for a laparoscopic approach or a robotic approach were based on the patient's wishes; robotic surgery tended to be chosen by obese patients and patients with cancer in a more advanced stage (*24*). According to the annual report on treatment for 2018, patients with endometrial cancer underwent 344 robotic surgeries, which accounted for 3.2% of all procedures for endometrial cancer (*5*). JSES reported the number of complications of robotic surgery for malignant uterine disease from 2018 to 2019, and it noted the feasibility of robotic gynecologic procedures in Japan (Table 2).

Table 1. Robotic hysterectomy for patients with endometrial cancer in recent studies

Author (*Ref.*)	Year	Number of patients	Surgical procedure	Operating time (min)	Blood loss	Conversion	Hospitalization (days)	Transfusion (%)
Salehi S, *et al.* (*13*)	2017	48	RAH + PLND + PALND	233 (166-320)	78 mL (20-300)	1	2 (1-5)	0
Maenpaa M, *et al.* (*18*)	2016	50	RAH + PLND	139 (86-197)	50 mL (5-500)	0	1 (1-4)	12
Ono K, *et al.* (*21*)	2016	1	RAH	243.5	86.3 mL	-	7.3	-
		3	RAH + PLND					
Baba T, *et al.* (*22*)	2019	8	RAH	304.6	91.9 g	-	5.4	-
		33	RAH + PLND	319.9	41.8 g		5.3	
		38	RAH + PLND + PALND	484.3	153.3 g		6.9	
Aoki T, *et al.* (*23*)	2020	21	RAH	233 (160-346)	0 mL (0-141)	1	4 (4-6)	0
		9	RAH + PLND					
		1	Conversion					
Aiko K, *et al.* (*24*)	2020	30	RAH + PLND + PALND	178	237 mL	1	8	0
		91	RAH + PLND + PALND					

RAH, robot-assisted hysterectomy; PLND, pelvic lymph node dissection; PALND, para-aortic lymph node dissection.

Table 2. Perioperative complications of robotic surgery for malignant uterine disease, excluding radical hysterectomy and radical trachelectomy, in Japan from 2018-2019

Variables	RAH (*n* = 617)	RAH + PLND (*n* = 341)	RAH + PLND + PALND (*n* = 22)	RMRH (*n* = 184)	RMRH + PLND (*n* = 66)	RMRH + PLND + PALND (*n* = 40)	Total number (*n* = 1,270)
Conversion to laparotomy	0	0	0	0	1 (1.52)	0	1 (0.08)
Intraoperative complication							
Blood loss > 500 mL	0	1 (0.29)	0	0	1 (1.52)	1 (2.5)	3 (0.24)
Vascular injury	0	0	0	0	0	0	0
Urinary tract injury	0	0	0	0	1 (1.52)	0	1 (0.08)
Bladder injury	0	0	0	0	0	0	0
Bowel injury	0	0	0	0	0	0	0
Others	1 (0.16)	6 (1.76)	1 (4.55)	1 (0.54)	0	0	9 (0.71)
Postoperative complication							
Intraperitoneal bleeding/Hematoma	0	1 (0.29)	0	0	0	0	1 (0.08)
Peritonitis	3	0	1 (4.55)	0	0	0	4 (0.31)
Surgical site infection	0	1 (0.29)	0	0	0	0	1 (0.08)
Vaginal cuff dehiscence	1 (0.16)	1 (0.29)	0	0	1 (1.52)	0	3 (0.24)
Bowel complication	0	0	0	0	0	0	0
Urinary tract injury	0	0	0	0	0	0	0
Bladder injury	0	0	0	0	0	0	0
Respiratory complication	0	0	0	0	0	0	0
Other	1 (0.16)	4 (1.17)	2 (9.09)	1 (0.54)	3 (4.55)	0	11 (0.87)

RAH, robot-assisted hysterectomy; RMRH, robotic modified radical hysterectomy; PLND, pelvic lymph node dissection; PALND, para-aortic lymph node dissection. Data are presented as *n* (%). Data were adapted from (*6*).

The future prospects of robotic surgery

The da Vinci surgical system is the most popular system for robotic surgery. Recently, several venture companies, including domestic companies, have been planning to start developing robotic surgical systems. As a result, reduced costs and technological innovation will promote the introduction of robotic surgery in clinical practice. Advances in techniques will improve surgical performance as well as outcomes.

Currently, the dearth of surgeons and medical disparities between urban and rural areas are urgent problems in Japan. Robotic surgery is a useful way to efficiently utilize human resources. Laparoscopic surgery requires at least 3 surgeons and a laparotomy requires at least 2 surgeons, whereas robotic surgery is performed almost solo. Moreover, the learning curve for robotic surgery is shorter than that for other approaches, and the surgeon is likely to feel less fatigue with robotic surgery than conventional laparoscopic surgery because of the ergonomic design of surgical systems (*25*).

In the future, remote surgery and artificial intelligence-guided surgery might overcome regional disparities, but there are still problems with the protection of personal information, costs, and the management of emergencies.

Preoperative registration in the National Clinical Database (NCD) has become mandatory in gynecology since July 2020, and the safety of robotic surgery will be evaluated. In conclusion, gynecologic robotic surgery has several advantages in solving many problems peculiar to Japan. We need to aware of its risks and medical economics in order to safely introduce this new technology to benefit patients.

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**Address correspondence to*:
Tomoko Gota, Department of Obstetrics and Gynecology, Center Hospital of the National Center for Global Health and Medicine, 1-21-1 Toyama, Shinjuku-ku, Tokyo 162-8655, Japan.
E-mail: tgota@hosp.ncgm.go.jp