Minimally invasive surgery is now becoming the standard surgical method for early stage endometrial cancer. In this review, we describe the path minimally invasive surgery has travelled from being an exceptional treatment to be the current standard in Japan. At the beginning of the 21st century, laparoscopic surgery has been employed for the treatment of gynecologic malignancies including cervical cancer and endometrial cancer. Robotic-assisted surgical system, which appeared a little later than laparoscope, has begun to be actively applied to surgical treatments for gynecologic malignancies that require particularly elaborate technologies. Both laparoscopic and robotic surgery have attracted the attention of surgeons because they enable safe, precise and less invasive surgery. Since the safety of minimally invasive surgery depends largely on the skill and experience of the surgeon, there is an urgent need to establish an educational system for implementing minimally invasive surgery. Here we describe various issues regarding minimally invasive surgery that Japan is currently facing, such as the medical economy, regulations by the Japanese health insurance system, a shortage of surgeons, the educational system for implementing minimally invasive surgery. As we discuss, the development of minimally invasive surgery is strongly related to the development of laparoscopic surgery, robotic surgery, and technology improvement. In recent years, minimally invasive procedures utilizing a laparoscope and robotic-assisted surgery system have been gradually introduced for the treatment of endometrial cancer. Classic vaginal surgery fails to satisfy the minimal requirements of procedures for a comprehensive staging defined by FIGO. It does not allow adequate observation of the peritoneal cavity. Neither it allows retroperitoneal procedures such as a lymphadenectomy or an adequate omentectomy if certain histologies prompt its need. On the contrary, laparoscopic surgery and robotic-assisted surgery enable a sufficient search of the peritoneal and retroperitoneal cavities and effective treatment based on this.

The principle of surgery for malignant tumors is to provide the greatest therapeutic effect despite the smallest range of surgery and the least invasive procedure. Of special significance, a recent study from Japan indicated that no matter which type of hysterectomy (total hysterectomy or radical hysterectomy) you employed to remove the uterus for early-stage endometrial cancer hardly impact on the rate of local
The study may provide a theoretical basis for laparoscopic surgery and robotic-assisted surgery being the best-suited minimally invasive surgery at present for early-stage endometrial cancer.

In Japan, enrollment to the health insurance system is mandatory. In addition, almost all the medical practice, including minimally invasive surgery, is carried out within the framework of the health insurance system.

In this review, we have introduced the current status and issues of minimally invasive surgery for early endometrial cancer in Japan with such a background may be of some help for the countries trying to spread minimally invasive surgery.

2. Minimally invasive surgery for endometrial cancer in Japan: avenues from its introduction to the approval as treatment methods covered by health insurance

2.1 Laparoscopic surgery

In 2008, the clinical trial of laparoscopic surgery for the treatment of endometrial cancer was initiated as advanced medical treatments in ten medical institutions designated by the Japanese Ministry of Health, Labour and Welfare (MHLW). The advanced medical treatment is intended to assess the suitability of the treatment in question for the Japanese health insurance coverage from the viewpoint of efficacy and safety. Until the approval by the government as the treatment methods covered by the health insurance system, medical costs for advanced medical treatments are at patients’ or hospitals’ own expenses. After carefully evaluating the results of laparoscopic surgery as an advanced medical treatment, MHLW decided to cover the treatment costs of laparoscopic surgery for endometrial cancer by the Japanese health insurance system in 2014.

In order to ensure safety of laparoscopic surgery, implementation of the procedures (hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy as needed) is allowed only in medical facilities that meet the prescribed standards for the treatment. At present, patients covered by the health insurance system are limited to stage 1A low recurrence risk. As for stage 1 and 2 with moderate to high risk cases, a clinical study has started in 2017 as the advanced medical treatment to evaluate whether or not laparoscopic surgery for these cases is appropriate as a treatment covered by the health insurance system.

2.2 Robotic-assisted surgery

Robotic-assisted surgery, in a broad sense, is considered to be a type of laparoscopic surgery with further improved performance. The difference from the conventional laparoscopic surgery is that the surgical instruments are directly operated by a robot manipulated by a doctor. More importantly, the range of motion of operating equipment, such as forceps, has expanded, allowing flexible movement even in narrow spaces. Moreover, the operator’s fine hand shaking is eliminated, which may improve dexterity [6]. Robotic-assisted surgery, therefore, has been assumed to be essentially the same technology as laparoscopic surgery. The greatest advantage with robotic-assisted surgery is that it can be operated remotely. The first publication on robotic surgery appeared in 1993 [7]. In the United States, Food and Drug Administration (FDA) officially approved the clinical application of Robotic surgical devices in 2000. In the field of gynecology, the first case of robotic surgery for fibroids was reported in 2004 [8].

Looking back on the trajectory of robot surgery in Japan, the da Vinci Standard surgical system was first used in Keio University Hospital in 2000 [9]. After that, several medical institutions introduced robotic surgical systems, including the Zeus® robotic surgical systems. However, neither was approved by the Japanese Government as a medical device. Then, Tokyo Medical Hospital introduced da Vinci® S (the next generation surgical system) for the treatment of prostate cancer in 2006, which was at last approved by MHLW as medical equipment in 2009. As a result, robotic surgery gradually disseminated as a treatment tool for diseases in digestive surgery, urology, gynecology, thoracic surgery. Because MHLW considered robotic surgery to be a type of laparoscopic surgery, the step of the advanced medical treatment was omitted for the approval of reimbursable treatment as was done with laparoscopic surgery. Meanwhile, doctors had conducted robotic surgery in compliance with the guidelines specified by relevant societies under the approval of the intramural ethics committee until the authorization of robotic surgery as reimbursable medical treatment. MHLW tried to judge whether or not robotic surgery is suitable for reimbursable medical treatment in consideration of the demands of the relevant academic societies, the degree of diffusion of the technology in respective clinical fields and opinions of experts. As a result, in 2012, robotic-assisted radical prostatectomy was authorized as a reimbursable medical treatment. In Japan, if patients receive both reimbursable and not reimbursable treatments for the same disease, the health insurance payment fund refuses to reimburse both treatment costs so that patients will pay 100% of treatment costs of both. This is called the prohibition of the mixed billing in Japan. For this reason, performing robotic surgery on diseases other than prostate cancer has been hampered. Despite the headwind specific to Japan, in the end, in 2018, the robotic surgery has been able to be performed for endometrial cancer within the frame of the health insurance treatments. The approval would spur the implementation of robotic surgery in the treatment of endometrial cancer.

3. Current status of robotic surgery in Japan

As of the year 2018, Japan has about 300 da Vinci® robotic surgical instruments, accounting for more than half of all Asian countries. The number of the instruments is on the increase almost linearly from 2011 to 2018. Robotic surgery is approved for reimbursable medical treatments for 18 diseases as of the year 2018. The number is expected to even increase in the near future.
With regard to the introduction of robotic surgery for gynecologic malignancies, it was first applied for early-stage cervical cancer preceded [10]. However, as a concern about long-term prognosis after robotic surgery have been raised, its application to cervical cancer has been extremely limited. Thus, endometrial cancer is now the main target of robotic surgery in the field of gynecology.

The average annual number of operated cases by a robotic-assisted surgery device, however, is around 100, the operating status being at the lowest level in the world. To state differently, it seems unprofitable for many hospitals to own the device. In particular, except for robotic surgery for prostate cancer, it is difficult to expect profits because the costs of treatment set by the health insurance system for robotic surgery are the same as, or slightly higher than those of laparoscopic surgery. In the face of this situation in Japan, further spread of robotic surgery is largely related to the future medico-economic situation in Japan. What should be considered here is that robotic surgery does not seem to improve the long-term prognosis of malignant tumors compared with conventional open surgery. However, nevertheless, we must calculate the added value of its elaborate technique and the resulting minimal invasiveness. The treatment costs of robotic surgery based on this calculation will be appropriate. Aside from the medico-economic issues with robotic surgery, what should be emphasize is that robotic surgery has elevated the motivation of surgeons and resultantly helped a hospital in securing surgeons.

4. Prerequisites for starting robotic surgery

The Japan Society of Obstetrics and Gynecology has defined the guidelines for performing robotic surgery for gynecologic malignancies. The outline is as follows. Surgeons trying to perform robotic surgery must meet the following requirements. First of all, they are required to participate in a lecture on robotic surgery and observe a given number of operated cases using a robot surgical instrument conducted by accredited doctors. Needless to say, they have to acquire the operating skills of da Vinci surgical system® using robotic surgery simulators spent for a minimum of 20 hours. Before practicing robotic surgery, 20 cases of both open surgery on gynecological malignancies and laparoscopic surgery regardless of disease, must be experienced. Moreover, implementation of robotic surgery is limited to government approved medical facilities. When robotic surgery is actually started after meeting the above-mentioned conditions, performing first given number of cases (5 cases or more) requires the presence of an experienced doctor from an external medical facility as a proctor. At the moment, the related societies are currently preparing formal surgical proctoring system in the gynecologic field.

5. Academic organizations overseeing robotic surgery

Currently, there are two academic societies which organize the entire surgical departments involved in endoscopic surgery including robotic surgery in Japan, i.e. Japan Society of Endoscopic Surgery and Japan Robotic Surgery Society. As far as academic societies specific to gynecology are concerned, the following societies supervise the implementation of robotic surgery, namely, Japan Society of Obstetrics and Gynecology (the fundamental society for obstetrics and gynecology in Japan), Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy, and Japan Society of Gynecologic Oncology. Besides, the Japan Society of Obstetrics and Gynecology has overall responsibility for the surgical practice in Obstetrics and Gynecology. The society, however, is not actually involved in the technical certification of robotic surgery.

Recently, the board certification system for robotic surgery was established in Japan under the initiative of Japan Robotic Surgery Society which is composed of urology, gastrointestinal surgery, cardiac surgery, gynecology, and otolaryngology. As of the year 2020, more than 50 gynecological surgeons were board certified. However, it is not limited to the board certified specialists of the society who can carry out robotic surgery as reimbursable medical treatment. As such, the supervision of robotic surgery is dispersed to many academic societies. It is, therefore, difficult for doctors to participate in all the societies involved in robotic surgery. In addition, the considerable amount of energy is spent to obtain and hold the certification for performing robotic surgery. Besides, the registration of cases is charged and could be a burden on each medical facility. Since Japan has adopted the public health care insurance system with treatment fees being set low, the implementation of robotic surgery does not necessarily lead to the actual profit of the hospital. In addition, the spread of robotic surgery in the future largely depends on how to incentivize doctors to perform robotic surgery.
| FIGO stage | operative method | Open surgery | Laparoscopy | Robotic-assisted |
|------------|------------------|--------------|-------------|-----------------|
| AEMH       | hysterectomy     | ○            | ○           | ○               |
| I A        | Hysterectomy + BSO + PLA (± PALA) | ○ | ○ | ○ |
| I B, II    | Hysterectomy + BSO (± PLA ± PALA) | ○ | × | × |
| III, IV    | hysterectomy     | ○            | ×           | ×               |
| CIN        | hysterectomy     | ○            | ○           | ○               |
| I A1       | hysterectomy     | ○            | ○           | ○               |
| I A2, I B1, II A1 | Radical hysterectomy | ○ | ○ | × |
| I B2, II A2, II B | Radical hysterectomy | ○ | × | × |
| OC any     |                  | ○            | ×           | ×               |

In endometrial cancer, laparoscopic and robotic procedure is admitted only for early endometrial cancer. The indication for laparoscopic and robotic procedure is the same.

○: reimbursable
×: not reimbursable
EC: endometrial cancer
CC: cervical cancer
OC: ovarian cancer
AEMH: atypical endometrial hyperplasia
CIN: cervical intraepithelial neoplasia
BSO: bilateral salpingo-oophorectomy
PLA: pelvic lymphadenectomy
PALA: para-aortic lymphadenectomy

6. Laparoscopic surgery for endometrial cancer

Laparoscopic surgery for endometrial cancer was first reported in 1992. The authors emphasized that laparoscopic surgery is less invasive. Nevertheless, it offers the same pathological information as open surgery [11]. After that, the clinical data on laparoscopic procedures for endometrial cancer were published one after another. In addition to hysterectomy, removal of pelvic and para-aortic lymph nodes can be achieved by laparoscopic surgery [12].

Lymph node metastasis is a crucial determinant of the prognosis of endometrial cancer. As mentioned before, laparoscopic surgery for endometrial cancer is limited to stage IA under the Japanese health insurance system. The Japanese health insurance system further regulates surgical procedures for endometrial cancer which include hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy excluding para-aortic lymphadenectomy. In view of that the frequency of nodal involvement in low-risk endometrial cancer such as stage 1A is less than 1%, the provisions of the insurance system in Japan seem to be appropriate [13, 14]. Very recently, laparoscopic para-aortic lymphadenectomy has been covered by the insurance system if there is an obvious reason to do that after the first surgery.

Of note, according to the study conducted in Japan, para-aortic node metastasis is relatively high even in the early stage of endometrial cancer with intermediate and high risk such as grade 3, serous adenocarcinoma, clear cell carcinoma, etc. Para-aortic node dissection should be considered in these cases [15]. Randomized clinical research is underway in Japan to see whether performing para-aortic lymphadenectomy in patients with intermediate and high risk endometrial cancer is beneficial or not.

As for sentinel lymph node biopsy, laparoscopic surgery may be suitable for conducting it because the surgical field is magnified and brightened. However, at present in Japan, the target of laparoscopic surgery is limited to stage 1a endometrial cancer, which has an extremely low rate of lymph node involvement [13]. Thus, the need for sentinel lymph node biopsy is not high. Accordingly, sentinel lymph node biopsy is not covered by the Japanese health insurance system. We are currently examining the usefulness of sentinel lymph node biopsy as a clinical study at selected institutions.

To date, a large body of papers has documented the usefulness of laparoscopic surgery over laparotomy for the treatment of early-stage endometrial cancer [16–21]. Currently, relevant societies consider this point to be a consensus. The papers from Japan on the results of laparoscopic surgery for endometrial cancer are in line with those from other countries [22–25]. The conclusions of these papers are that laparoscopic surgery is superior to laparotomy in terms of the following points, i.e. smaller intraoperative blood loss, fewer days of hospitalization, without a large incision and consequently less painful in postoperative periods, decreased postoperative morbidity, etc. The benefits with laparoscopic surgery for the treatment of endometrial cancer over open surgery have been demonstrated in many randomized controlled clinical studies [18, 26, 27]. With the accumulation of evidence on the benefits of laparoscopic maneuvers, the use of laparoscopes as therapeutic tools for early-stage endometrial cancer has rapidly expanded in developed countries in the last 15 years.
Most importantly, laparoscopic surgery does not affect long-term survival [28, 29]. In view of that laparoscopic surgery can remove lymph nodes to the same extent as open surgery, it makes sense that laparoscopic surgery does not compromise prognosis in spite of its low invasiveness [30, 31].

It has been pointed out that the operation time could be longer compared with that of laparotomy as a downside of laparoscopic surgery. However, the operation time would vary depending on the skill level of the operator and, therefore, it might be difficult to generalize this. Anyway, it goes without saying that the benefits with laparoscopic surgery come under the condition that the surgery is performed by a surgeon who has a lot of experience in laparoscopic surgeries for cancer. As for how much experience should be gained, experience on surgery for 30-40 cases with endometrial cancer is the minimum required level according to the study from Japan [32]. On the other hand, regarding long-term outcomes, no appreciable differences were noted as for recurrence rates and survival rates between laparoscopic surgery versus laparotomy.

However, it is to be noted that the advantages of laparoscopic surgery described thus far cannot be extended to endometrial cancers with stage 1b or more advanced, or with histological type other than endometrioid type. For instance, local recurrence rates are higher with laparoscopic surgery relative to laparotomy, when operating on stage 2-3 endometrial cancer patients [33]. It should be, therefore, emphasized that laparoscopic surgery is suitable for properly selected endometrial cancer.

7. Robotic-assisted surgery for endometrial cancer

In 2005, robotic surgery was performed on gynecologic malignancies including endometrial cancer. The first report appeared in 2005, which described that robotic-assisted technology is feasible for total hysterectomy and staging of gynecologic malignancies [34]. Then, radical hysterectomy and pelvic node dissection for early stage cervical cancer has been performed by robotic surgery. Most notably, the patients undergoing the surgery were discharged the next day [35].

Nearly 10 years after laparoscopic surgery was introduced into gynecologic malignancies, robotic surgery is about to change for it [36]. One of the reasons for this is that robotic technologies for operating laparoscopic instruments were available as medical devices shortly after the introduction of the laparoscope. Secondly, the basic procedures of robotic surgery have much in common with laparoscopic surgery so that surgeons familiar with laparoscopic surgery were able to switch to robotic surgery with relative ease.

According to the results of studies reported so far, robotic surgery for endometrial cancer is associated with shorter hospital stays, reduced blood loss, lower transition rate to open surgery and lower incidence of intraoperative damages to surrounding organs, when compared with laparoscopic surgery. However, the operation time with robotic surgery tends to be longer relative to laparoscopic surgery.

To summarize, robotic surgery for endometrial cancer may be safer than laparoscopic surgery [37, 38]. Though, the data on the long-term prognosis undergoing robotic surgery have not yet been accumulated, there seems to be no difference, compared with laparoscopic surgery and laparotomy [39].

The surgical procedures with robotic surgery for early-stage endometrial cancer are basically the same as laparoscopic surgery under the current Japanese health insurance system. That is, para-aortic lymphadenectomy is not reimbursable. But it may be that robotic-assisted surgery seems suitable for performing para-aortic lymphadenectomy compared with laparoscopic surgery for the following reasons. Firstly, there seems to be less hand shake with robotic surgery. Secondly, robotic surgery facilitates deep manipulation. Currently, a study to see the clinical significance on para-aortic lymphadenectomy using robot surgical instruments is being conducted as a clinical trial at specific facilities in Japan.

Regarding learning curve, robotic surgery for endometrial cancer seems to reach a certain level by experiencing about 20 cases. Thus, the acquisition of a technical level above the required level can be realized earlier than laparoscopic surgery [40, 41]. In Japan, a total of 357 robotic surgeries were conducted on gynecologic malignancies during the four years ranging from 2014 to 2017. Over 60% of them were for the treatment of cervical cancer. Data with robotic surgery on operation time and blood loss appeared to be better, if conducted in medical facilities which dealt with a larger number of cases. In some hospitals where robotic surgery was done with the number of cases being not large, there were no board accredited doctors [42].

In 2018, an unexpected report was published that survival time of cervical cancer patients undergoing radical hysterectomy through minimally invasive surgery was shorter compared with surgery through an abdominal incision [43]. After this report, an abdominal radical hysterectomy has been preferred for the treatment of cervical cancer in many countries. Even in Japan, robotic surgery for cervical cancer has become extremely limited. At the moment, when applying minimally invasive surgery to cervical cancer, Japan Society of Obstetrics and Gynecology has established guidelines regarding case selection (IA1, IA2, IB1, IIa1), experience and qualifications of surgeons, etc.

As of the year 2018, about 1/6 of gynecologic malignancies treated by minimally invasive surgery were conducted by robotic-assisted surgery in Japan. As of March 2020, the Japan Society of Obstetrics and Gynecology issued a detailed compliance matters on medical facilities and surgeons performing robotic surgery. This notification of the society focuses on the safety of the implementation of robotic surgery. Although, the requirements for conducting robotic surgery have become stricter, it is attributed to ensuring safety.
8. Issues surrounding minimally invasive surgery currently facing Japan

At present, there are some issues to be solved for the further spread of minimally invasive surgery in Japan. First, it is necessary to secure the number of surgeons who are proficient in minimally invasive surgery. Secondly, in Japan, any advanced medical care should be implemented basically within the framework of the Japanese health insurance system managed by the government. Treatment costs, therefore, are kept at a certain level nationwide. At the moment, the costs for endometrial cancer surgery under the health insurance system in Japan are as follows; 620000 yen (equivalent to approximately 5900 US dollars) for laparotomy and 702000 yen (equivalent to approximately 6900 US dollars) for laparoscopic surgery. Although, it may be hard to understand, the cost of robotic surgery is set to be the same as laparoscopic surgery. Incidentally, the Japanese health insurance covers 70% of the medical bills, so the patients are charged 30% of medical expenses. Anyway, given the purchasing expensive robotic-assisted surgery system and its running costs, each hospital is struggling how to improve the financial balance.

Japan has adopted the health insurance system that allows all citizens to receive medical care under the control of the health insurance without exception. That is, everyone has the right to access the same level of health care wherever they are. Many Japanese are proud of and cherish the Japanese health insurance system. Table 1 shows the extent to which surgery is approved for gynecologic cancers by the health insurance system [44].

However, as far as minimally invasive surgery is concerned, it is not easy to embody what the Japanese medical system aims for. More specifically, the number of doctors and facilities qualified to carry out minimally invasive surgery are limited. Besides, they are unevenly distributed regionally. The reasons for this are employing skilled specialist for minimally invasive surgery is difficult. Besides, purchasing expensive medical devices for robotic surgery and maintaining them are a burden on hospital management because most medical facilities in Japan must stand on their own feet financially. Additionally, there are quite a few small and medium-sized medical facilities that perform laparoscopic surgery exclusively for benign diseases. On the other hand, when it comes to facilities dealing with malignant tumors, it is restricted to large-scale hospitals where they can handle various situations employing multidisciplinary measures in case something unexpected happens. For regional core hospital, however, high-priority medical care like an emergency illness, goes ahead whereas time-requiring treatments, such as robotic surgery might be reduced in priority. As such, minimally invasive surgery for endometrial cancer is mainly conducted in university hospitals where doctors are relatively abundant and all medical departments are available.

In Japan, subspecialties in the field of Obstetrics/Gynecology are categorized into the following subdivisions, i.e. gynecologic oncology, maternal-fetal medicine reproductive medicine, primary health care for women, urogynecology/reconstructive pelvic surgery. The proportion of obstetricians and gynecologists is declining these days. Especially, obstetricians and gynecologists in their 20s to 30s account for approximately 4% of the total medical doctors. Despite the relatively smaller number of obstetricians and gynecologists, subdivision for subspecialties in obstetrics and gynecology is accelerated. Surgery for endometrial cancer is supposed to be handled by an oncologist. However, the work of oncologist is extremely diverse and heavy responsibility. Hence, it is difficult for gynecologic oncologist to gain minimally invasive surgery experience and specialist qualification for it. That is why the number of surgeons involved in minimally invasive surgery for malignancies does not increase in Japan. Perhaps, we will have to train gynecologic oncologists who specialize in minimally invasive surgery. To achieve that, related academic societies should hold training courses for accredited gynecologic oncologists. Such an attempt could increase the availability of minimally invasive surgery for gynecologic malignancies. However, this might lead to further subdivision of obstetrics and gynecology.

Another explanation for delaying the spread of robotic surgery in Japan is the Japanese health insurance system. In the United States, the costs of medical care are often determined by the balance between supply and demand. On the other hand, in Japan, the government sets the fees. In other words, the cost of a particular operation is constant no matter which hospital the operation is done or whoever the operator is. When we look at the reimbursable price in Japan, the costs of robotic surgery for each disease is, at the moment, the same as those of laparoscopic surgery, except for surgery for prostate cancer and kidney cancer. This makes it impossible for hospitals to make money commensurate with the purchase costs of surgical robots and their running costs. Now domestically produced surgery-supporting robots are about to enter the market. This may lead to price competition for surgery-supporting robots, which in turn could lower their costs.

9. Conclusions

In this review, we introduced the current state of minimally invasive surgery for the treatment of endometrial cancer in Japan and various issues in implementing it. In Japan, all citizens have the right to receive the same level of medical care by enrolling in the health insurance system without exception. Under such a medical system, how to spread advanced and expensive medical technologies as exemplified by robotic-assisted surgery is a problem to be solved unique to Japan.
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Conflict of interest
The authors of this publication declare no competing interests to declare.

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