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Technical innovation, standardization, and skill qualification for pediatric minimally invasive surgery in Japan

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Abstract This is a presentation of sharing endeavors at modifying and standardizing surgical procedures as well as establishing endoscopic surgical skill qualification in the field of pediatric surgery in Japan.

First of all, I would like to give my heartfelt thanks to Dr Moritz Ziegler and the entire American Pediatric Surgical Association for this wonderful privilege of inviting me as an international guest speaker. My talk is based on the training and research work I did while in the United States from October 1994 to March 1997. After coming back to Saitama Children's Medical Center, Saitama, Japan, my colleagues and I started a variety of pediatric minimally invasive surgeries. I would like to share our endeavors at modifying and standardizing the surgical procedures, as well as establishing an endoscopic surgical skill qualification (ESSQ) system in the field of pediatric surgery in Japan.

1. From research laboratory to operating theater

Collaboration between basic science and clinical medicine is very important. I have personally conducted laboratory research that has subsequently been applied clinically in the fields of minimally invasive surgery (MIS) and abdominal neuroblastoma.

1.1. Port-site recurrence after laparoscopic surgery

In 1990s, the use of MIS had become a common procedure for the treatment of certain cancers. However, port-site recurrence (PSR) after laparoscopic tumor surgery was a serious complication that had been reported in operations for various kinds of abdominal cancer [1-3]. The incidence of PSR after laparoscopic colectomy was reported to range from 1.1% to 6.3% [4-6] in contrast to 0.7% wound tumor recurrence rate in patients undergoing curative open colectomy [7]. These clinical reports hypothesized that PSR was caused by direct implantation of viable exfoliated tumor cells after laparoscopic cancer surgery [1,8,9]. However, the etiology of PSR remained unclear. This necessitated further study and development of an effective method to prevent PSR after MIS in cancer patients [10-13]. In the pediatric surgical field, there was one report of PSR after thoracoscopic surgery for osteogenic sarcoma [14]. However, Holcomb et al [15] reported no PSR in their clinical series for MIS procedures in children. Because most malignant tumors in children differ

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from adult gastrointestinal cancers, it is important to have a pediatric model of clinical and basic research to evaluate such postoperative complications. Therefore, we planned to evaluate PSR after laparoscopic biopsy and a potentially effective treatment in an immature murine neuroblastoma model [16].

Immature 5- to 7-week-old male A/J mice (18-23 g) were subcutaneously inoculated with the minimally immunogenic TBJ neuroblastoma in the left flank and then divided into 3 treatment groups. Simulated laparoscopic tumor biopsy after carbon dioxide insufflation was performed 14 days after tumor inoculation: intraperitoneal chemotherapy using cyclophosphamide at a dose of 0.08 mg/g body weight on postoperative days 0 and 3 (IP-chemo), intravenous chemotherapy using the same dose of cyclophosphamide (IV-chemo), and no chemotherapy (No-chemo) groups. Mice killed on postoperative days 1, 4, and 7 were used to count free intraperitoneal tumor cells, whereas mice killed on postoperative day 11 were used to evaluate the influence of chemotherapy on the incidence of PSR. Fig. 1 shows the number of viable exfoliated neuroblastoma cells in the peritoneal cavity after simulated laparoscopic tumor biopsy and postoperative chemotherapy. At each time-point, the number of tumor cells harvested in both chemotherapy groups was significantly less than that in the No-chemo group. However, there was no significant difference in the number of free intraperitoneal tumor cells between the IP-chemo group and IV-chemo group. The incidence of PSR in both adjuvant chemotherapy groups was significantly less when compared with No-chemo group (Table 1). We concluded that postoperative chemotherapy may be useful in preventing PSR after MIS in cancer patients who have a chemotherapy-sensitive tumor.

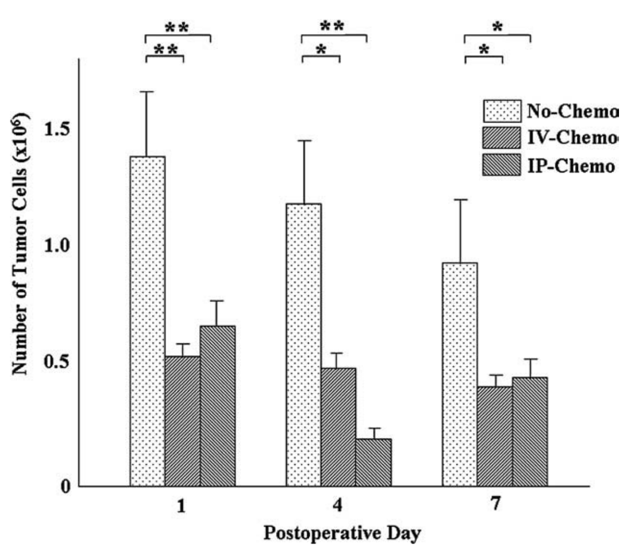

Fig. 1 The number of viable exfoliated neuroblastoma cells in peritoneal cavity after simulated laparoscopic tumor biopsy and postoperative chemotherapy [16]. Data were shown as mean ± SEM. *$P < .05$ and **$P < .01$ by analysis of variance vs No-chemo group.

Table 1 The incidence of PSR and efficacy of chemotherapy after simulated laparoscopic tumor biopsy [16]

Group	Total PSR	PSR in insufflation site	PSR in biopsy site
No-chemo	16/18 (89%)	14/16	14/16
IP-chemo	2/17 (12%) *	1/2	1/2
IV-chemo	2/16 (13%) *	1/2	2/2

* $P < .01$ vs No-chemo group by χ^2 test.

1.2. Surgical intervention for abdominal neuroblastoma in the laparoscopic era

From the results of our research using a murine model, we started clinical laparoscopic biopsy with postoperative adjuvant chemotherapy for advanced abdominal neuroblastoma at Saitama Children's Medical Center, Saitama, Japan after obtaining informed consent from the parents.

From November 1998 to January 2000, 6 laparoscopic biopsy (International Neuroblastoma Staging System stages 3 and 4) and 4 laparoscopic excisions (INSS stages 1 and 2) were performed. Length of stay, time to postoperative feeding, and chemotherapy after tumor biopsy were significantly lower in the laparoscopic group than in the open surgery group. However, there were no significant differences between the 2 groups in length of operation and intraoperative blood loss [17]. The efficacy and safety of laparoscopic excision for early localized abdominal neuroblastoma was further demonstrated by the lack of intraoperative complications. There was no PSR after either laparoscopic tumor biopsy or excision for abdominal neuroblastoma [17]. There were also some reports about the usefulness of laparoscopic

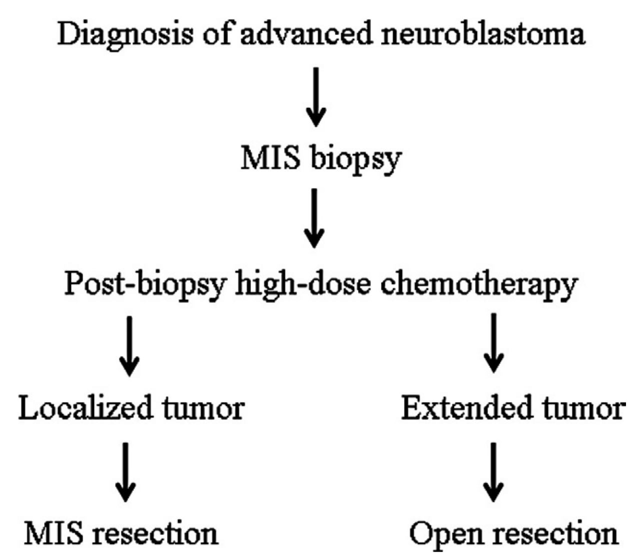

Fig. 2 Algorithm for the management of advanced neuroblastoma. Laparoscopic resection of neuroblastoma with lymphadenectomy is also feasible when postbiopsy high-dose chemotherapy is very effective and good visualization of the primary tumor and large vessels is laparoscopically achieved.

procedures for pediatric solid tumors, with no reported occurrence of PSR [18-21]. In adults, the ratio of PSR ranged from 1.1% to 6.3% [4-6]. Consequently, we estimated that clinical data of at least 100 laparoscopic tumor surgeries would be necessary to analyze the incidence of PSR in childhood cancers. In September 2001, we mailed questionnaires for experiences of MIS tumor procedure and postoperative PSR to the member institutions of the Japanese Society of Pediatric Endoscopic Surgeons. A total of 129 endosurgical procedures for pediatric malignancies were performed among 29 institutions in Japan between 1994 and 2001, with a follow-up period of 5 months to 8 years. No PSR was detected in any of these patients after endosurgical procedures [22]. We recently performed 28 MIS biopsies for advanced neuroblastoma and 17 MIS excisions for localized neuroblastoma, with no PSR after either procedure. Fig. 2 shows our algorithm for the management of advanced neuroblastoma. When postbiopsy high-dose chemotherapy reduces the size of primary tumor and attached lymph nodes, laparoscopy reveals good visualization of large vessels, thus, facilitating laparoscopic resection of localized advanced neuroblastoma with lymphadenectomy [23].

2. Modification of surgical procedure with technical innovations

Technical innovation of surgical procedure offers a better postoperative quality of life for the patient. For example, technical innovations of laparoscopically assisted anorectoplasty (LAARP) for the treatment of high-type imperforate anus are reported in Japan.

2.1. Modification of LAARP procedure for postoperative good anal function

Anorectal malformations are challenging for pediatric surgeons because many children with these malformations experience fecal incontinence after anorectoplasty. For the past 2 decades, posterior sagittal anorectoplasty (PSARP) has been the standard method for surgical management of high-type imperforate anus [24-26]. Posterior sagittal anorectoplasty allows the surgeon to directly visualize the anatomy of the malformation. The main advantages of PSARP are easy separation of the rectum from the vagina or urinary tract and the exposure of puborectal muscle sling and muscle complex. However, this procedure requires a large incision of the pelvic structures that may damage the sphincter muscles as well as the tiny nerves that maintain anorectal sensation and motility. In patients with anorectal malformations, impairments in rectal motility, anorectal sensation, and the anorectal sphincter complex can lead to subsequent problems with fecal incontinence, even though patients may have a very well reconstructed anus.

Recently, a new technique using laparoscopy was reported to have considerably minimized the postoperative complications associated with PSARP [27]. This technique uses minimal perineal dissection as well as preservation of the distal rectum, whereas offering good visualization of the fistula and the immature pelvic muscles. Despite the aforementioned advantages, this technique has its limitations. Even with the use of a perineal muscle stimulator, it was difficult to accurately detect the center of very immature levator muscles. Yamataka et al [28] have reported the efficacy of Pena’s muscle electrostimulator intracorporeally under the laparoscopic view to detect the center of puborectal muscle sling. We too have reported the newly designed 5-mm-diameter laparoscopic muscle stimulator capable of adequately stimulating the immature muscles [29]. Although optimal contraction of the extremely weak puborectal muscle sling and muscle complex in cases with rectovesical fistula was not achieved with transcutaneous electrostimulation, our laparoscopic muscle stimulator was able to precisely contract the puborectal muscle sling toward the pubic bone and indicate the small center of the top of the muscle complex for accurate positioning of rectal pull-through (Fig. 3). The efficacy of intraoperative ultrasound in accurately detecting the center of puborectal muscle sling has been reported [30,31]. Although laparoscopic intrasphincteric dissection is blind with only laparoscopic backlighting as a guide, intraoperative endosonography clearly shows the external sphincter, the muscle complex, and the levator sling, consequently reducing the risk of injury to the genitourinary structures during LAARP [30]. Kubota et al [31] applied a linear-type ultrasound probe to the perineum, which clearly demonstrated the urethra, thereby reducing the risk of injury. Instead of intraoperative ultrasound, we have used light guidance of intraoperative urethrofiberscopy or vaginofiberscopy to accurately detect the posterior wall of urethra or vagina. This procedure makes it very easy to find

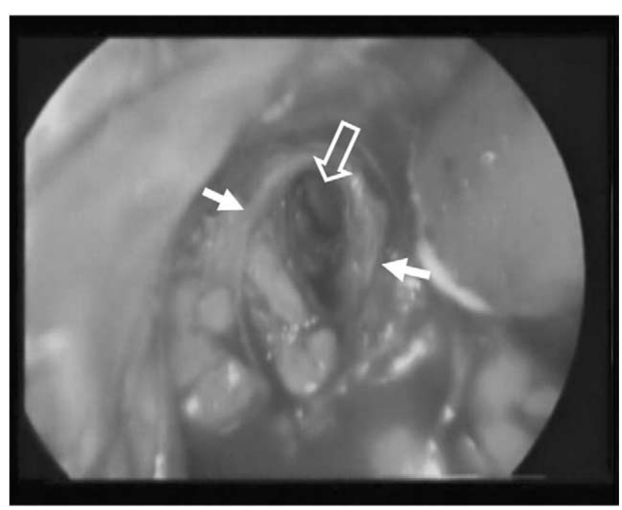

Fig. 3 Pelvic muscles in a patient with a rectovesical fistula. More immature puborectal muscle sling (closed arrow) and the center of very weak muscle complex (open arrow) are shown clearly.

the attachment of the fistula to the posterior wall of urethra or vagina (Fig. 4) and can accurately pinpoint the tiny center of the puborectal muscle sling. Laparoscopically assisted anorectoplasty with technical innovations, such as laparoscopic electrostimulation, use of intraoperative ultrasound, and light guidance of urethrofiberscopy or vaginofiberscopy, requires minimal perineal and rectal dissection. This not only facilitates accurate division of fistula and midline tunneling for rectal pull-through, but also preserves the sphincter muscles and sensory and motor innervation, thereby reducing the risk of complications resulting in better anal function in patients with high-type imperforate anus.

2.2. Follow-up study of high-type imperforate anus after LAARP

Before May 2000, all patients with high-type imperforate anus underwent PSARP or abdominosacroperineal anorectoplasty at our hospital. However, because of the first report of Georgeson et al [27] about LAARP, all patients with that diagnosis underwent LAARP with no conversions to PSARP. Because postoperative anal function after LAARP has not been reported, this new procedure is performed at only a limited number of hospitals around the world. Lin et al [32] have reported short-term follow-up study using anorectal manometry, in which patients repaired with LAARP had significantly higher positive ratio of rectoanal relaxation reflex (8/9) compared with patients repaired with PSARP (4/13); but there was no significant difference in daily stooling between the 2 groups. We also have reported midterm follow-up study using Kelly's clinical score and anorectal manometry [33]. In this report, there was no significant difference in either clinical score or the results of anorectal manometry; however, the age at evaluation in LAARP group was younger than in the PSARP group (51 ± 10 vs 73 ± 12 months, $P < .05$).

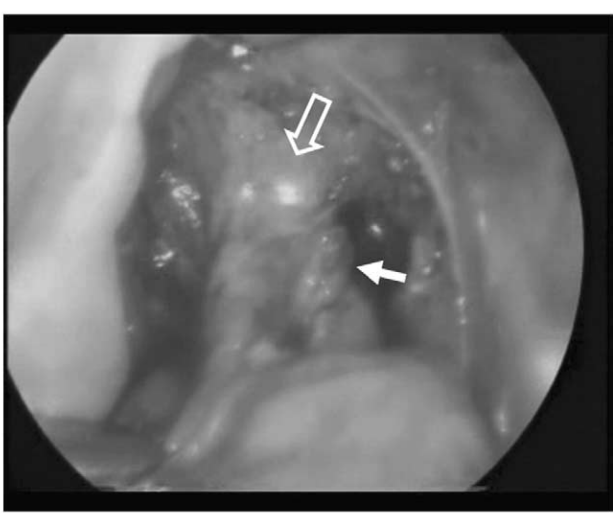

Fig. 4 Laparoscopic view of rectocloacal fistula (closed arrow). The attachment of fistula is well indicated using light guidance of vaginofiberscopy (open arrow).

Table 2 Postoperative anorectal function after LAARP and PSARP

Operative procedure	LAARP (n = 13)	LAARP (n = 13)	PSARP (n = 7)
Age at evaluation (mo)	51 ± 10	77 ± 10	73 ± 12
Kelly's clinical score	3.8 ± 1.3	4.5 ± 1.1 *	3.4 ± 0.8
Resting pressure (cm H_2O)	31 ± 11	41 ± 9	34 ± 16
Length of sphincter (mm)	15.4 ± 6.4	17.7 ± 6.0	14.9 ± 11.5

* $P < .05$ by χ^2 test compared with PSARP group.

Table 2 shows the results of our recent reevaluation of anorectal function after LAARP. There is a significant difference in the data of Kelly's clinical score between the same age groups in LAARP and PSARP. Also, our results on the ratio of rectoanal relaxation reflex showed a higher positive ratio in patients with LAARP (8/13, 62%) compared with that in patients with PSARP (2/7). This difference did not achieve statistical significance ($P = .16$) probably because of the small number of patients. Better anal function in patients with LAARP might be because of minimum rectal dissection and preservation of sphincter muscles and sensory and motor innervation. We did, however, experience cyst formation from the residual fistula in a couple of the patients who underwent surgical resection of the cyst. Furthermore, postoperative MRI detected tiny cystic structures in 5 of 14 cases of rectoprostatic urethral fistula, but the voiding cystourethrogram did not show any abnormal findings on the posterior wall of the prostatic urethra in 4 of these 5 patients (Fig. 5). The cause of residual cystic structure is still unclear, thereby emphasizing the need for further technical innovations to avoid this serious complication.

3. Skill qualification of pediatric MIS in Japan

The skills required to perform laparoscopic surgery are much different than those needed for open surgery. The surgeon has to enter the peritoneal cavity using a smaller incision, use long instruments, and perform surgery by viewing a 2-dimensional video image on a screen with limited tactile feedback.

Traditional methods of acquiring surgical skill by using the apprenticeship model cannot accommodate the new skills required for laparoscopic surgery. It was therefore necessary for the surgical curriculum to evolve toward the teaching of skills in a systematic and logical fashion by actually performing the surgeries rather than just observing them [34,35].

There are 2 ways of introduction courses on MIS for pediatric surgeons: one is to learn basic laparoscopic skills within a structured curriculum using a surgical trainer, a virtual reality system, and a simulated surgery using animate

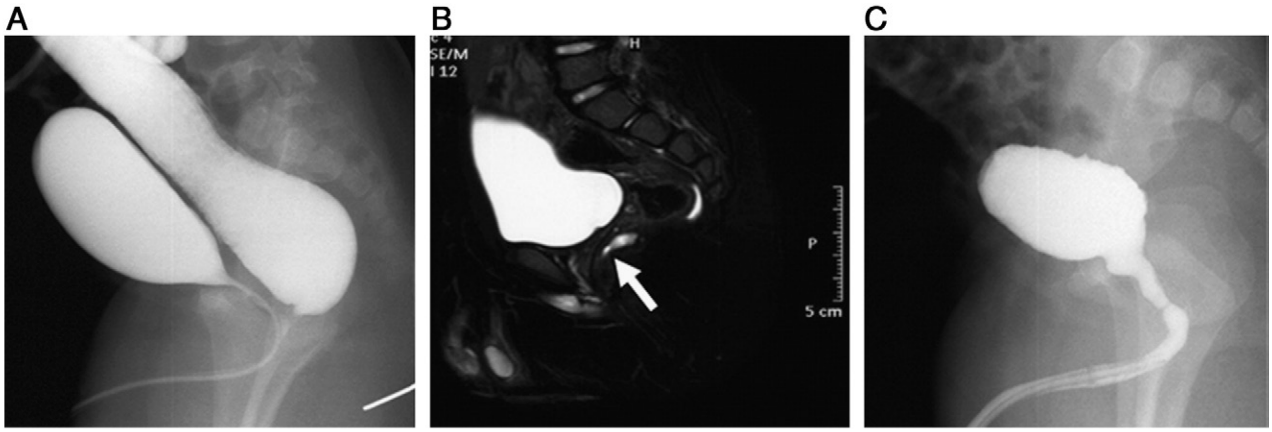

Fig. 5 Cystic structure in a case of rectoprostatic urethral fistula after LAARP. A, Preoperative colostogram and urethrogram. B, Postoperative MRI showed a tiny cystic structure from the posterior urethral wall. C, Voiding cystourethrography did not show any cystic structure in the same patient.

models, and the other way is to learn them from human laparoscopic surgery in adult patients. After many experiences of laparoscopic training both inside and outside the operating theater, young pediatric surgeons start to perform pediatric MIS. However, it is very difficult to evaluate the surgical competencies including assessment of knowledge, technical skill, and judgment of each surgeon. Because there are a wide variety of procedures that are done using MIS techniques in children but not that many patients in each category, young pediatric surgeons have limited opportunities to perform each type of pediatric MISs. We have reported the efficacy of laparoscopic pyloromyotomy and its learning curve and found that each pediatric surgeon needed to perform about 7 to 10 of this procedure to achieve safe and good surgical skills even though it is such an easy procedure [36]. Simulators currently have the ability to teach basic laparoscopic skills, enabling novice surgeons to progress along the early part of the learning curve before entering the operating theater. With further developments in technology, it may be possible to practice complete procedures, such as Nissen fundoplications. However, further training will still be needed for surgeons to reach expert levels of skill in the operating theater [34]. Every patient wants a laparoscopic surgeon with good skills, but it is not easy to identify an expert pediatric laparoscopic surgeon.

In 2003, the ESSQ system started in Japan in the fields of gastrointestinal surgery, urology, and gynecology. The entire system is controlled by the Japan Society for Endoscopic Surgery. The standard requirement of this system for skill qualification is the ability to complete common laparoscopic surgeries in each field by the individual efforts of the applicant. The main goal of the system is to decrease complications because of laparoscopic surgery by evaluating the surgical skills of each applicant and certifying laparoscopic surgeons with sufficient skill to perform operations safely [37]. Skill assessment is performed by evaluating an unedited videotape of the surgeon completing the entire procedure in a double-blinded fashion. This system also has the potential to set appropriate standards for laparoscopic surgery, with feedback on the results of the skill assessment that would result in improvement of the skills of each applicant.

In 2006, the Japanese Society of Pediatric Endoscopic Surgeons also devised a plan to develop a pediatric ESSQ system. A Committee of Pediatric ESSQ consisting of 12 expert pediatric laparoscopic surgeons with more than 10 years of experience created a checklist to be used to assess the applicant's laparoscopic surgical skills. Applicants should

Table 3 Checklist of endoscopic technical skill assessment of pediatric laparoscopic fundoplications

A. General procedure
Planning of procedure
Collaboration with assistants
Maintaining good surgical field
Appropriate distance among camera and instruments
Keeping good surgical field in the center of the camera view
Procedures under vision with unfogged lens
Smooth camera movement including zoom in and out
Performance of important procedure by an assistant
Performance of important procedures by an applicant
Use of appropriate energy source
Control of bleeding
B. Each maneuver
Introduction of the ports
Dissection plane between esophagus and crus of diaphragma
Division of short gastric vessels
Dissection and freeing of gastric fundus
Blunt dissection to develop the posterior abdominal esophagus
Gentle maneuver for esophagus and stomach
Gentle maneuver for vagal nerves including hepatic branch
Appropriate crural repair
Fundoplication
Position of secure wrapping
Length of wrapping
Suturing technique

have completed at least a 7-year general and pediatric surgical training program and have performed more than 50 pediatric MIS procedures. They are required to complete a laparoscopic fundoplication; their surgical skills as demonstrated in the unedited videotapes of the entire laparoscopic procedure from insertion of ports to their removal are discussed by 2 to 3 committee members. The first application of pediatric ESSQ system will start this December. Because the main purpose of this system is to decrease complications by increasing safety, we focus on dangerous maneuvers that may result in accidents or complications. Because all committee members need to agree on deducting the same number of points for similar dangerous maneuver or immature procedure, we continue to discuss further details of the technical skills assessment form (Table 3). Our final goal is to provide safe and appropriate pediatric minimally invasive procedures and to avoid severe complications. An outcomes survey of the operations performed by qualified pediatric surgeons is mandatory to prove the predictive validity of this system.

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