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ORIGINAL ARTICLE – HEAD AND NECK ONCOLOGY

The First Human Trial of Transoral Robotic Surgery Using a Single-Port Robotic System in the Treatment of Laryngo-Pharyngeal Cancer

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ABSTRACT

Background. This study aimed to evaluate the feasibility and safety of the DaVinci SP system for performing transoral robotic surgery (TORS) in patients with head and neck cancer.

Methods. From October 2018 to April 2019, the medical records of 41 patients who underwent TORS using the DaVinci SP system were retrospectively reviewed.

Results. During TORS, three robotic arms could be used to perform a geometric resection of the lesion in a narrow working space. The mean total operation time was 60 min, and the average time required to set up the robotic system was 10 min or less. All patients successfully underwent TORS. All robotic arms were inserted through a single port, which widened the working space around the patient's head and allowed the operative assistant an easy approach to the patient during the operation. The joggle joint of the robotic arms aided easy manipulation within the confined working space. The joggle joints of the endoscopic arm were controlled through the navigation system, which was very helpful in securing superior visualization of the surgical site, especially in the area of the larynx and the hypopharynx.

Conclusion. The study confirmed that the DaVinci SP system provided technical advantages above the Si and Xi systems for performing TORS. It was especially helpful in ensuring proper visualization of the surgical field and in performing precise surgery during surgery to the tongue base or the hypopharyngeal lesion.

Important considerations in the treatment of head and neck cancers include cure of the disease and quality of life for the patient after treatment. Even if the disease is cured after intensive treatment, the patient's quality of life will be suboptimal if treatment induces deterioration of swallowing and speech functions. Therefore, several studies have been conducted to determine ways to reduce surgical morbidity, including studies investigating minimally invasive transoral head and neck surgeries.[1] Using a laser and microscope, Steiner[2] introduced transoral laser microsurgery for the treatment of head and neck malignancies and reported acceptable oncologic and functional outcomes. However, the technique has not been widely adopted because of technical limitations inherent to long endoscopic instruments and microscopes. Then in 2005, Weinstein et al.[3] reported transoral robotic surgery (TORS) using the DaVinci robotic system, and since then, TORS has been performed for patients with head and neck cancer at various institutions around the world. Many studies have reported that TORS showed comparable oncologic outcomes, and patients who underwent TORS recovered rapidly due to low morbidity associated with its use.[3–5]

Although the clinical utility and efficacy of TORS have been verified for the treatment of malignant tumors originating in the upper aerodigestive tract (including the larynx and pharynx), TORS using the DaVinci surgical system has several limitations that need improvement. Previous DaVinci systems were initially developed for abdominal and urologic surgeries. A 5-mm-sized Maryland forcep and monopolar cautery usually are used to perform TORS via the DaVinci Si system (Intuitive Surgical, Sunnyvale, CA).

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Because 5-mm-sized instruments are not available with the DaVinci Xi system, many head and neck surgeons prefer the DaVinci Si system over the DaVinci Xi system for performing TORS. Additionally, the range of motion in the elbow joint of its robotic arm is relatively wider than the lumen of the oral cavity and the pharynx, so collision between robotic arms is likely to occur. Furthermore, instruments mounted on the robotic arms are rigid and therefore have limited movement after insertion into the confined space of the pharynx and larynx, which have flexures. Also, in TORS using the DaVinci Si or Xi systems, only two robotic arms can be inserted into the mouth during the operation, and an assistant must be positioned around the patient's head to suck out the blood in the surgical field and pull tissue to the opposite side in line with the operational process.

In 2014, a single-port, flexible, robotic surgical system (DaVinci SP Surgical System; Intuitive Surgical, Inc., Sunnyvale, CA) was developed and approved by the Food and Drug Administration for urologic surgery, and prospective clinical studies have confirmed the system's feasibility for urologic surgery. In the field of otorhinolaryngology, a preclinical study of human cadavers was performed to evaluate the feasibility of the system for performing TORS, but no clinical studies have reported the usefulness and safety of the DaVinci SP system for the treatment of head and neck cancer.[6–8]

Recently, we performed TORS using the DaVinci SP system for the treatment of head and neck cancer, especially laryngo-pharyngeal cancer, which involves the most challenging anatomic area for transoral surgery. In this study, we analyzed the advantages of the system for performing TORS of head and neck cancer and evaluated the feasibility and safety of TORS using the DaVinci SP system.

MATERIALS AND METHODS

Patients

From October 2018 to April 2019, we retrospectively reviewed the medical records of 41 patients with malignant tumors of the upper aerodigestive tract who underwent TORS using the DaVinci SP system at Severance Hospital. This study was approved by the Institutional Review Board of Yonsei University.

The study sample comprised 35 men and 6 women ranging in age from 41 to 78 years (mean, 60.1 years). The inclusion criteria specified a patient age of 18 years or older at the time of surgery and a diagnosis of tumor in the upper gastrointestinal tract. Only patients with surgical treatment were included in the study. The exclusion criteria ruled out patients with a contraindication for general anesthesia, patients with distant metastasis at the time of diagnosis, and patients with unresectable nodal disease such as carotid artery invasion. Other information on the patients are summarized in Table 1.

Configuration of the DaVinci SP System

Because the DaVinci Si and Xi systems were originally designed for abdominal and urologic surgery, these systems have a wide working range, and collisions between robotic arms can occur when the arms are moving in a narrow and deep pharyngeal lumen. In contrast, the DaVinci SP system was developed as a single-port system more suitable for use in a long narrow working space because all the robotic arms can be inserted through a single port with a diameter of 2.5 cm. In addition, two joggle joints in the robotic arms and endoscope play the same role as the elbow joint in the human arm, allowing the robotic arms to be arranged in a triangular shape toward the target surgical site within a limited working space (Fig. 1).

Appropriate Settings and Preparation of the DaVinci SP for TORS

The patient's cart with robotic arms and a surgical bed were placed perpendicular to one another. The robotic system was aligned with the center of the patient's mouth, and the cannula was placed approximately 10 cm outside the mouth. The height and angle of the single arm then

TABLE 1 Clinical information of all the patients

Characteristics	Patients *n* (%)
Sex	
Male	35 (85.3)
Female	6 (14.7)
Mean age: years (range)	60 (41–78)
Primary subsite	
Tonsil	14 (34.1)
Base of tongue	10 (24.4)
Pyriform sinus	5 (12.2)
False vocal cord	4 (9.6)
Posterior pharyngeal wall	2 (4.8)
True vocal cord	2 (4.8)
Aryepiglottic fold	1 (2.4)
Others	3 (7.7)
Histopathology	
Squamous cell carcinoma	35 (85.3)
Others	6 (14.7)

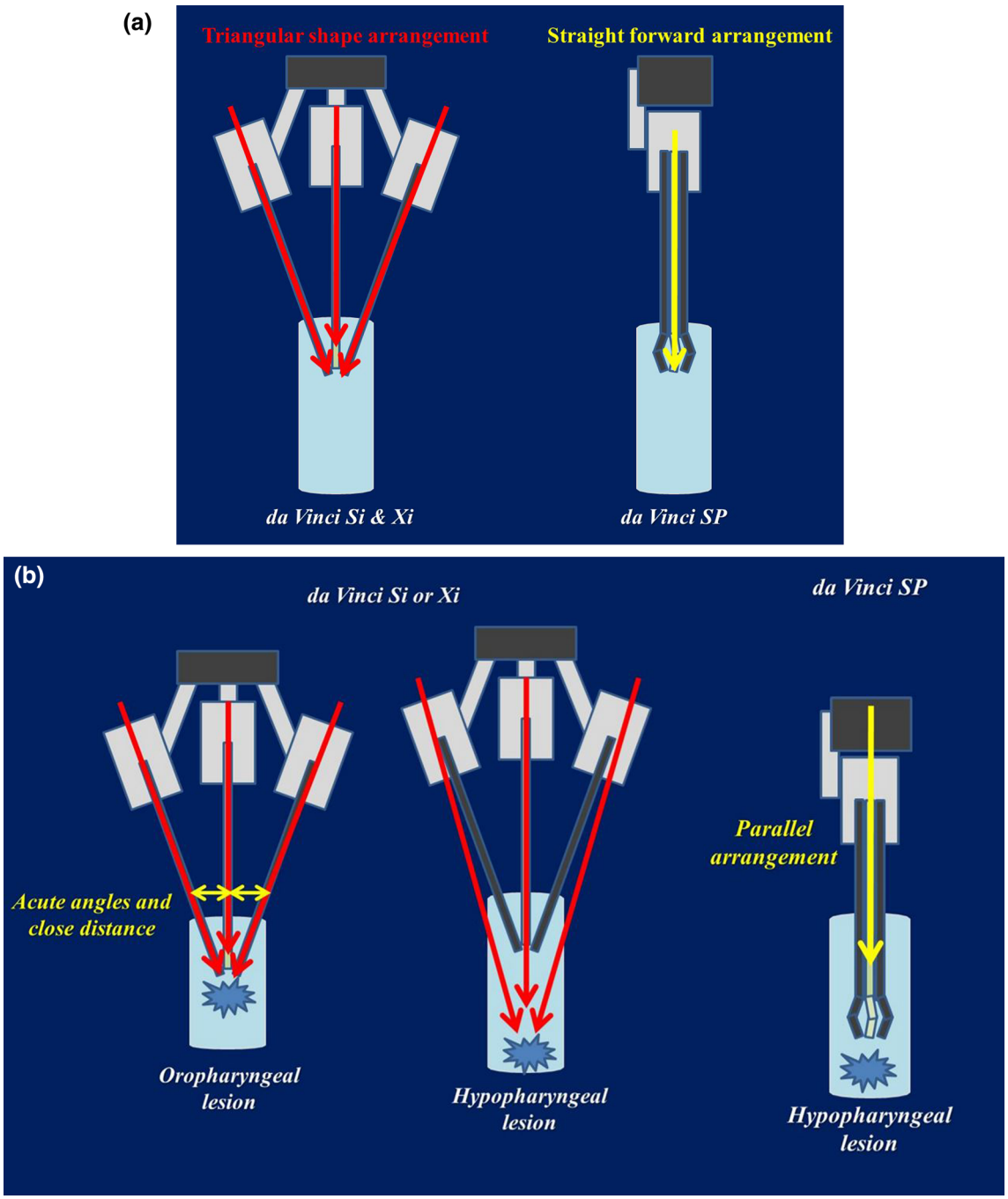

FIG. 1 Comparison between the DaVinci Si/Xi and DaVinci SP systems in performing transoral robotic surgery (TORS). **a** With the DaVinci Si and Xi systems, two robotic arms and an endoscopic arm are inserted through each cannula and arranged in triangular shape outside the oral cavity, risking collision between the robotic arms. This collision phenomenon especially occurs more frequently when TORS is performed for resection of hypopharyngeal cancer. **b** Because the hypopharyngeal lesion is located much deeper than the oropharyngeal lesion, the angles between the robotic arms are more acute, and the distance between the arms is closer. However, with the DaVinci SP system, all the robotic arms and the endoscopic arm are inserted through a single port 2.5 cm in diameter, and the two joggle joints of the robotic arms enable more freedom of movement within a limited working space. Therefore, collisions between the robotic arms can be minimized. These technical advantages of the DaVinci SP system make TORS more suitable for hypopharyngeal surgery

were adjusted so the axis of the single port was parallel to the axis of the oral cavity. Two or three robotic instruments were inserted through the single port, and the endoscopic arm also was inserted into the oral cavity through the same port. Both the first and second joggle joints of the robotic arm could be placed in the patient's mouth when the

cannula was 10 cm from the mouth. As three robotic arms and one endoscopic arm were inserted through a single port in the DaVinci SP system, the assistant, nurse, and anesthesiologist could easily approach the patient's head due to the decreased complexity of the working space around the patient's head (Fig. 2).

Operative Procedure

Transoral lateral oropharyngectomy was performed for the resection of tonsillar cancer. First, the pterygomandibular raphe was excised to identify the median pterygoid muscle and the parapharyngeal fat pad. The soft palate and the posterior pharyngeal wall then were excised, and dissection was performed along the prevertebral fascia (Fig. 3a–d).

For the patients with tongue-base cancer, robotic tongue base resection was performed using the following method. The location and extent of the tumor were determined, and the appropriate resection margin was taken into consideration. To ensure a proper surgical field of this region, the joggle joint of the endoscope was controlled using a navigation system to secure the optimal angle necessary to maximize the operative visualization of the surgical field. Therefore, in contrast to the DaVinci Si and Xi systems, the assistant did not need to adjust the axis and location of the endoscopic arm during the procedure with the DaVinci SP system (Fig. 3e–h). Also, we were able to use the fourth arm in TORS using the DaVinci SP system, and the folded surrounding mucosa was retracted by using the systems, allowing us to obtain the optimal view of the surgical field.

The DaVinci SP system also was used in the surgical approach for patients with hypopharynx cancer. The patients were placed in supine position with their neck extended. The tongue was pulled from the mouth as far as possible, and the tongue blade was attached to an FK

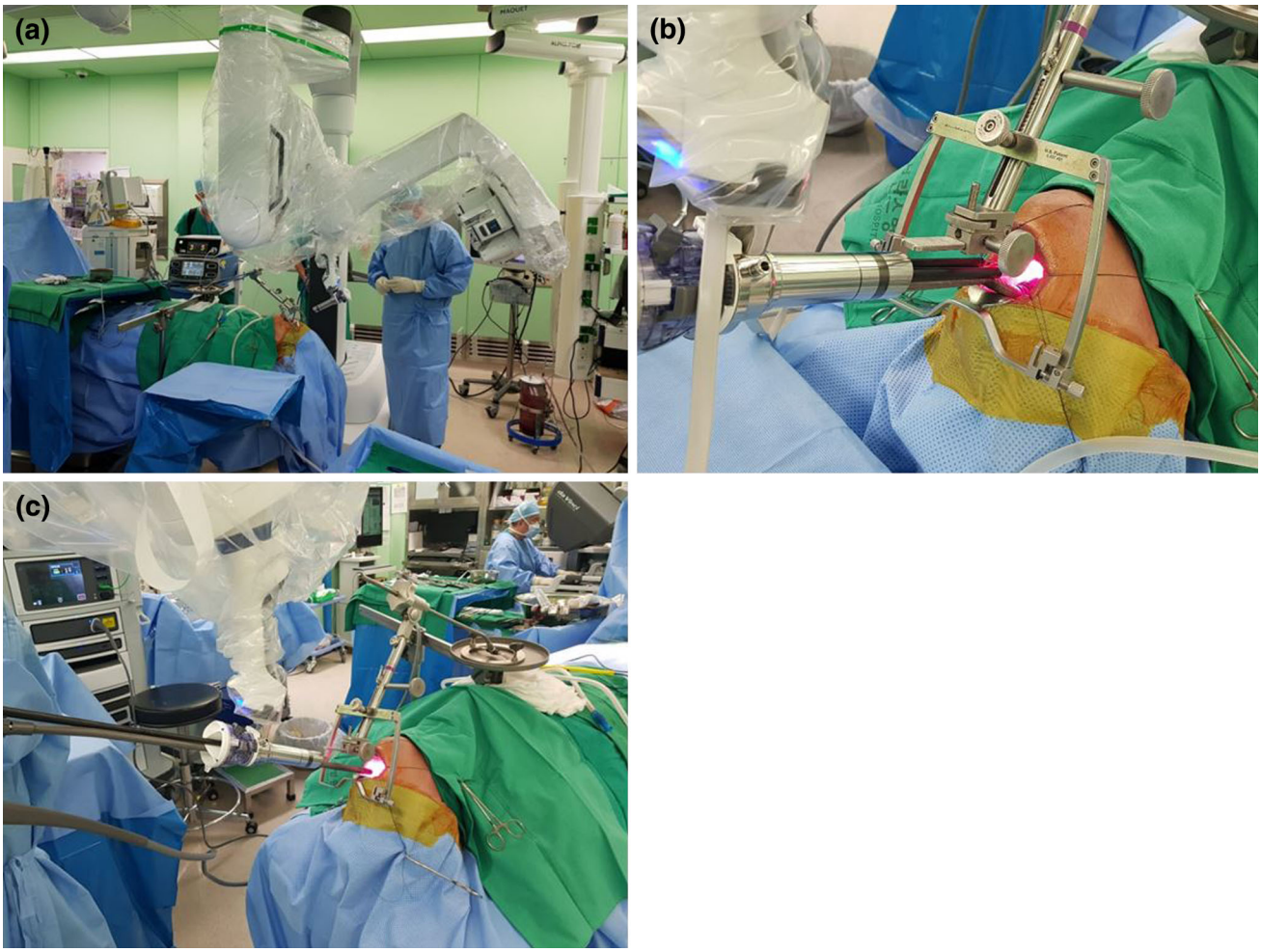

FIG. 2 Proper setting and preparation of the DaVinci SP to perform transoral robotic surgery (TORS). **a** The patient's cart with the robotic arms and the surgical bed placed perpendicular to one another. **b** The robotic system aligned to the center of the patient's mouth and the cannula placed approximately 10 cm from the mouth. **c** Two or three robotic instruments inserted through a single port, with the endoscopic arm also inserted into the oral cavity through the same port

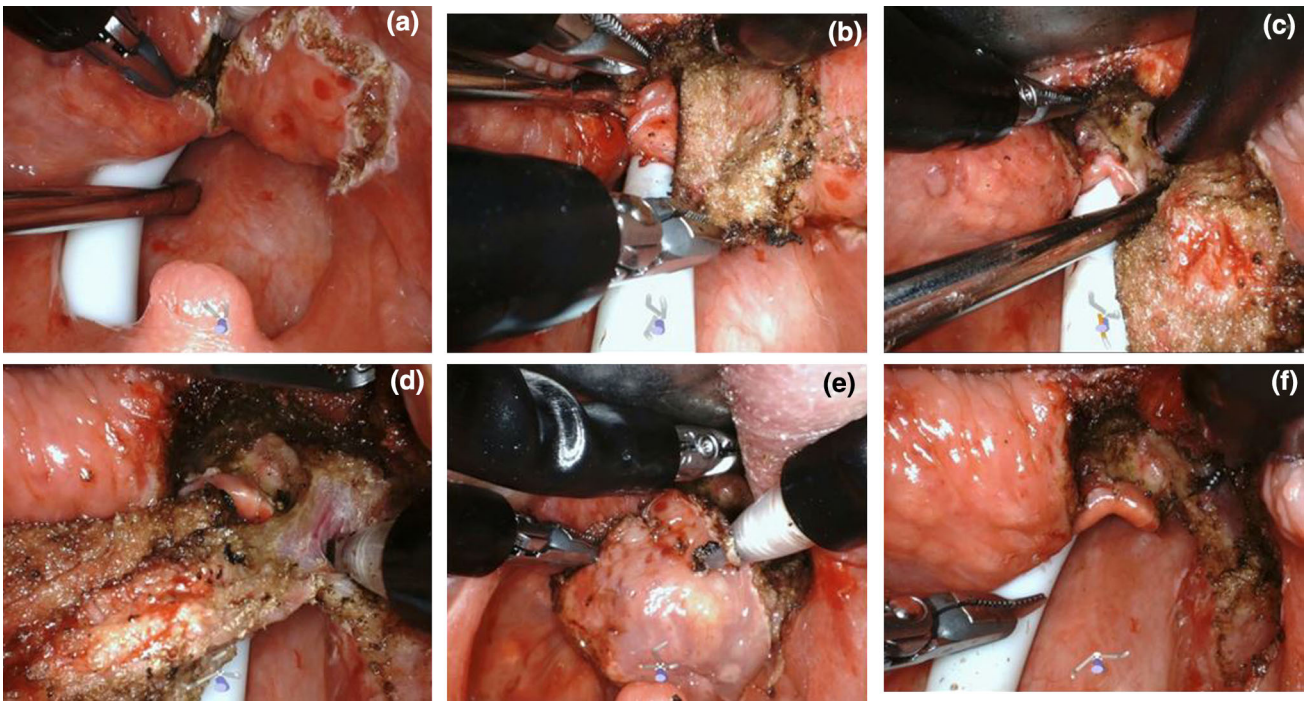

FIG. 3 a–d Transoral robotic lateral oropharyngectomy using the DaVinci SP. First, the pterygomandibular raphe is excised to identify the median pterygoid muscle and the parapharyngeal fat pad. The soft palate and the posterior pharyngeal wall then are excised, and the dissection proceeds along the prevertebral fascia. **e**, **f** Transoral robotic tongue base resection using the DaVinci SP system

retractor to expose the hypopharynx. Before surgery, the "cobra"-shaped location of endoscope was used to ensure the proper exposure angle and optimal visualization of the surgical site. Using this characteristic of the DaVinci SP system, the superior view of the hypopharyngeal lesion could be obtained compared with the view of the DaVinci Si or Xi (Fig. 4a). Hypopharyngeal resection then was performed in a fashion similar to the previously reported method.

Treatment of the Neck

In the absence of pathologic nodal disease, elective selective neck dissection (SND) was performed. If pathologic nodal disease was present, modified radical neck dissection (mRND) was performed. All patients underwent neck dissection in a single TORS session, which was performed before TORS.

Treatment with Adjuvant Therapy

Adjuvant therapy was performed for patients with advanced neck disease (N2, N3), a positive margin, extracapsular spread, and perineural invasion or angioinvasion.

Statistical Analysis

An independent two-sample t test was used to assess differences in continuous variables between the two independent groups. A p value lower than 0.05 indicated statistical significance. Statistical analyses were performed using SPSS 18.0 for Windows (SPSS, Chicago, IL, USA).

RESULTS

Ability to Perform TORS Using the DaVinci SP System

After application of the FK retractor to open the mouth, two or three instrument arms were inserted into the mouth through a single port. For the patients with oropharyngeal cancer, the fourth arm usually was inserted through the single cannula to retract surrounding tissue and expose the lesion appropriately. Unlike the DaVinci Si and Xi systems, the DaVinci SP system enabled use of three robotic instrument arms to perform TORS. In laryngeal and hypopharyngeal surgeries, the superior view of the surgical filed could be obtained by adjusting the location and axis of the endoscopic arm. Because the surgeon could control the endoscopic arm's joggle joint by using the navigation system, the surgical view of the field could be obtained optimally according to the process of the operation. Using the joggle joint of the endoscope and the third robotic arm,

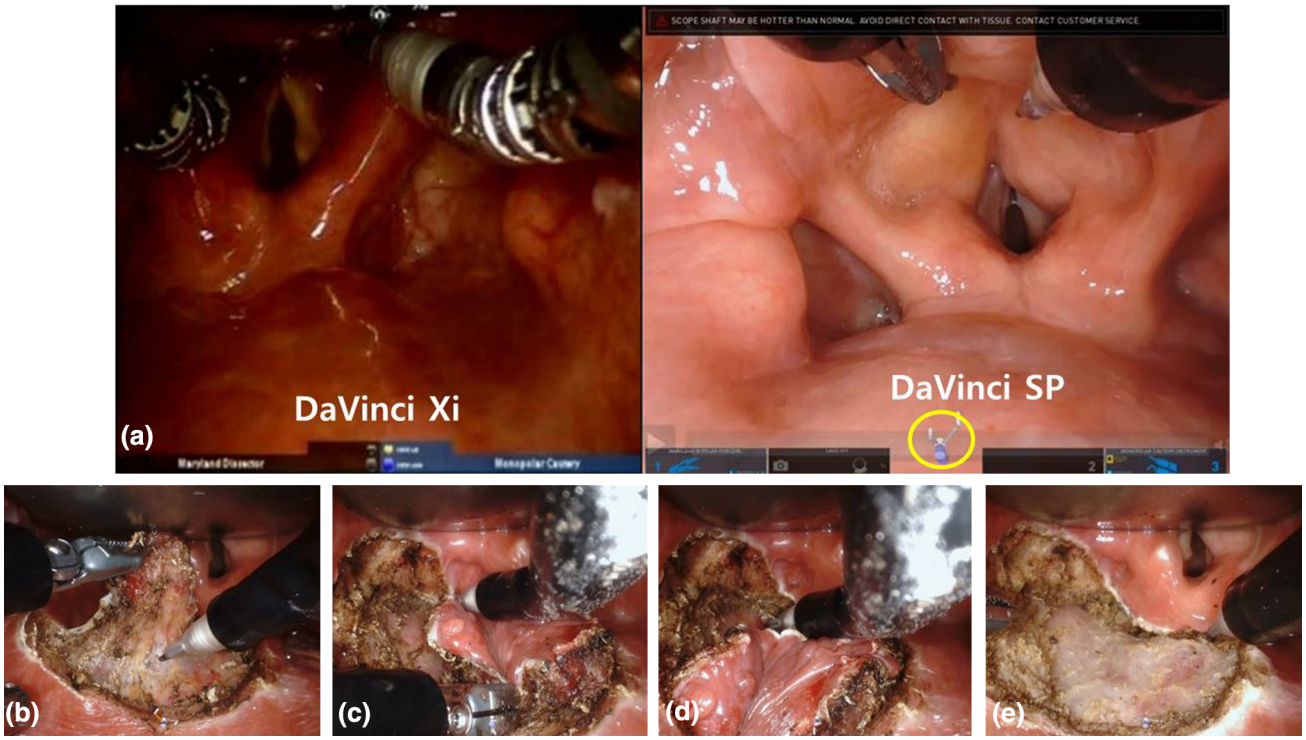

FIG. 4 **a** Surgical view of the hypopharyngeal lesion compared between the two systems. With the DaVinci SP system, the two joggle joints of the endoscopic arm can be adjusted according to the situation. It can approach the lesion closely, and the superior view of the surgical field can be obtained. **b–e** Transoral robotic hypopharyngectomy using the DaVinci SP system. *Yellow circle:* navigation display

we were able to expose the pyriform sinus and posterior pharyngeal wall appropriately, allowing for complete dissection of the lesion (Fig. 4).

All the patients in this study successfully underwent TORS. There was no case of conversion to operation due to a technical issue or severe bleeding.

Advantages and Disadvantages of the DaVinci SP System in Performing TORS

The single-port system, with two or three robotic arms and one endoscopic arm inserted through a single port, was more convenient to set up for performing TORS than the previous Si or Xi robotic system. Insertion of all the robotic arms through a single port decreased the complexity of the work space around the patient's head and made it easier for the operative assistant or nurse to approach the patient during surgery. Furthermore, the two joggle joints of the robotic arm allowed for freer movement within the narrow and bent pharyngeal lumen.

The DaVinci SP system provides a navigation system for the surgeon to adjust the position and angle of the endoscopic arm while seated in the console. The image displayed on the lower part of the screen can be used to show the three-dimensional position of the instrument arms and the endoscope arm, helping the surgeon to apprehend the orientation of the entire robotic system. Because the endoscope arm of the DaVinci SP system has two joggle joints, adjustment of the axis and position of the joggle joint in accordance with the operative procedure helps to obtain an optimal view of the surgical field (Fig. 4a).

However, DaVinci SP system also has several limitations that need improvement. Although the DaVinci SP system is more suitable for a long narrow working space, a cannula should be placed 10 cm from the oral cavity for performance of TORS. This means that the DaVinci SP system is not designed for transoral surgery. Also, the diameter of the single port into which all the robotic arms are inserted is approximately 2.5 cm, and the diameter of each robotic arm is 6 mm, but the arm diameter should be smaller for easier access to the deep narrow larynx or hypopharynx.

In addition, the types of robotic devices that can be installed and used with the DaVinci SP system are limited, so it is necessary to develop various surgical instruments for performing TORS. An advanced energy device, such as a harmonic device, is not available with the DaVinci SP system.

Operative Data Including Setting Time and Operation Time

The mean setting time for the patients who underwent TORS using the DaVinci SP was 8.04 ± 4.62 min, and their mean operation time was 56.95 ± 30.0 min. Meanwhile, for the 30 patients who underwent TORS using the DaVinci Si system, the mean setting time was 13.04 ± 8.91 min, and the mean operation time was 107 ± 44 min.

Through statistical analysis, we found a significant decrease in the setting time ($p = 0.002$) and operation time ($p < 0.001$) when the DaVinci SP system was used to perform TORS compared with the DaVinci Si system. When we compared the extent of mouth opening between the DaVinci SP group and the DaVinci Si group, we found no significant differences between the two groups (3.9 vs 4.1 cm).

Treatment Outcomes

We tried to obtain a clear margin in all the patients, and we the confirmed margin status through intraoperative frozen section. When necessary, additional resection was performed to obtain a clear margin. Of the 35 patients, 6 showed a positive margin in the permanent pathologic examination after the operation, and the remaining 29 patients showed a clear margin. Adjuvant therapy was performed for 26 patients with adverse pathologic features. The treatment outcomes for the patients are summarized in Table 2.

Perioperative Complications and Blood Loss

Postoperative bleeding occurred for one patient with tonsillar cancer and was managed using bipolar cautery with the patient under general anesthesia. When performing tongue base resection or hypopharyngectomy, we prophylactically ligated the lingual artery or superior laryngeal artery in the neck, and this was helpful in preventing significant bleeding during the operation. Also, we experienced no significant bleeding during the postoperative period in this study. We found no other significant complication related to the operation in this study. The average volume of blood loss during surgery was 126.5 mL, and no transfusions due to severe bleeding were needed. All surgical sites underwent secondary healing without special reconstruction, and complications such as wound infection did not occur.

Functional Outcomes

The indications for elective tracheotomy are laryngeal or hypopharyngeal cancer with the risk of airway obstruction after surgery and a high risk of postsurgical bleeding after wide resection of the lesion. Nasotracheal

TABLE 2 Treatment outcomes according to primary tumor sites

Variables	Patients		
	Larynx cancer ($n = 7$) *n* (%)	Hypopharynx cancer ($n = 7$) *n* (%)	Oral cavity and oropharynx cancer ($n = 22$) *n* (%)
Margin status			
Negative	5 (71)	5 (71)	20 (91)
Positive	2 (29)	2 (29)	2 (9)
Extranodal spread			
Yes	1 (14)	4 (57)	8 (36)
No	6 (86)	3 (43)	14 (64)
Lymphovascular invasion			
Yes	1 (14)	2 (29)	3 (14)
No	6 (86)	5 (71)	19 (86)
Perineural invasion			
Yes	1 (14)	3 (43)	1 (5)
No	6 (86)	4 (57)	21 (95)
Adjuvant therapy			
CCRTx	3 (43)	6 (86)	13 (59)
RTx	1 (14)	0 (0)	4 (18)
Surgery alone	3 (43)	1 (14)	5 (23)

CCRTx concurrent chemoradiotherapy, *RTx* radiotherapy

intubation was performed intraoperatively for the patients who underwent surgery for an oropharyngeal tumor. None of these patients experienced airway obstruction due to airway edema or postsurgical bleeding. In the case of hypopharyngeal carcinoma, a transient tracheostomy was performed to lessen the risk of postsurgical airway obstruction, and the average time to decannulation was 28 days or less. The average time to initiation of oral ingestion was 11 days or less after surgery. The average hospital stay was 23.3 days.

DISCUSSION

Previous studies on the feasibility of TORS using the DaVinci SP system have been performed with cadavers, but this was the first human trial to evaluate the system's feasibility and safety in treating patients with head or neck cancer including oropharynx, larynx, and hypopharynx cancer.[6–8] During the course of this study, 41 patients with oropharyngeal, laryngeal, and hypopharyngeal cancer successfully underwent surgery, with no cases of early termination due to severe bleeding or technical issues.

To set up the DaVinci SP system for TORS, the surgical bed and the patient's cart were placed at a right angle to one another, and the cannula was placed approximately 10 cm from the mouth, which allowed the robotic arms to be inserted into the mouth without colliding. Using the joggle joint of the robotic arms and the endoscope allowed for easy insertion and movement of the instrument within the confined working space.

Generally, the larynx and hypopharynx are narrower and deeper than the oropharynx, so insufficient visual field and limited working space might be obstacles in performing transoral surgery using the endoscope or surgical robot through the oral cavity. However, due to the technical advantages of the DaVinci SP system such as flexibility of the robotic arms and endoscope as well as insertion of robotic arms through a single port, it was possible to obtain superior visualization of the surgical site of the laryngo-hypopharynx and perform geometric resection of laryngeal and hypopharyngeal cancers with fine tissue manipulation.

We found that the DaVinci SP system had many advantages over the DaVinci Si and Xi systems in the performance of TORS. In performing transoral surgery, it is very important to ensure adequate exposure and visualization of the lesion, and to obtain the space required for proper movement of surgical tools. If these preconditions are not satisfied, the surgery may be terminated incomplete, with residual disease.

The flexible instruments mounted on the single port of the DaVinci SP system have two joggle joints, allowing up to three robotic arms to be inserted and manipulated within the long narrow working space of the pharyngeal lumen. Also, the single-port system of the DaVinci SP allows robotic arms to be inserted into the mouth with less opening.[4,5] The system also has a binocular stereoscopic endoscopic arm and a built-in digital zoom function that provides a 2× or 4× magnified view. In addition, if the endoscope arm is made into a "cobra shape" due to the two joggle joints of the endoscopic arm itself and positioned upside down, it can provide a superior view, especially of the larynx and hypopharynx.

During TORS using the DaVinci SP system, a third instrument arm can be inserted through the oral cavity, and this is very useful for providing counter-traction of the surrounding mucosa during dissection of the tongue base area to ensure proper vision of folded or hidden mucosa around the glossopharyngeal sulcus. When the oropharynx is dissected, retraction of the surrounding folded mucosa using a third arm may maximally expose the tongue base area. Furthermore, all the instrument arms and the endoscope are inserted into the oral cavity through the single cannula, making the working space around the patient's head less complex. As a result, the operative assistant and nurses can access the patient more comfortably during the surgical procedure.

However, the DaVinci SP system also has drawbacks that need improvement. When using the DaVinci SP system, we still used Crowe Davis, Dingman, and FK retractors to expose the lesion for TORS. In oropharyngeal surgery, it is relatively easy to obtain a sufficient field of view using any retractor, but an optimized retractor has not been developed that exposes the larynx or hypopharynx and secures the workspace for performing TORS for patients with laryngo-hypopharyngeal lesions. Thanks to the flexibility of the robotic arms of the DaVinci SP system, it is much easier to access the larynx and hypopharynx through the oral cavity, but a challenge still exists in some cases. Also, in this study, Maryland forceps, monopolar cautery, and Prograsp forceps could be used to perform TORS using the DaVinci SP, but more sophisticated and various surgical tools should be developed for more complicated surgeries.

CONCLUSION

Our experience using the DaVinci SP system to perform TORS confirmed that it provides technical advantages above the Si and Xi systems for performing TORS. It was especially helpful for ensuring proper visualization of the surgical field and performing precise surgery during operations on the laryngeal or hypopharyngeal lesion. In future studies, it will be important to ascertain how much these

technical advantages improve treatment outcomes for patients with head and neck cancer who undergo TORS using the DaVinci SP system.

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