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ORIGINAL

EVALUATION OF ORVIL ANASTOMOSIS TECHNOLOGY IN ESOPHAGEAL CANCER SURGERY: IMPLICATIONS FOR POSTOPERATIVE RECOVERY AND PHYSICAL REHABILITATION OUTCOMES

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ABSTRACT

Objective: To evaluate the application and safety of the Through-Mouth Nail Anvil Head Conveying System (Orvil) anastomosis technology in esophageal cancer treatment and its implications for postoperative recovery and physical rehabilitation. **Methods:** A retrospective analysis was conducted on 91 esophageal cancer patients treated with Orvil anastomosis technology between 2019 and 2022 (research group) and compared with 52 patients treated with traditional anastomosis between 2011 and 2013 (control group). Key surgical indicators, lymph node dissection, and postoperative safety outcomes were analyzed, with a focus on factors influencing physical recovery and rehabilitation potential. **Results:** There was no significant difference in gender or TNM staging between the groups ($P > 0.05$), but significant differences were observed in age and tumor location ($P < 0.05$). The research group experienced significantly shorter operation and hospitalization times and reduced total postoperative drainage volume compared to the control group ($P < 0.05$). However, chest tube indwelling time was longer in the research group ($P < 0.05$). Intraoperative blood loss and postoperative discharge time did not differ significantly between groups ($P > 0.05$). The research group had a significantly higher number of lymph node dissections ($P < 0.05$), while the number of positive lymph nodes was similar ($P > 0.05$). Complications in the research group included recurrent laryngeal nerve injury (1.10%), chylothorax (1.10%), anastomotic leakage (1.10%), respiratory complications (12.09%), and other

complications (13.19%), with an overall complication rate of 28.57%. In the control group, the overall complication rate was 21.15%, with no statistically significant difference between the groups ($P > 0.05$). **Conclusion:** Orvil anastomosis technology is a feasible and relatively safe surgical approach for esophageal cancer, offering significant advantages in shorter operation and hospitalization times, reduced postoperative drainage, and more thorough lymph node dissection. These benefits contribute to enhanced early postoperative recovery, potentially improving patients' ability to engage in physical rehabilitation and maintain functional capacity. Further research should explore the long-term impacts of this technology on physical activity and overall quality of life, particularly in the context of sports and exercise rehabilitation programs.

KEYWORDS: Anastomotic Technology of the Transoral Anvil Conveying System; Esophageal Cancer; Safety

1. INTRODUCTION

Esophageal cancer is a significant global health challenge, often associated with poor prognosis and complex treatment modalities. Surgical resection remains a primary treatment option, but it is a procedure that demands precision and is often accompanied by postoperative complications, prolonged recovery periods, and significant impacts on patients' physical function (Ashok et al., 2020; Nomura et al., 2021).. The integration of advanced surgical technologies that enhance safety, reduce complications, and promote faster recovery is crucial, especially for facilitating early physical rehabilitation and functional restoration. In recent years (Sung et al., 2021), the Through-Mouth Nail Anvil Head Conveying System (Orvil) anastomosis technology has emerged as an innovative surgical approach in the treatment of esophageal cancer (Uhlenhopp, Then, Sunkara, & Gaduputi, 2020; Zeng et al., 2018). By enabling minimally invasive anastomosis with enhanced precision, Orvil technology has demonstrated potential in reducing operative time and improving surgical outcomes. While its clinical safety and efficacy have been documented, its implications for postoperative recovery, including aspects critical to physical rehabilitation and the resumption of activity, warrant further exploration. Postoperative recovery is a critical period for patients with esophageal cancer, as it often dictates their ability to regain physical strength, mobility, and overall quality of life. Early initiation of physical rehabilitation is essential to prevent complications such as muscle deconditioning, reduced respiratory function, and diminished capacity for physical activity. Surgical innovations like Orvil not only hold promise for improving clinical outcomes but also for accelerating the recovery process, enabling patients to re-engage in physical activity and rehabilitation programs more effectively. (Ashok et al., 2020; Fabbi, Hagens, van Berge Henegouwen, & Gisbertz, 2021; Watanabe et al., 2020). However, due to the oral insertion of anvil, there may be esophageal

mucosal injury and thoracic infection. Studies have found that (Hosoda et al., 2019; Tokuhara et al., 2019), Orvil anastomosis technology can play an important role in the treatment of gastric cancer. In this research, patients with esophageal cancer who were diagnosed and treated in our hospital were selected and treated with Orvil anastomosis technology, in order to explore its related role in esophageal cancer and provide certain references for the treatment of clinical diseases.

2. Data and Methods

2.1 General Data

A retrospective analysis of 91 patients with esophageal cancer treated in our hospital from 2019 to 2022 was performed, and these patients were selected as the research group, and 52 patients with esophageal cancer treated in our hospital from 2011 to 2013 were selected as the control group. Among them, there were 69 males and 22 females in the study group, with an average age of (66.26 ± 8.06) years. There were 43 males and 9 females in the control group, with an average age of (62.35 ± 7.35) years. Inclusion criteria: ① All patients met the diagnosis and treatment guidelines for esophageal cancer (LeBlanc, Takahashi, Huston, Shridhar, & Meredith, 2023) and were confirmed by pathological examination; ② Patients with relatively high degree of cooperation in surgical research; ③ The patients and their family members gave informed consent, and signed on the informed consent; ④ Patients with no previous history of esophageal cancer or surgery. Exclusion criteria: ① Patients with abnormal coagulation function; ② Patients with infectious diseases such as hepatitis B; ③ Patients who were in pregnancy or lactation; ④ Patients with obvious abnormalities of cardiac function or liver and kidney function.

2.2 Methods

Patients were fasting for 10 hours and drinking for more than 4 hours before operation, and gastric contents were emptied. The control group was treated with traditional anastomosis. The operation steps were as follows:

1. After the anesthesia was satisfactory, took the head high and foot low about 15 degrees, and routinely disinfected the towel.
2. A 1cm small incision under the umbilicus was made, punctured the abdominal cavity with a pneumoperitoneum needle, and filled carbon dioxide to produce pneumoperitoneum.
3. A 12mm trocar was placed 1cm below the abdominal umbilicus as the observation hole. A 12mm trocar was placed 3cm near the right umbilicus as the main operation hole. A 5mm trocar was placed 3cm near the left umbilicus, under the right costal arch and under the xiphoid process as the auxiliary operation hole. The ultrasonic scalpel was set, ultrasonic scalpel

was used to clean the greater and lesser omentum, free the whole stomach and abdominal esophagus, skeletonize the three branches of the abdominal trunk, the common hepatic artery, the left gastric artery and the splenic artery, and the left gastric artery was cut off after clamping with Homo lock, and paid attention to protecting the right gastroepiploic artery. The lesser curvature of stomach 3cm above the pyloric canal was treated with Johnson & Johnson 60 intraluminal stapler (ecr60d) to form most of the tubular stomach, and the seromuscular layer was sutured under the microscope. 4. One abdominal drainage tube was indwelt and each incision was closed. 5. Then the left half prone position was taken, and routine skin disinfection and towel laying were performed. 6. A 12mm trocar was placed at the anterior axillary line of the 6th intercostal line of the right chest as the observation hole, a 5mm trocar was placed at the 5th intercostal line of the lateral scapular line of the right chest and the 4th intercostal line of the anterior axillary line, and a 12mm trocar was placed at the 9th intercostal line of the posterior axillary line of the right chest as the operation hole. The esophagus was carefully dissected out, dissected the azygos vein after occlusion with Homo lock, and dissociated the esophagus from the top of the chest to the diaphragm hiatus. 7. The fourth intercostal operation hole was extended to 3.5cm, the esophagus was sutured with a purse string with 7 sutures at the position 5cm away from the edge of the tumor, cut the esophagus, sterilized it and sent it to the mushroom head of the CDH25 tubular stapler, tightened the suture and tied it with a knot pusher. After transection of the esophagus, the tubular stomach was lifted to the outside of the thoracic cavity to remove the lesser curvature of the stomach, gastric fundus and diseased esophagus. The stapler was inserted, the central rod was inserted into the hole of the stapler host, and screwed it to the scale position, so that the posterior wall of the gastric body and the esophageal stump could be completely closed together, and then held the handle to strike successfully.

The proximal gastric body was closed with Johnson & Johnson 60 intracavitary stapler (ecr60b). 8. The gastric tube was inserted, two thoracic drainage tubes were indwelt, and the chest was closed layer by layer. The study group was treated with Orvil anastomosis technology (Yu et al., 2017). Operation steps: after general anesthesia, the patients were taken to the flat position, the routine abdominal disinfection and towel laying were performed, pneumoperitoneum was established, and the card was placed in the same position as the control group. Ultrasonic scalpel was set, and ultrasonic scalpel was used to clean the greater and lesser omentum and free the whole stomach, skeletonize the three branches of the celiac trunk, the common hepatic artery, the left gastric artery and the splenic artery, and the left gastric artery was cut off after clamping with Homo lock, and paid attention to protecting the right gastroepiploic artery. Then, cut 1/2 of the right diaphragmatic foot, cut 1 circle of the phrenic esophageal ligament, continued to free the esophagus to the lower edge of the lower pulmonary vein in the direction of the chest, 1

abdominal drainage tube was indwelt, and sutured the abdominal incisions. And changed to the left lying position, conventional disinfection and towel laying were performed, and a 1cm endoscopic hole was made at the back of the 8th intercostal line on the right posterior line, 2cm auxiliary operation holes were respectively made at the 3rd intercostal line on the right axillary midline and the 5th intercostal line on the right anterior line, and a 2.5cm main operation hole was made at the 7th intercostal line on the side of the shoulder and spleen. The esophagus was acutely dissociated along the long axis to the entrance of the thorax.

The azygos vein was dissected after occlusion with Homo lock. The esophagus was transected with the EC60-3.5 linear cutting suture device 5cm away from the upper edge of the tumor, and the CEEA25 stapler anvil was placed through the mouth for standby. Nondestructive injury oval forceps lifted the lower esophagus, lifted the stomach to the thoracic cavity, and then cut off the esophagus at the cardia to remove the tumor. The CEEA25mm stapler host was inserted from the cardiac stump, and the esophagogastric end-to-side anastomosis was performed at the top of the chest. The cardiac stump was removed with EC60-3.5 cutting stapler. Gastric tube was placed during operation. 3-0 non-invasive suture was used to sew 3 stitches to fold the lesser curvature of the stomach to make a non-cutting tubular stomach. The anastomotic stoma was fixed at the top of the chest, and the stomach body was fixed at the same level of the chest wall. Two drainage tubes were indwelt and each incision was sutured in turn.

2.3 Observation Indicators

(1) The operation related indicators of patients in the two groups were compared, including the total operation time, intraoperative blood loss, postoperative total drainage volume, ICU indwelling time, chest tube indwelling time, length of stay, and postoperative discharge and others. (2) The lymph node dissection of the two groups was analyzed, including the number of lymph nodes and the positive number of lymph nodes. (3) The postoperative safety of the two groups was observed, including the occurrence of recurrent laryngeal nerve injury, tracheal injury, chylothorax, anastomotic leakage, respiratory complications, cardiac complications, and other complications.

2.4 Statistical Methods

The adverse reactions and other count data in this research were expressed in [cases (%)], using χ^2 inspection. The measurement data were tested by normal distribution, which were in line with normal distribution, and the measurement data were in the form of $(\bar{x} \pm s)$. The measurement data between the two groups were tested by t test. Spss22.0 software was used for statistical data analysis in this research, and the statistical results of $P < 0.05$

were regarded as statistically significant difference.

3. Results

3.1 Clinical Data of the two Groups

The difference in gender and TNM staging between the two groups was not statistically significant ($P > 0.05$), but the difference in age and tumor location between the two groups was statistically significant ($P < 0.05$). See Table 1

Table 1: Comparison of two Groups of General Data

GROUPING	RESEARCH GROUP (N=91)	CONTROL GROUP (N=52)	X ² /T	P
AGE (YEARS)	66.26 ± 8.06	62.35 ± 7.35	2.880	0.005
SEX (%)				
MALE	69 (75.82)	43 (82.69)	0.148	0.700
FEMALE	22 (24.18)	9 (17.31)		
TUMOR LOCATION (%)			7.301	0.026
IN	69 (75.82)	30 (57.69)		
LOWER	21 (23.08)	18 (34.62)		
LOWER-MIDDLE	1 (1.10)	4 (7.69)		
TNM STAGING (%)			7.016	0.071
I	23 (25.27)	10 (19.23)		
II	28 (30.77)	14 (26.92)		
III	37 (40.66)	20 (38.46)		
IV	3 (3.30)	8 (15.38)		

3.2 Analysis of Operation Related Indicators of the two Groups

Compared with the control group, the total operation time and length of stay of the study group were significantly shorter, and the total postoperative drainage volume was significantly less ($P < 0.05$). Compared with the control group, the chest tube indwelling time of patients in the study group was significantly longer ($P < 0.05$). The difference in intraoperative blood loss and postoperative discharge time between the two groups was not statistically significant ($P > 0.05$). See Table 2 and Figure 1 for details.

Table 2(a): Comparison of operation related indicators between the two groups ($\bar{x} \pm s$)

OPERATION RELATED INDICATORS	RESEARCH GROUP (N=91)	CONTROL GROUP (N=52)	T	P
TOTAL OPERATION TIME (MIN)	251.60 ± 57.34	316.29 ± 52.21	6.700	< 0.001
INTRAOPERATIVE BLOOD LOSS (ML)	135.16 ± 185.61	113.33 ± 101.55	0.783	0.435
TOTAL POSTOPERATIVE DRAINAGE VOLUME (ML)	2168.32 ± 1115.60	2662.86 ± 1678.00	2.113	0.036
ICU RETENTION TIME (D)	0.12 ± 0.75	0.00 ± 0.00	/	/

Table 2(b): Comparison of operation related indicators between the two groups ($\bar{x} \pm s$)

OPERATION RELATED INDICATORS	RESEARCH GROUP (N=91)	CONTROL GROUP (N=52)	T	P
INDWELLING TIME OF CHEST TUBE (D)	10.3 ± 3.07	8.86 ± 3.91	2.438	0.016
LENGTH OF STAY (D)	23.15 ± 5.08	25.29 ± 5.39	2.370	0.019
DISCHARGED SEVERAL DAYS AFTER OPERATION (D)	14.04 ± 4.65	13.14 ± 4.45	1.131	0.260

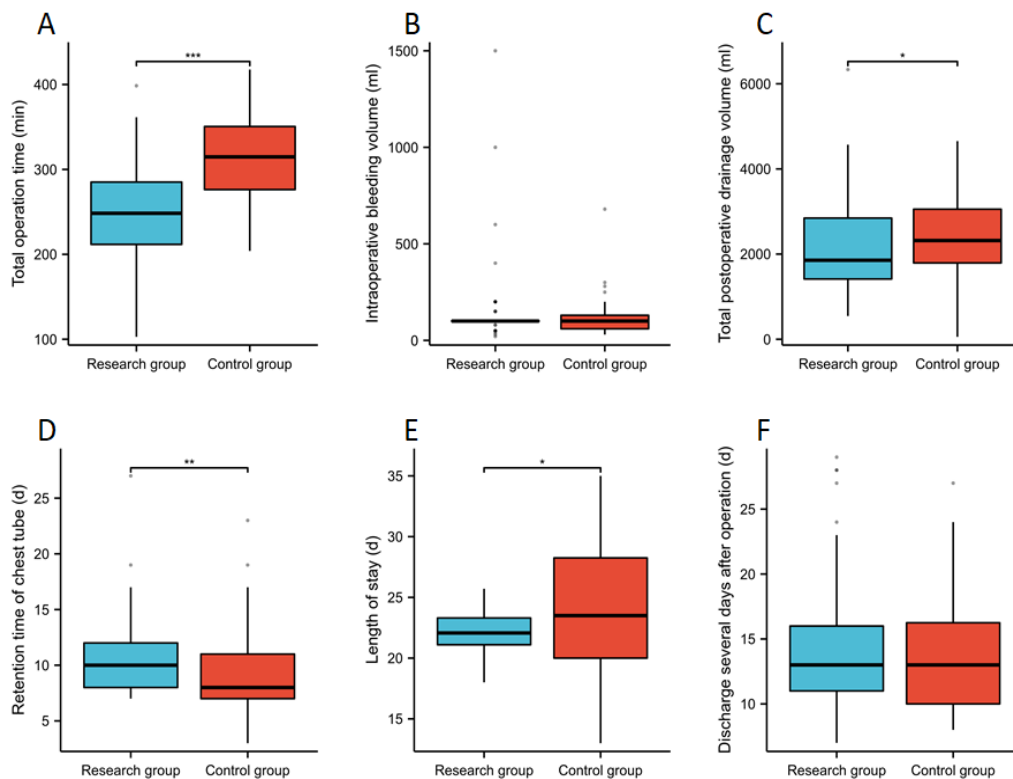


Figure 1: Comparison of operation related indicators between the two groups. A: Comparison of the total operation time of the two groups; B: Comparison of intraoperative blood loss between the two groups; C: Comparison of the total drainage volume between the two groups; D: Comparison of the indwelling time of chest tube between the two groups; E: Comparison of the length of hospital stay between the two groups; F: Comparison of postoperative hospital stay between the two groups

Note: * indicates $P < 0.05$, ** indicates $P < 0.01$, *** indicates $P < 0.001$

3.3 Analysis of two Groups of Lymph Node Dissection

Compared with the control group, the number of lymph node dissection in the study group was significantly increased ($P < 0.05$), and the difference in the number of positive lymph nodes between the two groups was not statistically significant ($P > 0.05$). See Table 3 and Figure 2 for details.

Table 3: Comparison of Lymph Node Dissection between the two Groups ($\bar{x} \pm s$)

GROUPING	NUMBER OF CASES	NUMBER OF LYMPH NODES REMOVED	NUMBER OF POSITIVE LYMPH NODES
RESEARCH GROUP	91	25.48 ± 9.04	1.57 ± 2.96
CONTROL GROUP	52	20.29 ± 9.03	2.43 ± 3.27
T		3.304	1.608
P		< 0.001	0.110

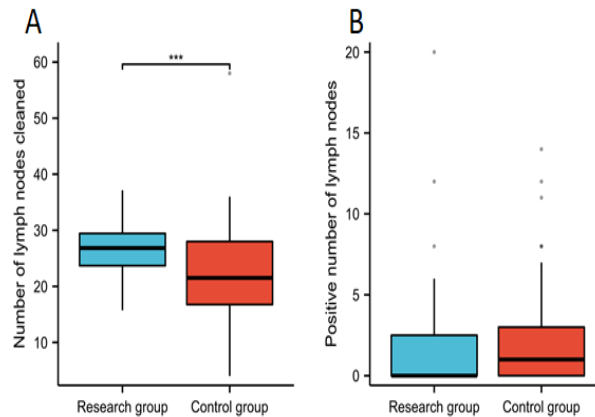


Figure 2: Comparison of Lymph Node Dissection between the two Groups. A: Comparison of the number of dissected lymph nodes between the two groups; B: Comparison of positive number of lymph nodes between the two groups

Note: *** indicates $P < 0.001$

3.4 Analysis of Postoperative Safety between the two Groups

In the study group, there were 1 cases of recurrent laryngeal nerve injury (1.10%), 1 case of chylothorax (1.10%), 1 cases of anastomotic leakage (1.10%), 11 cases of respiratory complications (12.09%), 12 cases of other complications (13.19%), with a total incidence of complications of 28.57%. In the control group, there were 1 cases of anastomotic leakage (1.92%), 5 cases of respiratory complications (9.62%), and 5 cases of other complications (9.62%), with a total incidence of complications of 21.15%. The difference between the two groups was not statistically significant ($P > 0.05$). See Table 4 and Figure 3 for details.

Table 4: Analysis of Postoperative Safety between the two Groups [cases (%)]

COMPLICATIONS	RESEARCH GROUP (N=91)	CONTROL GROUP (N=52)	X ²	P
INJURY OF RECURRENT LARYNGEAL NERVE	1 (1.10)	0 (0.00)	0.576	0.448
TRACHEA INJURY	0 (0.00)	0 (0.00)	/	/
CHYLOTHORAX	1 (1.10)	0 (0.00)	0.576	0.448
ANASTOMOTIC FISTULA	1 (1.10)	1 (1.92)	0.163	0.686
RESPIRATORY COMPLICATIONS	11 (12.09)	5 (9.62)	0.204	0.652
CARDIAC COMPLICATIONS	0 (0.00)	0 (0.00)	/	/
OTHER COMPLICATIONS	12 (13.19)	5 (9.62)	0.403	0.526

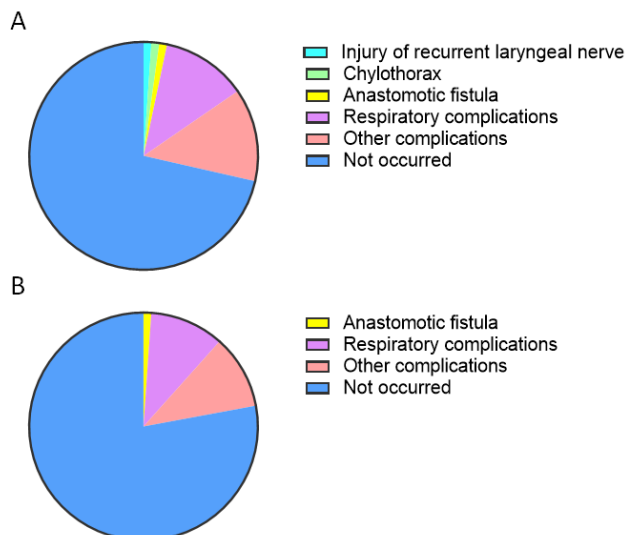


Figure 3: Analysis of Postoperative Safety between the two Groups. A: Research Group; B: Control Group

4. Discussion

Esophageal cancer is a common digestive tract tumor. A large number of patients with esophageal cancer will be added every year in the world, and its incidence and mortality vary greatly among countries. The incidence in western countries such as the United States and Europe is significantly lower than that in Asia and Africa. China is one of the high incidence areas of esophageal cancer in the world. Due to the progress of management and treatment, the 5-year survival rate of patients with esophageal cancer has improved in recent years, but the overall prognosis is still relatively poor. For patients with locally advanced esophageal cancer, esophagectomy is the best chance to cure, which plays an important role in achieving local regional control and reducing the mortality of patients with esophageal cancer (Bedirli, Salman, Nasirov, & Dogan, 2017; Jajosky & Elliott, 2022; Magouliotis et al., 2022). The reconstruction of esophagus by using part of intestine or stomach is a relatively good method for the treatment of esophageal cancer (Qiu, you, Wang, Cao, & Lyu, 2020 Jan 69; Wei & Friedland, 2021). Esophageal cancer resection includes open and minimally invasive methods. Traditional esophageal cancer surgery often requires "thoracotomy, laparotomy, and neck opening". It is the most complex operation in thoracic surgery and one of the most traumatic operations in surgery. This surgery has a great impact on patients' heart and lung function and a high degree of risk. Postoperative incision pain of patients is obvious and surgical complications are more common. But without surgery, patients' life and diet will also be affected, even life-threatening. While minimally invasive esophagectomy has been widely used in clinic because it can effectively reduce intraoperative blood loss and reduce patients' pain. Anastomotic technique is considered to be an important factor in postoperative

anastomotic leakage (Plat et al., 2021). Orvil anastomosis technology is a new method applied in recent years, which can fundamentally change the traditional esophageal gastric anastomosis technology. Orvil anastomosis technique is a relatively good method to complete esophagogastrostomy by implanting anvil through the mouth. It not only reduces the difficulty of high anastomosis, reduces surgical injury, but also simplifies the operation process without suturing the purse. Studies have found that (Cao, Liu, Yu, & Chai, 2023; Kang et al., 2018), Orvil anastomosis technology can effectively improve the technical feasibility and safety of esophageal gastric anastomosis. In addition, anastomotic leakage is one of the most serious complications after esophagectomy for esophageal cancer, and anastomotic stenosis and esophageal reflux are also common complications after esophagectomy. In a study (Foley et al., 2021; Hong et al., 2021; Lin et al., 2021 Dec 16), multivariate logistic regression analysis show that anastomotic technique and pulmonary infection are the independent factors of the occurrence of anastomotic leakage after surgery. In this research, patients were given traditional anastomosis technology and Orvil anastomosis technology in the treatment of esophageal cancer. The results showed Orvil anastomosis technology had better perioperative effects in the treatment of patients with esophageal cancer. The reason may be that Orvil anastomosis technology innovatively adopts the design of stapling anvil through the mouth. With the help of circular stapler, the anastomosis can be carried out quickly and safely, which improves the technical safety of esophagogastrostomy without additional suture, reduces the incidence of postoperative anastomotic leakage and others, shortens the length of stay and reduces the hospitalization expenses. The new improved Orvil anastomosis technology has been upgraded on the basis of the original Orvil anastomosis technology, and a guide traction line has been added at the head of the anvil, which is more maneuverable and convenient in the process of implantation. It provides the best choice for surgeons and patients. Lymph node metastasis is an important way of distant metastasis of esophageal cancer and one of the important factors affecting the prognosis of patients (Betancourt-Cuellar, Benveniste, Palacio, & Hofstetter, 2021; B. Xu et al., 2022). Cancer cells first enter the submucosal lymph nodes of the esophagus, cross the muscle layer and enter the regional lymph nodes draining the tumor site, thus affecting the prognosis of patients (Alcan, Ergin, keskin, & erdo, 2022 Jan 28; Chen et al., 2022). Therefore, reasonable lymph node dissection is not only conducive to accurate pathological staging, but also to improving the postoperative survival rate of patients. In this research, it was found that the number of lymph node dissections of patients in the research group was significantly increased, showing that Orvil anastomosis technology can perform more thorough lymph node dissection. It may be related to the more flexible, simple operation and clearer visual field exposure of Orvil anastomosis technology. Although the lung tissue is not removed in the operation of esophageal cancer, the integrity of chest wall and intercostal muscle is

damaged, especially the integrity of diaphragm. Due to the damage of lung ventilation exchange function, respiratory tract infection is easy to occur, and patients may have varying degrees of dyspnea and shortness of breath after the operation (Kanazawa et al., 2021). Recent studies have shown that (Latzko, Ahmed, & Awad, 2021; Q. xu, Li, Zhu, & Xu, 2020 Jul 6), among 2704 patients, about 28% had severe respiratory complications, 15% had pneumonia, and 7% had respiratory failure. Orvil anastomosis is a minimally invasive surgery, which can effectively avoid the pain caused by chest wall incision, and can avoid the reduction of the patients' respiratory depth, and can cause the weakness of sputum excretion or cough, damage the lung ventilation function, and prevent the effective sputum excretion, leading to the occurrence of respiratory complications. The findings of this study demonstrate that the Through-Mouth Nail Anvil Head Conveying System (Orvil) anastomosis technology is a safe and effective surgical approach for treating esophageal cancer. By reducing operation and hospitalization times, minimizing postoperative drainage, and enabling thorough lymph node dissection, Orvil technology offers significant advantages in promoting early recovery. Although the complication rates were comparable to traditional methods, the benefits of shorter recovery periods and enhanced surgical precision make Orvil a valuable tool in improving postoperative outcomes. These improvements have significant implications for physical rehabilitation and functional recovery in esophageal cancer patients. The accelerated recovery facilitated by Orvil technology provides a foundation for earlier initiation of physical activity and rehabilitation programs, which are essential for restoring strength, mobility, and overall quality of life. This aligns with the broader goals of sports and health sciences, emphasizing the importance of integrating advanced surgical techniques with rehabilitation strategies to optimize patient outcomes. Future research should explore the long-term impacts of Orvil-assisted surgeries on physical performance and quality of life, particularly in the context of sports and exercise-based rehabilitation. By bridging the gap between surgical innovation and recovery science, this approach has the potential to redefine the standard of care for patients undergoing esophageal cancer treatment.

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