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Comparison of the Efficiency and Safety of Three Kinds of Mucosal Resection Knives for Endoscopic Submucosal Dissection of Esophageal Lesions

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Abstract

Objective: To evaluate the safety and efficacy of a composite knife by comparing the dual knife, IT knife, and composite knife in the treatment of esophageal lesions. **Methods:** Patients from First Affiliated Hospital of Guilin Medical University and Liuzhou People's Hospital of Guangxi Medical University were selected as study subjects from May 2020 to May 2024. The patients were divided into three groups for surgery: 40 patients in the dual knife group, 40 patients in the IT knife group, and 40 patients in the composite knife group. The operation time, resection speed, complete resection rate, and complication rate of the three groups were compared. **Results:** The stripping speed was 22.80 ± 7.31 mm/min for the composite knife group, 19.20 ± 7.24 mm/min for the Dual-knife group, and 15.32 ± 6.2 mm/min for the IT knife group. The differences were statistically significant (t = 3.67, P = 0.03). The operation time for the composite knife group was 42.4 ± 19.79 min, which was significantly shorter than that for the dual knife group (66.21 ± 21.23 min) and the IT knife group (57.86 ± 24.61 min) (t = 2.67, P = 0.04). The operation time in the composite knife group was shorter than that in the dual knife group and the IT knife group. Additionally, the stripping speed was faster in the composite knife group than in the dual knife group and the IT knife group. The rates of whole piece excision and complete excision were similar in all three groups. The resection rate was similar among the three groups. One case of muscle layer injury (2.5%) occurred in each group. In the IT knife group, two cases of postoperative esophageal stenosis were reported, while in the dual-knife group and the composite knife group, one case of postoperative esophageal stenosis oc-

curred each. The difference was not statistically significant (P = 0.45). **Conclusion:** Compared with the dual knife and IT knife methods, the composite knife technique can shorten the operation time and increase the speed of resection for endoscopic submucosal dissection of esophageal lesions. It also offers certain advantages in terms of safety and effectiveness.

Subject Areas

Gastroenterology & Hepatology

Keywords

Gastroscopy, Endoscopic Resection, Mucotomy Knife, Esophageal Tumor

1. Introduction

With the rapid development of medical equipment and technology and the continuous updating of health concepts among the population, minimally invasive procedures have become a major focus of medical advancement. The indications for endoscopic surgery have been expanding, from initial endoscopic mucosal resection (EMR) to endoscopic submucosal dissection (ESD). In recent years, natural orifice transluminal endoscopic surgery (NOTES) has rapidly emerged and matured [1]-[4]. In recent years, NOTES has the advantages of a high complete resection rate, low recurrence rate, less pain, fast recovery, and low cost. It can achieve efficacy similar to that of traditional surgery. Endoscopic surgery has become progressively more challenging to perform and manipulate accurately, and the steps involved have become increasingly complex. This has led to new requirements for the precision, practicality, and versatility of surgical instruments. For lesions of different origins and natures, operators often need to choose the appropriate type of incision knife based on the level of the lesion, its adhesion to surrounding tissues, its location, and other factors. They may even need to switch between different incision knives to complete steps such as incision, stripping, electrocoagulation, or submucosal supplemental injections during the operation [5]-[7]. However, frequent intraoperative instrument changes not only complicate the surgery and extend the operation time but also impose an economic burden on patients. The endoscopic mucosal dissection knife (endoscopic mucosal electrosurgical dissection knife with a composite head) produced by Anrui Medical Devices (Hangzhou) can interchange the most commonly used IT knife group head and dual-knife head during endoscopic resection. It allows for submucosal injections to be administered at any point during surgery, enhancing surgical safety, reducing perioperative complications, and ultimately easing the financial burden on patients and society. In this study, a new multifunctional endoscopic electrosurgical resection knife was utilized to conduct simulated lesion resection experiments in isolated and living porcine gastrointestines. The safety and efficacy of this novel endoscopic electrosurgical resection knife were evaluated.

2. Materials and Methods

2.1. Main Instruments and Apparatus

Gastroscope (GIF260, Olympus, Japan), injection needle (Shanghai ADEN), high-frequency electrosurgical equipment (VIO-300S, ERBE, Germany). Main instruments and apparatus: gastroscope (GIF260, Olympus, Japan), injection needle (Shanghai ADEN, China), high-frequency electrosurgical equipment (VIO-300S, ERBE, Germany). The endoscopic mucosal electrosurgical cutter with composite tip (Anrui Medical Instruments, China) and two kinds of disposable mucosal cutters (Dual and IT cutter sets, Olympus, Japan) are detailed in Figures 1 and 2.

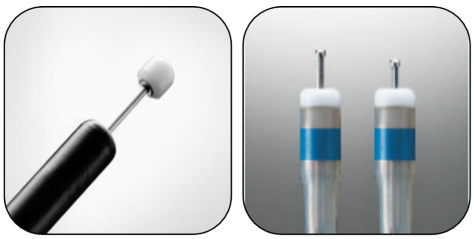

Figure 1. Schematic diagram of two mucotomy knives; A: Dual knife, B: IT knife.

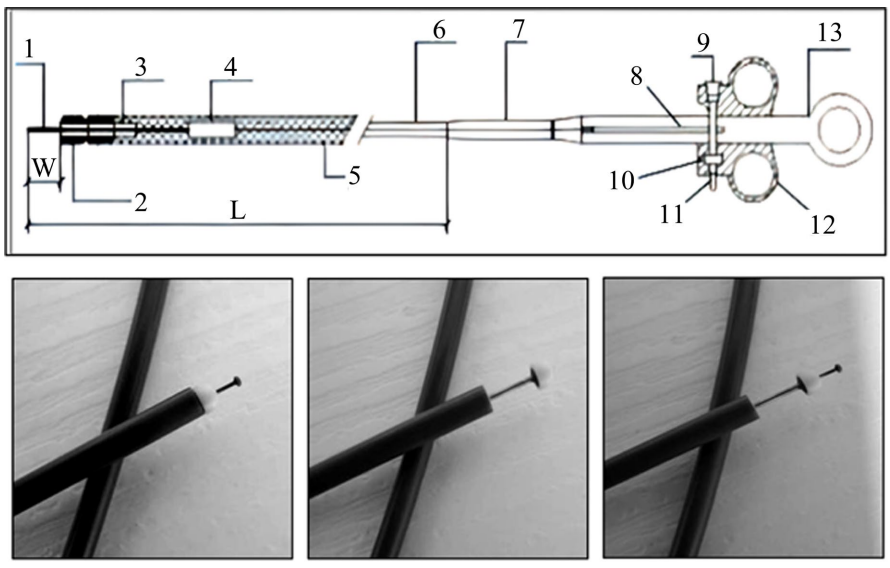

Figure 2. Schematic diagram of a multifunctional endoscopic subtotal electrosurgical cutter with a composite cutter head; structure of a multifunctional endoscopic subtotal electrosurgical cutter (1: cutter head; 2: insulated head; 3: stripping tube; 4: connecting tube; 5: tube sheath; 6: traction wire; 7: sheath tube; 8: pull rod; 9: mullion; 10: hexagonal nut; 11: electrical plug; 12: clamp ring; 13: handle; D: working outer diameter; W: needle outlet length; L: working length); different modes of the multifunctional endoscopic electrosurgical cutter with a composite tip.

2.2. Structure of the Endoscopic Submucosal Electrosurgical Cutter with a Composite Tip

The multifunctional endoscopic submucosal electrosurgical cutter with a compo-

site tip was manufactured by Anrui Medical Devices Co. The device is characterized by a working section located at one end, away from the operator. It has a hollow tube sheath structure with a connecting tube attached to a cutting knife. The cutting knife's end, away from the operator, is positioned at the outer opening of the tube sheath, away from the operator. The tube sheath's end features a movable stripping tube, which surrounds the cutting knife's outer periphery. An insulating head is located at the end of the stripping tube, away from the operator, and another insulating head is positioned near the operator. Additionally, a traction wire is situated within the tube sheath. One end of the stripping tube is connected to one end of the traction wire in the pipe sheath. The distance of the movable stripping tube extending from the pipe sheath is greater than or equal to the distance of the cutting knife extending from the pipe sheath. The part of the cutting knife that protrudes outside the opening at the end of the pipe sheath is called the cutter head. The cutter head is needle-shaped, commonly known as the dual cutter head. The insulating head, located at the outer edge of the stripping pipe, is hemispherical in shape. By pushing the handle forward, the insulating cutter head can move toward the needle cutter head. This mechanism is commonly referred to as the T cutter set head. When the insulated head is retracted, it is suitable for cutting in the needle-shaped Dual knife mode; when the insulated head is pushed to the needle-shaped head, it is suitable for peeling in the spherical IT knife group mode. Thus, the operator can adjust the two different incision knives at any time during the procedure based on the level and location of the lesion, as well as the cutting requirements (refer to **Figure 2**).

2.3. Basic Patient Data

A total of 120 patients who met the inclusion criteria were selected from May 2020 to May 2024, including 40 patients in the dual knife group, 40 patients in the IT knife group, and 40 patients in the composite knife group. Which were assigned cyclically by A (Dual knife), B (IT knife), and C (Composite knife), and within each block group, the assignment was strictly cyclic in the order of A→B→C→A→B→C (**Table 1**). The patients were selected from the Liuzhou People's Hospital affiliated with Guangxi Medical University and the First Affiliated Hospital of Guilin Medical University. All enrolled patients provided signed informed consent, and this study was approved by the First Affiliated Hospital of Guilin Medical University.

The inclusion criteria were as follows: (1) esophageal lesions such as mucosal muscular layer mesenchymal tumors; intermediate- to high-grade intraepithelial neoplasia; carcinoma in situ; intramucosal carcinoma; and carcinoma with partial involvement of the submucosal layer. (2) Patients whose biopsy or endoscopy confirms that they are amenable to endoscopic treatment and who meet the indications for ESD for esophageal lesions. (3) The size of the lesion was ≥ 2 × 2 cm. (4) Patients who understood and voluntarily signed the informed consent form.

The exclusion criteria for patients were as follows: (1) had clear progressive

esophageal cancer or obvious elevated or depressed lesions found under endoscopy; (2) had recurrent lesions or postoperative esophageal lesions that may cause obvious fibrosis; (3) had malignant tumors or other progressive diseases with a life expectancy of less than 6 months; (4) had abnormal coagulation function, such as thrombocytopenia or coagulation abnormalities caused by hematological system diseases, or were taking anticoagulant drugs such as aspirin; (5) had severe cardiac, hepatic or renal insufficiency; (6) had severe cardiac, hepatic or renal insufficiency; and (7) the selected cases excluded lesions at the esophageal inlet, esophagogastric junction.

Table 1. Basic information of patients who underwent endoscopic submucosal dissection with different tools.

Clinical data	Dual knife group	IT knife group	Composite knife group	Statistical value	P value
Male/Female	18/22	24/16	21/19	t = 1.51	0.12
Age (years, Mean ± SD)	61.09 ± 4.2	63.19 ± 3.2	62.11 ± 3.8	F = 0.29	0.74
Location of lesions (cases)				F = 1.30	0.89
Upper 1/3 of the esophagus	3	4	3		
Middle 1/3 of the esophagus	20	16	19		
Down 1/3 of the esophagus	17	20	18		
Extent of lesions (cases)				F = 1.51	0.28
≤Esophageal 1/2 week	26	25	22		
>Esophageal 1/2 week	14	15	18		
Lesion morphology (cases)				χ^2 = 5.55	0.62
flatten	17	14	10		
elevated	5	7	6		
sunken	12	15	14		
Complications (cases)				F = 0.02	0.95
high blood pressure	4	3	5		
diabetes	3	2	3		
COPD	2	2	1		

COPD: chronic obstructive pulmonary disease

3. Surgical Methods

3.1. Lesion Excision Procedure

All patients fasted for 8 hours before the operation, which was performed under tracheal intubation and general anesthesia. The operation was performed by three specialists who conduct more than 100 ESD operations per year, the operator is an associate director physician or above. Before the operation, the lesion site was subjected to gastroscopy using a special ESD transparent cap, and the esophageal

lesion was stained with Lugol's iodine. The dual knife group and IT knife were visible. Supplementary submucosal injections were administered during the peeling process if necessary to make the boundaries of the peeling range clearly visible. Composite Knife Group: A multifunctional endoscopic electrosurgical incision knife with a composite tip was used to perform the surgery (Figure 3). The specific operation steps were as follows: (1) marking and injection: similar to those used for the Dual Knife Group and the IT Knife Group; (2) circumferential incision: the peripheral mucous membrane of the simulated lesion was partially incised using the Dual Knife mode. Then, the handle of the composite electrosurgical incision knife was pushed out of the incision knife to release the ceramic tip. The peripheral mucous membrane was cut along the edge of the liquid pad in the IT knife Group mode. (3) The composite knife group was used to cut the peripheral mucous membrane, followed by the IT knife group to cut the peripheral mucous membrane; (4) Complete whole lesion stripping in dual knife mode combined with IT knife group mode (Endocut rapid electrocoagulation mode, effect 3, output power 45 W) and supplemental submucosal injections during stripping to make the stripping range boundaries clearly visible, if necessary (Figure 3).

In all three groups, the lesion mucosa was excised completely and sent to the pathology department for histological examination. CO_2 was used as an insufflation gas during the ESD procedure. The calculation of the treatment operation time started with gastroscopy to locate the lesion site, followed by the preparation of the mucosal marking or incision and then the removal of the specimen through complete stripping of the lesion mucosa.

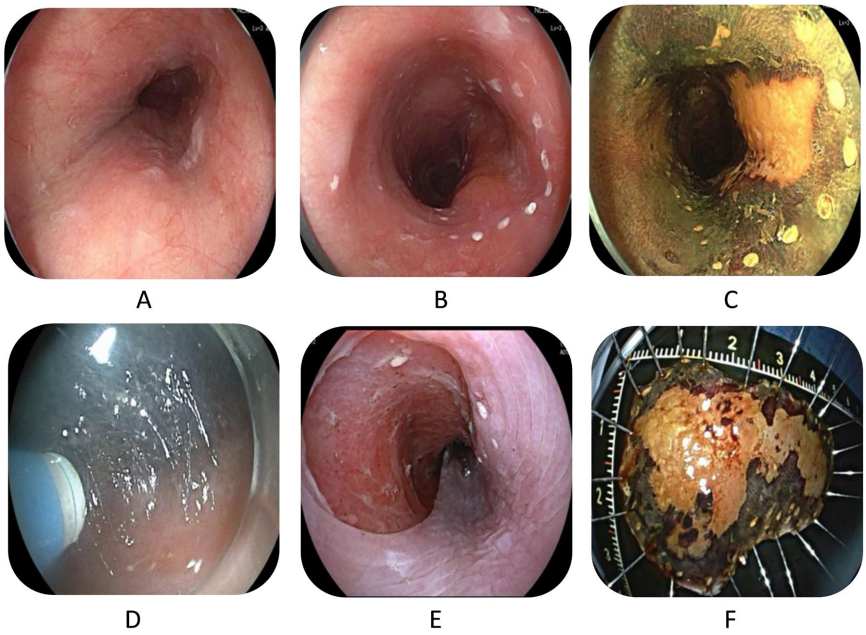

Figure 3. Endoscopic submucosal dissection of esophageal lesions using a multifunctional endoscopic electrosurgical dissector with a composite tip: A: reddened and roughened esophageal mucosa; B: marking; C: observation with Lugol's iodine staining ; D: mucosal dissection with a composite dissector; E: postoperative wound. F: specimen.

3.2. Specimen Processing

The excised lesion mucosa should be carefully observed for vascular breaks, and intraoperative hemostasis should be performed. The specimen was fixed with a specimen fixation plate and needle. After staining, the diameter of the lesion was measured and recorded, and the integrity of the tissue cutting edge was observed. All specimens were immersed in 10% neutral buffered formalin fixative and sent for pathological examination.

3.3. Postoperative Treatment

Postoperative patients received oxygen and cardiac monitoring, routine rehydration, and antibiotics on the day of the operation and for 3 days postoperation. Additionally, proton pump inhibitors and an appropriate amount of hemostatic drugs were administered. Special attention was given to monitoring for symptoms such as vomiting blood, black stools, abdominal pain, and distension.

3.4. Postoperative Review

Gastroscopy was repeated 3 weeks after the operation to observe wound healing and assess any signs of recurrence. Lugol's iodine staining was also performed during the esophageal examination.

4. Therapeutic Efficacy and Safety Evaluation Indices

4.1. Main Indicators

(1) Surgical operation time included lesion marking, complete excision of the lesion, and hemostasis. (2) Complete resection rate: The lesion was completely resected endoscopically, and a single specimen was obtained. (3) Complete resection rate: Specimens with negative horizontal and vertical margins were considered completely resected.

4.2. Secondary Indicators

(1) Submucosal peeling time refers to the duration from the incision of the mucosa on the lesion surface to the complete excision of the lesion, excluding the time needed for marking and hemostasis. (2) The lesion peeling speed can be calculated as the peeled lesion area divided by the total operation time. The peeled lesion area was determined using the elliptical area formula: area = (peeled lesion long diameter/2) × (peeled lesion short diameter/2) × π. (3) Bleeding: The diagnosis of intraoperative bleeding can be determined using the bleeding scoring system (refer to **Table 2** [6]). (4) Rating of myofibrillar damage: Grade 0 indicates no damage; Grade 1 indicates superficial damage (exposure of circular muscle fibers); Grade 2 indicates deep damage (exposure of longitudinal muscle fibers); and Grade 3 indicates perforation.

Table 2. Bleeding grading criteria.

Grade	Definition
Grade 0	No significant bleeding during surgery.
Grade 1	Small amount of bleeding that can be stopped on its own or by electrocoagulation with an incision knife.
Grade 2	Repeated electrocoagulation with incision knife or use of hot biopsy forceps. Required to stop bleeding.
Grade 3	Repeated haemostasis with hot biopsy forceps or use of metal clip.

4.3. Postoperative Pathology

If the postoperative pathology indicates the presence of a residual lesion at the surgical margin, additional information regarding the complete pathology of the postoperative specimen should be acquired to elucidate the pathological characteristics of the main body of the specimen. Endoscopic surgical image verification should be conducted to confirm whether the lesion identified preoperatively and its surrounding areas have been completely excised.

4.4. Statistical Methods

The data were analyzed using SPSS 24 statistical software. Normally distributed data are presented as the mean ± SD. The Z test was utilized to compare groups. Count data are presented as cases (%), and the chi-square test was used for group comparisons. A p-value less than 0.05 was considered to indicate a statistically significant difference.

5. Results

5.1. Comparison of Surgical Conditions

Forty patients in each group (in the dual knife, IT knife, and composite knife groups) were successfully and completely resected. During lesion resection, the stripping speed of the composite knife group was 22.80 ± 7.31 mm/min, the dual knife group had a stripping speed of 19.20 ± 7.24 mm/min, and the IT knife group had a stripping speed of 15.32 ± 6.2 mm/min. The differences were statistically significant ($t = 3.67$, $P = 0.03$). The operation time for the composite knife group was 42.4 ± 19.79 min, while the operation times for the dual knife group and the D-knife group were 66.21 ± 7.79 min and 66.21 ± 1.79 min, respectively, which were also statistically significant. In the present study, the mean surgical time was 42.4 ± 19.79 minutes in the composite knife group, 66.21 ± 7.79 minutes in the dual knife group, and 57.86 ± 1.79 minutes in the IT knife group. There was a statistically significant difference ($t = 2.67$, $P = 0.04$) in surgical time among the groups. The surgical time in the composite knife group was shorter than that in the dual knife group and the IT knife group. Additionally, the speed of peeling was significantly greater in the composite knife group than in the dual knife and IT knife groups ($t = 2.67$, $P = 0.04$). The rates of whole-piece resection and com-

plete resection were similar. Each of the three groups experienced one case of muscle layer injury (2.5%). In the IT knife group, two cases of postoperative esophageal stenosis were reported, while in the dual-knife group and the composite knife group, one case of postoperative esophageal stenosis occurred each. The differences were not statistically significant (P = 0.45). None of the three groups experienced postoperative perforation or bleeding. There was no statistically significant difference in the overall complication rates among the three groups, as illustrated in Table 3.

Table 3. Comparison of outcomes of patients undergoing endoscopic submucosal dissection with different tools.

Groups	Operating time (min, Mean ± SD)	Lesion size (cm, Mean ± SD)	Stripping speed (mm/min, Mean ± SD)	Rate of complete resection (%)	Complications (%)
IT knife group (n = 40)	57.86 ± 24.61	4.25 ± 1.26	15.32 ± 6.24	37 (92.5%)	3 (7.5%)
Dual knife group (n = 40)	66.21 ± 21.23	4.45 ± 1.48	19.20 ± 7.24	38 (95.0%)	2 (5.0%)
Composite knife group (n = 40)	42.4 ± 19.79	4.51 ± 1.18	22.80 ± 7.31	38 (95.0%)	2 (5.0%)
Statistical value	F = 2.67	F = 0.11	F = 3.67	$\chi^2 = 0.32$	$\chi^2 = 0.57$
P value	0.04	0.90	0.03	0.63	0.45

5.2. Pathological Results

Postoperative pathological findings revealed smooth muscle tumors, lipomas, early esophageal carcinomas, high-grade intraepithelial neoplasia, and mesenchymal tumors in 9, 4, 12, 13, and 2 patients, respectively, in the Dual Knife group; 10, 3, 13, 11, and 3 patients, respectively, in the IT knife group; and 8, 5, 11, 14, and 2 patients, respectively, in the Composite Knife group.

5.3. Follow-Up Results

A total of 120 patients were included in the shorter-term follow-up, which lasted for 3 months. During the follow-up period, none of the patients experienced delayed bleeding or poor wound healing complicating peritonitis, and no cancer recurrence or metastasis was detected.

6. Discussion

In China, digestive tract tumors (esophageal, gastric, and colorectal cancers) are among the five most common tumors and are the major malignant tumors endangering the health of the national population [8]. In the treatment of gastrointestinal tumors, high-quality, indication-compliant endoscopic minimally invasive resection is believed to achieve the same efficacy as surgery. It also aims to preserve intact organs, reduce treatment costs, and improve the quality of life of patients [9] [10]. In this regard, the electric knife plays a pivotal role in the surgical procedure. The types of electric knives commonly used in endoscopic surgery are

very diverse, with various structures and functions. They need to be selected based on the characteristics of the lesion and intraoperative requirements. The IT knife, developed in the early stages of ESD development, features an insulated head that reduces the risk of perforation while efficiently resecting the lesion. However, the precision of the operation is limited [11]. On the other hand, the Dual knife enhances the precision of the operation but increases the risk of perforation compared to the IT knife [12]. Consequently, it is often necessary to switch between knives to enhance the efficiency and safety of resection. In addition, submucosal injections are also necessary for ESD, and frequent changes in surgical instruments significantly affect the surgical procedure. Therefore, electric knives with combined functions have been developed, such as the incision knife with submucosal injection [13] and the integration of the loop function [14], which offer significant advantages in reducing operation time and enhancing operational efficiency. In the present study, two IT knife and Dual knives with different characteristics were combined to create a freely switchable multifunctional endoscopic electrosurgical knife, and their safety and efficacy were evaluated. In this study, the "marking-submucosal injection-step-by-step block dissection-electrocoagulation and hemostasis" surgical procedure was adopted. For comparison, gastric mucosal lesions and submucosal lesions were endoscopically resected in the conventional Dual-knife and IT knife groups. Resection. In this study, both mucosal and submucosal lesions were effectively resected. The operative time of the composite knife group was shorter than that of the Dual knife and IT knife groups, highlighting the advantages of the composite knife group over the traditional method group. In the endoscopic resection of gastrointestinal mucosal lesions, the operating time of the composite knife group was shorter than that of the Dual knife group and the IT knife group, further highlighting the effectiveness of the new composite knife head in endoscopic resection.

For the safety assessment of this new electrosurgical knife, no bleeding or perforation complications were observed in any of the three groups in this study. Therefore, the index of muscle layer injury was used for further assessment. The results of the available meta-analysis showed that the rate of medically induced perforation in the resection of intestinal lesions was 1.5% [15]. This was often associated with damage to the intrinsic muscularis layer caused by electrocoagulation or electrocutaneous dissection during the surgical procedure. During the replacement of surgical instruments in traditional surgical methods, the original surgical field often changes and needs to be readjusted after the subsequent completion of the replacement. However, when using a multifunctional endoscopic electrosurgical resection knife with a composite tip, it can be seamlessly integrated. This integration leads to a smoother endoscopic resection process, thereby reducing the risk of muscular layer injury. In the resection of gastrointestinal mucosal lesions in this study, the incidence of myotomy injury was lower in the composite knife group than in the dual knife group and the IT knife group.

This observation reflects the favorable safety profile of this new type of electro-

surgical knife. Although the difference was not significant, it may be related to the small sample size, which needs to be further expanded to verify the results. This demonstrates that endoscopic electrosurgical resection with a tip can be used to switch between ceramic protection and tip placement. It is safe and effective for esophageal surgery. As an endoscopic surgical instrument for the resection of mucosal and submucosal lesions, it can be flexibly adapted for various types of resection electrocoagulation. This adaptability saves time by eliminating the need to change the instruments, simplifies the surgical process, and reduces the time. Clinically, this technique is associated with surgical risks, lower costs, lower surgical costs, and greater patient burden. Additionally, this approach can help young people quickly shorten the number of cycles. However, further clinical trials are needed to verify the safety and effectiveness of its clinical application.

Conflicts of Interest

The authors declare no conflicts of interest.

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