Transanal Endoscopic Microsurgical Submucosal Dissection: An Efficient Treatment Option for Giant Superficial Neoplastic Lesions of the Rectum

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Keywords
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Abstract

Introduction: The resection of giant superficial neoplastic lesions of the rectum (>5 cm) is challenging even for experienced specialists. Endoscopic mucosal resection, endoscopic submucosal dissection (ESD), and transanal endoscopic microsurgery (TEM) have all been used for the treatment of such tumors. However, because of their individual disadvantages, the ideal technique for the treatment of these lesions has yet to be determined. Transanal endoscopic microsurgical submucosal dissection (TEM-ESD) is a recently developed hybrid technique that combines the advantages of conventional TEM and flexible ESD. The aim of our study was to assess the feasibility and outcomes of TEM-ESD for the resection of giant superficial rectal neoplasms.

Methods: We retrospectively analyzed all cases of TEM-ESD performed in the Department of Surgery of the Municipal Hospital of Karlsruhe between 2010 and 2020 and isolated 43 patients with superficial rectal lesions >5 cm according to the postoperative histology report. The diagnostic, perioperative, histological, and follow-up data of the patients were analyzed in the form of a retrospective, observational cohort study.

Results: We identified 43 cases matching our criteria, including 35 adenomas and 8 occult adenocarcinomas. The median size of the lesions was 75 mm and the median operating time was 81.5 min. En bloc resection was possible in all cases, and histologically complete en bloc resection was confirmed in 29 cases. Five patients presented with postoperative bleeding, 2 of which were treated conservatively, 2 were treated endoscopically, and 1 required revision surgery. The median follow-up period was 15 months. There was no recurrence among patients with adenomas, 1 recurrence of a low-risk carcinoma, and 1 recurrence after the resection of a high-risk carcinoma in a patient that refused further treatment. During the follow-up period, 3 patients developed a stenosis, which was treated endoscopically.

Conclusions: TEM-ESD is a feasible and safe therapeutic option for the treatment of giant superficial rectal neoplasms.
TEM-ESD for Giant Rectal Neoplastic Lesions

We retrospectively analyzed all patients undergoing TEM-ESD in the Department of Surgery of the Municipal Hospital of Karlsruhe between 2010 and 2020, and we included all cases of rectal adenomas with a diameter of more than 5 cm according to the German guidelines [17]. The aim of our study was to analyze the feasibility and outcomes of TEM-ESD for the resection of giant rectal lesions with a maximum diameter of more than 50 mm.

**Materials and Methods**

We retrospectively analyzed all patients undergoing TEM-ESD in the Department of Surgery of the Municipal Hospital of Karlsruhe between 2010 and 2020, and we included all cases of rectal adenomas with a diameter of more than 5 cm according to the postoperative pathology report.

The preoperative staging included flexible endoscopy and transrectal ultrasound or MRI to rule out an invasion beyond the submucosal layer. All the surgical procedures were performed after complete bowel preparation and under general anesthesia, using the original technique as in its initial description [17]. The original TEM platform and instruments (Richard Wolf GmbH, Knittlingen, Germany) and the water-jet system (ERBEJET®; Erbe Elektromedizin GmbH, Tübingen, Germany) were used. After insertion of the TEM rectoscope in the rectum, the target lesion was positioned at 6 o’clock and a pneumorectum was established with the insufflation of CO₂. Initially, a saline solution with indigo carmine dye was injected in the submucosal layer with the water-jet applicator, followed by the mucosal incision on the anal side of the tumor. The lesion was then lifted with a grasper, thus better revealing the submucosal layer, and the dissection of the submucosal fibers was performed with the electrocautery needle directly over the muscularis propria layer. The dissection was performed from the anal to the oral margin. After completion of the resection, the specimen was pinned on cork before being sent for histopathological analysis.

In cases of occult carcinomas, the pathological findings were discussed in the multidisciplinary gastrointestinal tumor board. Low-risk early rectal cancer was defined as pT1 sm1-2, G1-2, L0, V0. Complete en bloc resections of low-risk tumors were considered curative and no further treatment was necessary, whereas high-risk tumors required further oncologic treatment with radical surgery and total mesorectal excision.

Follow-up after local resection included endoscopy after 3–6 months and further colonoscopy depending on the histological type of the lesion. In case of adenomas with low-grade dysplasia, the next follow-up colonoscopy was scheduled in 3 years, in case of high-risk dysplasia in 2 years. Follow-up after curative treatment of low-risk early rectal adenocarcinomas included endoscopic control every 3 months in the first year, every 6 months in the second year, and yearly controls afterward.

Demographical, diagnostic, perioperative, histological, and follow-up data were retrospectively entered in an electronic database after pseudonymization. Approval from the local Ethics Committee was acquired.

The following were analyzed: demographic characteristics; endoscopic findings including size, localization, and morphology of the lesion; total operative time; postoperative adverse events including their treatment; histopathological findings including resection status; overall hospital stay; and follow-up data.

The statistical analysis was performed with SigmaStat 3.0 (Systat Software GmbH). For variables approximately normally distributed (i.e., age), mean and standard deviation were calculated. Skewed data are presented by their median together with the range. For categorical factors, absolute and relative frequencies are given together with exact 95% confidence intervals (CIs). The statistical review of the study was performed by a biomedical statistician.

**Results**

Out of a total of 192 procedures, we were able to identify 43 cases fulfilling our inclusion criteria. The patient characteristics of our cohort are summarized in Table 1. The median size of the lesions, as described in the postoperative pathology report, was 75 mm (range: 51–185 mm). The median distance of the anal margin of the lesion to the anal verge was 6 cm (range: 0–15 cm). The exact distribution of the lesions in the rectum is depicted

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**Table 1. Patient characteristics**

| Patients, n | 43 |
| Age, years (mean ± SD) | 70.4 (±10.46) |
| Sex | |
| Male | 27 |
| Female | 16 |
| Indication for initial endoscopy | |
| Screening | 12 |
| Follow-up | 8 |
| Rectal bleeding | 14 |
| Alteration of the bowel function | 9 |
in Table 2. Three of the lesions were recurrent adenomas after EMR.

The median operating time was 81.5 min (range: 30–340 min). Five patients (11.6%; CI: [4%; 25%]) presented with delayed bleeding, 2 of which could be treated conservatively, 2 required an endoscopic intervention, and 1 required a transanal surgical revision. No other adverse events were recorded. Thus, the major complication rate (>IIIa according to the Dindo-Clavien classification) was 2.3% (CI: [0; 12]) [18]. The median overall hospital stay was 4 days (range: 2–8 days).

The histological features of the resected lesions are summarized in Table 3. The histopathological report revealed an occult adenocarcinoma in 8 (18.6%) cases. According to their histological features, 4 were low risk and the remaining 4 were high risk.

All resections were completed using the TEM-ESD technique and no conversions to other methods were necessary. All lesions were resected en bloc and macroscopically completely. The postoperative pathology report confirmed a complete en bloc resection in 29 (67.4%, CI: [51%; 81%]) cases. All adenomas had a free deep resection margin; however, in 13 cases (37.1% of the adenomas, CI: [21%; 55%]) the tears on the lateral margin did not allow for an accurate evaluation of the resection status. Seven out of 8 carcinomas were resected completely. The lateral margin was free in all 8 cases, whereas the deep margin was positive in 1 case of deep submucosa infiltrating carcinoma (sm3). The resection was curative in all cases of low-risk carcinomas and in 50% of all carcinomas. The interdisciplinary tumor board set the indication for oncologic surgical resection in all cases of high-risk carcinomas; however, all 4 patients refused to undergo any further treatment.

The median follow-up was 15 months. Three patients (7.0%; CI: [1.5%; 19%]) developed a stenosis, which was successfully treated with endoscopic balloon dilation. All 3 patients had lesions involving more than 3/4 of the rectal wall circumference. No recurrence was recorded among the patients with adenomas. One patient with a curative resection of a low-risk carcinoma presented with a local recurrence 6 months after surgery and could be treated successfully with a full-thickness TEM. Among the high-risk carcinomas, 1 local recurrence was reported, but the patient refused any further treatment.

Discussion

The local resection of giant rectal adenomas and early adenocarcinomas is a controversial issue and the ideal technique for that has yet to be determined. Most authors define giant rectal lesions as those with a maximum diameter of more than 5 cm [4, 5]. Very few studies have addressed the en bloc resection of these lesions, mostly using TEM and more recently also ESD. These studies have shown the feasibility of those methods, but at the same time, they pointed out the high risk of tissue fragmentation and adverse events or the high level of technical difficulty of the procedures [19–23]. That is probably the reason why many of these lesions are still referred for radical surgical treatment, including anterior resection with total mesorectal excision or abdominoperineal resection [24]. The findings of our study suggest that TEM-ESD is a feasible therapeutic alternative for the local resection of giant rectal lesions, offering a high en bloc resection rate with minimal morbidity and optimal long-term results.

The minimally invasive approach and low recurrence rates of flexible ESD make this technique very promising; however, the lack of traction is considered to be one of its main technical disadvantages. Various traction methods and devices have been described in order to allow easier access to the submucosal plane, none of which has gained wide acceptance to date [25–27]. In the case of large lesions, visualization can be obstructed by the flap, which
TEM-ESD for Giant Rectal Neoplastic Lesions

significantly increases the total procedure time and sometimes does not allow for completion of the procedure [13]. TEM-ESD addresses this issue by introducing traction with a second, independently controlled, rigid instrument during submucosal dissection. This innovation facilitates both visualization and dissection and thus reduces overall procedure time. In our study, median operating time was 81.5 min and thus 35–50% shorter than those reported for ESD [20, 21].

Our findings also demonstrate the feasibility of TEM-ESD for large lesions in the entire rectum, including tumors located from the dentate line to the rectosigmoidal junction. For lesions located in the upper rectum, the use of a longer TEM rectoscope was necessary. The length of the tube makes the movement of the rigid instruments more difficult but allows for a good visualization of the surgical field. For lesions in the lower rectum and especially when the dentate line is involved, the short TEM rectoscope is preferable. The oblique opening of the rectoscope allows for a stable positioning without loss of the pneumorectum even in the anal canal, while allowing for a good visualization of the lesion. The increased risk of bleeding during incision or dissection close to the hemorrhoidal plexus did not pose a challenge in our procedures, since the vessels could be clearly visualized and coagulated [28].

In terms of morbidity, in our study, TEM-ESD showed an acceptable safety profile, with overall morbidity of 8% and major complications occurring in only 1 case. Our findings are similar to previous reports for smaller lesions, implying that size might not increase the periprocedural risk [17]. We consider this factor to be a major advantage of TEM-ESD, since flexible ESD has been associated with a significantly higher risk of adverse events when used for the treatment of lesions >5 cm, reaching morbidity rates of up to 44% for lesions >10 cm [13, 19]. The same principle applies to TEM, with morbidity rates of 26.5% for lesions 5–8 cm and up to 36.1% for lesions larger than 8 cm [22]. In particular, dehiscence of the suture line, reported in 15% of full-thickness TEM resections for large tumors, is not an issue when performing TEM-ESD, since the M. propria layer remains intact and no closure of the defect is necessary [29].

Another important feature of TEM-ESD is its ability to achieve high en bloc resection rates. In our first published case series, we were able to perform en bloc resection of all 78 lesions analyzed [17]. This cohort included 11 of the patients of the current study; however, the small number of cases did not allow us to address the feasibility of the technique particularly for these challenging lesions. Our current findings support that the advantages of TEM-ESD apply for giant lesions as well, since an en bloc resection was possible in all cases included in this study. The importance of en bloc resection of rectal adenomas and its direct association with low recurrence rates has often been pointed out in the literature [7]. Additionally, the risk of occult invasive cancer is significantly higher in large rectal adenomas, rising up to 20% for lesions >50 mm according to the literature [21, 22, 30]. Our findings confirm these results, as we were able to detect an adenocarcinoma in 18.6% of our cases. En bloc resection of these potentially malignant lesions allows for an accurate estimation of invasion depth and evaluation of the deep resection margin, and thus for adequate staging [21, 31]. In the case of low-risk tumors, a complete en bloc resection is curative and spares the patient a major surgical procedure. TEM was initially introduced as a technique that enables en bloc resection of rectal lesions; however, the risk of fragmentation seems to increase significantly for larger tumors and en bloc resection is possible in 63–87% of cases according to different studies [22, 23]. ESD has been reported to achieve higher en bloc resection rates, comparable to those reported in our study [21].

Our data show a discrepancy between en bloc and complete en bloc resections, with the latter being histologically confirmed in 67.1% of the specimens. Although this difference is not as obvious after conventional TEM, it has been reported frequently after ESD but has not been associated with higher recurrence rates [22, 32, 33]. These findings are probably a result of the fragility of the ESD specimens, which do not include the M. propria and are thus susceptible to tears. These artifacts do not allow for an exact evaluation of the lateral margins and decrease the complete en bloc resection rates. In the case of TEM-ESD, the manipulation of the lateral specimen margins with the grasper during submucosal dissection is an additional risk factor leading to such artifacts, especially influencing large lesions, requiring frequent repositioning of the instruments to achieve optimal traction. Nevertheless, a complete resection still seems to be possible in most cases, even if not histologically confirmed, as suggested by the low local recurrence rates.

No recurrence was reported after resection of adenomas in our study. There was only 1 case of local recurrence after curative resection of a low-risk adenocarcinoma, which could be successfully treated with a full-thickness TEM procedure. Interestingly enough, there was only 1 case of local recurrence among the patients with high-risk adenocarcinomas refusing further treatment, although the small number of cases does not allow for solid conclusions about the prognosis of such lesions. Similar long-term results have been reported after ESD for large rectal lesions [13, 20]. On the contrary, recurrence rates range from 11% to 25% after TEM, probably because of the higher risk of fragmentation during the resection, implying a long-term advantage of submucosal dissection techniques [23, 34].
Postoperative strictures have been reported as long-term adverse events after resection of large tumors in different parts of the gastrointestinal tract, especially if they involve more than 50% of the circumference. In the case of ESD, this is a major issue after resection of esophageal lesions, but symptomatic strictures are less common in the colorectum, probably because of the size of the lumen [21]. The risk of stenosis increases with the size of the lesion, but the most important factor seems to be the involvement of more than 75% of the circumference, in which case, the rate of stenosis is almost 20% [35]. The same applies for TEM, after which the risk of stenosis is estimated to be 7% after resection of lesions between 5 and 8 cm and can reach 23% for circumferential lesions [22, 36]. In our study, we had 3 cases of stricture, all after resection of lesions involving more than 3/4 of the circumference. All cases could be treated endoscopically, confirming the findings of other authors [35].

A limitation of TEM-ESD in comparison to flexible ESD is the necessity of general anesthesia [17]. Spinal anesthesia has been attempted in some cases; however, the intense peristalsis of the colon makes maintenance of a stable pneumorectum and precise dissection difficult. In our case series, we have experienced no anesthesia-related complications and we believe that the short duration of the procedure and the consequent duration of anesthesia do not significantly increase the risk for the patient, especially in comparison to a much longer sedation in the endoscopy suite. A proper assessment of this issue, however, can only be performed in comparison studies in the future. A further limitation of our technique is that it requires experience in transanal surgery. Nevertheless, this kind of experience is much more common than ESD experience in the western world. Besides, previous animal studies have confirmed that the learning curve for TEM-ESD is steeper than for flexible ESD [37].

Our study is the first to analyze the periprocedural and long-term outcomes of TEM-ESD for the resection of giant rectal adenomas and early adenocarcinomas. The number of patients included is larger than that of most similar studies published to date and the report of all consecutive cases in a 10-year period reduces selection bias [13, 20, 23, 34]. Nevertheless, the retrospective and observational design, as well as the rather small sample size of the study, remains a significant limitation. The small number of such resections performed even in specialized centers makes a prospective comparison of different techniques difficult to perform, especially since very few centers have the necessary expertise in more than one of these techniques. With increasing experience, a multicenter, prospective, randomized study will be able to give a definitive answer to the question of the ideal resection technique in the future.

Conclusions

TEM-ESD appears to be a safe and feasible treatment option for giant rectal adenomas and early adenocarcinomas. Traction and triangulation allow for a quick and accurate resection of these challenging lesions, achieving high rates of en bloc resections. The large size of the lesions does not seem to increase periprocedural morbidity, and long-term adverse events, such as strictures, are rare and can be treated endoscopically. Most importantly, TEM-ESD offers excellent long-term outcomes with low recurrence rates for both adenomas and low-risk adenocarcinomas. Taking all these factors into consideration, we believe that TEM-ESD is the optimal treatment for large rectal lesions, particularly demonstrating its technical advantages in this challenging group of patients.

Statement of Ethics

Approval from the local Ethics Committee (University of Heidelberg, Germany) was acquired, approval number 2021-801. All data were pseudonymized and retrospectively analyzed, so that no informed consent was necessary according to the Ethics Committee. This is a retrospective analysis of pseudonymized data. According to the approval of the Ethics Committee of the University of Heidelberg, Germany (approval number 2021-801), no informed consent was necessary.

Conflict of Interest Statement

Jörg Baral declares he has a consulting contract with Richard Wolf GmbH, Knittlingen, Germany. Konstantinos Kouladouros has none to declare.

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Author Contributions

K. Kouladouros planned the study design, gathered and analyzed the data, and wrote the manuscript. J. Baral performed the operations, assisted and supervised the analysis of the data, and reviewed the manuscript.

Data Availability Statement

The original data can be made available only upon special request and after approval of the local Ethics Committee.
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