

Comparison of endoscopic mucosal resection and endoscopic submucosal dissection in the treatment of flat neoplastic lesions in the rectum

Srovnání endoskopické slizniční resekce a endoskopické submukózní disekce při léčbě plochých neoplastických lézí konečníku

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Summary: Endoscopic submucosal dissection (ESD) is used for en bloc removal of colorectal lesions > 20 mm. As shown by studies mostly from Japan, ESD is more effective than endoscopic mucosal resection (EMR) in achieving en bloc and R0 resection. Nevertheless, the associated high risk of perforation still prevents the wider use of ESD in the West, including in the Czech Republic. The aim of this study was to compare EMR and ESD for the treatment of rectal superficial neoplastic lesions. Main study outcomes were proportion of en bloc, R0 and curative resections, occurrence of complications, and occurrence of local residual neoplasia. A total of 27 and 30 patients were included in ESD and EMR groups, resp. There were no significant differences in gender, lesion size, and presence of invasive carcinoma between the two groups. En bloc resection was achieved in 21 (78%) vs. 2 (7%; $p < 0.005$) while perforation not requiring surgery occurred in 3 (11%) vs. 0 ($p = 0.099$) and local residual neoplasia in 2 (9%) vs. 9 (41%) cases ($p = 0,017$). No procedure was related to lethality in either group. ESD is a promising method for the treatment of rectal neoplastic lesions.

Key words: colorectal neoplasia – endoscopic submucosal dissection – local residual neoplasia

Souhrn: Endoskopická submukózní disekce (ESD) je metoda používaná k en bloc resekci kolorektálních lézí > 20 mm. Jak ukázaly především studie z Japonska, ESD je účinnější než endoskopická slizniční resekce (EMR) v dosažení en bloc a R0 resekce. Většimu rozšíření ESD v západních zemích vč. České republiky však brání vysoké riziko perforace. Cílem předložené studie je srovnat metody EMR a ESD v léčbě povrchových neoplastických lézí rekta. Hlavní sledované výstupy jsou en bloc, R0 a kurativní resekce, výskyt komplikací a lokální reziduální neoplazie. Do skupiny ESD jsme zařadili 27, a do skupiny EMR 30 nemocných. Mezi oběma skupinami nebyl významný rozdíl v zastoupení pohlaví, velikosti lézí a přítomnosti invazivního karcinomu. En bloc resekce jsme dosáhli ve 21 (78 %) vs. 2 (7 %) ($p < 0,005$), perforace nevyžadující chirurgickou léčbu nastala ve 3 (11 %) vs. 0 ($p = 0,099$) a lokální reziduální neoplazie se vyskytla ve 2 (9 %) vs. 9 (41 %) případech, ($p = 0,017$). Letalita v souvislosti s endoskopickým výkonem se v souborech nevyskytla. ESD se jeví jako slibná metoda léčby neoplastických lézí rekta.

Klíčová slova: kolorektální neoplazie – endoskopická submukózní disekce – lokální reziduální neoplazie

Introduction

Colorectal cancer (CRC) is a major cause of morbidity and mortality in Western countries [1–3]. Screening proved to

reduce CRC incidence and mortality [4,5]. The pillars of screening are detection and treatment of precancerous lesions and early cancer [6]. Nowadays, a majority

of them can be treated endoscopically. Polypoid lesions represent most prevalent early lesion morphology treated by endoscopic polypectomy as a method

of choice. Nevertheless, flat and depressed morphology occur in 40 and 4%, resp. [7]. Flat lesions \leq 20 mm in diameter can be usually resected en bloc by endoscopic mucosal resection (EMR) technique. For lesions $>$ 20 mm, piecemeal EMR (EPMR) or endoscopic submucosal dissection (ESD) can be used. As shown by studies mostly from Japan, ESD is more effective in achieving en bloc and R0 resection. Nevertheless, associated high risk of perforation still prevents ESD from wider use in the West, the Czech Republic included. Therefore, more studies showing efficacy and safety of colorectal ESD from Western centres are needed. The aim of our study is to compare EMR and ESD in the treatment of rectal superficial neoplastic lesions. Main study outcomes were a proportion of en bloc, R0 and curative resection, occurrence of complication and local residual neoplasia.

Patients and methods

Our study was conducted in a single tertiary referral centre in the Czech Republic. Patients were included prospectively. The study protocol was approved by the local ethics committee at Vitkovice Hospital.

Between January 2013 and December 2014 all consecutive patients treated with ESD were enrolled. Lesions were included if they 1. could be managed endoscopically, 2. required en bloc excision and 3. would require piecemeal removal if treated with EMR. Exclusion criteria were age $<$ 18 years, inability to provide informed consent, signs of deep (\geq SM2–3) submucosal neoplastic invasion, polyposis syndrome, previous treatment of the same lesion and lesion not amenable for ESD with regard to the experience of the attending endoscopist.

Patients treated with EMR between January 2010 and December 2011 served as a control group. In that period of time, rectal ESD was not routinely used in the centre. Patients were enrolled prospectively as a part of another study.

General measures

All endoscopy procedures were provided by a senior endoscopist. To avoid submucosal fibrosis, treatment was carried out without previous biopsy. The coagulation status was examined before each procedure. Rules for management of anticoagulation and antiplatelet agents in patients undergoing high-risk endoscopic procedures were applied. Most of the patients were admitted to the hospital in the morning of the day of the procedure. Colonoscopy was performed after standard split-dose preparation (Fortrans[®], Beaufour Ipsen Pharma, Paris, France) using Olympus 180/190 series high definition variable stiffness adult or paediatric colonoscopes (Olympus, Europe SE & Co. KG, Hamburg, Germany). During the procedure, an intravenous sedative such as midazolam or fentanyl was administered in individually adjusted doses. Carbon dioxide was used for colon insufflation. After each procedure, patients were kept under observation at the gastroenterology department. Fluids were allowed orally on the day of the procedure. The physical condition of the patient was monitored, and the blood cell count and C reactive protein (CRP) – the CRP level was evaluated. In the absence of complications, patients were discharged from the hospital on the following day.

Lesion description and staging

The Paris classification was used to describe lesion morphology [7]. Laterally spreading tumours (LSTs) were further classified on the basis of their endoscopic macroscopic appearance into granular (LST-G) and non-granular (LST-NG) types. Moreover, LST-G type was subdivided into homogenous and mixed types, whereas LST-NG type was subdivided into flat elevated pseudo-depressed types [7,8]. The size of each lesion was measured by making a comparison with a diameter of polypectomy snares. The depth of neoplastic invasion was diagnosed using either pit pattern classification and/or high frequency (20 MHz, 30 MHz) ultrasound probe

sonography (Olympus UM-DP20-25R or UM-S30-25R). Type Vn pit pattern and significant ($>$ 1/3) narrowing of the third endosonographic layer corresponding to submucosa were considered as signs of deep submucosal invasion.

ESD procedure

Standard ESD procedure starting with semi-circumferential incision followed by submucosal dissection was used. In all cases, Flush knife (Fujifilm Europe GmbH, Düsseldorf, Germany) or Dual-knife (Olympus, Europe SE & Co. KG, Hamburg, Germany) were used. For submucosal injection, 10% hydroxyethylstarch solution (Voluven, Fresenius Kabi, Bad Homburg, Germany) mixed with epinephrine (100,000 : 1) and dyed with methylene blue, was used. Setting of the electrosurgical generator (ESG 100, Olympus, Europe SE & Co. KG, Hamburg, Germany) was Puls Cut Slow 40–60 W for circumferential incision and Forced Coag 10–60 W for submucosal dissection.

EMR procedure

For EMR, the standard “lift and cut” technique was used. For submucosal injection, a saline or 10% hydroxyethyl-starch solution, both mixed with epinephrine (100,000 : 1) and dyed with methylene blue, were used. Elevated lesion was excised using standard polypectomy snare. As a rule, lesions with diameter \leq 20 mm were treated en bloc while lesions $>$ 20 mm were excised using EPMR.

Specimen evaluation

Retrieved specimens were fixed on a cork plate and placed in a 10% formaldehyde solution. Histological results were reported in accordance with the revised Vienna classification of gastrointestinal neoplasia [9]. “R0 resection” was confirmed if both lateral and vertical margins were free of tumour cells. The R0 resection was considered curative when there was no deep (\geq SM2, $>$ 1,000 μ m) submucosal invasion, lymphatic invasion, vascular involvement or poorly differentiated component of neoplasia.

Follow-up

Patients with non-curative lesion resections were considered candidates for surgery. In all other cases, patients were advised to undertake a first follow-up colonoscopy after 3 months. During this procedure, post ESD/EMR scar was identified and examined by either narrow band imaging or 0,2% indigo carmine chromoendoscopy. Local residual neoplasia was defined as the histological presence of neoplastic tissue in the biopsy performed on the scar site or from the endoscopically visible lesion.

Statistical analysis

All statistical analyses were carried out using NCSS 2004 and PASS (Number Cruncher Statistical Systems, Kaysville, Utah, USA) with a two-tailed t-test used for parametric continuous variables, Mann-Whitney U test for nonparametric continuous data, and chi-squared test for categorical variables. A p value of < 0.05 was regarded as significant.

Results

The study group consists of 27 patients with 27 lesions (74% males, mean age 68 years) treated with ESD. The basic demographic and clinical data are summarized in Tab. 1. According to size of the lesions they were distributed as follows (range): 10–19 mm in 4 (15%), 20–29 mm in 11 (41%) and \geq 30 mm in 12 (44%) of cases.

En bloc and piecemeal resection were achieved in 21 (78%), and 6 (22%) patients, resp. All but one (74%) en bloc resections were R0. Submucosal invasive cancer (SMIC) was diagnosed in 5 (19%) cases. Of these, curative resection was achieved in 4 (80%) while resection of one remaining SMIC was non-curative due to deep (1,583 μ m) submucosal neoplastic invasion. There was no procedure-related death. In 3 (11%) patients, intraprocedural perforation occurred which could be successfully closed with endoscopic clips without the need for emergency surgery. Nevertheless, perforation resulted in

Tab. 1. Endoscopic submucosal dissection – basic demographic and clinical data.

Tab. 1. Endoskopická submukózní disekce – základní demografické a klinické charakteristiky.

Patient	Age (years)	Gender	Lesion morphology	Lesion size	En bloc	Histology	LRN
1	64	M	LST-GM	2	yes	HGIEN	no
2	78	F	LST-GM	3	no	uncompleted	N.A.
3	68	M	LST-GM	2	yes	HGIEN	yes
4	62	M	LST-GM	2	yes	LGIEN	LFU
5	62	M	LST-NGF	3	no	AdCa (m)	no
6	74	F	LST-GH	3	yes	HGIEN	no
7	72	M	LST-GM	3	yes	AdCa (sm2)	no
8	60	M	LST-GM	2	yes	AdCa (m)	no
9	63	F	LST-GH	3	no	HGIEN	no
10	73	F	LST-NGF	2	no	uncompleted	N.A.
11	69	F	LST-GH	3	yes	AdCa (m)	LFU
12	69	M	LST-GH	3	yes	HGIEN	no
13	86	M	LST-GM	1	yes	AdCa (sm1)	no
14	63	F	LST-GM	3	no	AdCa (sm1)	no
15	67	M	LST-GM	3	yes	AdCa (m)	no
16	69	M	LST-GM	3	yes	HGIEN	no
17	71	F	LST-NG	1	yes	NET	yes
18	75	M	LST-NGPD	2	yes	AdCa (sm1)	no
19	74	M	LST-GM	2	yes	AdCa (m)	no
20	72	M	LST-GH	2	yes	AdCa (m)	no
21	69	M	LST-NG	1	yes	HGIEN	no
22	58	M	LST-GH	2	yes	AdCa (m)	no
23	72	M	LST-GH	3	no	HGIEN	no
24	68	M	LST-GM	2	yes	AdCa (sm1)	no
25	60	M	LST-GH	2	yes	HGIEN	no
26	61	M	LST-GM	3	yes	HGIEN	no
27	63	M	LST-NG	1	yes	NET	no

lesion size: 1 (10–19 mm), 2 (20–29 mm) 3 (30+ mm)

AdCa – adenocarcinoma, m – intramucosal, sm – submucosal invasive, NET – neuroendocrine tumour, LFU – lost from follow-up, LRN – local residual neoplasia, M – male, F – female, LST – laterally spreading tumours, GM – granular-nodular mixed, GH – granular-homogenous, NGF – non-granular flat, NGPD – non-granular pseudodepressed, HGIEN – high-grade intraepithelial neoplasia, LGIEN – low-grade intraepithelial neoplasia

incomplete resection in 2 (7%) patients who undertook elective surgical rescue treatment. The mean ESD procedure time was 176 (range 55–240) min. The first follow-up colonoscopy was carried out in 23 (85%) patients. Of these, local residual neoplasia was diagnosed in 2 (9%) cases.

The control group consists of 30 patients with 30 lesions (57% males, mean age 66 years) treated with EMR. The basic demographic and clinical data are summarized in Tab. 2. According to the

size of lesions they were distributed as follows (range): 10–19 mm in 5 (17%), 20–29 mm in 8 (27%) and \geq 30 mm in 17 (57%) of cases. En bloc and piecemeal resection was achieved in 2 (7%) and 28 (93%) of patients, resp. Both en bloc resections were R0. SMIC was diagnosed in 2 (7%) cases, both treated piecemeal. There was no procedure-related death and no complicating perforation. Mean EMR procedure time was 32 min. The first follow-up colonoscopy was carried

Tab. 2. Endoscopic mucosal resection – basic demographic and clinical data.

Tab. 2. Endoskopická slizniční resekcce – základní demografické a klinické charakteristiky.

Patient	Age (years)	Gender	Lesion morphology	Lesion size	En bloc	Histology	LRN
1	47	M	LST-GM	2	yes	HGIEN	no
2	88	F	LST-GM	2	no	LGIEN	LFU
3	50	M	LST-GM	3	no	LGIEN	no
4	64	F	LST-GM	3	no	HGIEN	yes
5	79	M	LST-NGF	3	no	AdCa (sm)	no
6	88	M	LST-GH	2	no	AdCa (m)	LFU
7	74	M	LST-GM	3	no	AdCa (m)	no
8	63	F	LST-GM	3	no	HGIEN	yes
9	63	M	LST-GH	1	no	HGIEN	no
10	79	F	LST-NGF	3	no	HGIEN	no
11	68	M	LST-GH	3	no	HGIEN	yes
12	60	M	LST-GH	3	no	HGIEN	LFU
13	73	M	LST-GM	3	no	HGIEN	LFU
14	69	F	LST-GM	3	no	AdCa (m)	yes
15	58	F	LST-GM	3	no	HGIEN	no
16	58	F	LST-GM	3	no	LGIEN	yes
17	68	M	LST-GM	2	no	HGIEN	LFU
18	64	M	LST-NGPD	1	no	AdCa (sm)	yes
19	47	M	LST-GM	3	no	HGIEN	yes
20	72	F	LST-GH	3	no	HGIEN	no
21	64	M	LST-NGF	1	yes	HGIEN	no
22	65	M	LST-GH	2	no	LGIEN	LFU
23	36	F	LST-GH	3	no	LGIEN	no
24	72	F	LST-GM	3	no	HGIEN	LFU
25	74	M	LST-GH	2	no	HGIEN	yes
26	72	F	LST-GM	1	no	HGIEN	no
27	67	M	LST-GM	1	no	HGIEN	no
28	77	M	LST-GH	2	no	HGIEN	yes
29	81	F	LST-GM	3	no	HGIEN	no
30	52	F	LST-GH	2	no	LGIEN	LFU

lesion size: 1 (10–19 mm), 2 (20–29 mm), 3 (30+ mm)

AdCa – adenocarcinoma, m – intramucosal, sm – submucosal invasive, LFU – lost from follow-up, LRN – local residual neoplasia, M – male, F – female, LST – laterally spreading tumours, GM – granular-nodular mixed, GH – granular-homogenous, NGF – non-granular flat, NGPD – non-granular pseudodepressed, HGIEN – high-grade intraepithelial neoplasia, LGIEN – low-grade intraepithelial neoplasia

out in 22 (73%) patients. Of these, local residual neoplasia was diagnosed in 9 (41%) of them.

There was no significant difference in gender, size of the lesions and presence of SMIC between both groups. The en bloc resection rate was significantly higher ($p < 0.005$) and the local residual neoplasia rate was significantly lower

($p = 0.017$) in the ESD group. There was no significant difference in the rate of perforations ($p = 0.099$) which can be attributed to the low number of cases.

Discussion

In Japan and Korea, ESD is used for en bloc resection of mucosal and superficially invasive cancers both in the upper and

lower gastrointestinal tract [10]. While its usage in the oesophagus and stomach has been already adopted in the West, treatment of colorectal lesions is still considered controversial due to high risk of perforation [11–14].

The Czech Republic belongs to the countries with the highest incidence of CRC in the world. Since 2000, a screening programme is organised by the state. Although colorectal ESD is performed in several Czech centres, detailed analysis of treatment results have not been published yet. This study shows that, compared to EMR, ESD provides a significantly higher en bloc resection rate and a significantly lower local residual neoplasia rate. Although higher occurrence of perforation in the ESD group was noted the difference was not statistically significant.

En bloc resection is clinically relevant especially in patients with SMIC [15]. In such lesions, to avoid unnecessary surgery, R0 curative resection must be histologically confirmed, which is generally not possible after piecemeal excision. Since the need for surgery after endoscopic treatment of colorectal neoplasms is the most important outcome criterion, piecemeal resection should be avoided when signs of SMIC are present [16].

In the ESD group, we achieved R0 resection in 5 (100%) patients with SMIC. Of these, curative and non-curative resection occurred in 4 (80%) and 1 (20%) cases, resp. On the other side, in the EMR group, R0 resection was confirmed in none of the 2 SMIC patients who had to be referred to surgery. Our results are in accordance with other studies showing that SMIC was diagnosed more frequently in patients treated with ESD as compared to EPMR (16 vs. 2%) [17].

There is a lot of debate about the safety of ESD in Western centres. In our present study, the rate of ESD related perforation was 11% as compared to 0% after EMR. Although the difference was not statistically significant the trend is obvious. We consider ESD to be

a technically more complex procedure. Nevertheless, compared to EMR, our experience with ESD was shorter. In accordance with chronological trends from Japanese series we expect that the risk of ESD related perforation can be decreased to that of EMR. For instance, in a comparison of EMR and ESD of lesions ≥ 40 mm one study from Japan has recently shown perforation in 1.9 and 2.4%, resp. [18]. It has been shown by others that intraprocedural perforation can be closed endoscopically and treated without the need for surgery in most of the cases [19]. Similarly, all three perforations in our series were closed using clips. Nevertheless, perforation did not allow complete endoscopic resection in two of them and they had to undertake elective surgery.

The literature data, including ours, show occurrence of local residual neoplasia after successful ESD in 0–2.8% as compared to 5–54% after EMR [20,21]. In our present study, LRN occurred in 9 and 41% after ESD and EMR, resp. This difference corresponds to the rate of en bloc resection that was achieved in 78% of ESD patients as compared to 9% of EMR patients ($p < 0.005$).

There are effective surgical alternatives for rectal ESD, namely transanal endoscopic surgery (TEM) and laparoscopically assisted colorectal surgery (LACS). No prospective randomized study comparing these methods is available at the moment. One retrospective study from Asia comparing TEM and ESD shows the same rate of en bloc resection, R0 resection and local residual neoplasia while the time spent in the hospital and operation time were longer in TEM group [22]. On the other side, in a recent meta-analysis, TEM proved higher en bloc and R0 resection rates (99 vs. 88% and 89 vs. 75%) while complication rates were similar [23]. In one retrospective study, ESD was compared with LACS in the treatment of early CRC. While both R0 and curative resection rates were higher in LACS group (87% and 87 vs. 100%), the

operation time (106 vs. 206 min), length of hospital stay (5 vs. 13 days) and complications (6 vs. 14%) were shorter and less frequent in the ESD group [24]. In another study, outcomes of surgical treatment (open surgery 45, LACS 90, TEM 22) of 175 patients with benign polyps were analysed. Complications occurred in 24%, of these 10 patients had to be re-operated on and 1 patient died [25]. Based on our own experience and literature data, we recommend ESD as a method of choice for the en bloc treatment of rectal lesions. In the Czech medical environment with a widely available endoscopy service, patients with difficult rectal lesion should be referred to an endoscopy centre with experience with endoscopy treatment. Surgery should be reserved for technically difficult lesions, secondary treatment of lesions with non-curative resection and emergency treatment of complications.

There were two patients with neuroendocrine tumours (NETs) in our ESD group. Both lesions had a diameter of 10 mm. Based on histology, ESD was curative in one case while a deep resection margin could not be histologically assessed in one remaining case due to burning artefacts. Nevertheless, no residual tumour was endoscopically and histologically found during follow up. Literature evidence shows that NET with diameter ≤ 10 mm should be considered for endoscopic resection, while surgery is a method of choice for lesions ≥ 15 mm. In cases of NET 10–14 mm in size, endoscopy is acceptable as a definite treatment for lesions without muscularis propria invasion, lymphovascular involvement and with mitotic index $< 2/10$ high power fields [26].

The length of hospital stay in uncomplicated cases in our ESD group of patients was 2 days. Although there is no consensus in the literature we believe that 2–3 days are optimal, since delayed perforation only rarely occurs later.

Our study has several limitations. Firstly, the study is not randomized and selection bias cannot be excluded. Nevertheless, the indication criteria for EMR and ESD differ and randomized study is ethically difficult to organize. Secondly, both groups of patients are relatively small. To compare with Western published series, results of treatment of 58 patients with rectal lesions from 6 large centres in the USA were published in 2016 [27]. In Europe, a total of 4 studies published between 2012 and 2015 includes 201 mostly rectal lesions [28–31]. Nevertheless, one other European study published in 2017 could recruit as many as 302 patients for rectal ESD [32]. Thirdly, the follow-up of our patients is not long enough to show long term survival without recurrence. Nevertheless, it has been shown by the others that the risk of recurrence after R0 resection is very low. Recently published long-term data showed an endoscopic recurrence rate of 2.9% and cancer recurrence rate of 1.1% [33]. Finally, all ESDs were performed by a single endoscopist which reflects the reality of most Western centres where low number of suitable lesions prohibits the participation of more endoscopists. The strength of the study is its prospective design with low (7%) drop of follow-up.

In conclusion, our study shows that rectal ESD can be safely performed. It is most beneficial for patients with curative resection of cancer with superficial submucosal invasion. Compared to EMR, ESD offers a significantly higher en bloc resection rate and a significantly lower local residual neoplasia rate. Intraprocedural perforation in the ESD arm occurred in 11%, and could always be treated endoscopically. Although our data are promising, more studies are needed to confirm the position of ESD in the therapeutic algorithm of colorectal lesions.

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