Hospital Authority audit of the outcome of endoscopic resection of superficial upper gastro-intestinal lesions in Hong Kong

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A B S T R A C T

Objectives: To review the short-term outcome of endoscopic resection of superficial upper gastro-intestinal lesions in Hong Kong.

Design: Historical cohort study.

Setting: All Hospital Authority hospitals in Hong Kong.

Patients: This was a multicentre retrospective study of all patients who underwent endoscopic resection of superficial upper gastro-intestinal lesions between January 2010 and June 2013 in all government-funded hospitals in Hong Kong.

Main outcome measures: Indication of the procedures, peri-procedural and procedural parameters, oncological outcomes, morbidity, and mortality.

Results: During the study period, 187 lesions in 168 patients were resected. Endoscopic mucosal resection was performed in 34 (18.2%) lesions and endoscopic submucosal dissection in 153 (81.8%) lesions. The mean size of the lesions was 2.6 (standard deviation, 1.8) cm. The 30-day morbidity rate was 14.4%, and perforations and severe bleeding occurred in 4.3% and 3.2% of the patients, respectively. Among patients who had dysplasia or carcinoma, R0 resection was achieved in 78% and the piecemeal resection rate was 11.8%. Lateral margin involvement was 14% and vertical margin involvement was 8%. Local recurrence occurred in 9% of patients and 15% had residual disease. The 2-year overall survival rate and disease-specific survival rate was 90.6% and 100%, respectively.

Conclusion: Endoscopic mucosal resection and endoscopic submucosal dissection were introduced in low-to-moderate–volume hospitals with acceptable morbidity rates. The short-term survival was excellent. However, other oncological outcomes were poorer than those observed in high-volume centres and more secondary procedures were required.

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New knowledge added by this study

- Endoscopic mucosal resection and endoscopic submucosal dissection (ESD) were introduced in low-to-moderate–volume hospitals with acceptable morbidity rates and excellent short-term survival.
- Other oncological outcomes were poorer than those observed in high-volume centres and more secondary procedures were required.

Implications for clinical practice or policy

- Better education in recognition of early upper gastro-intestinal neoplasms and pre-ESD workup is required.
- Key personnel who perform ESD in individual hospitals should be identified for further advanced training.
- A minimal level of competence should be established before beginners perform the procedure independently.

Introduction

The use of endoscopic resection in the treatment of superficial gastro-intestinal neoplasms is gaining popularity worldwide.[1-11] Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are the key endoscopic methods pioneered in Japan and Korea for resection of these lesions.[1-7] Early gastric or oesophageal neoplasms are associated with a low rate of lymph node metastasis and endoscopic resection of these neoplasms has been shown to be associated with a low rate of morbidity and high long-term survival.[6,7] Nevertheless, the adoption of these techniques outside high-volume countries has been slow, as the recognition of early gastric and oesophageal neoplasms is difficult and the procedures required for endoscopic resection are technically demanding and have a long learning curve.[8-14]

In Hong Kong, an increased awareness and recognition of early gastro-intestinal neoplasms have resulted in greater frequency of diagnosis of these lesions. Hence advanced endoscopic resection procedures such as EMR or ESD are also being performed increasingly. However, the scope of these services provided by government-funded hospitals operated by the Hospital Authority of Hong Kong has not been previously defined. In addition there are limited data on the outcome of these advanced endoscopic procedures outside high-volume centres of Japan and Korea.

The aim of the current study was to perform a region-wide audit of the short-term clinical and oncological outcomes of EMR and ESD for superficial upper gastro-intestinal neoplasms in all government-funded hospitals in Hong Kong.

Methods

This was a Hong Kong–wide retrospective review commissioned by the Hospital Authority of Hong Kong of all patients who underwent EMR or ESD for superficial upper gastro-intestinal lesions between January 2010 and June 2013 in 12 government-funded hospitals. Patients were identified using the Clinical Data Analysis and Reporting System (CDARS) based on their diagnostic and procedural coding (9th edition of the International Classification of Diseases). The CDARS is a computer-based administration database that records all the diagnostic and procedural coding of admitted patients. Patient data were retrieved and reviewed manually through the system. Data were recorded for indication of the procedures, peri-procedural and procedural parameters, oncological outcomes, and morbidity and mortality. The study was performed according to the Declaration of Helsinki.

內視鏡粘膜切除表淺性上消化道病變的結果：香港醫院管理局審核報告

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目的：回顧香港內視鏡粘膜切除表淺性上消化道病變的短期結果。

設計：歷史隊列研究。

安排：香港醫院管理局轄下的所有醫院。

患者：這是一項多間醫院參與的回顧性研究，對象包括於2010年1月至2013年6月期間，因進行內視鏡粘膜切除表淺性上消化道病變而到香港政府資助的醫院求診的所有病人。

主要結果測量：進行手術的原因、圍手術期和手術過程中的影響因素、腫瘤控制結果、發病率和死亡率。

結果：研究期間共有168名患者（187例病變）接受切除術，其中34例（18.2%）為內視鏡黏膜切除術，153例（81.8%）為內視鏡黏膜下剝離切除術。病灶平均大小為2.6 cm（標準差1.8 cm）。30天患病率為14.4%，4.3%的患者出現穿破，3.2%的患者有嚴重出血。有細胞異生或腫瘤的患者中，78%達至R0（根治性切除），11.8%進行分塊切除。14%累及水平緣，8%累及垂直緣。患者中，9%有局部復發，15%因殘留癌細胞而有復發。兩年總存活率和疾病特定存活率分別為90.6%和100%。

結論：在低至中收容量醫院進行內視鏡黏膜切除術和內視鏡黏膜下剝離術的發病率屬可接受範圍。短期存活率極佳。然而，與高收容量醫院比較，低至中收容量醫院的術後腫瘤控制結果較差，跟進手術的次數也較多。

Endoscopic mucosal resection or endoscopic submucosal dissection procedure

All patients who underwent EMR or ESD of the oesophagus, stomach, and duodenum were included in the study. To differentiate these patients from those that received simple polypectomy, EMR was defined as the act of performing mucosectomy with prior injection of a cushioning fluid into the submucosa to hasten removal of the lesions. It was acknowledged that EMR could be performed by a variety of methods but this review did not attempt to sub-classify patients according to the different techniques used.[1] On the other hand, ESD was defined as a more refined form of mucosectomy that involved submucosal injection of a cushioning fluid, circumferential incision of the mucosa, followed by dissection of the submucosal tissue to free the lesion away from surrounding tissue. The type of endoscopic knives used for mucosal incision and submucosal dissection were also recorded.

The outcomes of EMR and ESD were assessed clinically and oncologically.

Assessment of clinical outcomes

Compared with conventional polypectomy, ESD is a technically demanding procedure that is associated

TABLE 1. Background demographics of patients who underwent endoscopic mucosal resection or endoscopic submucosal dissection

Demographics	Data (168 patients; 187 lesions)*
Age (years)	61.9 ± 14.3
Male / female	103 (61.3) / 65 (38.7)
Smoker / drinker	23 (13.7) / 17 (10.1)
ASA grading	
I / II / III / IV	45 (26.8) / 65 (38.7) / 45 (26.8) / 13 (7.7)
Oesophagus / stomach / duodenum	43 (23) / 132 (70.6) / 12 (6.4)
EMR	34 (18.2)
Oesophagus / stomach / duodenum	12 / 16 / 6
ESD	153 (81.8)
Oesophagus / stomach / duodenum	31 / 116 / 6
Location†	
Stomach (L / M / U / A)	95 / 16 / 19 / 2
Oesophagus (L / M / U / A)	8 / 20 / 14 / 1
Pre-procedural indications	
Oesophagus	
Dysplasia	29
Leiomyoma	6
Carcinoma	5
Oesophageal polyp	2
GIST	1
Stomach	
Dysplasia	41
Hyperplastic polyp	26
Adenocarcinoma	22
GIST	13
Adenomatous polyp	10
Neuroendocrine tumour	4
Submucosal tumours	4
Miscellaneous conditions	12
Duodenum	
Adenomatous polyp	4
Neuroendocrine tumour	4
Hyperplastic polyp	1
Non-specific polyp	3

Abbreviations: ASA = American Society of Anesthesiologists; EMR = endoscopic mucosal resection; ESD = endoscopic submucosal dissection; GIST = gastro-intestinal stromal tumour

* Data are shown in mean ± standard deviation, No. (%), or No.

† L = lower; M = middle; U = upper; A = anastomosis

with an increased risk of complications. In particular, the risk of perforation and bleeding are heightened in inexperienced operators.[13,14] In the current study, intra-procedural and post-procedural complications were recorded and factors alluding to development of these complications were also reviewed.

Assessment of oncological outcomes

To determine whether EMR or ESD can provide adequate oncological clearance for neoplastic lesions, assessment of long-term survival is essential. However, since EMR or ESD procedures have been performed in Hong Kong for only a short period of time, such assessment was not possible. Thus, the adequacy of oncological control of EMR or ESD was based on completeness of resection as judged during the procedure, presence of margin involvement (lateral and deep), the need for piecemeal resection, and recurrence rates. En-bloc resection was defined as resection of the tumour in one piece. R0 resection was defined as resection of the tumour with clear lateral and vertical margins. R1 resection was defined as microscopic involvement of the margins. R2 resection was defined as macroscopic involvement of margins as noted during endoscopy. Local recurrence was defined as recurrent cancer detected at the primary resection site during follow-up oesophagogastroduodenoscopy when pathological review of the ESD specimen revealed no tumour on the lateral and vertical margins.

Statistical analyses

Statistical analyses were done mainly using descriptive analysis. The predictors of morbidity and local recurrences were analysed by multivariate logistic regression analysis using the following factors: sex, American Society of Anesthesiologists grading, presence of neoplastic lesions (adenoma, dysplasia, carcinoma), ESD performed as a staging procedure, the need for piecemeal resection, pathological size, lateral and vertical margin involvement, depth of pathological invasion, R0 resection, and the institution volume of ESD. The 2-year overall and disease-specific survivals were calculated using the Kaplan-Meier estimator. A two-sided P value of <0.05 was considered statistically significant. Statistical analyses of data were performed using the Statistical Package for the Social Sciences (Windows version 20.0; SPSS Inc, Chicago [IL], US).

Results

During the study period, 187 lesions in 168 patients were resected. The patient demographics are shown in Table 1. The mean (± standard deviation) age of patients was 61.9 ± 14.3 years and 61.3% were male. Overall, EMR was performed in 34 (18.2%) lesions and ESD in 153 (81.8%) lesions for dysplasia or carcinoma with the majority of lesions located in the stomach (132 lesions, 70.6%), followed by the oesophagus (43 lesions, 23%) and the duodenum (12 lesions, 6.4%). The distribution in the numbers of the procedures among various hospitals is shown in Figure a.

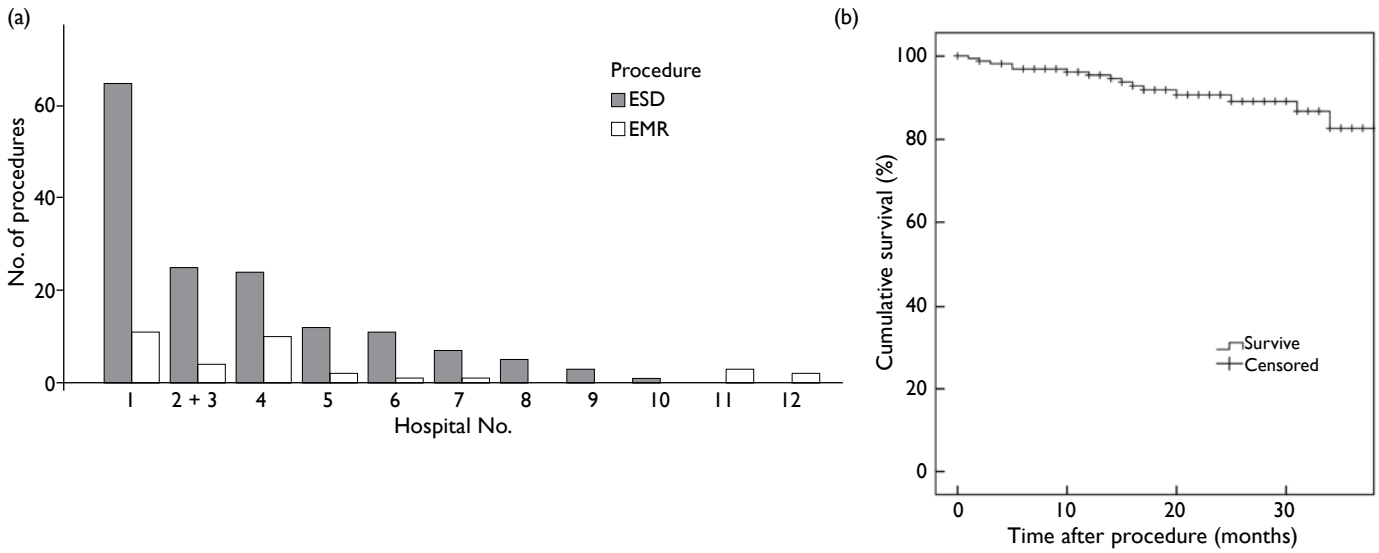

FIG. (a) The distribution of procedures among hospitals in Hong Kong; ESDs in hospitals 2 and 3 were performed by the same doctors and were considered as one group. (b) The 2-year overall survival of patients with adenoma, dysplasia, or carcinoma
Abbreviations: EMR = endoscopic mucosal resection; ESD = endoscopic submucosal dissection

The clinical outcomes of the procedures are shown in Table 2. General anaesthesia with tracheal intubation was required for the majority of procedures (n=148, 79.1%). The procedural times were recorded in 50 (26.7%) procedures only and were not representative of the actual time required for the procedures. The mean size of the lesions was 2.6 ± 1.8 cm. The 30-day morbidity rate was 14.4%. Intra-procedural complications occurred in 13 (7.0%) procedures, with one procedure having both bleeding and perforation. Perforations occurred in eight (4.3%) procedures and all were controlled with endoscopic clipping. Severe bleeding requiring endoscopic clipping or transfusion occurred in six (3.2%) procedures. One procedure required conversion to open surgery due to uncontrolled bleeding. Post-procedural complications occurred in 14 (7.5%) procedures; the most common causes of which were bleeding (4.3%), stricture formation (1.6%), and perforations (1.1%). All post-procedural bleeding and stricture formation were managed endoscopically. The procedures having perforation were managed conservatively. No patients had post-procedural mortality. The mean hospital stay was 3.7 ± 3.1 days. Haemoglobin level was checked on the first post-procedural day in 116 (62%) procedures. Proton pump inhibitors were prescribed to 171 (91.4%) procedures; of these, 93 (80.2%) were administered to ESD in the stomach. No difference in size of lesions, hospital stay, or morbidities was observed between university– and non-university–affiliated hospitals.

The types of knives used for mucosal incision included the Dual knife (35.8%; KD-650U, Olympus Co Ltd, Tokyo, Japan), the triangular tip knife (14.4%; KD-640L, Olympus Co Ltd, Tokyo, Japan), the needle knife (8%; KD-1L-1, Olympus Co Ltd, Tokyo, Japan), the insulated tip (IT2) knife (7%; KD-610L, Olympus Co Ltd, Tokyo, Japan), and the Hybrid knife (3.7%; ERBE, Tübingen, Germany). Knives used for submucosal dissection included the Dual knife

TABLE 2. Assessment of clinical outcome

Clinical outcome	Data (168 patients; 187 lesions)*
General anaesthesia / conscious sedation	148 (79.1) / 39 (20.9)
Procedural time (mins)†	31.3 ± 26.3
Size of lesions (cm)	2.6 ± 1.8
30-Day mortality	0
30-Day morbidity	27 (14.4)
Intra-procedural complications	13 (7.0)‡
Bleeding	6 (3.2)
Perforation	8 (4.3)
Post-procedural complications	14 (7.5)
Bleeding	8 (4.3)
Perforation	2 (1.1)
Stricture	3 (1.6)
Bronchospasm	1 (0.5)
Hospital stay (days)	3.7 ± 3.1

* Data are shown in mean ± standard deviation or No. (%)
† Only the time for 50 procedures were recorded
‡ One case had both bleeding and perforation

TABLE 3. Assessment of oncological outcome

Oncological outcome	No. (%) of lesions (n=187)*
Pathological diagnosis	
Oesophagus	
Squamous cell carcinoma	7
Adenocarcinoma	3
Severe dysplasia	10
Moderate dysplasia	6
Mild dysplasia	3
Leiomyoma	8
Hyperplastic polyp	1
Benign mucosa	5
Stomach	
Adenocarcinoma	21
Severe dysplasia	14
Moderate dysplasia	9
Mild dysplasia	16
Adenomatous polyp	11
Hyperplastic polyp	26
Inflammatory fibroblastic polyp	3
Neuroendocrine tumour	5
Gastro-intestinal stromal tumour	4
Schwannoma	1
Miscellaneous benign conditions	22
Duodenum	
Severe dysplasia	1
Neuroendocrine tumour	3
Adenomatous polyp	1
Brunner's gland adenoma	4
Inflammatory pseudotumour	1
Ectopic gastric mucosa	2
Piecemeal resection	22 (11.8)
R0 resection (n=100)	78 (78)
Oesophagus / gastric	24 (30.8) / 53 (67.9) / 1 (1.3)
Staging procedure (n=100)	7 (7)
Lateral margin involvement (n=100)	
Focal (oesophagus / gastric / duodenum)	9 (9) [3 / 6 / 0]
Gross (oesophagus / gastric / duodenum	5 (5) [1 / 4 / 0])
Not assessed	8 (8)
Vertical margin involvement (n=100)	
Focal (oesophagus / gastric / duodenum)	4 (4) [0 / 4 / 0]
Gross (oesophagus / gastric / duodenum)	4 (4) [0 / 4 / 0]
Not assessed	8 (8)
Residual disease	15 (15)
Local recurrence	9 (9)

* Data are shown in No. or No. (%)

(48%; KD-650U, Olympus Co Ltd), the insulated tip (IT2) knife (24.6%; KD-610L, Olympus Co Ltd), the triangular tip knife (11.2.%; KD-640L, Olympus Co Ltd), and the Hybrid knife (4.3%; ERBE).

The oncological outcome of the procedures is shown in Table 3. In 22 (11.8%) lesions, en-bloc resection was not possible and the lesions had to be resected in piecemeal. Among patients having adenoma, dysplasia, or carcinoma (n=100), R0 resection was achieved in 78%. In 7% of the patients, pre-procedural investigations were inconclusive on the feasibility of endoscopic resection and ESD was performed as a staging procedure. Lateral margin involvement occurred in 14 (14%) procedures and vertical margin involvement occurred in eight (8%) procedures. Local recurrences occurred in nine (9%) patients and five were treated by further ESD. Residual disease was present in 15 (15%) patients, four due to failure to complete ESD and 11 due to margin involvement. Of these 15 patients with residual disease, complete resection was achieved in eight during salvage surgical resection, two patients underwent repeat endoscopic resection, two underwent radiofrequency ablation, and three refused treatment. The mean follow-up time of patients was 20.6 ± 10.8 months and the 2-year overall survival rate and disease-specific survival rate was 90.6% and 100%, respectively (Fig b). Overall, 38.5% of patients were followed up for at least 2 years. No differences in oncological outcomes were observed between university– and non-university–affiliated hospitals.

The predictors of morbidity in patients who received endoscopic resection were then analysed with multivariate logistic regression (Table 4). Specimen size of ≥5 cm (P=0.001), the need for piecemeal resection (P=0.032), and pathological invasion to the submucosa or deeper (P=0.042) were independent predictors of morbidity. The predictors for local recurrences were also analysed: the need for piecemeal resection was the only independent predictor (P=0.011; Table 5).

Discussion

Using a hospital admission database, the outcome for patients who underwent endoscopic resection of superficial upper gastro-intestinal neoplasms among 12 government-funded hospitals in Hong Kong was reviewed. The total number of procedures performed was higher than expected and the procedures were associated with a low risk of morbidity. Nonetheless there may be room for improvement in the oncological outcome, particularly in terms of rates of margin involvement and the number of patients with residual disease. The predictors of morbidity and local recurrence were in line with those reported from high-volume centres and the 2-year survival of patients who had adenoma, dysplasia, or carcinoma

TABLE 4. Multivariate analysis of predictors to morbidity

Variable	Odds ratio (95% CI)	P value
Specimen size ≥5 cm	10.76 (2.51-43.77)	0.001
Piecemeal resection	7.80 (1.20-50.78)	0.032
Pathological invasion to submucosa or deeper	5.12 (1.06-24.65)	0.042
Neoplastic lesions (adenoma, dysplasia, or carcinoma)	4.21 (0.95-18.60)	0.058
Sex	1.10 (0.34-3.52)	0.878
ASA grading	0.79 (0.16-18.63)	0.450
ESD performed as staging procedure	1.72 (0.16-18.63)	0.657
Lateral margin involvement	1.62 (0.57-4.65)	0.368
Vertical margin involvement	0.76 (0.27-2.13)	0.594
Institution volume of ESD procedures ≥20	0.76 (0.21-42.65)	0.682

Abbreviations: ASA = American Society of Anesthesiologists; CI = confidence interval; ESD = endoscopic submucosal dissection

TABLE 5. Multivariate analysis of predictors to local recurrence

Variable	Odds ratio (95% CI)	P value
Piecemeal resection	17.47 (1.94-157.72)	0.011
Specimen size ≥5 cm	6.08 (0.94-39.37)	0.058
Pathological invasion to submucosa or deeper	3.27 (0.49-21.95)	0.223
Neoplastic lesions (adenoma, dysplasia, or carcinoma)	2.12 (0.42-10.62)	0.363
Sex	0.67 (0.19-2.41)	0.537
ASA grading	0.93 (0.46-1.90)	0.846
Institution volume of ESD procedures ≥20	1.98 (0.47-8.32)	0.351

Abbreviations: ASA = American Society of Anesthesiologists; CI = confidence interval; ESD = endoscopic submucosal dissection

was excellent following endoscopic resection.

The adoption of ESD outside Japan and Korea has been slow.[5,8,15-18] The reported studies were mostly small series and the results were variable. In four European and two South-East Asian studies, the number of patients included was between 23 and 70, the en-bloc resection rate ranged from 25% to 100% and morbidity 0% to 24%. These results contrast with those obtained from Japan and Korea. In the stomach, the rate of en-bloc resection was 94.9% to 95.3% and piecemeal resection was 4.1%. The risk of bleeding was 1.8% to 16.2% and perforation was 1.2% to 4.5%. The risk of recurrence was less than 1% and the 3- and 5-year overall survival rates were 98.4% and 97.1% respectively.[6,7] These results reflect the difficulty of introducing a technically demanding ESD programme in low-to-medium volume localities outside Japan and Korea.[19] The reasons for poorer clinical and oncological outcomes may be explained by a combination of factors. These include the early experience and learning curve issues, technical difficulties leading to the need for piecemeal resection, and failure to recognise tumour margins.

The current study is the largest non-Japanese and non-Korean report on the outcomes of ESD. The results illustrate that an acceptable en-bloc resection rate and morbidity rate can be achieved in low-to-medium–volume hospitals. The introduction of endoscopic resection techniques in Hong Kong is in its infancy with many challenges similar to those described in western literature.[20-22] The emphasis in our region, however, was not just on the technical performance of ESD but also the ability to detect and diagnose these lesions. In 2011, a total of 1101 new cases of gastric cancer were diagnosed in Hong Kong but the percentage of cases that were amenable to endoscopic resection is unknown.[23] Based on the findings of this study, the percentages are likely to have been much less than 10%. This figure contrasts significantly with those reported from Spain (20%) and Japan (53%).[24,25] Hence, measures to further improve the early diagnosis of upper gastro-intestinal malignancies are needed. Key personnel to perform ESD in individual hospitals should be identified and receive intensive training in screening endoscopy to improve detection of early lesions.[26] These individuals should attend local workshops

and clinical attachments at high-volume centres in Japan and Korea to acquire such skills. Enhanced endoscopic imaging systems (narrow band imaging, flexible spectral imaging colour enhancement, or autofluorescence imaging) that may improve the ease of diagnosing early upper gastro-intestinal lesions should also be obtained by those hospitals interested in developing the technique and these should be supported by the government on a regional scale.[27-29] The use of population-based screening programmes in our locality may not be justified because of the moderate incidence of upper gastro-intestinal cancers, but studies to evaluate screening of high-risk groups may be justified.[30,31] Better recognition of early upper gastro-intestinal neoplasms not only increases the detection rates but may also allow more accurate pre-ESD assessment and improve the rates of margin involvement and oncological outcomes.

It is acknowledged that ESD remains a technically demanding procedure that is associated with risk of perforation and bleeding. To master such skills, the surgeon must be familiar not only with the ESD procedure, but also with the methods used to treat complications. In addition, the difficulty of ESD depends on the organ involved, as well as the location within that organ.[32,33] Thus, in high-volume centres, learning of ESD is usually done in a stepwise approach, starting from easy small lesions located at the antrum of the stomach and progressing to more difficult lesions or lesions located in other parts of the gastro-intestinal tract.[34,35] The number required for mastering the technique is 20 to 40 procedures in each location. These numbers are unlikely to be attainable within a short period of time in Hong Kong and most western countries. Hence, each locality will need to decide on the most appropriate training strategy to overcome the learning curve: this will likely involve intensive training with the use of animal models, apprenticeship with local experts, and overseas training in high-volume centres.[13,20,24] It may also be beneficial to the region to restrict the performance of ESD to a few key personnel in the main institutions and once they are proficient, involve other endoscopists in the process.

To further improve the outcome of endoscopic resection of upper gastro-intestinal lesions in Hong Kong, a number of measures should be implemented. The establishment of a task force on endoscopic diagnosis and treatment of early gastro-intestinal cancers with regular training should be considered. A local standard in endoscopic reporting and pathological examination is required as these assessments of early upper gastro-intestinal neoplasms are unique and pivotal to guiding treatment. A 'best practice' guideline for performing ESD and the provision of pre- and post-ESD care should be established to provide a benchmark for future audits.

There were a number of limitations to the current study. First, patients included in the study were identified using CDARS based on the diagnosis and procedural coding. There is a risk of unidentified procedures if they were incorrectly coded. Also, those procedures that were performed outside the Hospital Authority hospitals could not be accounted for. Second, since this is a retrospective review, some outcome parameters might not have been properly defined or available for all patients. Finally, since there is no standardised reporting system in Hong Kong for ESD or EMR and pathological assessment, there was a risk of information bias during extraction of the data.

Conclusion

The introduction of ESD in Hong Kong is still in its infancy; EMR and ESD were introduced in low-to-moderate–volume hospitals with acceptable morbidity rates. The short-term survival was excellent. Nonetheless, other oncological outcomes were poorer than those observed in high-volume centres and more secondary procedures were required.

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