



EUROPEAN COLORECTAL CONGRESS

Spotlight on the colon

1 – 5 December 2019, St.Gallen, Switzerland

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André d'Hoore, Leuven, BE

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Poster award
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Evaluation of the necessity for gastrectomy with lymph node dissection for patients with submucosal invasive gastric cancer

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Background: When cancer cells are found in the submucosal layer of an endoscopically resected specimen, patients are recommended to undergo gastrectomy with lymph node dissection. If it were possible to identify those patients in whom the risk of lymph node metastasis was negligible, it might be possible to avoid surgery.

Methods: Among those who underwent gastrectomy for gastric cancer from 1980 to 1999, 1091 patients with a cancer invading the submucosa were studied. Clinicopathological factors (sex, age, tumour location, macroscopic type, size, ulceration, histological type, lymphatic-vascular involvement and degree of submucosal penetration) were investigated for their possible association with lymph node metastasis.

Results: Lymph node metastases were found in 222 patients (20.3 per cent). Univariate analysis showed that larger tumour size (more than 30 mm), undifferentiated histological type, lymphatic-vascular involvement and massive submucosal penetration had a significant association with lymph node metastasis. Tumour size, histological type and lymphatic-vascular involvement were independent risk factors for lymph node metastasis. By combining these three factors with submucosal penetration of less than 500 µm, 117 patients could be selected as having a minimal risk of lymph node metastasis (95 per cent confidence interval 0–3.1 per cent).

Conclusion: Lymphadenectomy may not be necessary for patients with gastric cancer invading the submucosa who fulfil the above conditions

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Introduction

Early gastric cancer (EGC) is defined as cancer in which tumour invasion is confined to the mucosa or submucosa regardless of the presence of regional lymph node metastasis¹. For intramucosal cancer, it has already been noted that lesions with a differentiated histological type and without lymphatic-vascular involvement or ulcerative findings within the cancerous lesion have a minimal risk of lymph node metastasis². Recently, local treatment for intramucosal cancer by endoscopic resection has been generally accepted as an adequate therapeutic method in Japan. In patients with submucosal invasive cancer, gastrectomy with complete removal of first- and second-tier lymph nodes has been performed as the standard treatment^{3–6}, because the incidence of lymph node metastasis is approximately 20 per cent^{4,7–14}. If a group of

patients with submucosal invasive cancer and a negligible risk of lymph node metastasis can be defined, it may be possible to modify this therapeutic strategy, possibly avoiding the risks of gastrectomy and the effects of this operation on the patient's quality of life^{15–20}. Although the relationship between lymph node metastasis and the depth of submucosal invasion has been reported recently^{12,21}, the number of patients was too small to show statistical significance. The purpose of this study was to evaluate whether local treatment for submucosal invasive cancer might be acceptable using data from a large number of patients from a single institution.

Patients and methods

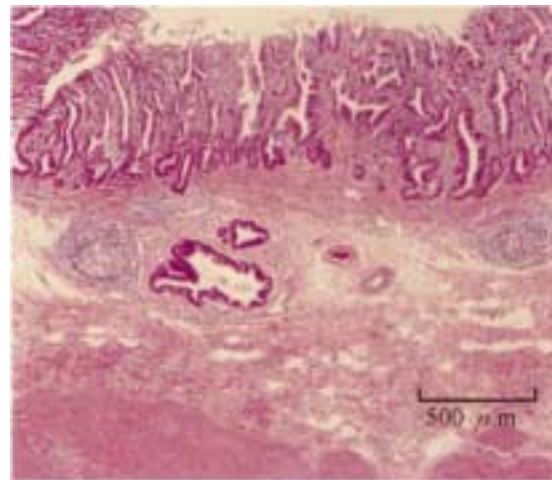
Among those who underwent gastrectomy for gastric cancer from 1980 to 1999, 1091 patients with a cancer

invading the submucosa were studied. Nine clinicopathological factors were evaluated by means of univariate analysis for their possible association with lymph node metastasis. Furthermore, multivariate analysis was performed using a logistic model with a stepwise method. The factors analysed, according to the Japanese classification of gastric carcinoma¹, were sex, age, tumour location, macroscopic type, size, presence or absence of peptic ulceration, the two major histological types (differentiated or undifferentiated type), lymphatic-vascular involvement and degree of submucosal penetration. Histologically, well and moderately differentiated tubular adenocarcinoma and papillary adenocarcinoma were classified as differentiated histological type; poorly differentiated adenocarcinoma and signet-ring cell carcinoma were classified as undifferentiated histological type²². The presence of a peptic ulcer or peptic ulcer scar (defined endoscopically as converging folds and histologically as a deformity of the muscularis propria or fibrosis in the submucosal or deeper layer) within a cancerous lesion was defined as a positive ulcerative finding. The depth of invasion into the submucosal layer was measured at the deepest level of penetration of the cancer cells with an ocular lens scale (*Fig. 1*). The degree of submucosal penetration was classified as SM1 (penetration of submucosal layer less than 500 μm from the muscularis mucosa) or SM2 (500 μm or more).

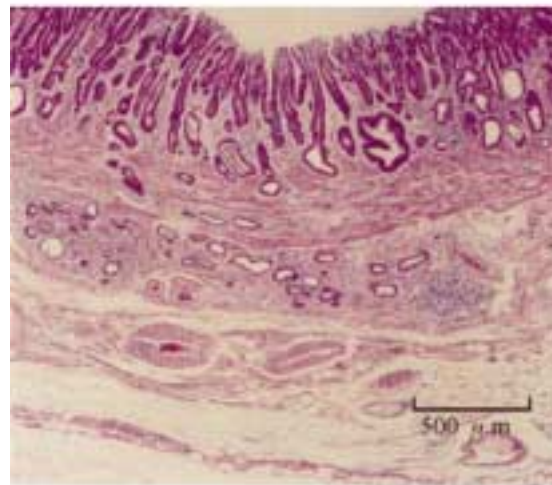
Statistical analysis was carried out using the SAS program (SAS Institute, Cary, North Carolina, USA). The association of lymph node metastasis with clinicopathological variables was assessed using a simple χ^2 test. $P < 0.05$ was considered significant. The probability of lymph node metastasis was estimated with 95 per cent confidence intervals (c.i.).

Results

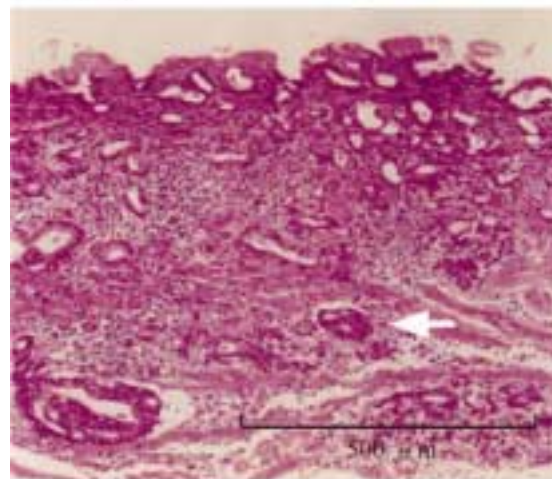
The mean age of the patients with cancer invading the submucosa was 59.4 years. The mean tumour size was 33.4 mm and the incidence of lymph node metastasis was 20.3 per cent. The presence of lymph node metastasis had a



a SM1 only



b SM1 only



c SM1 plus lymphovascular invasion

Fig. 1 Estimation of submucosal invasion measured with an ocular lens scale. In **a** and **b** the degree of submucosal penetration was classified as SM1 (less than 500 μm from the muscularis mucosa) (haematoxylin and eosin stain, original magnification $\times 4$). In **c**, although the depth of invasion into the submucosal layer measured at the deepest penetration of the cancer cells was classified as SM1, lymphatic-vascular involvement was found (white arrow) (haematoxylin and eosin stain, original magnification $\times 10$)

significant correlation with tumour size larger than 30 mm, undifferentiated histological type, lymphatic–vascular involvement and submucosal penetration classified as SM2 (Table 1). These four clinicopathological factors were assessed by multivariate analysis using a logistic model with a stepwise method (Table 2). Independent risk factors for lymph node metastasis were presence of lymphatic–vascular involvement, undifferentiated histological type and tumour

size larger than 30 mm in diameter. The incidence of lymph node metastasis of submucosal invasive cancer that was negative for these three risk factors was 5.6 (95 per cent c.i. 3.1–9.0) per cent (15 of 270 patients). Furthermore, when these three risk factors were absent, and there was only minimal submucosal penetration (SM1), the incidence of lymph node metastasis was zero (95 per cent c.i. 0–3.1 per cent) (none of 117 patients).

Table 1 Relationship between clinicopathological factors and lymph node metastasis of submucosal invasive cancer, and results of univariate analysis

| | No. of patients | Lymph node metastasis | | P |
|----------------------------------|-----------------|-----------------------|------------|---------|
| | | No | Yes | |
| Sex | | | | 0.221 |
| Male | 761 | 613 | 148 (19.4) | |
| Female | 330 | 256 | 74 (22.4) | |
| Age (years) | | | | 0.198 |
| < 59 | 484 | 377 | 107 (22.1) | |
| ≥ 59 | 607 | 492 | 115 (18.9) | |
| Location in stomach | | | | 0.100 |
| Upper third | 159 | 136 | 23 (14.5) | |
| Middle third | 575 | 457 | 118 (20.5) | |
| Lower third | 357 | 276 | 81 (22.7) | |
| Macroscopic type | | | | 0.091 |
| Raised | 285 | 216 | 69 (24.2) | |
| Depressed | 806 | 653 | 153 (19.0) | |
| Tumour size (mm) | | | | < 0.001 |
| ≤ 30 | 602 | 510 | 92 (15.3) | |
| > 30 | 489 | 359 | 130 (26.6) | |
| Ulcer findings | | | | 0.797 |
| No | 523 | 418 | 105 (20.1) | |
| Yes | 568 | 451 | 117 (20.6) | |
| Histological type* | | | | 0.002 |
| Differentiated | 683 | 563 | 120 (17.6) | |
| Undifferentiated | 408 | 306 | 102 (25.0) | |
| Lymphatic–vascular involvement | | | | < 0.001 |
| No | 703 | 641 | 62 (8.8) | |
| Yes | 388 | 228 | 160 (41.2) | |
| Degree of submucosal penetration | | | | < 0.001 |
| SM1 | 296 | 267 | 29 (9.8) | |
| SM2 | 795 | 602 | 193 (24.3) | |

Values in parentheses are percentages. *Differentiated type includes papillary and tubular adenocarcinoma; poorly differentiated adenocarcinoma and signet-ring cell carcinoma are classified as undifferentiated type

Table 2 Independent risk factors for lymph node metastasis from submucosal invasive cancer

| | Relative risk | Standard error | P |
|--|---------------|----------------|---------|
| Lymphatic–vascular involvement (absence <i>versus</i> presence) | 6.422 | 0.176 | < 0.001 |
| Histological type (differentiated <i>versus</i> undifferentiated) | 1.752 | 0.172 | 0.001 |
| Tumour size (≤ 30 <i>versus</i> > 30 mm) | 1.569 | 0.170 | 0.008 |

Discussion

The presence of lymph node metastasis is the most important prognostic factor for patients with EGC^{3,23,24}. Radical surgery with lymph node dissection has provided an excellent therapeutic outcome; the 5-year survival rate after curative resection is more than 90 per cent including recent European series^{3,25–29}. Local tumour resection without lymph node dissection can be employed for some EGCs, but the indications for this should be considered carefully and a detailed evaluation of a large number of cases is required.

Endoscopic mucosal resection (EMR) for selected intramucosal EGCs, for which the possibility of lymph node metastasis is almost zero, has been widely accepted as a curative therapeutic strategy in Japan. Patients with submucosal invasive cancer, on the other hand, are recommended to undergo surgical gastrectomy with regional lymph node dissection. In this institution the survival rate in these patients, excluding non-cancer deaths, was 96 per cent at 5 years after radical surgery²⁷. However, considering the negative effect of gastrectomy on the quality of life^{15–20}, further subclassification of submucosal invasive cancer to select those with a minimal risk of lymph node metastasis would be beneficial. Several authors have suggested that tumours with a maximum depth of invasion of less than 300 µm have a limited risk of lymph node metastasis^{12,21,30–33}, but the numbers of patients analysed were too small to give a meaningful upper limit of the 95 per cent c.i.

The present study analysed the risk factors for lymph node metastasis from submucosal invasive cancer using a large number of patients treated in a single institution to identify lesions that were curable by local treatment. Among differentiated tumours smaller than 30 mm without lymphatic–vascular involvement, the incidence of lymph node metastasis was 5.6 (95 per cent c.i. 3.1–9.0) per cent. This figure is not acceptable for good-risk Japanese patients whose operative mortality and 5-year survival rates are excellent. When the degree of submucosal penetration was added to above factors, no lymph node metastasis (95 per cent c.i. 0–3.1 per cent) was seen in patients with SM1 grade of invasion in the absence of the three independent risk factors.

These criteria are based on complete histological examination of the resected specimen. Some factors, especially lack of lymphatic–vascular involvement or SM1 grade, which are associated with a minimal risk of lymph node metastasis, are available only after histological examination of the resected specimen. Therefore it is of paramount importance that the specimen is resected endoscopically such that accurate histological examination

can be carried out. When the wider application of local treatment for patients with such submucosal invasive cancer is considered, it is essential to evaluate the resected specimen accurately and decide whether an additional surgical procedure is warranted. Korenaga *et al.*³⁴ reported that correct assessment of the depth of submucosal invasion in an endoscopically resected specimen was difficult when the size of tumour exceeded 15 mm. This is because such lesions are often resected in multiple fragments. A new technique of endoscopic resection using an insulation-tipped electrosurgical knife to remove a large lesion *en bloc* has been developed³⁵. If resected *en bloc*, lesions larger than 15 mm can be examined as accurately as surgically resected material. This enables EMR to be offered to many patients who would otherwise have been treated by surgical intervention.

The endoscopic distinction between mucosal and submucosal invasion is made correctly in only approximately 80 per cent of tumours^{36,37}, which means that the pretreatment diagnosis would be incorrect for 20 per cent of the tumours that are candidates for local treatment.

In conclusion, additional surgery with lymph node dissection is of little benefit for tumours that satisfy the following four conditions: (1) no lymphatic–vascular involvement, (2) tumour size smaller than 30 mm, (3) differentiated histological type and (4) depth of submucosal penetration classified as SM1.

Acknowledgements

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