Introduction

Although radical gastrectomy with lymphadenectomy is the standard treatment for gastric cancer [1], many patients experience postoperative morbidities [2]. For instance, gastrectomy with lymphadenectomy can cause postgastrectomy syndrome, which includes delayed gastric emptying, reflux esophagitis, anastomotic leakage, bleeding, stricture, or anemia. These side effects lead to a poor quality of life postoperatively [3]. Endoscopic resection is increasingly used worldwide as a minimally invasive therapy to avoid poor outcomes after gastrectomy with lymphadenectomy and improve the quality of life of patients with early gastric cancer (EGC) [4, 5].

Nomogram to predict lymph node metastasis in patients with early gastric cancer: a useful clinical tool to reduce gastrectomy after endoscopic resection

Authors
Su Mi Kim1,2,*, Byung-Hoon Min3,*, Joong Hyun Ahn4, Sin-Ho Jung5, Ji Yeong An1, Min Gew Choi1, Tae Sung Sohn1, Jae Moon Bae1, Sung Kim1, Hyuk Lee1, Jun Haeng Lee3, Young Woo Kim6, Keun Won Ryu6, Jae J. Kim3, Jun Ho Lee1

Institutions
1 Department of Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea
2 Department of Surgery, CHA Bundang Hospital, CHA University School of Medicine, Seoul, Republic of Korea (current address)
3 Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea
4 Biostatistics, Samsung Medical Center, Seoul, Republic of Korea
5 Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina, USA
6 Gastric Cancer Branch, Division of Translational & Clinical Research, National Cancer Center, Seoul, Republic of Korea

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Corresponding author
Jun Ho Lee, MD, PhD, Department of Surgery, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea
Fax: 82-2-34106981
gsjunholee@gmail.com

ABSTRACT

Background The indications for endoscopic dissection have been expanded to improve the quality of life of patients with early gastric cancer (EGC). This study aimed to develop a nomogram to predict the status of lymph node metastasis with the aim of avoiding unnecessary gastrectomies.

Methods We reviewed the clinicopathological data of 10,579 patients who underwent curative resection for EGC. The nomogram was developed by multivariate analysis and was evaluated by external validation. Overall, disease-free and recurrence-free survival were compared between the gastrectomy group of 6,641 patients and the endoscopic dissection group of 999 patients to show the efficacy of the nomogram.

Results Multivariate analyses revealed that age, tumor size, lymphatic invasion, depth of invasion, and histologic differentiation were all significant prognostic factors for lymph node metastasis. The nomogram had good discriminatory performance, with a concordance index of 0.846. This was supported by the external validation point of 0.813. For patients with low risk of lymph node metastasis on the nomogram (≤ 3% of the provisional value in this study), the endoscopic dissection and gastrectomy groups had comparable rates of overall (P = 0.32), disease-free (P = 0.47), and recurrence-free (P = 0.09) survival.

Conclusions We developed and validated a nomogram that predicts the risk of lymph node metastasis in EGC based on a large database. This precision nomogram is useful to avoid unnecessary gastrectomy after endoscopic dissection, which may ultimately improve the quality of life of patients with EGC.
Endoscopic submucosal dissection (ESD) is performed in selected patients with diagnostic endoscopic findings. The Japan Gastroenterological Endoscopy Society and Japanese Gastric Cancer Association have suggested that differentiated-type EGC confined to the mucosa without ulcerative findings and with a tumor diameter ≤ 2 cm is an absolute indication for ESD. The expanded indications for ESD include mucosal gastric cancers of the following categories: (a) differentiated-type, ulceration (–), diameter > 2 cm; (b) differentiated-type, ulceration (+), diameter ≤ 3 cm; (c) undifferentiated-type, ulceration (–), diameter ≤ 2 cm [6]. If the pathological findings do not meet these indications after ESD, the patients should undergo gastrectomy.

Subsequent gastrectomy was reportedly required in 0.9% of patients with absolute indications and 19.2% with expanded indications [7]. Residual cancer and lymph node metastasis (LNM) were detected in subsequent gastrectomy specimens from 5.6%–11.5% and 7.5%–16.7% of the patients, respectively [8–11]. Therefore, with the accurate prediction of LNM, it may be possible to avoid unnecessary gastrectomy after ESD.

Studies on the risk factors for LNM of gastric cancer would provide additional information; however, this may not be achievable. Presently, a nomogram is a precision tool that enables patients and clinicians to predict the probability of survival or LNM in the perioperative period. It also provides personalized quantified information for various carcinomas [12–15]. In gastric cancer, several nomograms have been introduced to predict postoperative outcomes, including complications and survival [16–18]. A nomogram may also be useful for predicting the probability of LNM and identifying those patients who should undergo gastrectomy.

This study aimed to develop and validate a nomogram with the goal of developing a more predictive tool than the ESD indications for identifying LNM and ultimately avoiding unnecessary gastrectomy in patients with EGC.

Methods

Study population and data source

We retrospectively reviewed the data of 10 579 patients who underwent gastrectomy for EGC between January 2001 and December 2015 at Samsung Medical Center. This validation dataset (n = 2100) satisfied the aforementioned inclusion and exclusion criteria and assessed the clinicopathological variables included in the nomogram.

The indications for ESD of gastric cancer were absolute (intraduodenal histologically differentiated EGC without ulcerative findings with diameter ≤ 2 cm) or expanded (criterion I, intraduodenal histologically differentiated EGC without ulcerative findings with diameter > 2 cm; criterion II, intraduodenal histologically differentiated EGC with ulcerative findings with diameter ≤ 3 cm; and criterion III, subduodenal invasion < 500 μm (sm1) and histologically differentiated EGC with diameter ≤ 3 cm).

Overall survival (OS) was determined from the date of endoscopic resection or surgery to the time of death. Disease-free survival (DFS) was determined from the date of endoscopic resection or surgery to the first relapse or death due to any cause. Finally, recurrence-free survival (RFS) was determined from the date of endoscopic resection or surgery to the first relapse or death with evidence of recurrence.

Statistical methods and analyses

The baseline characteristics are summarized as mean and standard deviation (SD) for continuous variables and as frequency and proportion for categorical variables. The statistical analysis
involved the development and validation cohorts. Two-sided $P$ values less than 0.05 were considered statistically significant.

The predictive accuracy of the model was displayed using receiver operating characteristic (ROC) curves. The ROC curve is a plot of sensitivity versus 1 – specificity for different threshold probabilities of LNM. Nomogram accuracy was quantified using the area under the curve (AUC) for validation. An AUC of 1.0 indicates perfect concordance, whereas an AUC of 0.5 indicates no relationship. Harrell’s concordance-index (C-index) was applied to evaluate nomogram performance. The C-index was a useful evaluation value similar to calculating the area under the ROC curve, with C-indices ranging from 0.5 to 1.0, indicating total chance and perfect matching, respectively.

All statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, North Carolina, USA), SPSS version 23 (SPSS, IBM Corp., Armonk, New York, USA), and R software version 3.4.3 (http://www.r-project.org) with the “rms” and “survival” packages.

**Development**

Using the development set ($n=10,579$), we selected variables that were identified to be significant by simple logistic regression analysis of the probability of metastasis. The backward selection method was applied to these variables to select the variables for the final logistic regression model. A nomogram was developed using the final logistic model.

**Validation and calibration of logistic regression for nomogram**

The nomogram developed from the development set was applied to the validation dataset from the National Cancer Center ($n=2100$) for external validation and calibration of the nomogram. This validation set had similar baseline characteristics to the development set, except for the tumor histologic type. While in the development set the most frequent type was moderately differentiated cancer, in the validation set the most frequent type was signet-ring cell carcinoma.

The discrimination was evaluated using a C-index, which provides the probability that, for two randomly selected patients, when one patient has an event before the other, this patient has a poorer predicted outcome than the other patient, as determined by the nomogram. The nomogram was calibrated by comparing the predicted LNM with the actual LNM after grouping the nomogram-predicted LNM by decile.

**Survival analysis to estimate clinical efficacy**

The survival analysis included patients who had achieved 5-year survival (a gastrectomy group of 6641 patients; an endoscopic dissection group of 999 patients). The nomogram classified 2726 patients who underwent gastrectomy from the development set as being in a low ($\leq 3\%$) LNM risk group. Among the clinical dataset of patients from Samsung Medical Center who underwent endoscopic resection, the nomogram identified 1519 patients at low risk of LNM. The Kaplan–Meier curves for OS, DFS, and RFS were developed for the gastrectomy and endoscopic dissection groups. Multivariate Cox regression analysis was performed with adjustment for age, tumor stage, and comorbidities.

**Results**

**Nomogram development and validation**

The clinicopathological characteristics of the development and validation sets are listed in **Table 1**. The median (range) number of examined lymph nodes was 37 (6–120) and 35 (6–150) in the development and validation sets, respectively. The incidence of LNM was 9.5% (1006/10,579) and 11.4% (239/2100) for the development and validation sets, respectively.

If the range of tumor sizes was too wide (e.g. 0.05–18.3 cm) to use in the Cox proportional hazards regression model, the data were transformed to log values – when data ranges over

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Development set ($n=10579$)</th>
<th>Validation set ($n=2100$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>56.3 (11.5)</td>
<td>58.4 (11.7)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6771 (64.0)</td>
<td>1354 (64.5)</td>
</tr>
<tr>
<td>Female</td>
<td>3808 (36.0)</td>
<td>746 (35.5)</td>
</tr>
<tr>
<td>Tumor size, mean (SD), cm</td>
<td>3.0 (1.9)</td>
<td>3.19 (1.8)</td>
</tr>
<tr>
<td>Tumor histologic type, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Well differentiated</td>
<td>11280 (12.1)</td>
<td>412 (19.6)</td>
</tr>
<tr>
<td>Moderately differentiated</td>
<td>3631 (34.3)</td>
<td>315 (15.0)</td>
</tr>
<tr>
<td>Poorly differentiated</td>
<td>2667 (25.2)</td>
<td>541 (25.8)</td>
</tr>
<tr>
<td>Signet-ring cell carcinoma</td>
<td>2790 (26.5)</td>
<td>832 (39.6)</td>
</tr>
<tr>
<td>Other</td>
<td>211 (1.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ulceration, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>7082 (66.9)</td>
<td>1728 (82.3)</td>
</tr>
<tr>
<td>Present</td>
<td>3497 (33.1)</td>
<td>372 (17.7)</td>
</tr>
<tr>
<td>Tumor depth of invasion, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucosa</td>
<td>5999 (56.7)</td>
<td>1096 (52.2)</td>
</tr>
<tr>
<td>Submucosa</td>
<td>4580 (43.3)</td>
<td>1004 (47.8)</td>
</tr>
<tr>
<td>Lymph node metastasis, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>9573 (90.5)</td>
<td>1861 (88.6)</td>
</tr>
<tr>
<td>Present</td>
<td>1006 (9.5)</td>
<td>239 (11.4)</td>
</tr>
<tr>
<td>Lymphatic invasion, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>9015 (85.2)</td>
<td>1721 (82.0)</td>
</tr>
<tr>
<td>Present</td>
<td>1564 (14.8)</td>
<td>379 (18.0)</td>
</tr>
<tr>
<td>Dissected lymph nodes, median (range)</td>
<td>37 (6–120)</td>
<td>35 (6–150)</td>
</tr>
</tbody>
</table>

SD, standard deviation.
several orders of magnitude, log scales can be useful. After the variables had been examined and transformed to fit the Cox proportional hazards regression model, they were selected by the backward and stepwise selection method ($P < 0.05$). Table 2 shows the included variables and their hazard ratios (HRs). The HRs were significantly higher for older age, male sex, larger diameter, undifferentiated type (poorly differentiated and signet-ring cell carcinoma), submucosal depth, and presence of lymphatic invasion. The presence of ulceration was not significant. This model showed an AUC of 0.846 (range 0.832–0.858) (Fig. 1).

Fig. 2 presents the nomogram for the prediction of LNM that was constructed based on the selected variables and HRs. The nomogram can assign the probability of LNM using the sum of the scores identified on the point scale for each variable. The mark for total points score aligned with the bottom scale indi-
cates the probability of LNM. ▶ Table 3 shows several examples of how to use the nomogram.

In the validation set, the AUC for predicting LNM was 0.813 (▶ Fig. 1). ▶ Fig. 3 shows the calibration plot of the nomogram. The x-axis shows the predicted LNM rate calculated by the nomogram, while the y-axis shows the actual LNM rate. The solid line represents the ideal reference line where the predicted LNM rate corresponds to the actual LNM rate. The dotted lines represent a 3% margin of error. The actual LNM rate corresponded closely with the predicted metastasis rate, and was almost within the 3% margin of error.

Clinical performance of the nomogram for the actual LNM status

We evaluated the actual LNM rate in patients with gastrectomy for EGC according to the predicted LNM rate on the nomogram (▶ Table 4). Among the 10 579 patients in the development set, 2726 patients had a ≤ 2% risk of LNM on the nomogram. The actual rate of LNM in this subgroup was 1.02%. The predicted LNM rate was higher than the actual LNM rate for all subgroups; however, the predicted LNM rate was similar to the actual LNM rate for those subgroups with a predicted risk ≤ 5% (1.0% in the ≤ 2% group, 2.7% in > 2% – 3% group, 3.7% in > 3% – 5% group). Among the 1350 patients with expanded indications for ESD who underwent gastrectomy, 29 patients (2.1%) actually presented with LNM. If the cutoff value was taken as 3% on the nomogram, 4245 patients, with an actual LNM rate of 1.6% (68/4245), would be able to avoid gastrectomy.

Several temporary cutoff values were established to estimate the diagnostic performance at each cutoff in the development dataset and validation dataset (▶ Table 5). When the cutoff value was set at ≤ 1.8%, none of the patients in the development dataset had LNM, while 0.5% (2/391) of the patients in the validation dataset showed LNM. At the cutoff of 3%, 1.6% of patients in the development dataset and 1.3% of those in the validation dataset had LNM. A total of 2.1% of the patients (29/1350) meeting the expanded criteria for ESD in the development group had LNM.

Application of the nomogram to the clinical outcomes of patients undergoing ESD

Among a total of 2091 patients who underwent ESD, 360 underwent subsequent gastrectomy and 1731 underwent ESD alone (▶ Fig. 4). A total of 690 patients with absolute indications and 851 patients with expanded indications underwent ESD alone. In addition, there were 190 patients who required a subsequent gastrectomy but did not undergo gastrectomy for various reasons, such as high surgical risk or patient’s request. The mean (SD) LNM risk on the nomogram was 1.7% (3.4%) for

<table>
<thead>
<tr>
<th>Patient #1</th>
<th>Patient #2</th>
<th>Patient #3</th>
<th>Patient #4</th>
<th>Patient #5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual value</td>
<td>Nomogram point</td>
<td>Actual value</td>
<td>Nomogram point</td>
<td>Actual value</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>0</td>
<td>Male</td>
<td>0</td>
</tr>
<tr>
<td>Age</td>
<td>60</td>
<td>5.99</td>
<td>63</td>
<td>5.34</td>
</tr>
<tr>
<td>Lymphatic invasion</td>
<td>–</td>
<td>0</td>
<td>–</td>
<td>0</td>
</tr>
<tr>
<td>T stage</td>
<td>SM</td>
<td>22.67</td>
<td>M</td>
<td>0</td>
</tr>
<tr>
<td>Log_tumor size</td>
<td>0.58</td>
<td>60.71</td>
<td>–1.60</td>
<td>23.49</td>
</tr>
<tr>
<td>Differentiation</td>
<td>MD</td>
<td>9.7</td>
<td>WD</td>
<td>0</td>
</tr>
<tr>
<td>Total points</td>
<td>99.06</td>
<td>28.83</td>
<td>80.07</td>
<td>55.74</td>
</tr>
<tr>
<td>Predicted LNM risk, %</td>
<td>4.12</td>
<td>0.13</td>
<td>1.64</td>
<td>0.49</td>
</tr>
</tbody>
</table>

M, mucosa; MD, moderately differentiated; no., number; PD, poorly differentiated; SM, submucosa; WD, well differentiated; LNM, lymph node metastasis.

▶ Fig. 3 Calibration plot for the nomogram.
We assessed the 5-year survival rate of the 6641 patients who underwent gastrectomy and 999 who underwent ESD alone. We assumed a cutoff value of 3 \% which is considered to indicate low risk for LNM in patients undergoing ESD. We focused on patients at low risk (\leq 3 \%) for LNM. A total of 2726 of the patients who underwent gastrectomy (41.0\%) and 798 of the patients who underwent ESD (79.9\%) were included in the survival analysis. Among these patients with low risk for LNM on the nomogram, the endoscopic dissection group had similar OS (\textit{P}=0.32), DFS (\textit{P}=0.47), and RFS (\textit{P}=0.09) compared with those in the gastrectomy group after adjusting for age, comorbidities, and tumor stage (\textit{Fig. 5}).

**Discussion**

Endoscopic resection has been widely accepted as an alternative treatment to maintain the quality of life for patients with EGC who meet the appropriate criteria [20, 21]. Predicting LNM is an important step in the selection of the treatment options for EGC. Several nomograms have been developed to predict the risk of LNM in gastric cancer [22–25]; however, most nomograms were developed using a small sample population, or a patient population that included patients with advanced gastric cancer and a significant burden of LNM.

Here, we developed a nomogram to predict LNM in 10579 patients with EGC. We used the following six independent variables identified on logistic regression analysis: sex, age, tumor size, depth of invasion, differentiation, and presence of lymphatic invasion. According to our nomogram, if a patient achieves a score of 180 or higher, the probability of LNM is \geq 75 \%. This...
probability would be difficult to achieve with other clinical sources. Our nomogram also underwent successful external validation against an independent cohort and showed reliable clinical performance for a cohort of patients who underwent endoscopic resection.

We developed this nomogram to avoid unnecessary gastrectomies being performed (after endoscopic submucosal resection) in patients with EGC. A study reported that approximately 6.3% of the patients who underwent gastrectomy after ESD had LNM [26]. The expanded indications for endoscopic resection were suggested on the basis of the very low risk for detected LNM based on the pathological results of patients with EGC who underwent gastrectomy [27]. Although the expanded indications have shown favorable long-term outcomes, with 5-year OS rates of 93.4%–97.2%, comparable to those for the absolute indications [28,29], several recent reports have suggested that LNM may occur even in an EGC that meets the expanded indications [30–32]. The expanded indications have been limited in increasing the rate of endoscopic resection as a less invasive treatment option for EGC.

As the population ages worldwide, the number of elderly patients is increasing. According to the American Cancer Society, the average age at which patients are diagnosed with stomach cancer is 68 years [33]. The rates of mortality and complications after gastrectomy are higher among elderly patients than among those who are younger [34]. Therefore, avoiding unnecessary gastrectomy after ESD could both preserve quality of life and decrease cancer-related morbidity and mortality rates. With respect to the high morbidity and mortality rates after gastrectomy, the predictive tools for LNM play an important role in optimizing the quality of life of patients with gastric cancer.

The predicted LNM rate was higher than the actual LNM rates in all subgroups in our study. The predicted LNM rates were similar to the rates in subgroups with <5% LNM. In addition, among patients who underwent gastrectomy, 29 of 1350 patients (2.1%) with expanded indications for ESD had LNM.

When the cutoff value was assumed to be 3% on the nomogram, 68 of 4245 patients (1.6%) had actual LNM. Therefore, our nomogram can spare patients from undergoing unnecessary gastrectomy while securing lower LNM rates compared with those predicted by the expanded indications.

An additional analysis was performed to estimate the clinical performance of this nomogram for survival. We found that patients at low risk on the nomogram showed similar clinical outcomes, including for OS, DFS, and RFS, regardless of the treatment modality used (endoscopic resection or gastrectomy). These results suggest that this nomogram can effectively predict the clinical outcomes.

A strength of this study is that we used data from a large cohort of patients who underwent gastrectomy for EGC with low rates of LNM to develop the nomogram. Our nomogram was successfully and independently externally validated and had good discrimination performance in the validation cohorts; the nomogram was well-calibrated in the development and validation cohorts. It is important to note that these nomograms are applicable only to patients with EGC who underwent complete endoscopic resection. More detailed objective values, which were confirmed pathologically, can enhance the predictive power and effectiveness of its clinical implications.

Recent data have suggested that sentinel node (SLN) biopsy may decrease the demand for standard lymphadenectomy in EGC patients. The predictive accuracy of this nomogram was comparable to recently published data from a prospective multicenter study on SLN biopsy. Kitagawa et al. [35] reported that SLN biopsy has an accuracy of 93% for clinically T1 or T2 gastric cancer with an LNM prevalence of 9.6%. There was only one false-negative LN biopsy among 341 patients with clinical T1 gastric cancer. This group reported a sensitivity and negative predictive value of 73.1% and 96.6%, respectively, with an LNM prevalence of 9.5%. We believe that we can more accurately identify node-negative patients with the combined use of SLN biopsy and our nomogram. The most important benefit
of the nomogram is that it offers noninvasive risk prediction preoperatively. An individualized prediction using a patient’s preoperative variables that is based on the nomogram could help inform the physicians’ and patient’s decision-making process.

We have compared the accuracy for patients fulfilling the absolute and individual expanded criteria with the results of the nomogram (Table 6). Interestingly, only undifferentiated type had a result where the predicted LNM rate was lower than the actual LNM rate. Several studies [36, 37] have revealed that patients with poorly differentiated EGC meeting the expanded ESD criteria have a relatively high prevalence of LNM, leading to consideration of whether or not ESD is a feasible and effective clinical approach for treating poorly differentiated EGC. We thought the nomogram could also have a similar limitation. This issue should be considered in additional external validations in the future.

We also analyzed the subgroup of submucosal 1 (SM1) invasion to enhance the accuracy of this nomogram in the early stages of development. However, the validation set from the National Cancer Center did not give invasion depth. In addition, deciding submucosal invasion depths, such as SM1, SM2, and SM3, may have subjective characteristics depending on the pathologist [38]. Therefore, specific submucosal invasion depth was not considered in this nomogram.

The independent risk factors for LNM might improve the predictive power of nomograms. Although this nomogram did not include genomic data or biomarkers as variables, the risk of LNM may be more accurately predicted by incorporating these data into next-generation nomograms. In addition, relevant cutoff values should be established for its clinical application. We validated our model using independent external data, and the model was found to be well-fitted on external validation; however, this nomogram should be validated by other institutions and/or using a Western cohort before it is used for a general patient population. In addition, these results do not suggest that routine lymphadenectomy is beneficial for patients not at low risk of LNM. Although the actual LNM rate was 14.8 % in the high-risk (≥3 %) group, the therapeutic value of lymphadenectomy in this group must be evaluated in clinical trials. Our study findings indicate that patients undergoing ESD classified as having low LNM risk, based on our nomogram, showed similar outcomes compared with those who underwent lymphadenectomy.

In conclusion, we have developed and validated a nomogram that predicts LNM in patients with EGC based on data from a large database. This precision nomogram is useful for avoiding unnecessary gastrectomy after endoscopic dissection, so improving the quality of life of patients with EGC.

Acknowledgments

This study was presented during a poster session at the American Society of Clinical Oncology (ASCO) 2016 annual meeting.

Competing interests

The authors declare that they have no conflict of interest.

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