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ORIGINAL RESEARCH

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Nomogram for the prediction of disease-free survival in FIGO 2023 stage IA2 endometrial cancer patients

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Abstract

The purpose of the research is to assess the risk factors that contribute to the recurrence of International Federation of Gynecology and Obstetrics (FIGO) 2023 stage IA2 endometrial cancer (EC) patients. The study was conducted by examining stage IA2 patients who underwent surgery for EC in the gynecological oncology clinic between 2008–2022. Study data were collected by retrospective evaluation. A total of 185 patients, 37 with recurrence and 148 in the control group, were included in the study. In the study, the recurrence rate among all stage IA2 EC was found to be 3.9%. The mean age was similar between the groups. Grade 2 tumors were found in 73.0% of patients in the case group and 34.5% in the control group. Tumor size was larger in the case group. Neutrophil lymphocyte ratio (NLR) value was significantly higher in the case group. Adjuvant radiotherapy was given to 42.6% of patients in the control group and 59.5% in the case group. The nomogram's score was assessed for disease-free survival (DFS) using Concordance Correlation Coefficient analysis. The Concordance index (C-index) for the nomogram was 0.903. When 5-year DFS times were analyzed according to total nomogram score, a significant difference was found. Grade 2 tumor classification, negative estrogen receptor status, elevated cancer antigen 125 (CA125) levels (>35), large tumor size (≥ 3.0 cm) and high NLR (≥ 1.9) are identified as significant risk factors for recurrence in early-stage (IA2) and low-Grade EC patients. The total score derived from the nomogram constructed with these risk factors shows a notable variation in DFS.

Keywords

Endometrial cancer; Disease-free survival; Recurrence; Neutrophil lymphocyte ratio

1. Introduction

Endometrial cancer (EC), the most common cancer of the reproductive system, is the fourth most common type of malignancy [1]. While about 70% of cases are detected in the early stages, there is a 15–20% risk of recurrence [2]. The majority of relapses occur within the first 3 years. Most patients with EC have stage I tumors with Grade 1–2 endometrioid tumors at the time of diagnosis [3]. These tumors typically have a high survival rate.

Endometrial cancer staging was revised in 2023 by incorporating prognostic factors of the disease [4]. Histological type, lymphovascular space invasion (LVSI), and molecular pattern, which were not previously included in the 2009 staging, were now included. Since these prognostic factors were not present in the old staging, the presence of patients with different disease-free and overall survival rates in the same stage causes the group to be heterogeneous. Especially, approximately half of the recurrences in early stages are limited to the pelvic region [5]. The 5-year survival rates for recurrent cases are 55–65% for pelvic recurrences and 17% for extrapelvic relapses [6, 7]. The average time to recurrence is 12 months [7]. According to the International Federation of Gynecology and Obstetrics (FIGO) 2009 staging system, recurrence rate for stage IA patients was 4.4%, while it was 9.2% for IB patients [7].

The purpose of the research is to assess the risk factors that contribute to the recurrence of FIGO 2023 stage IA2 endometrial cancer (EC) patients.

2. Material and method

The study included a retrospective analysis of patients who underwent surgery for EC at the gynecological oncology clinic between 2008–2022. Thirty-seven patients with recurrence (case group) of endometrioid type tumors in the same staging stage IA2 were enrolled in the study, along with 148 patients with the same tumor type and stage but without recurrence (control group), who were selected using a dependent random sampling method. Patients who were not followed up at our center, did not undergo lymph node dissection/sampling or sentinel lymph node biopsy, or were considered inoperable due to medical reasons at the time of diagnosis were excluded from the study.

In the staging process, the patient's stages were revised

based on the FIGO 2023 staging system [4]. Preoperative evaluations, surgical procedures, postoperative pathology results, and adjuvant treatments were retrospectively reviewed from patient files. Prior to surgery, CA125 value, hemoglobin, neutrophil, lymphocyte, platelet and albumin levels were recorded. For patients with multiple values, the ones closest to the surgery were used. Postoperatively, histological type, Grade, LVSI, cervical involvement, myometrial invasion depth, tumor size, adnexal involvement, and lymph node status were noted. However, for unable undergo these exams, diagnosis was made using imaging methods and treatment was initiated.

All surgical procedures were performed by gynecologic oncology specialists. A midline vertical incision was used in the surgeries. When the surgery began, a detailed exploration was conducted after entering the abdomen. Peritoneal surfaces, omentum, liver surface, diaphragm, colon, small intestines, mesentery, paracolic, pelvic and paraaortic areas were examined through observation and palpation. After exploration, a sample of peritoneal cytology was taken. Hysterectomy, bilateral salpingo-oophorectomy, pelvic lymph node dissection/sampling or sentinel lymph node biopsy, and para-aortic lymph node dissection were performed. The pelvic lymphadenectomy consisted of removing lymphatic tissue along the external and common iliac vessels, as well as in the obturator fossa. Para-aortic lymph node dissection was defined as the removal of lymphatic tissue below the left renal vein, starting from the bifurcation of the aorta. Patients with Grade 1–2 tumors and a depth of myometrial invasion of less than 50% were recommended observation according to the National Comprehensive Cancer Network (NCCN) guidelines. However, patients with LVSI or those aged $\geq$60 years were offered the option of adjuvant brachytherapy. Adjuvant vaginal brachytherapy was started between 6–8th postoperative weeks. The upper 2/3 vagina was generally selected as the target. A 7 Gy $\times$ 3 fraction regimen was applied at a depth of 0.5 cm from the vaginal surface.

Complete blood counts were performed using a Coulter LH 750 instrument (Beckman Coulter, Brea; CA, USA). CA125 values were assessed using a Roche E170 Modular System and measured using the chemiluminescence method; concentrations are reported in U/mL. The neutrophil lymphocyte ratio (NLR) value was calculated by dividing the absolute neutrophil count by the absolute lymphocyte count; the platelet lymphocyte ratio (PLR) value was found by dividing the absolute platelet count by the absolute lymphocyte count.

Patients were scheduled for follow-up every 3–4 months for the first two years, every 6 months for the next three years, and every year after 5 years. During the follow-up visits, vaginal examination with a speculum and vaginal ultrasonographic evaluation were conducted. An abdominal examination using computed tomography or magnetic resonance was performed once a year. Positron emission tomography was used to examine those with suspicious lesions. The time between initial treatment and the onset of relapse was defined as disease-free survival (DFS).

Categorical data were presented as numbers and percentages and evaluated using the Chi-Square test. Numerical data were expressed as mean and standard deviation. The Student-*T* test was used to compare numerical data. Survival analysis was performed using the Kaplan-Meier method and the results were compared using the log-rank test. Receiver Operating Characteristic (ROC) analysis was used to determine cut-off values, as well as the sensitivity and specificity. The Area Under Curve (AUC) value was reported. Logistic regression analysis was used to identify factors for recurrence. The results were presented as Odds Ratios (OR) with corresponding 95% Confidence Intervals (CI). The β value indicates the average change in the dependent variable for each unit change in the independent variable. A nomogram was constructed based on the results of the logistic regression analysis. The nomogram was internally validated for discrimination and calibration. The accuracy of the nomograms were measured using the Concordance Index (C-index). The statistic measures the model's ability to distinguish between high-risk and low-risk subjects, ranging from 0.0 (indicating no better than chance) to 1.0 (perfect predictive power). Calibration curves were plotted by comparing the predicted survival probabilities from the nomogram to the observed probabilities using methods such as Deming regression (orthogonal regression), Bland-Altman plot, or Kendall's W Concordance Correlation Coefficient (CCC). Data collection and statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) software (version 17, SPSS, Inc, Chicago, IL, USA). A p value of < 0.05 was considered statistically significant.

3. Results

A total of 185 patients, 37 with recurrence and 148 in the control group, were included in the study. In the study, the recurrence rate among all stage IA2 EC was found to be 3.9% (37/941). All patients underwent hysterectomy, bilateral salpingo-oophorectomy and pelvic lymph node dissection/sampling or sentinel lymph node biopsy. All patients were stage IA2 with superficial myometrial invasion. None of the patients had LVSI, cervical involment, or adnexal involvement. Adjuvant chemotherapy was not given to any patient. Pelvic recurrence occurred in 16 (43.2%) and extrapelvic recurrence in 21 (56.8%) patients in the recurrence group. Clinical and pathological characteristics of the case and control groups are given in Table 1. The mean age was similar between the groups. Grade 2 tumors were found in 73.0% of patients in the case group and 34.5% in the control group ($p < 0.001$). Estrogen and progesterone receptor positivity was more common in the control group, and the difference was significant. Tumor size was larger in the case group (2.8 ± 1.4 *vs.* 3.6 ± 1.5; $p = 0.002$). NLR value was significantly higher in the case group (2.2 ± 1.2 *vs.* 2.7 ± 1.6; $p = 0.023$). Adjuvant vaginal brachytherapy was given to 42.6% of patients in the control group and 59.5% in the case group ($p = 0.049$).

ROC analysis was used to evaluate the optimal cut-off values of tumor size, NLR and PLR for recurrence (Fig. 1). The cut-off for tumor size was 3.0, with a sensitivity of 62.2% and specificity of 68.9% (AUC = 0.661, p = 0.002). The NLR cut-off was 1.9, with a sensitivity of 70.3% and specificity of 44.9% (AUC = 0.634, $p = 0.012$). For PLR, the sensitivity was 40.5% and specificity was 64.2% (cut-off = 141, AUC = 0.524, $p = 0.655$).

TABLE 1. Demographic characteristics and clinical characteristics of patients.

	Control (n = 148)	Recurrent (n = 37)	*p*
Age	58.9 ± 9.7	60.9 ± 8.5	0.246
Hypertension	65 (43.9%)	20 (54.1%)	0.178
Diabetes mellitus	48 (32.4%)	17 (45.9%)	0.090
Grade			
1	97 (65.5%)	10 (27.0%)	<0.001
2	51 (34.5%)	27 (73.0%)	
Positive estrogen receptor	141 (95.3%)	21 (56.8%)	<0.001
Positive progesterone receptor	132 (89.2%)	23 (62.2%)	<0.001
Tumor size (cm)	2.8 ± 1.4	3.6 ± 1.5	0.002
Number of PLN	18.1 ± 7.9	18.4 ± 9.8	0.850
Number of PaLN	8.3 ± 4.8	10.0 ± 4.9	0.102
CA125	21.9 ± 44.7	25.7 ± 19.9	0.610
Hemoglobin	12.2 ± 1.9	12.3 ± 1.5	0.822
Platelet, ($\times 10^3$)	268 ± 68	283 ± 68	0.253
Neutrophil, ($\times 10^3$)	4.3 ± 1.7	5.2 ± 1.7	0.008
Lymphocyte, ($\times 10^3$)	2.2 ± 0.7	2.1 ± 0.6	0.629
NLR	2.2 ± 1.2	2.7 ± 1.6	0.023
PLR	137 ± 58	150 ± 72	0.249
Albumin	4.1 ± 0.8	4.1 ± 0.4	0.586
Adjuvant radiotherapy	63 (42.6%)	22 (59.5%)	0.049

PLN: Pelvic lymph node; PaLN: Para-aortic lymph node; CA125: Cancer antigen 125; NLR: Neutrophil lymphocyte ratio; PLR: Platelet lymphocyte ratio.

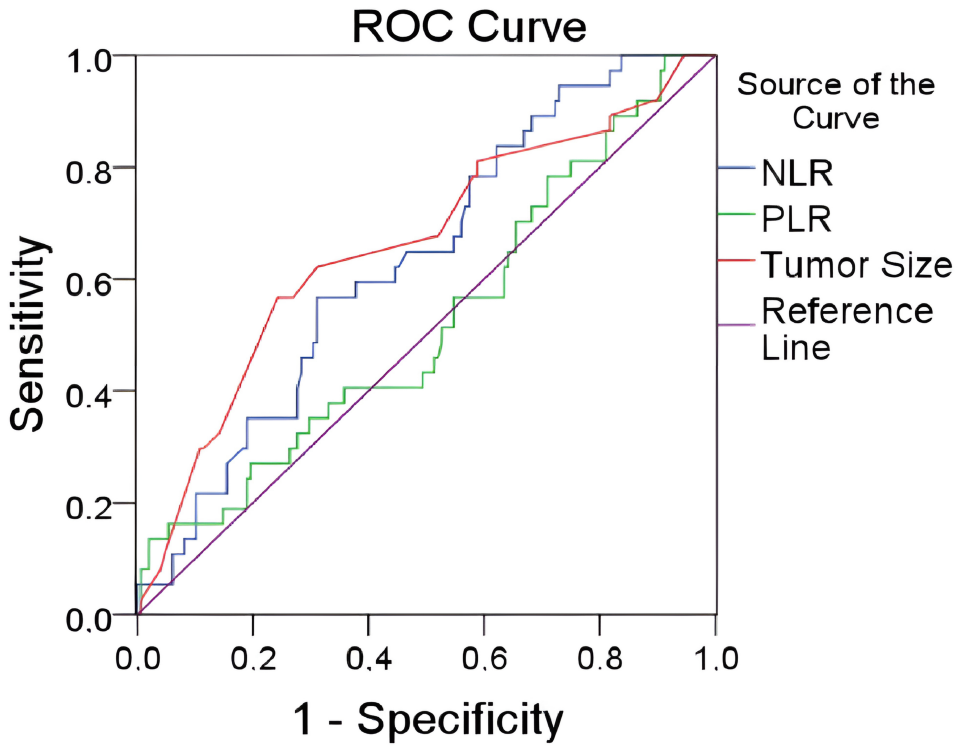

FIGURE 1. Tumor size, NLR and PLR values for recurrence were evaluated by ROC analysis. ROC: Receiver Operating Characteristic; NLR: Neutrophil lymphocyte ratio; PLR: Platelet lymphocyte ratio.

The relationship between prognostic factors and recurrence was analyzed using the univariable Logistic regression model (Table 2). B values of the statistically significant factors from the univariable penalized regression model were utilized as nomogram scores (Fig. 2). Prognostic factors included in the nomogram and their frequency in the study were determined as Grade 2 (42.2%), negative estrogen receptor (12.4%), high CA125 (>35) (12.4%), large tumor (>3 cm) (54.6%) and high NLR (>1.9) (63.2%). Upon preparation of the nomogram, the risk factors' scores ranged from 0 to 7.3 points. The nomogram's score was assessed for DFS using Concordance Correlation Coefficient analysis. The C-index for the nomogram was 0.903 (95% CI, 0.82 to 0.96). A scatter diagram depicted the association between the nomogram and DFS times in the case group (Fig. 3).

When 5-year DFS times were analyzed according to total nomogram score, a significant difference was found ($p < 0.001$). The Kaplan Meier test is shown in Fig. 4. Specifically, the mean 5-year DFS rates were as follows: 94.4% for patients scoring 0–1.7 on the nomogram, 89.8% for those scoring 1.8–3.4, 59.7% for those scoring 3.5–5.1, and 33.3% for patients scoring 5.2–7.3.

4. Discussion

In this study, risk factors for recurrence were assessed in patients with early stage (IA2) and low Grade, which represents the most prevalent group. The analysis revealed that Grade 2, negative estrogen receptor status, high CA125 levels (>35), large tumor size (≥3.0 cm) and elevated NLR (≥1.9) were identified as significant risk factors for recurrence. The total score obtained from the nomogram incorporating these risk factors demonstrated a statistically significant difference in the mean disease-free survival rate ($p < 0.001$).

Characteristics identified through genomic evaluations as delineated by the Cancer Genome Atlas (TCGA) offer significant insights regarding disease prevalence [8]. Nonetheless, the widespread integration of these assessments remains limited. The recurrence of early-stage disease is rare at 4–6% [7, 9], with a notably decreased local recurrence rate of 3.7% [10]. Notably, around two-thirds of all recurrences manifest in patients at stages I to II [6]. Within the existing literature, the vaginal cuff emerges as the predominant site of recurrence [7, 11, 12]. This study focused on evaluating stage IA2 patients, revealing a recurrence rate of 3.9% in this subset, with a pelvic recurrence rate of 43.2%.

Early detection of recurrences assumes paramount importance, necessitating a closer examination of pertinent factors to determine optimal monitoring for early-stage patients and provide precise prognostic information. Literature underscores that adjuvant radiotherapy diminishes locoregional recurrence rates sans a significant improvement in overall survival among early-stage EC patients [13, 14]. Notably, the recurrence rate stood at 12.9% in women subjected to adjuvant radiotherapy (RT) compared to 5.3% in those who did not receive this treatment [9]. When exclusively evaluating the local recurrence rate, it stood at 4.0% in patients who received adjuvant radiotherapy and 14.9% in those who did not [15]. It has been reported that the staging is a pivotal parameter predicting the recurrence risk [7], with LVSI and tumor size emerging as significant contributors to increased recurrence risks in early stages [16, 17]. In our study, risk factor analysis for recurrence was performed in stage IA2 patients, which is a common patient cohort according to the updated 2023 staging criteria. Regression analysis unveiled that factors such as Grade 2, negative estrogen receptor status, elevated CA125 levels (>35), large tumor size (≥3.0 cm) and high NLR (≥1.9) significantly impact the risk of recurrence. According to this analysis, the association between the nomogram score and DFS was evaluated, demonstrating a statistically significant influence of the score on DFS values. The nomogram's C-index was determined to be 0.903. Notably, 5-year DFS rates decline sharply from 94.4% to 33.3% in patients with nomogram scores ranging 0–1.7 to 5.1–7.3 points, respectively ($p < 0.001$). The risk factors identified with the highest score on the nomogram, indicating a poor prognosis, were found to be Grade 2 tumor classification and elevated NLR.

Total systematic lymphadenectomy, along with the many complications it carries (such as vascular injury, lymphedema, lymphocele and associated cellulitis) and the advantages of shortening the operation time with sentinel LN biopsy, is now being replaced by sentinel LN biopsy, especially in the early stages [18]. Almost all cases with metastatic LNs are detected with sentinel LN application [19]. In this way, it can be used

TABLE 2. Logistic hazard ratios for recurrence for the predictors used in the nomogram.

	β	OR	95% CI	p
Grade 2	1.7	5.6	1.7–18.5	0.004
Negative estrogen receptor	1.4	3.3	1.3–9.8	0.011
Negative progesterone receptor	0.4	1.5	0.1–5.1	0.643
Adjuvant radiotherapy	0.1	1.0	0.3–2.9	0.985
High CA125 (>35)	1.3	3.6	1.1–12.9	0.043
Large tumor (≥3.0 cm)	1.2	3.4	1.1–9.8	0.023
High NLR (≥1.9)	1.7	5.7	1.6–19.9	0.006
High PLR (≥141)	0.8	0.4	0.1–1.2	0.112

CA125: Cancer antigen 125; NLR: Neutrophil lymphocyte ratio; PLR: Platelet lymphocyte ratio; OR: Odds Ratios; CI: Confidence Intervals.

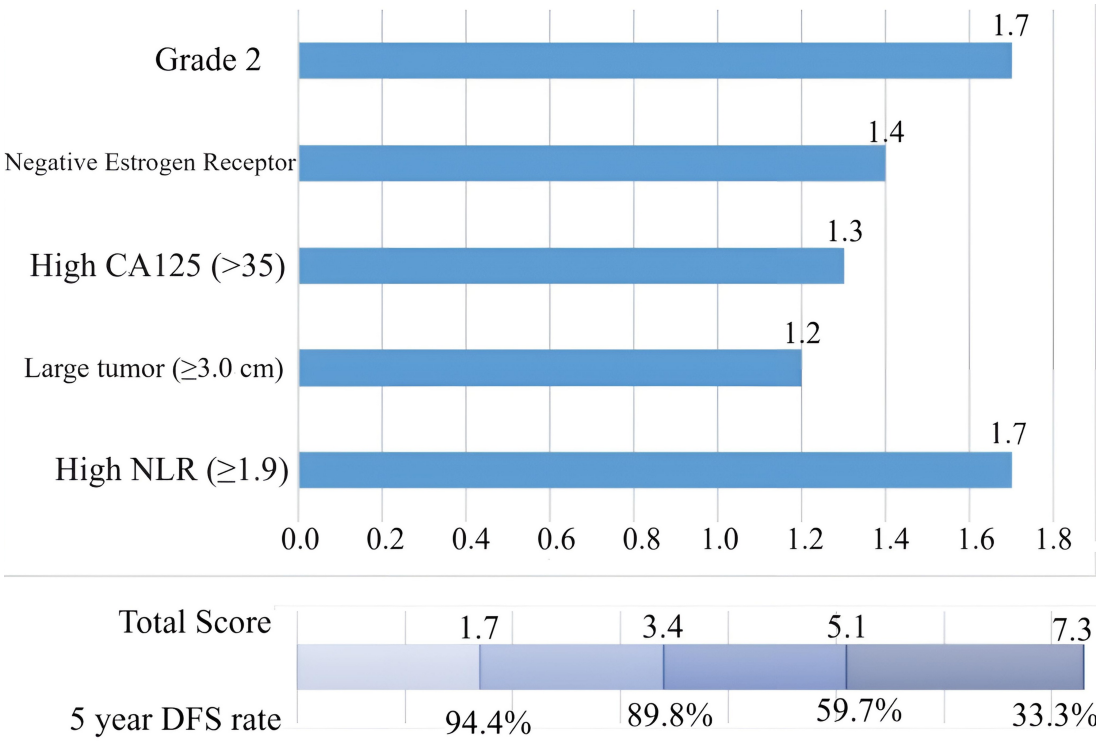

FIGURE 2. Nomogram for predicting 5-year disease-free survival (DFS) using five clinical characteristics. To use the nomogram, locate a patient's variable on the corresponding axis, then draw a line to the points axis, sum the points, and draw a line from the total points axis to the 5-year DFS probability axis. CA125: Cancer antigen 125; NLR: Neutrophil lymphocyte ratio.

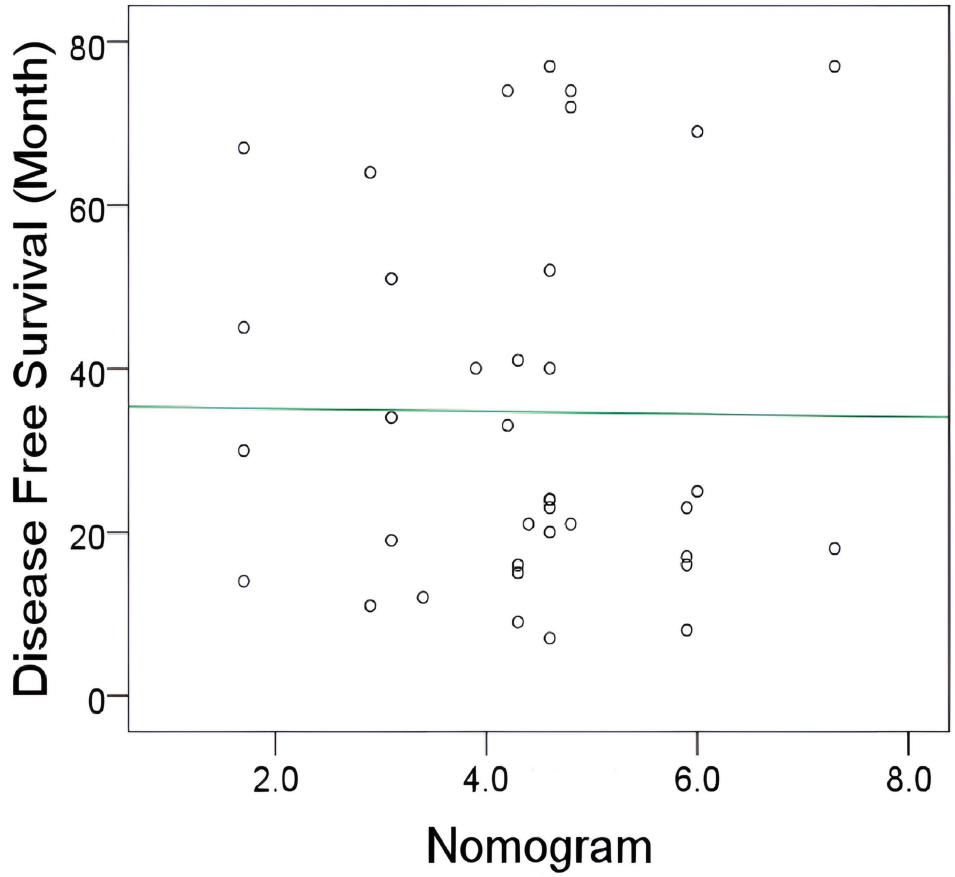

FIGURE 3. Relationship between the nomogram and DFS times in the case group, Scatter diagram.

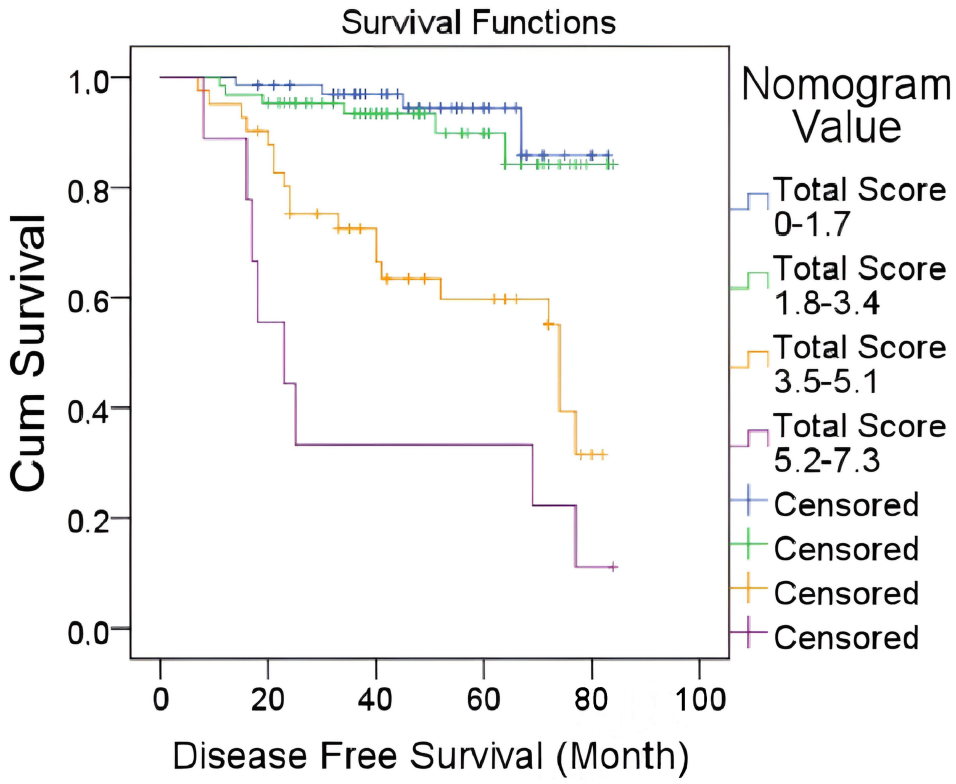

FIGURE 4. According to Kaplan-Meier, total nomogram score and disease-free survival curve.

safely.

The study is noted to have certain limitations. First of all, it can be classified as retrospective. Additionally, the absence of pathologic staining can be attributed to the retrospective nature of the study. Nevertheless, despite these limitations, the study's value is elevated by the consistency in follow-up procedures and treatments for patients with isolated, early-stage, low-Grade tumors, as well as the presence of a systematic filing system that enhances the study's credibility.

5. Conclusions

In conclusion, Grade 2 tumor classification, negative estrogen receptor status, elevated CA125 levels (>35), large tumor size (≥3.0 cm) and high NLR (≥1.9) are identified as significant risk factors for recurrence in early-stage (IA2) and low-Grade EC patients. The total score derived from the nomogram constructed with these risk factors shows a notable variation in disease-free survival rates. It is crucial to note that further studies are necessary to validate these findings and provide more robust evidence in this area of research.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

AÖ and VG—designed the research study. İÇ—performed the research. MÖ and MS—analyzed the data. AÖ and VG—wrote the manuscript. KG—edited. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethics committee approval was received from İzmir Katip Çelebi University for the study (Date: 21 March 2024, Decision no: 173), and all procedures adhered to the ethical standards outlined in the 1964 Helsinki declaration and its subsequent amendments or equivalent ethical standards. Informed consent was obtained from all subjects we could reach (retrospective study and due to the presence of deceased patients) who participated in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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