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Pathological Response and Survival Outcomes Following Neoadjuvant Chemotherapy in HR+/HER2- Breast Cancer: Real-world Experience

Şahin BEDİR[1], Uğur Alp YEŞİLOVA[2], Burçin ÇAKAN DEMİREL[1], Merve TOKOÇİN[3], Nida SÜNNETÇİ ARIKAN[4], Ali MUHAMMEDOĞLU[5], Aynur ÖZEN[6], Nigar ERKOÇ[7], Emir ÇELİK[8], Ezgi DEĞERLİ[9], Nilay ŞENGÜL[10], Nilüfer BULUT[2], Gökmen Umut ERDEM[2]

[1]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Medical Oncology, İstanbul, Türkiye
[2]University of Health Sciences Türkiye, Başakşehir Çam and Sakura City Hospital, Department of Medical Oncology, İstanbul, Türkiye
[3]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of General Surgery, İstanbul, Türkiye
[4]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Radiation Oncology, İstanbul, Türkiye
[5]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Pathology, İstanbul, Türkiye
[6]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Nuclear Medicine, İstanbul, Türkiye
[7]University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Radiology, İstanbul, Türkiye
[8]University of Health Sciences Türkiye, İstanbul Prof. Dr. Cemil Taşcıoğlu City Hospital, Department of Medical Oncology, İstanbul, Türkiye
[9]University of Health Sciences Türkiye, Bakırköy Dr. Sadi Konuk Training and Research Hospital, Department of Medical Oncology, İstanbul, Türkiye
[10]Medicana Ataköy Hospital, Clinic of Medical Oncology, İstanbul, Türkiye

ABSTRACT

Objective: Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer (BC) is the most common subtype but shows limited sensitivity to neoadjuvant chemotherapy (NAC), and its clinical benefit remains controversial. This study evaluated clinicopathological characteristics, pathological response patterns, and survival outcomes in HR+/HER2- BC patients treated with NAC.

Material and Methods: This retrospective cohort study included 186 women with stage II-III HR+/HER2- BC who received NAC followed by surgery between 2015 and 2024 at two tertiary centers. Pathological responses, event-free survival (EFS), and overall survival (OS) were analyzed. Logistic regression identified predictors of pathological complete response (pCR), and Cox models evaluated prognostic factors for survival.

Results: After a median follow-up of 30.6 months, pCR was achieved in 13.4% of patients and 42.5% showed a partial pathological response, resulting in a total pathological response rate of 55.9%. Grade 3 tumors and estrogen receptor (ER) expression <90% independently predicted pCR. Five-year EFS and OS rates were 77% and 88%, respectively. High ER expression (≥90%) and any pathological response were strong independent predictors of improved EFS and OS, whereas pCR alone was not associated with survival.

Conclusion: In HR+/HER2- BC treated with NAC, overall pathological response and ER expression provide greater prognostic value than pCR alone.

Keywords: Hormone receptor-positive breast cancer; neoadjuvant chemotherapy; pathological response; prognostic factors

INTRODUCTION

Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer (BC) represents the most common molecular subtype of invasive BC, accounting for approximately 70% of all newly diagnosed cases.[1,2] Despite generally favorable long-term outcomes, HR+/HER2- BC is biologically heterogeneous and encompasses tumors with varying proliferation rates, endocrine sensitivity, recurrence risks, and treatment responses.[3,4] In particular,

Correspondence: Şahin BEDİR MD;
University of Health Sciences Türkiye, Bağcılar Training and Research Hospital, Department of Medical Oncology, İstanbul, Türkiye

E-mail: sahinbedir7786@hotmail.com

ORCID ID: orcid.org/0000-0002-5797-0804

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luminal B tumors are associated with higher proliferative activity, more aggressive clinical behavior, and poorer prognosis compared with luminal A tumors.[5]

Neoadjuvant therapy has become increasingly utilized in early-stage disease.[6] In HR+/HER2- patients, neoadjuvant chemotherapy (NAC) may facilitate surgical resection by downstaging the tumor, increase the feasibility of breast-conserving surgery, and provide early assessment of treatment efficacy to guide subsequent adjuvant therapy.[7,8] However, compared to other subtypes, HR+/HER2- tumors generally exhibit lower chemosensitivity, with pathological complete response (pCR) rates significantly lower than those seen in triple-negative or HER2-positive disease.[9,10] Although pCR has traditionally been considered a surrogate marker for improved survival in aggressive BC subtypes, its prognostic significance in HR+/HER2- disease remains controversial.[11-13] Several studies have suggested that long-term outcomes in HR+/HER2- tumors may depend more strongly on endocrine responsiveness and tumor biology than on pCR achievement alone.[14,15] Consequently, concerns regarding overtreatment and the optimal selection of patients for NAC continue to be debated in clinical practice.[16]

In recent years, the use of NAC in HR+/HER2- BC has increased, particularly among patients with high-risk clinicopathological features.[17,18] Nevertheless, most available evidence originates from clinical trials with highly selected patient populations, whereas real-world data reflecting routine oncology practice remain relatively limited.[19,20] Therefore, further studies are needed to better define pathological response (pR) patterns, prognostic factors, and survival outcomes in this heterogeneous subgroup.

Accordingly, the present study aimed to evaluate the clinicopathological characteristics, pR patterns, and survival outcomes of HR+/HER2- BC patients treated with NAC in a real-world, multicenter cohort.

MATERIAL AND METHODS

Study Population

This retrospective study included 186 consecutive female patients diagnosed with stage II-III HR+/HER2- BC cancer who received NAC between January 2015 and September 2024 at University of Health Sciences Türkiye, Bağcılar Training and Research Hospital and University of Health Sciences Türkiye, Başakşehir Çam and Sakura City Hospital.

The inclusion criteria were as follows:

1. Age ≥18 years.

2. Histologically confirmed invasive breast carcinoma.

3. HR-positive status was determined via immunohistochemistry (IHC).

4. HER2- status confirmed via IHC and/or fluorescence *in situ* hybridization (FISH).

5. Completion of surgery following NAC.

The exclusion criteria were as follows:

1. Stage IV disease at diagnosis.

2. No surgery after NAC.

3. Incomplete follow-up data (Figure 1).

The indication for NAC was determined by multidisciplinary BC teams at each participating institution. NAC was generally preferred for patients with locally advanced disease, large primary tumors, clinically positive axillary lymph nodes, high-risk biological features such as high histologic grade or elevated Ki-67 index, and tumor downstaging when considered necessary to improve operability or to increase the feasibility of breast-conserving surgery.

Clinical, pathological, and treatment-related data were collected from the electronic medical records, including age, menopausal status, body mass index (BMI), histologic subtype, clinical T and N stages, estrogen receptor (ER) and

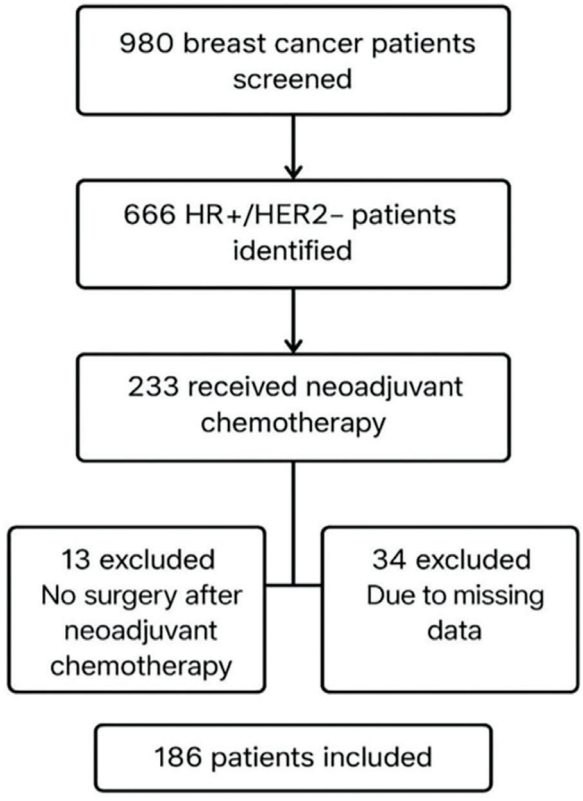

FIGURE 1: Patient selection flowchart for this study.

HER2: Human epidermal growth factor receptor 2; HR+: Hormone receptor positive

progesterone receptor (PR) status, HER2 status, Ki-67 index, chemotherapy regimen, pCR status, event-free survival (EFS), and overall survival (OS).

Adjuvant endocrine therapy was administered according to menopausal status and institutional treatment protocols. Postmenopausal patients received aromatase inhibitor therapy, whereas premenopausal patients received ovarian suppression combined with aromatase inhibitors. Perimenopausal patients received tamoxifen-based endocrine therapy.

Definitions

Staging was based on the eighth edition of the American Joint Committee on Cancer tumor, lymph node, and metastasis classification. HR positivity was defined as ≥1% tumor cells showing nuclear staining via IHC, according to American Society of Clinical Oncology/College of American Pathologists guidelines.[21,22] An ER expression level of 90% was used as the cut-off value based on previous studies demonstrating prognostic differences according to very high ER expression levels.[15] A PR cut-off value of 20% and a Ki-67 cut-off value of 20% were selected according to commonly used thresholds in luminal BCclassification and St. Gallen consensus recommendations.[5,23] HER2 was assessed via IHC, with scores of 3+ considered positive and 0-1+ considered negative; 2+ cases were further evaluated using FISH. HER2 negativity was defined as 2+ without amplification on FISH.[24,25]

Assessment of pR was based on postoperative pathology reports obtained after completion of NAC. pCR was defined as the absence of residual invasive carcinoma in both the breast and axillary lymph nodes (ypT0/TisN0).

Because the study was retrospective and multicenter, pR evaluation was not fully standardized across institutions. In some centers, pathological regression was assessed using the Miller-Payne grading system, whereas in others, residual disease was evaluated according to the residual cancer burden (RCB) classification. Therefore, partial pR (pPR) was defined as residual invasive disease characterized by documented pathological evidence of treatment-related tumor regression, including decreased tumor cellularity and/or a reduction in residual invasive tumor burden in the surgical specimen, without fulfilling the pCR criteria. Overall pR was defined as either pCR or pPR.

EFS was defined as the time from diagnosis to recurrence or death from any cause. OS was defined as the time from diagnosis to death from any cause.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the University of Health Sciences Türkiye, Bağcılar Training and Research Hospital (approval number: 2025/02/09/026, date: 28.02.2025). Written informed consent was obtained from all participants.

Statistical Analysis

All statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. Univariate and multivariate logistic regression analyses were used to identify predictors of pCR, with odds ratios (ORs) and 95% confidence intervals (CIs) reported. Survival curves for EFS and OS were estimated using the Kaplan-Meier method and compared using the log-rank test. Independent prognostic factors for EFS and OS were determined using Cox proportional hazards regression models, and hazard ratios and 95% CIs were calculated. A two-sided p-value <0.05 was considered statistically significant. Variables demonstrating statistical significance in univariate analysis(p <0.05)were included in the multivariate Cox regression models.

RESULTS

Patient Characteristics

A total of 186 female patients with HR+/HER2- BC who received NAC were included, with a median follow-up duration of 30.6 months. The mean age was 48.5 years (range: 28-74), and 82.3% had a BMI ≥ 25 kg/m^2. Menopausal status was pre-/perimenopausal in 51.1% of participants and postmenopausal in 48.9%. Histologically, 61.8% of tumors were grade 2, and 57.0% were invasive ductal carcinomas. A Ki-67 index ≥20% was observed in 72.0% of patients (median: 25%). Stage III disease was present in 59.7% of cases. ER expression ≥90% was detected in 60.2%, and PR expression ≥20% in 71.0%. Based on the molecular classification, 78.5% of tumors were classified as luminal B. Anthracycline- and taxane-based regimens were administered to 98.4% of patients. Total mastectomy was performed in 64.5% of patients, and axillary dissection in 81.7% of patients (Table 1).

pR

Overall, 25 patients (13.4%) achieved pCR. In the univariate analysis, ductal histology, grade 3 tumors, high Ki-67, ER <90%, and luminal B subtype were significantly associated with pCR. In multivariate logistic regression analysis, grade 3 tumors (OR: 4.49; 95% CI: 1.74-11.63; p=0.002) and ER <90% (OR: 2.64; 95% CI: 1.01-6.89; p=0.047) remained independent predictors of pCR.

TABLE 1: Demographic and clinical characteristics of patients.

Variable	Category	n (%)
Age	<50 years	102 (54.8)
	≥50 years	84 (45.2)
BMI	<25	33 (17.7)
	≥25	153 (82.3)
Menopausal status	Pre-/perimenopausal	95 (51.1)
	Postmenopausal	91 (48.9)
Histological subtype	Ductal carcinoma	106 (57.0)
	Lobular carcinoma	26 (14.0)
	Others	54 (29.0)
Histologic grade	Grade I	29 (15.6)
	Grade II	115 (61.8)
	Grade III	42 (22.6)
Ki-67 proliferation index	<20%	52 (28.0)
	≥20%	134 (72.0)
ER	<90%	74 (39.8)
	≥90%	112 (60.2)
PR	<20%	54 (29.0)
	≥20%	132 (71.0)
Molecular subtype	Luminal A	40 (21.5)
	Luminal B	146 (78.5)
Clinical stage (AJCC 8th)	Stage II	75 (40.3)
	Stage III	111 (59.7)

AJCC: American Joint Committee on Cancer; BMI: Body mass index; ER: Estrogen receptor; PR: Progesterone receptor; HR: Hazard ratio; CI: Confidence interval.

Survival Outcomes

During follow-up, 28 patients experienced recurrence or metastasis, and 18 died from BC. The median EFS was 92.02 months, while the median OS was not reached. The estimated 5 years EFS and OS rates were 77% and 88%, respectively.

Univariate Cox regression analysis identified ER ≥90%, PR ≥20%, and pR as favorable prognostic factors for EFS. In the multivariate analysis, ER ≥90% (hazard ratio: 2.70; 95% CI: 1.21-6.03; p=0.015) and pR (hazard ratio: 4.22; 95% CI: 1.40-12.74; p=0.011) were independently associated with improved EFS. The Kaplan-Meier curves demonstrated significant associations between the EFS and both ER ≥90% and pR. No significant association was found between pCR and EFS.

For OS, univariate Cox regression analysis showed that ER ≥90% and pR were favorable prognostic factors (Table 2).

In the multivariate model, ER ≥90% (hazard ratio: 3.159; 95% CI: 1.152-8.660; p=0.025) and pR (hazard ratio: 12.516; 95% CI: 2.921-53.627; p<0.001) remained independent predictors (Table 3). Kaplan-Meier analysis confirmed significant associations between OS and both ER ≥90% and pR (Figures 2 and 3), whereas no statistically significant correlation was observed between pCR and OS.

TABLE 2: Univariate Cox regression analysis for overall survival.

Variable	Univariate HR (95% CI)	p-value*
Age		
<50 years	1.175 (0.465-2.972)	0.733
≥50 years		
Menopausal status		
Pre-/perimenopausal	1.626 (0.627-4.216)	0.317
Postmenopausal		
BMI		
<25	2.125 (0.485-9.306)	0.317
≥25		
Histology		
Ductal	1.033 (0.385-2.771)	0.949
Others		
Histologic grade		
Grade III	1.212 (0.393-3.738)	0.738
Others		
ER		
<90%	2.680 (0.999-7.186)	0.042*
≥90%		
PR		
<20%	1.761 (0.690-4.492)	0.236
≥20%		
Ki-67		
<20	1.614 (0.565-4.612)	0.371
≥20		
Luminal groups		
Luminal A	1.265 (0.360-4.446)	0.714
Luminal B		
Clinical stage		
Stage II	1.438 (0.564-3.667)	0.447
Stage III		
pCR		
Yes	2.624 (0.348-19.805)	0.350
No		
pR		
Yes	9.860 (2.408-40.376)	<0.001*
No		

* Indicates statistically significant results. BMI: Body mass index; ER: Estrogen receptor; PR: Progesterone receptor; pR: Pathologic response; pCR: Pathologic complete response; HR: Hazard ratio; CI: Confidence interval.

TABLE 3: Multivariate Cox regression analysis for overall survival.

Variable	Multivariate HR (95% CI)	p-value*
ER		
<90%	3.159 (1.152-8.660)	0.025*
≥90%		
pR		
Yes	12.516 (2.921-53.627)	<0.001*
No		

* Indicates statistically significant results. ER: Estrogen receptor; pR: Pathologic response.

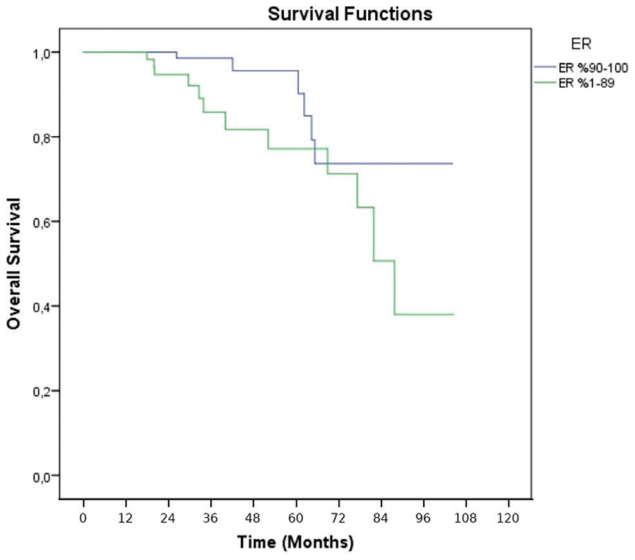

FIGURE 2: Kaplan-Meier curves for OS according to ER expression levels. Patients with high ER expression (90-100%, blue line) demonstrated significantly improved OS compared with those with lower ER expression (1-89%, green line) (log-rank test, p=0.042).

OS: Overall survival; ER: Estrogen receptor

DISCUSSION

This retrospective study evaluated pCR rates, survival outcomes, and prognostic factors among patients with HR+/HER2- BC treated with NAC. The pCR rate of 13.4% in our cohort is consistent with previously reported ranges (9.1-17%).[18-20] Differences in the pCR rates across studies may be attributed to variations in patient characteristics, treatment regimens, and pathological assessment criteria.

Our findings indicate that an ER expression <90% was independently associated with higher pCR rates, aligning with prior studies.[14,20] Lower ER expression may reflect a more proliferative tumor phenotype and potentially increase chemosensitivity. Similarly, grade 3 tumors were significantly associated with pCR, consistent with the previous literature.[18] These tumors generally have higher proliferation rates, rendering them more susceptible to cytotoxic agents.

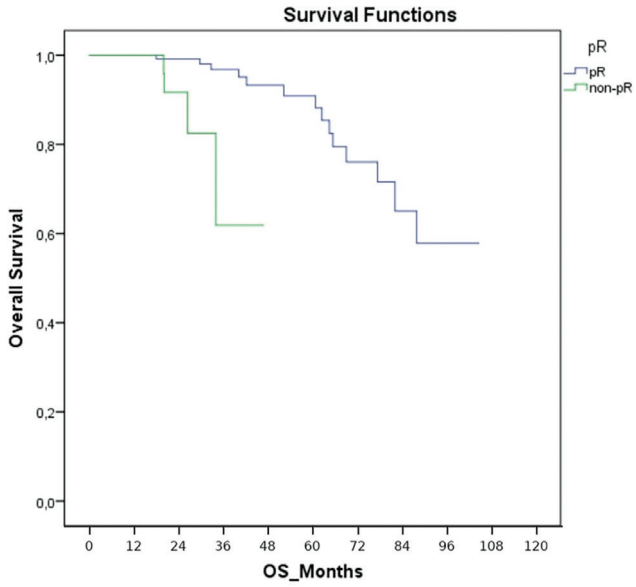

FIGURE 3: Kaplan-Meier curves for OS according to pR status. Patients achieving pR (blue line) demonstrated significantly improved OS compared with those without pR (green line) (log-rank test, p<0.001).

OS: Overall survival; pR: Pathologic response

Although pCR has traditionally been regarded as a surrogate marker for improved survival, our results show no statistically significant association between pCR and either EFS or OS in HR+/HER2- disease. However, when complete and pPR were combined (pR), both EFS and OS improved significantly. This finding suggests that in this subtype, achieving any degree of pathological tumor reduction may have prognostic relevance, as supported by von Minckwitz et al.[11]

The absence of a significant association between pCR and survival outcomes in our cohort may reflect the unique biological characteristics of HR+/HER2- BC. Unlike triple-negative and HER2-positive subtypes, HR+/HER2- tumors generally exhibit lower chemosensitivity and lower pCR rates following NAC.[12,13] Furthermore, several studies have suggested that pCR may not serve as a sufficiently robust surrogate marker for long-term survival in luminal BC, where endocrine responsiveness and intrinsic tumor biology play a more substantial prognostic role.[11,15]

In contrast, our findings demonstrated that overall pR, including both complete and partial pathological regression, was associated with improved EFS and OS. This observation suggests that even partial tumor reduction following NAC may indicate treatment sensitivity and less aggressive tumor biology in HR+/HER2- disease. Given the relatively indolent clinical course of many luminal tumors, modest pathological regression may still translate into favorable long-term outcomes despite residual disease.

Additionally, the limited number of patients achieving pCR in our cohort may have reduced the statistical power to detect a survival difference. Therefore, the prognostic significance of pCR alone in HR+/HER2- BC should be interpreted cautiously, particularly in retrospective real-world studies with heterogeneous pR patterns.

Our findings suggest that broader pR assessment beyond strict pCR definitions may provide additional prognostic information in HR+/HER2- BC. This may be particularly relevant in luminal tumors, where substantial but incomplete tumor regression could still reflect biologically meaningful treatment sensitivity.

Importantly, an ER ≥90% emerged as an independent predictor of longer EFS and OS, consistent with prior studies.[14,15] HR+ tumors typically exhibit less aggressive biology, and the prolonged benefit from adjuvant endocrine therapy likely contributes to improved outcomes in this subgroup.

Study Limitations

The limitations include its retrospective design, the absence of multigene assay data, and a relatively short median follow-up, which may limit the assessment of late recurrences, events that are typical of HR+/HER2- tumors. In addition, pR assessment was not completely standardized across participating centers, as Miller-Payne grading and RCB classifications were used according to institutional routine practice. Therefore, pPR evaluations may have been subject to interobserver variability.

CONCLUSION

HR+/HER2- BCs generally achieve lower pCR rates following NAC. Nevertheless, the presence of a pR, high ER expression, and adjuvant endocrine therapy were associated with improved survival outcomes. Prospective studies are warranted to validate these findings and refine NAC selection criteria in this patient population.

Ethics

Ethics Committee Approval: The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the University of Health Sciences Türkiye, Bağcılar Training and Research Hospital (approval number: 2025/02/09/026, date: 28.02.2025).

Informed Consent: Written informed consent was obtained from all participants.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Ş.B., U.A.Y., B.Ç.D., M.T., N.B., G.U.E., Concept: Ş.B., U.A.Y., B.Ç.D., M.T., N.S.A., A.M., N.E., E.Ç., E.D., N.Ş., G.U.E., Design: Ş.B., B.Ç.D., N.S.A., A.M., A.Ö., N.E., E.Ç., E.D., N.Ş., Data Collection or Processing: Ş.B., U.A.Y., B.Ç.D., N.S.A., A.Ö., E.Ç., N.B., G.U.E., Analysis or Interpretation: Ş.B., U.A.Y., M.T., A.M., N.E., E.D., N.Ş., N.B., G.U.E., Literature Search: Ş.B., A.Ö., E.D., G.U.E., Writing: Ş.B.

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