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Clinical Outcomes of Stage IS Non-seminomatous Germ Cell Testicular Tumors: Single-Center Experience

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ABSTRACT

Introduction: Stage IS non-seminomatous germ cell tumors (NSGCT) represent a rare and clinically heterogeneous subgroup characterised by persistent postoperative elevation of serum tumor markers despite the absence of radiological metastasis. Evidence guiding optimal management remains limited because most studies address this population only as part of broader stage I cohorts. To evaluate the clinical characteristics, treatment strategies, tumor marker dynamics, and long-term oncological outcomes of patients with stage IS NSGCT managed at a single tertiary centre.

Methods: This retrospective observational study included 25 patients diagnosed with stage IS NSGCT between 2008 and 2022. All patients demonstrated persistently elevated serum alpha-fetoprotein, beta-human chorionic gonadotropin, or lactate dehydrogenase following orchiectomy, with no radiological evidence of metastasis. Demographic, pathological, and treatment data were analysed. Disease-free survival (DFS) and overall survival (OS) were calculated using the Kaplan–Meier approach, and potential predictors of DFS were assessed through a univariate Cox regression model.

Results: The median patient age was 26 years; mixed germ cell tumor histology accounted for 80% of cases. After orchiectomy, all patients received bleomycin, etoposide, and cisplatin chemotherapy; receiving ≥3 cycles significantly reduced the risk of recurrence [hazard ratios (HR): 0.075, p=0.026)]. Rete testis invasion was associated with a trend toward an increased risk of relapse, although this did not reach statistical significance (HR: 8.389, p=0.066). At a median follow-up of 155.5 months, the 10-year relapse incidence was 16%, and median DFS and OS were not reached.

Conclusion: Stage IS NSGCT carries a substantial risk of occult metastatic disease despite negative imaging, supporting the need for systemic therapy in most cases. Adequate chemotherapy intensity appears crucial for long-term disease control. Although certain pathological features—such as rete testis invasion—may indicate more aggressive biology, their prognostic relevance requires confirmation in larger, prospective cohorts.

Keywords: Stage IS NSGCT, testicular cancer, tumor markers, BEP chemotherapy

Introduction

Even though testicular tumors account for only 1% of all solid malignancies in men, they constitute the most common solid malignancy among men aged 15–35 years (1). Testicular tumors are classified as solid malignancies in men and are broadly divided into two main categories: germ cell tumors and sex cord–stromal tumors. Approximately 95% of these cases are germ cell tumors, which are further classified into pure seminomas and non-seminomatous germ cell tumors (NSGCTs). NSGCT may consist of one or more of the following components: embryonal carcinoma, yolk sac tumor, teratoma, and choriocarcinoma (2).

Approximately 60% of NSGCTs are classified as stage I disease at initial presentation (3). Stage IS NSGCT is characterised by elevated tumor markers after orchiectomy, despite the disease being confined to the testicle. Elevated tumor markers were defined using threshold values of >15 ng/mL for alpha-fetoprotein (AFP), >5 U/L for beta-human chorionic gonadotropin (β-hCG), and >200 U/L for lactate dehydrogenase (LDH), and biological half-lives of AFP (5–7 days) and β-hCG (24–36 hours) were considered during evaluation. This group has a favourable prognosis in metastatic patients, but exhibits heterogeneity in stage and tumor burden. This heterogeneity is reflected in clinical practice by variations in the rate of tumor marker decline following orchiectomy, as well as by differences in histological subtypes, which variably influence clinical course and treatment requirements. Despite normal radiological findings, persistent elevation of serum tumor markers is the only indication of disease persistence. Close monitoring is often preferred for patients who

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show a downward trend in tumor markers after orchiectomy and in whom imaging detects no metastases. This approach allows patients to be monitored until tumor markers reach the lowest levels, revealing that a significant proportion of cases are stage IA or IB. This prevents unnecessary early initiation of chemotherapy and overtreatment. However, in patients whose marker levels remain markedly elevated or continue to rise after orchiectomy, the likelihood of metastatic disease is high. Therefore, this subgroup should be treated with the chemotherapy protocols used for advanced or metastatic NSGCT patients (4).

Consequently, stage IS NSGCT represents a subgroup with high clinical uncertainty. Furthermore, limited data in the literature for this patient group and the fact that most existing studies evaluate stage IS patients as a small subgroup within large stage I cohorts perpetuate uncertainty regarding the optimal timing of treatment strategies and long-term outcomes. In the management of this disease, which particularly affects the younger age group, both oncological outcomes and long-term morbidity are of great importance. The objective of this study is to retrospectively analyze the clinical features, tumor marker behavior, treatment strategies, and long-term oncological outcomes of patients with stage IS NSGCT managed at our center. Our hypothesis is that administration of three or more cycles of chemotherapy is associated with improved disease-free survival (DFS). By doing so, we aim to enhance the current understanding of this uncommon patient population and support the refinement of clinical decision-making in their care.

Methods

Study Design and Patient Selection

This retrospective, observational, single-center study analyzed patients with stage IS NSGCT who were diagnosed and followed at a tertiary oncology center between 2008 and 2022. The diagnosis of stage IS was based on persistently elevated serum tumor marker levels (AFP, β-hCG, and LDH) in the absence of metastatic disease on imaging after orchiectomy.

The inclusion criteria for the study were histopathologically confirmed diagnosis of NSGCT, prior orchiectomy, persistently elevated serum tumor markers in the postoperative period, and no evidence of metastatic disease on computed tomography scans of the thorax, abdomen, and pelvis. Furthermore, the availability of complete patient follow-up data is required for inclusion.

In histopathological evaluation, the presence of an embryonal carcinoma component constituting more than 30% of the tumor is considered indicative of embryonal carcinoma predominance.

Patients were classified into good- and intermediate-risk groups according to the IGCCCG prognostic classification based on the primary tumor site, presence of visceral metastases, and serum AFP, β-hCG, and LDH levels (5). Although the IGCCCG classification was originally developed for metastatic germ cell tumors, it was applied in the present study to provide a prognostic framework for stage IS patients with persistently elevated tumor markers, reflecting potential occult systemic disease.

Ethical approval for this study was obtained from Kartal Dr. Lütfi Kırdar City Hospital, Scientific Research Ethics Committee (approval number: 2025/010.99/21/9, date: 30.10.2025), and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Data Collection

Information regarding patients' demographic characteristics; tumor histology and location; tumor marker levels; pathological T stage; radiological imaging findings; treatment regimens; recurrence and development of metastatic disease; dates of death and recurrence and of recurrence; and the entire follow-up process was obtained through review of the hospital's electronic archive system, patient files, and clinical records.

Treatment Strategies

In the study, all patients received the standard bleomycin, etoposide, and cisplatin (BEP) chemotherapy regimen as systemic treatment. Bleomycin was administered at a total dose of 30 mg intravenously on days 2, 9, and 16 of each treatment cycle. Etoposide was given as a daily intravenous infusion at 100 mg/m² from days 1 to 5 of each cycle, and cisplatin was administered as a daily intravenous infusion at 20 mg/m² during the same period. The number of treatments administered varied according to the patient's clinical condition and was recorded separately for each patient.

Study Endpoints

The primary outcome measure of this study was DFS. DFS was defined as the time from completion of treatment following surgery until the first recurrence or progression; overall survival (OS) was defined as the time from surgery until death from any cause.

Follow-up Protocol

After treatment, all patients were followed according to a standard follow-up protocol consistent with the National Comprehensive Cancer Network guidelines (6). During the first year, patients underwent physical examinations every two months and serum tumor markers were assessed. During the same period, abdominopelvic computed tomography and chest X-rays were repeated every 4 to 6 months. In the second year, physical examinations and tumor markers were monitored every three months; abdominopelvic imaging and chest X-rays were performed at 6- to 12-month intervals. In the third year, patients underwent physical examinations and tumor marker measurements every 3–6 months, and abdominopelvic imaging was performed annually. In the fourth and fifth years, physical examinations and tumor-marker assessments were performed every six months; radiological investigations were conducted as clinically indicated. If any suspicion of recurrence arises during this process, patient follow-up is intensified with additional imaging modalities and appropriate clinical assessments.

Statistical Analysis

All statistical procedures were conducted using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as median values with their ranges

(minimum–maximum), whereas categorical variables were presented as frequencies and percentages. Survival probabilities for DFS and OS were estimated using the Kaplan–Meier method. Potential prognostic variables considered to influence DFS were examined using univariate Cox regression analysis. Outcomes from the univariate Cox models were expressed as hazard ratios (HRs) with 95% confidence intervals (CIs) and corresponding p values. A two-sided p value <0.05 was considered statistically significant. Because of the limited numbers of patients and events, a multivariate Cox regression model could not be performed.

Results

Patient Baseline Characteristics

A total of 25 patients were evaluated in this study. The median age was 26 years (range: 17–36 years), and the demographic and clinical features of the cohort are presented in Table 1. In terms of primary tumor stage, 12 patients (48%) were classified as T1 and 13 (52%) as T2. Rete testis invasion was present in 7 (28%) patients.

The most common subtype identified on histological evaluation was the mixed germ-cell tumor, detected in 20 patients (80%). Embryonal carcinoma was observed in 4 patients (16%), and yolk sac tumor was observed in 1 patient (4%). Tumor localisation was right-sided in 14 patients (56%) and left-sided in 11 patients (44%).

Table 1. Clinical and pathological characteristics of the patients

Characteristics	n, (%)
Age Median Range (minimum-maximum)	 26 (17-36)
Extent of primary tumor T1 T2	 12 (48%) 13 (52%)
Rete testis invasion Absent Present	 18 (72%) 7 (28%)
Histology Mixed germ cell tumor Embryonal carcinoma Yolk sac tumor	 20 (80%) 4 (16%) 1 (4%)
Tumor location Right Left	 14 (56%) 11 (44%)
AFP (ng/mL) Number elevated (>15) <15	 17 (68%) 8 (32%)
AFP (median)	81.0
hCG (U/L) Number elevated (>5) <5	 13 (52%) 12 (48%)
hCG (median)	1.0
LDH (U/L) Number elevated (>200) LDH <200	 12 (48%) 13 (52%)
LDH (median)	199

AFP: Alfa-fetoprotein, hCG: Human chorionic gonadotropin, LDH: Lactate dehydrogenase

When serum tumor markers were examined, AFP levels were elevated in 17 patients (68%), with a median AFP value of 81.0 ng/mL, and hCG levels were elevated in 13 patients (52%), with a median hCG value of 5.0 U/L. LDH levels were above 200 U/L in 12 patients (48%), with a median LDH of 199 U/l. Although the median LDH value was 199 U/L, the cut-off value of >200 U/L was used in accordance with established reference ranges and guideline-based definitions for elevated LDH levels.

According to the IGCCCG classification, 32% of patients were in the intermediate-risk group and 68% were in the good-prognosis group.

In terms of adjuvant chemotherapy, six patients (24%) received two cycles of BEP, five patients (20%) received three cycles, and fourteen patients (56%) received four cycles.

Univariable Cox Regression Analysis

In univariate Cox analysis, clinical and pathological factors potentially associated with DFS were evaluated. No significant associations were observed between age and T stage (T2 vs. T1) and between age and DFS (p=0.560 and p=0.379, respectively). Tumor location (right vs. left testis) did not affect DFS (p=0.729).

Although patients with rete testis invasion showed a higher tendency to recur, this association was close to but did not reach statistical significance (HR: 8.389; p=0.066). Lymphovascular invasion (LVI) was not significantly associated with DFS (p=0.632).

Predominance of embryonal carcinoma was not a significant predictor of DFS (p=0.863). However, the likelihood of recurrence was significantly lower in patients who received 3 or 4 courses of BEP than in those who received fewer courses (HR: 0.075, p=0.026).

The results of the univariable Cox regression analysis are presented in Table 2.

Kaplan–Meier Survival Analysis

The median follow-up period of the study was 155.5 months (approximately 13 years). Despite this long follow-up period the median DFS and OS values could not be reached at 10 years because of the low number of observed events (relapses).

Table 2. Univariable Cox regression analysis of disease free survival

Variables	DFS (HR, 95% CI, p value)
Age	HR: 1.056 (0.879–1.268), p=0.560
T stage (T1 vs. T2)	HR: 0.362 (0.038–3.483), p=0.379
Tumor side (right vs. left)	HR: 1.415 (0.199–10.055), p=0.729
Rete testis invasion (present vs. absent)	HR: 8.389 (0.869–80.936), p=0.066
Lymphovascular invasion (present vs. absent)	HR: 1.739 (0.181–16.727), p=0.632
BEP cycles (≥3 vs. <3)	HR: 0.075 (0.008–0.733), p=0.026
Embryonal carcinoma predominance (present vs. absent)	HR: 0.841 (0.118–5.978), p=0.863

DFS: Disease-free survival, HR: Hazard ratio, CI: Confidence interval, BEP: Bleomycin, etoposide, and cisplatin

The relapse incidence at ten years was approximately 16% (n=4). Kaplan–Meier curves indicate sustained long-term disease control, with the DFS curve presented in Figure 1 and the OS curve in Figure 2. Corresponding 95% CIs were calculated. During follow-up, five deaths were observed: four patients died following disease relapse, and one died from non-disease-related causes without documented evidence of relapse.

Discussion

This study examined the clinical features and long-term outcomes of individuals diagnosed with stage IS NSGCTs. These findings again demonstrate that stage IS is a rare but difficult-to-manage subgroup of testicular tumors. Persistent elevation of tumor markers following orchiectomy, even if imaging studies are normal, may indicate underlying microscopic metastatic disease; therefore, early systemic treatment is recommended for these patients.

Most studies examining stage IS patients are based on subgroup analyses of larger stage I cohorts. In the study by Klepp et al. (4), NSGCT IS patients had a significantly higher risk of retroperitoneal metastasis after orchiectomy than patients with normal tumor markers. Our study demonstrates that all patients diagnosed with stage IS received systemic chemotherapy and that a rate of recurrence was observed during long-term follow-up, indicating that this patient group exhibits the high metastatic potential reported in the literature.

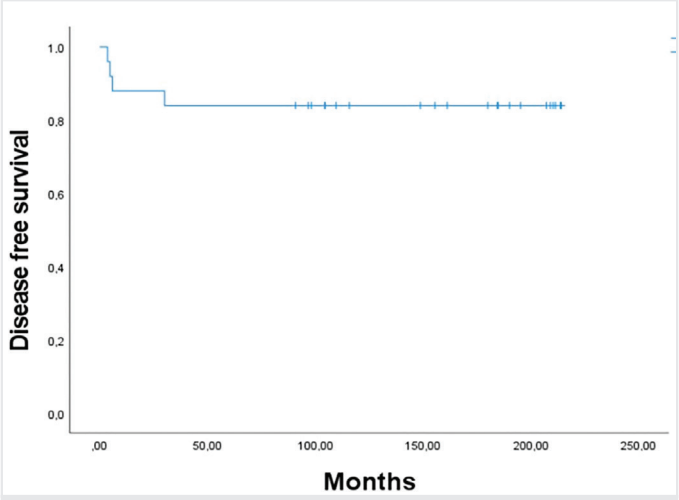

Figure 1. Kaplan–Meier curve for disease-free survival

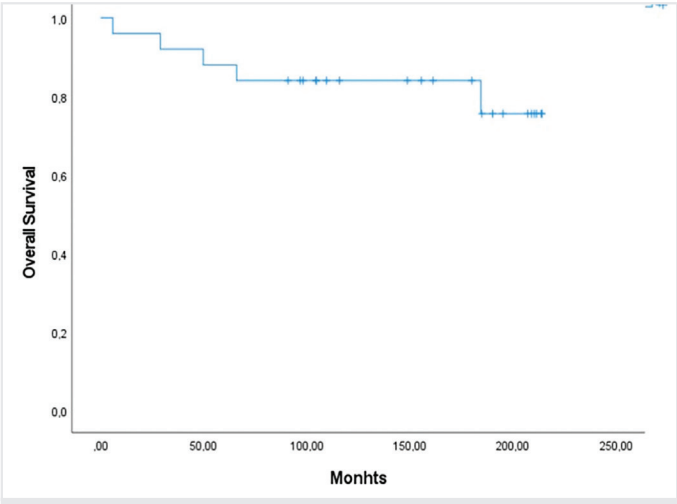

Figure 2. Kaplan–Meier curve for overall survival

Although a higher recurrence rate was observed in patients with rete testis invasion in our study, this did not reach statistical significance (HR: 8.389; p=0.066). The prognostic value of rete testis invasion is particularly evident in seminomas (7) , although studies claiming the opposite also exist (8-10). In some studies, an increased risk of metastasis has also been found in NSGCT subgroups (11,12). However, in patients with stage IS, this relationship has not been clearly established previously. Although our findings did not reach statistical significance due to the limited sample size, they suggest that this anatomical invasion may be associated with biologically more aggressive tumor behaviour. Studies with larger samples may more clearly demonstrate the prognostic value of rete testis invasion in stage IS patients.

Our study did not demonstrate a significant effect of LVI on DFS (p=0.632). Numerous studies have shown that LVI is one of the strongest pathological predictors of relapse, particularly in patients with stage I NSGCT (5,13,14). However, it has also been reported that in the large population-based analyses by Albers et al. (15) and by Daugaard et al. (16), the prognostic value of LVI was inconsistent and not significant in some series. Therefore, the lack of significance of LVI for DFS in our study is consistent with the limited sample size and with heterogeneous results reported in the literature. Similarly, no significant association was observed between embryonic carcinoma predominance and DFS (p=0.863). Although embryonal carcinoma may exhibit more aggressive biological behaviour due to its high proliferative capacity, and some studies have shown that a high proportion (>50%) of embryonal carcinoma in the primary tumor is associated with an increased risk of recurrence (13,14), other studies do not support this finding (15,16). The current literature indicates that embryonal carcinoma density does not have clear prognostic value, even in stage I NSGCT. In this context, it is not surprising that our study failed to identify a significant correlation in stage IS patients. These findings may be attributable to reduced statistical power, particularly resulting from the limited sample size. Similarly, a subgroup analysis of DFS according to IGCCCG risk groups was not performed due to the limited sample size and a low event rate.

When tumor location was evaluated in our study, no significant difference in DFS was observed between right- and left-sided testicular tumors (HR: 1.415; 95% CI: 0.199–10.055; p=0.729). This finding is consistent with previous studies in the literature reporting a limited prognostic impact of tumor laterality (17).

A significant reduction in the risk of relapse among patients receiving three to four courses of BEP (HR: 0.075; p=0.026) suggests that treatment intensity may be a critical determinant in patients with stage IS disease (18). The number of cycles administered to patients was determined based on individualized clinical assessments, taking into account treatment-related toxicities, patient tolerance, and physician discretion. Our study supports the notion that administering systemic therapy at a sufficient intensity to the stage IS subgroup is important for long-term disease control. However, larger studies targeting this patient group are

needed to avoid overtreatment and determine the optimal number of courses.

Over the ten-year follow-up period, the incidence of relapse was approximately 16% (n=4). The DFS rate during the same period was found to be 86%. In a study by Aparicio et al. (19) involving 106 stage IS NSGCT patients, the five- and ten-year DFS rates were reported as 87% and 85%, respectively, which demonstrate that our findings are consistent with the literature. These findings indicate that although the vast majority of patients achieve long-term DFS, there remains a certain risk of late recurrence.

In conclusion, stage IS NSGCT represents a heterogeneous group of patients, in whom tumor marker behaviour is decisive for treatment planning. Although cisplatin-based chemotherapy is effective in the vast majority of these patients, certain clinical and pathological factors may influence treatment response. Larger, multicentre, and prospective studies will contribute to a clearer risk classification in this rare patient group and to the optimisation of treatment strategies.

Study Limitations

The principal limitations of this study include its retrospective nature and the relatively limited patient cohort. However, its long follow-up period and focus on a rare patient group, such as stage IS, are among its strengths. Given the scarcity of data specific to this group in the literature, the findings are expected to contribute to the existing body of knowledge.

Conclusion

In conclusion, our study confirms that stage IS NSGCT represents a distinct clinical entity characterized by a high probability of subclinical metastasis, necessitating prompt systemic management. We observed favorable long-term oncological outcomes, with a 10-year DFS rate of 86% following cisplatin-based chemotherapy. Notably, the intensity of the treatment regimen appeared to be a critical prognostic factor; patients receiving three or four cycles of BEP chemotherapy demonstrated a significantly lower risk of recurrence than those receiving fewer cycles. While rete testis invasion showed a trend toward an increased risk of recurrence, larger multi-institutional cohorts are required to definitively validate its prognostic significance alongside other pathological markers. Ultimately, strict adherence to standard chemotherapy protocols and rigorous long-term surveillance remain the cornerstones of management to ensure durable disease control in this patient population.

Ethics

Ethics Committee Approval: Ethical approval for this study was obtained from Kartal Dr. Lütfi Kırdar City Hospital Scientific Research Ethics Committee (approval number: 2025/010.99/21/9, date: 30.10.2025).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions: Surgical and Medical Practices - E.T., G.A., S.Y., N.S.B., U.D.G., D.I., H.O., N.T.; Concept - E.T., G.A., S.Y., D.I., H.O., N.T.; Design - E.T., S.Y., D.I., H.O., N.T.; Data Collection or Processing - E.T., G.A., S.Y., N.S.B., U.D.G.; Analysis or Interpretation - E.T., D.I., H.O.; Literature Search - E.T., G.A., S.Y., N.S.B., U.D.G., H.O., N.T.; Writing - E.T., G.A., S.Y., N.S.B., U.D.G., N.T.

Conflict of Interest: No conflict of interest was declared by the authors.

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