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A Retrospective Analysis of 83 Patients with Testicular Mass Who Underwent Testis-Sparing Surgery: The Eurasian Uro-oncology Association Multicenter Study

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Keywords
Partial orchiectomy · Testis-sparing surgery · Testicular tumor · Germ cell testicular cancer

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Abstract

Introduction: Herein, we analyzed the histopathological, oncological and functional outcomes of testis-sparing surgery (TSS) in patients with distinct risk for testicular cancer. ***Methods:*** This is a multicenter retrospective study on consecutive patients who underwent TSS. Patients were categorized in high- or low-risk testicular germ cell tumor (TGCT) according to the presence/absence of features compatible with testicular dysgenesis syndrome. Histology was categorized per size and risk groups. ***Results:*** TSS was performed in 83 patients (86 tumors) of them, 27 in the high-risk group. Fifty-nine patients had a non-tumoral contralateral testis present. Sixty masses and 26 masses were benign and TGCTs, respectively. No statistical differences were observed in mean age (30.9 ± 10.32 years), pathological tumor size (14.67 ± 6.7 mm) between risk groups or between benign and malignant tumors (p = 0.608). When categorized per risk groups, 22 (73.3%) and 4 (7.1%) of the TSS specimens were malignant in the high- and low-risk patient groups, respectively. Univariate analysis showed that the only independent variable significantly related to malignant outcome was previous history of TGCT. During a mean follow-up of 25.5 ± 22.7 months, no patient developed systemic disease. Local recurrence was detected in 5 patients and received radical orchiectomy. Postoperative testosterone levels remained normal in 88% of those patients with normal preoperative level. No erectile dysfunction was reported in patients with benign lesions. ***Conclusion:*** TSS is a safe and feasible approach with adequate cancer control, and preservation of sexual function is possible in 2/3 of patients harboring malignancy. Incidence of TGCT varies extremely between patients at high and low risk for TGCT requiring a careful consideration and counseling.

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Introduction

Indications to perform testis-sparing surgery (TSS) are clearly stated in the European Association of Urology and other Guidelines [1, 2]. Those include patients with bilateral synchronous or metachronous tumors when technically feasible. Whether TSS should be considered as primary option in the management of small testicular tumors in the presence of a normal contralateral testis and normal hormonal function remains a matter of debate.

However, the increasing exposure to scrotal ultrasound or magnetic resonance imaging in case of unspecific scrotal symptoms and the routine implementation of scrotal imaging in the sub- or infertile population leads to a higher prevalence of small/undetermined testicular masses "incidentally diagnosed" in the presence of apparently normal contralateral testis [3–6]. Despite the lack of a definitive size threshold with low-enough acceptable rates of malignancy [7, 8], the inverse correlation between the testicular mass size and benign histology [9] and the impaired fertility substrate raise concerns on upfront radical orchiectomy (RO) in these specific pools of patients [10]. In both settings, either mandatory or elective, the aims of TSS are to preserve fertility and to maintain the hormonal function and in case of undetermined testicular masses to avoid overtreatment of benign lesions [1, 2].

Several reports highlight the feasibility of TSS, accompanied by frozen section examination (FSE) [1], when the abovementioned conditions coexist with negative serum tumor markers (STMs) [1]. Nonetheless, these surgical series frequently include heterogeneous population with a distinct risk for testicular germ cell tumors (TGCT) hence the variation in the reported rate of malignant/benign lesions [7, 11]. More recently two series confirm the value of maximum tumor size as the strongest predictor of malignancy [12, 13]. Although the best size cut-off predictor varies in these series (8.5–13.5 mm of diameter), both support the possible extension and feasibility of TSS in tumors up to 20 mm of maximum diameter based on the high reliability of the FSE and on the long-term oncological safety [12, 13]. Furthermore, in the frame and awareness of the testicular dysgenesis syndrome (TDS) different populations of patients at higher risk of TGCT have been identified, among them those with previous TGCT, bilateral synchronic presentation, testicular descend disorders, and those with impaired fertility [14].

Our primary objective was to assess the incidence of TGCT in a TSS series of patients with small testicular masses receiving TSS. Our secondary objectives were the relationship with preexisting risk factors for TGCT CC and histology and size and to assess oncological and functional outcomes.

Patients and Methods

A retrospective study was carried out in 20 centers of the Eurasian Uro-oncology Society on patients who underwent TSS between July 2007 and August 2019. Clinical files were reviewed and data including age, previous history and treatment of GCT or stromal testicular tumor, presence of risk factors for TGCT, complains at diagnosis (symptomatic, in follow-up because previous TGCT or infertility study), histopathology, perioperative complications, and oncological and functional outcomes were retrieved.

Patients were primarily categorized in low- or high-risk for TGCT based on clinical characteristics and histopathological outcomes reported accordingly. The sub-cohort of high-risk patients included those with TDS features (previous history of TGCT, bilateral

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Table 1. Baseline characteristics of the patients and tumors treated by TSS. TSS and histology according to number of TSS specimens

	All cohort (n pat 83)	High-risk (27 pat)	Low-risk (56 pat)
Age (mean±SD)	30.9 (10.3)	29.4 (11.2)	31.7 (7.5)
Solitary testis	16	15 (93.7%)	1 (6.2%)
Elevated markers	6	6 (100%)	0
AFP	229.0 (40.8–1,700.0)	229.0 (40.8–1,700.0)	
HCG	197.0 (177.0–576.0)	197.0 (177.0–576.0)	
Number of TSS	86	30 (34.8%)	56 (65.1%)
Clinical diagnostic (per patient)			
Previous contralateral TGCT	13	13	–
Infertility	3	3	–
Symptomatic	67		
• Synchronic bilateral palpable mass	9	9 (100%)	
• Mass in solitary testis**	2	2 (100%)	
• Scrotal pain or palpable mass***	56	–	56 (100%)
Pathology (per *TSS number of procedures*)			
Tumor size mm (mean±SD)*	14.67 (6.7)	16.2 (6.8)	14.2 (6.2)

TSS, testis-sparing surgery; GCT, germ cell tumor. *Not statistically significant. **Testicular descent disorder. ***Twelve testicular sparing procedures and 6 radical orchiectomies.

synchronic tumors at diagnostic, history of cryptorchidism, or impaired fertility) [1, 14]. Patients without any of those findings were considered at low risk (normal risk) of TGCT.

Histology was stratified according to pathological size (max diameter) in 4 categories: ≤10 mm, >10–15 mm, >15–20 mm, and >20 mm and further analyzed according to risk groups. The technique for TSS followed the surgical principles described elsewhere [15]. The use of ischemia, enucleation or inclusion of a rim of normal appearing parenchyma, FSE and biopsy of the remaining parenchyma were performed at discretion of the surgeon. There was no fix protocol for follow-up, although in general they were followed according to major guidelines.

Statistical Analysis

Descriptive statistics of the variables including risk factors (mean ± SD, median [1–3 quartile], and frequency) were calculated. Binary logistic regression analysis was used to calculate the effective impact shares of possible risk-factors (age, tumor size, tumor history in contralateral testis, testicular pain, AFP, and β-HCG levels) on the presence of malignancy. Dependent and independent variables were considered as categorical (yes/no): presence of malignancy, pain, history of malignancy, specific STMs elevation above the superior limit of normality; and continuous: age and pathological tumor size. p value <0.05 was considered statistically significant. SPSS 22.0 (IBM corp. USA) program was used for analysis.

Results

From July 2007 to August 2019, 83 patients with a mean age of 30.9 ± 10.32 years were diagnosed with unilateral palpable mass in the presence of normal contralateral testis (n = 55), solitary testes (n = 16 [13 previous TGCT and 3 benign pathology]), synchronic bilateral testis tumor (n = 9), or fertility impairment (n = 3) and received TSS for a total of 86 testicular masses, of which 70 (81.5%) ≤2 cm.

Table 1 depicts clinical patients and tumor characteristics and presentation according to the prespecified risk groups for TGCT. Indication was mandatory in 25 patients (30%), elective in 55 (66%), and impaired fertility in 3. At diagnosis 2, 1, and 3 patients presented with AFP only, b-hCG only or both STMs elevated, respectively, all known with previous TGCT.

No patient had TSS performed for multiple masses on the ipsilateral testis. In patients with synchronic bilateral masses, 12 TSS and 6 radical orchidectomies were performed.

Overall, 60 (69.8%) and 26 (30.2%) of the masses were benign and malignant (57.7% seminoma, 42.3% NSGCT), respectively. Figure 1 displays tumors and histology categorized by risk groups. Classification by tumor size and risk category is shown in Table 2. None of the Leydig or Sertoli cell tumors had malignant histological features. In the population considered at high risk for TGCT, 22 (73.3%) of the 30 TSS specimens were malignant, while TGCT was found in 4 (7.1%) of the 56 patients in the low-risk subgroup. Among the high-risk group, the highest proportion of malignancy was found in patients with previous TGCT (84.6%) followed by the population with synchronic bilateral tumors (75%). Rates of malignancy

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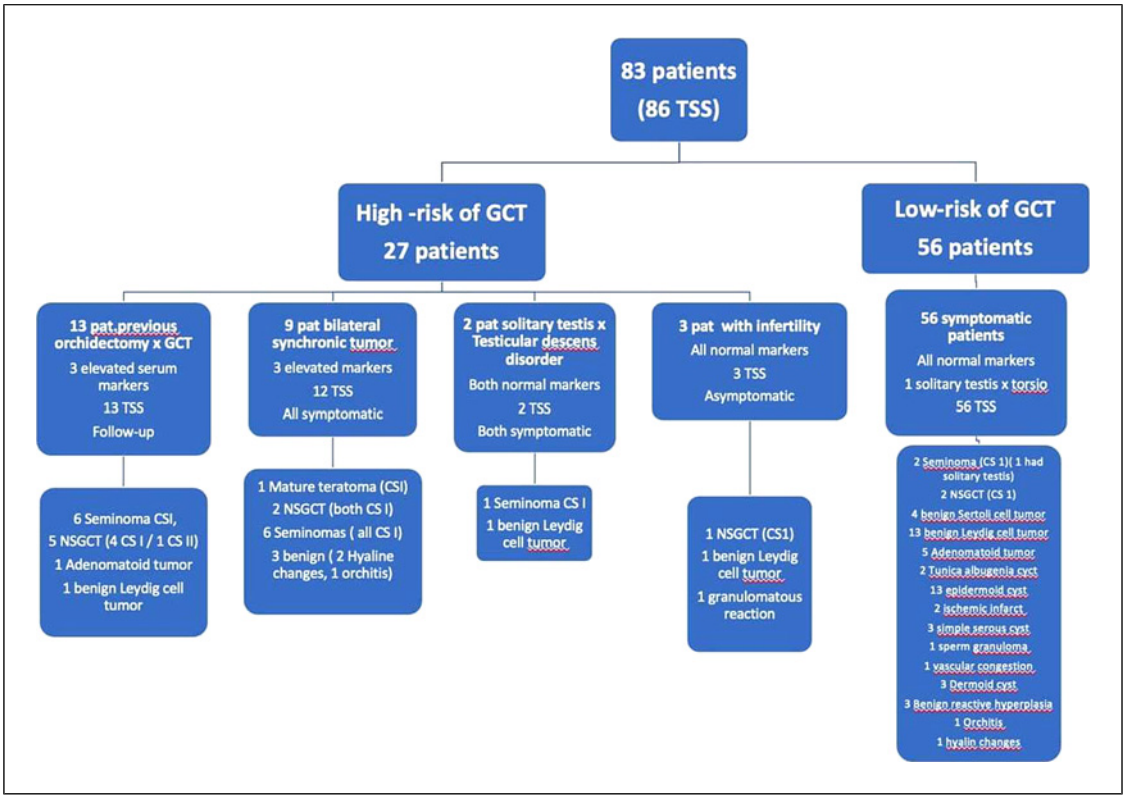


Fig. 1. Flowchart of patient selection and categorization in risk groups with corresponding histology.

of 50% and 33% were found in the subgroups with testicular descend disorders and infertility. All malignant masses were TGCTs (15 seminoma and 11 NSCGT); of them, 25 were CS I and one CS II A.

There was no difference (p = 0.441) in maximum tumor diameter between benign ((14.0 ± 6.6 mm) and malignant tumors (16.1 ± 6.8 mm) or between high- and low-risk categories. The incidence of malignant tumors increased with pathological size mostly at the expenses of the high-risk group (Table 2; Fig. 2).

Cumulative incidence of malignancy varied according to the risk group; in the high-risk group, it was 50% (4/8), 63.2% (12/19), 70.4% (19/27), and 73.3% (22/30) at 10, 15, 20, and >20 mm, respectively. In the low-risk group, it was 0% (0/22), 9% (3/33), 9.3% (4/43), and 7.1% (4/56) at 10, 15, 20, and >20 mm, respectively.

Binary logistic regression showed that history of TGCT was the only independent variable significantly related to malignant outcome (Table 3). Stage and histopathology of patients with solitary testis because previous TGCT or benign condition are shown in online supplementary Table 1 (for all online suppl. material, see https://doi.org/10.1159/000531645) and 11 (84%) had a metachronous TGCT (6 seminomas, 5 NSGCT); 10 were CS I and 1 CS II A. Concordance in histology type between the previous GCT and the current diagnosis was observed in 10 (91%) patients.

Among the bilateral synchronic tumors (online suppl. Table 2), 14 masses (77%) were TGCT, all CS I and 8 of the 9 patients had TGCT in at least one testis. Histology between testes was concordant in 5 patients (55.5%).

Intraoperative FSE was performed in 58 lesions (67.4%). It was informed as benign in all cases and confirmed by definitive histopathology in all patients. Tumor bed biopsies were taken in 23 (27.9%) patients with suspicion of bed involvement. GCNIS was diagnosed in 4 of them (17.4%).

During a mean follow-up of 25.5 ± 22.7 months, none of these patients developed systemic disease. Five patients with TGCT presented a local recurrence during follow-up (20%), 4 of them known with GCNIS without adjuvant local treatment and on regular follow-up. There was no local recurrence in patients with benign tumors.

Preoperative testosterone level was normal in 17 out of 20 patients (11 with solitary testis) with preoperative measurement. After TSS, serum testosterone levels remained within

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Table 2. Histology of the testicular masses according to tumor size and risk category (high or low risk) based on the presence or absence of clinical risk factors for GCT

Mass size	≤10 mm	>10–15 mm	>15–20 mm	>20 mm	Total (86)
Categorization by histology					
Malignant (*n* = 26) (%)	4 (15.4)	11 (42.3)	8 (30.8)	3 (11.5)	26
Benign (*n* = 60)	26 (43.3)	11 (18.3)	10 (16.7)	13 (21.7)	60
Categorization by risk groups					
High-risk (*n* = 30)	8	11	8	3	30
Malignant (*n* = 22)	4 (18.2%)	8 (36.4%)	7 (31.8%)	3 (13.7%)	22
Previous GCT	1	5	3	2	
Bilateral synchronic	3	3	2	1	
Testicular descend disorders	0	0	1	0	
Infertility	0	0	1	0	
Benign (*n* = 8)	4 (50%)	1 (12.5%)	2 (25%)	1 (12.5%)	8
Previous GCT	1	0	0	1	
Bilateral synchronic	2	0	1	0	
Descend disorders	1	0	0	0	
Infertility	0	1	1	0	
Low risk (*n* = 56)	22	11	10	13	56
Malignant	0	3 (75%)	1 (25%)	0	4
Benign	22 (42.3%)	8 (15.4%)	9 (17.3%)	13 (25%)	52

GCT, germ cell tumor.

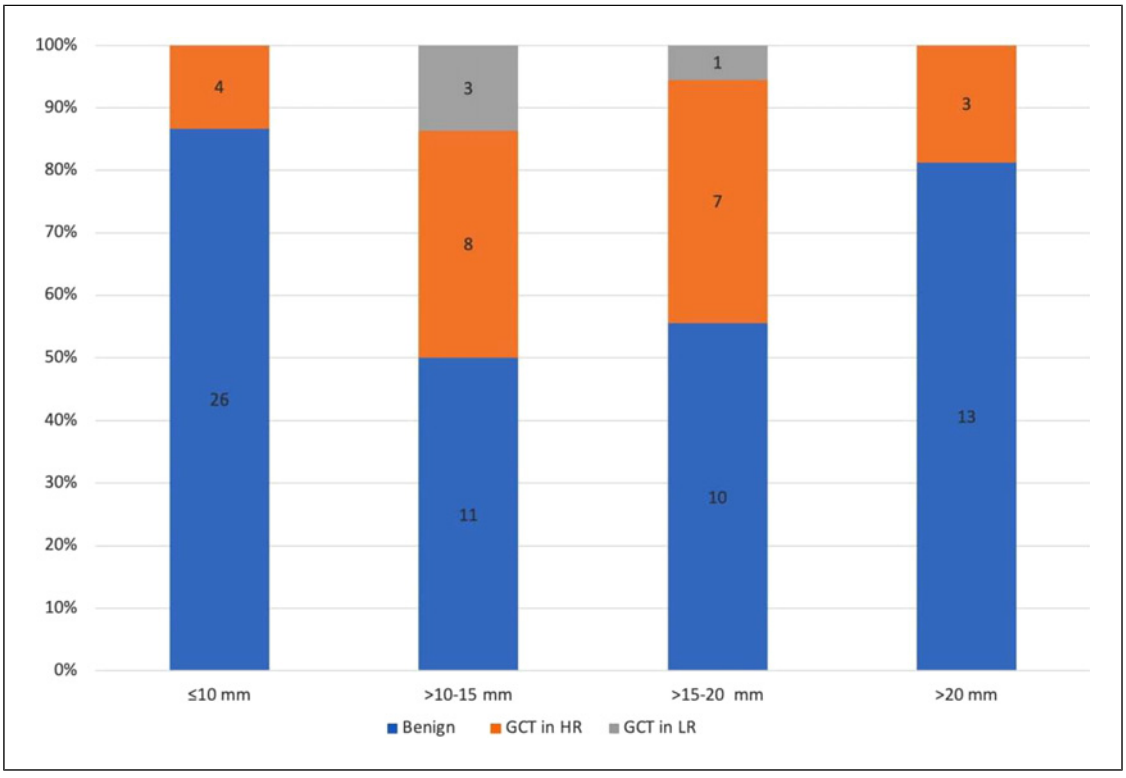


Fig. 2. Percentages of histology relative to different cut-offs of pathological tumor size in TSS. Blue: benign histology; orange: TGCT in patients with high risk of harboring TGCT; grey: TGCT in patients at low risk of harboring TGCT. Numbers in the columns represent the number of tumor per size group.

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Table 3. Univariate binary logistic regression model of factors that might affect presence of testicular malignancy

	Odds ratio	*p* value	95% CI
Continuous in years (age)	0.980	0.416	(0.935–1.028)
History of previous TGCT	0.041	<0.001	(0.008–0.210)
Pathological tumor size	0.996	0.417	(0.986–1.006)
AFP level above the limit	1.041	0.227	(0.975–1.112)
β-HCG level above the limit	1.009	0.102	(0.998–1.021)

AFP, alpha-fetoprotein; HCG, human chorionic gonadotropin; GCT, germ cell tumor. Dependent and independent variables were considered as categorical (yes/no): presence of malignancy, pain, history of malignancy, specific serum tumor marker elevation above the superior limit of normality; and continuous: age and pathological tumor size.

normal range in 15 (88.2%) patients, none of them reporting erectile dysfunction (ED). The two patients with postoperative testosterone levels below normative values reported ED. None of the patients with benign lesions reported ED.

Discussion

In our series of TSS in patients with small testicular masses, there were no differences at presentation in mean age and pathological tumors size between those patients at high-risk of TC and those at low-risk, namely considered as normal risk. However, when underlying risk factors for TC, the incidence of TGCT was radically different beyond statistical comparison, with rates of 73.3% and 7.1% for the high- and low-risk groups, respectively. The rate of TGCT were >50% for tumors up to 1 cm and increased linearly to 73% for tumors larger than 2 cm, while in the low-risk group remained <10% for all size cut-offs. Regarding oncological outcomes most of the TGCT were CS I and the concordance of histological type was very high in patients with previous TGCT. In patients with synchronic masses, histological concordance between testes was seen in half of the patients.

Recent literature describes an incidence of benign tumors in small testicular masses from 47% to 81% after TSS, depending on patient selection, diagnostic setting, and tumor size [6, 7, 13, 16–19]. Our 70% rate of benign tumors is between the figures described in the literature, although lower than in some recent series [6, 16]. However, in the range of the size suitable for TSS the incidence of TGCT is radically different when presence of TDS risk-factors for TC is considered. In our low-risk population without any feature of TDS, the incidence of TGCT was lower than the 14% reported in a recent multicenter series in patients without history of previous TC or synchronic testicular masses [13]. This difference may be justified for the fact that the sub- or infertile population was excluded in our low-risk population while it represented 25% of the population in the Gentile et al. [13] series. In fact, the rate of malignancy in our low-risk population was identical to their 7% of malignant tumors among lesions <1 cm with the particularity that we did not find any malignancy in pathological lesions <1 cm. Despite the serendipitous character of these figures, our series aligns and supports recently reports suggesting an extension of elective TSS in masses up to 2 cm in patient without risk factors for TC and normal contralateral testis [12]. Going one step further, it may reinforce a policy of initial observation in the very small testicular masses in patients at low risk [18, 20]. Nevertheless, a small but clinically relevant risk of testicular cancer still remains in low-risk patients with small testicular masses that mandates discussion and counseling on TSS, on the possible consequences should malignancy be found, and on compliance with surgical recommendations and the systematic use of FSE [1].

Conversely, the incidence of TGCT in the high-risk is extremely high (73.3%) even at a pathological size cut-off of 10 mm and with a cumulative risk of 70.4% in tumors up to 20 mm. Our data also suggest that the rate of malignancy increases with the severity of the TDS manifestations, at least when comparing the similar rates between patients with metachronous TGCT and synchronic suspected bilateral masses. Although the number of patients with testicular descent or impaired fertility of our series is too small to pronounce any conclusion, the hypothesis of variable association between the different phenotypes of TDS and the incidence of TGCT deserves further investigation.

The lack of difference in the mean pathological size between high- and low-risk tumors is clearly attributable to surgical bias. Although no data on ultrasonographic volume

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were available in our series, physicians should be aware that in terms of predicting malignancy volumetric measurement of a cut-off value of 2.8cc is likely more accurate than the solely maximal diameter [21] and that testicular tumors are not necessarily spherical, with regular boundaries or accompanied by elevated STMs. Those are relevant consideration that emphasizes the need for systematic ultrasound surveillance of the contralateral testis in the population with previous TGCT and even the opportunity for a US screening in the targeted high-risk population.

FSE was performed in our cohort at discretion of the surgeon, and it confirmed the high reliability of FSE at least for a benign diagnostic [19, 22]. It is likely that pre-surgical US, clinical characteristics or logistics (e.g., availability of FSE) as well as the historical nature of our series drove the practice of FSE that it is nowadays mandatory [1].

Our reported GCNIS rate in patients that received biopsy of the tumor bed (17.4%) was slightly higher than in other series [13, 16] and clearly higher than the 7.9% prevalence in tumors up to 2 cm recently reported in a systematic review [23]. The explanation for this apparent discrepancy is that in our cohort 30% of the patients were known at high-risk of TGCT before TSS, and the biopsy was mostly performed in this group. The high rate of GCNIS is similar to the 18% reported by Dieckmann et al. [24] in atrophic testes and supported by the fact that all asynchronous and synchronous TGCT were GCNIS derived. Although the low rate of reported complications of the testicular biopsy to rule out GCNIS supports the practice of distant or bed biopsy, a question arises if the biopsy can be obviated in patients without clinical risk-factor for TGCT with the double objective of maximizing the preservation of the germ line. Nonetheless, it should be systematically performed in those patients at high risk. FSE and biopsy to rule out GCNIS is a mandatory tandem in case of TSS when malignancy at FSE unless RO has been previously decided as definitive primary surgical option.

Regarding oncological outcomes, most of the TGCT were stage I (96%) with favorable evolution similar to previous single-center publications [25, 26] and systematic reviews [6, 16, 17]. However, as local recurrence amounts to 28% in some series, and may occur even in patients that received adjuvant local treatment [16], awareness in terms of ultrasonographic local examination added to regular controls is needed. Several notes of caution emerge related to the oncological data. First, histological concordance with the previous TGCT is high when metachronous TGCT presentation but lower when synchronic bilateral tumors. Second, local recurrences present exclusively in malignant tumors, making mandatory awareness on further delayed RO, adjuvant local treatment in case of GCNIS, or strict follow-up [1]. In terms of functional outcomes, although hormonal evaluation was performed in only 1 quarter of the patients, when normal at baseline the rate of preservation is very high after TSS in small testicular masses, extremely important in a population known with fertility impairment [17, 26].

Our series has several limitations. It is an heterogenous cohort with selection bias by tumor size, TSS feasibility, and classical mandatory indications. Albeit consecutive, it certainly precludes strong conclusions regarding definitive prevalence of malignancy according to tumor size although the findings are in line with previous reports. Data were retrospective gathered and some perioperative variables may be missed. Follow-up was not standardized although in most of the case oncological (ESMO/NCCN) or Urological Guidelines (EAU) was followed. While FSE was performed in a considerable number of patients, the lack of malignant diagnostic in the samples suggests a further bias likely induced by the preoperative findings (imaging or physical exploration). The lack of systematic biopsy performance (only in a quarter of the patients) may have underscored the rate of GCNIS. There was no central pathology review, an important quality requirement in TC and the number of patients with fertility or testicular descent disorders was too low to pronounce definitive conclusions in these subgroups at high-risk. Lastly, functional outcomes were determined in a small sub-cohort and required of confirmation in well-designed studies. However, despite these limitations the categorization according to individualized clinical risk phenotype clearly identifies two clinical populations with small testicular masses candidates for TSS but with completely different histological outcomes.

In conclusion, our data support the feasibility and effectiveness of TSS in the population at high-risk of TGCT, the capital importance of a thorough anamnesis in patients with small testicular masses, and the need to individualize treatment policies to avoid overtreatment of benign masses. Additionally, it suggests that initial surveillance may be considered in a very small mass (up to 1 cm) in patients at low-risk of harboring TGCT provided thorough informed decision.

Statement of Ethics

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Erciyes University School of Medicine Institutional

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Review Board (Decision date: 11.09.2019, IRB Decision no: 2019/601). Patient informed consent was waived due to the retrospective character of the study.

Conflict of Interest Statement

The authors have no relevant financial or nonfinancial interests to disclose.

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Author Contributions

Murat Keske: project development, data collection, manuscript writing, and manuscript editing. Abdullah Erdem Canda: project development, data management, and manuscript editing. Mert Ali Karadag and Ziya Akbulut: data collection, data analysis, and manuscript editing. Halil Ciftci, Sakıp Erturhan, Cağrı Kactan, Fatih Ozkaya, Isa Ozbey, Asıf Yildirim, Yunus Colakoglu, Uğur Boylu, Bülent Erol, Murat Can Kiremit, and Eser Ordek: data collection and data management. Mustafa Soytas, Ali Fuat Atmaca: data collection and manuscript editing. Selçuk Sahin, Turhan Caskurlu, Hakan Kilicarslan, Hasan Rıza Aydin, Yılmaz Aslan, Nurullah Hamidi: data collection and data analysis. Ozer Ural Cakici: project development, data collection, and manuscript editing. Gökhan Sonmez: project development, data collection, and data analysis. Onnur Kaygisiz, Selami Albayrak, Selahattin Bedir, Hakan Vuruskan, Yunus Erol Bozkurt, Ural Oguz, Erem Kaan Basok, Bilal Gumus, Altuğ Tuncel, Ahmet Yaser Müslümanoğlu, and Muhammed Murat Dinçer: data collection and data management. Mevlana Derya Balbay: project development and data collection. Maria Del Pilar Laguna: project development, manuscript writing, and manuscript editing.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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