World Journal of Urology (2019) 37:2699–2705
https://doi.org/10.1007/s00345-019-02681-2

ORIGINAL ARTICLE

Utility of the EORTC risk tables and CUETO scoring model for predicting recurrence and progression in non-muscle-invasive bladder cancer patients treated with routine second transurethral resection

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Received: 6 December 2018 / Accepted: 9 February 2019 / Published online: 25 March 2019

Abstract

Purpose Routine second transurethral resection (TUR) for non-muscle-invasive bladder cancer (NMIBC) is common practice in Germany. Applicability of European Organization for Research and Treatment of Cancer (EORTC) and Spanish Urological Club for Oncological Treatment (CUETO) models in NMIBC patients is still controversial. Aim of the study was to assess the performance of EORTC and CUETO predictive models in NMIBC patients treated with second TUR.

Methods 479 NMIBC patients with routine second TUR were analyzed retrospectively between 2003 and 2011, and investigated with clinical and pathological variables in regard to tumor recurrence and progression. Furthermore, recurrencefree survival (RFS) and progression-free survival (PFS) were evaluated according to EORTC and CUETO, and the discrimination of the models assessed.

Results With a median follow-up of 60 months, prior recurrence rate, grade, and second TUR pathology were independent prognostic factors for the risk of disease recurrence and progression. The concordance index of the EORTC and the CUETO model was 0.563 and 0.516 for recurrence and 0.681 and 0.702 for progression, respectively. The positive pathology after second TUR was significantly associated with risk of disease recurrence and progression. EORTC and CUETO risk models estimated progression better than recurrence, especially with higherscore groups.

Conclusions Improved predictive tools should be developed for optimal treatment selection.

Keywords Second TUR · EORTC · CUETO · Recurrence · Progression · Bladder cancer

Introduction

Non-muscle-invasive bladder cancer (NMIBC) is associated with a high recurrence rate and a lifetime survival, so the treatment cost is the highest per patient of all cancers [1]. Transurethral resection (TUR) is the first-line surgical procedure used to diagnose and treat patients with NMIBC [2]. Several studies have shown the clinical value of second resection performed 2–6 weeks after initial TUR, especially for high-risk tumors [3, 4]. The major goals in treating patients with NMIBC are to reduce recurrence frequency and to prevent muscle-invasive progression [2, 5]. Therefore, it is important to predict risk of recurrence and progression of individual patients based on the clinical and pathological factors to facilitate subsequently optimal treatment modalities.

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The European Organization for Research and Treatment of Cancer (EORTC) and Spanish Urological Club for Oncological Treatment (CUETO) scoring systems and risk tables are considered the most reliable evaluation systems [6, 7]. Sylvester and colleagues developed the EORTC scoring system with TaT1 bladder tumors in 2006, which provided urologists with the 1- and 5-year risk of recurrence and progression to make a decision regarding the scheme of adjuvant therapy [6]. In response to the main limitations of the EORTC model, which included a low number of patients treated with bacillus CalmetteGuerin (BCG) in high-risk patients, CUETO was developed as a new model, which predicts the probability of disease recurrence and progression regarding BCG-treated patients in 1 year, 2 years and 5 years [7]. To evaluate the applicability of EORTC and CUETO in different countries, several external validation studies have been performed, with controversial conclusions [8]. Meanwhile, a second TUR was not part of the treatment strategy in these EORTC and CUETO trials. Consequently, validation of the EORTC and CUETO models still has not been reported in NMIBC patients treated currently with routine second resection.

The goal of this study was to confirm the significance of second TUR and compare the utility of the EORTC and CUETO scoring models in a German NMIBC population who underwent routine second resection.

Patients and methods

In total, 611 patients underwent TUR with histology-proven NMIBC at our institution between January 2003 and December 2011. Of these NMIBC patients, 132 patients with incomplete data, no follow-up, concomitant other urothelial carcinoma, no second TUR, or carcinoma in situ or in whom the second TUR identified muscle-invasive disease and who underwent subsequent radical cystectomy were excluded. Therefore, 479 patients treated with second TUR were analyzed. The present study was performed with the approval of the institutional review board at our University (No. 4265 11/14). The database including the clinicopathologic factors and follow-up variables generated from medical records until April 2015. Tumor stage and grade of specimens were diagnosed by pathologists in our institution according to the 2002 TNM classification and the 1973 World Health Organization system, respectively.

Routine second TUR is common practice in Germany. A second resection was recommended for all NMIBC patients within 2–8 weeks after initial TUR except those with small, single focus, grade papillary tumors (TaGI) based on our discretion. The interval between first and second TUR was analyzed compared 14–42 days and 43–90 days. According to EAU risk classification, the scheme of adjuvant intravesical chemotherapies proposed with single immediate postoperative instillation in low-risk patients, one immediate instillation of chemotherapy followed by further instillations for a

Table 1 Clinical and pathologic characteristics of 479 NMIBC patients treated with routine second TUR

Variable	*N* (%)
Age (years)	
≤ 60	91 (18.9%)
61–70	156 (32.5%)
71–80	164 (34.4%)
> 80	68 (14.2%)
Gender	
Male	364 (75.8%)
Female	115 (24.2%)
Prior recurrence rate	
Primary	409 (85.4%)
Recurrence	70 (14.6%)
Number of tumors	
1	363 (75.8%)
2–3	92 (19.2%)
4–7	19 (3.9%)
> 7	5 (1.1%)
Tumor size (cm)	
< 3	444 (92.7%)
≥ 3	35 (7.3%)
T category	
Ta	387 (80.8%)
T1	92 (19.2%)
Grade	
G1	274 (57.2%)
G2	164 (34.2%)
G3	41 (8.6%)
Concomitant CIS	
No	473 (98.7%)
Yes	6 (1.3%)
Second TURB pathology	
Negative	399 (83.3%)
Positive	80 (16.7%)
Interval between first and second TURB	
14–42 days	266 (55.5%)
43–90 days	149 (31.1%)
Unknown	64 (13.4%)
Intravesical treatment	
Chemotherapy	184 (38.4%)
BCG	40 (8.4%)
No treatment record	255 (53.2%)
EAU risk classification	
Low risk	168 (35.1%)
Intermediate risk	208 (43.4%)
High risk	103 (21.5%)

maximum of 1 year or 1 year full-dose BCG in the intermediate-risk group, and intravesical full-dose BCG instillations for high-risk tumors. Patients were followed up regularly every 3–6 months during the first 2 years, biannually up to 5 years, and yearly thereafter [2, 9].

Disease recurrence was defined as a new cystoscopically detected tumor with histological confirmation appearing in the bladder after initial TUR. However, tumor recurrence in the upper urinary tract was not considered disease recurrence. Patients who were still alive and without recurrence were censored at the date of the last available follow-up cystoscopy. The definition of progression was from Ta, T1 or CIS to stage T2 or higher disease in the bladder. Patients who were still alive and without muscle invasion were censored at the date of the last available follow-up cystoscopy. ddition, patients who died of causes unrelated to bladder cancer were censored in the recurrence and progression analysis. We calculated a score for recurrence and progression according to the EORTC and CUETO models for each patient and stratified the patients into 3–4 risk groups [6, 7].

For statistical analysis, Kaplan–Meier survival were used to assess recurrence and progression curves in both models, and different groups were compared using the logrank test. Univariate and multivariate Cox proportional hazards regression were used to identify prognostic factors for recurrence and progression. A backward stepwise elimination procedure was performed to identify factors associated with survival at the 0.05 significance level. The discriminative ability of the two models was assessed using Harrell's c-index. A *p*value of less than 0.05 was considered statistically significant for all tests. All statistical were conducted using IBM SPSS version 19.0 (IBM Co., Armonk, NY, USA) and R 3.2.3 (RProject, www.r-project.org).

Results

Median follow-up for patients was 60 months. Furthermore, 227 patients (47.4%) recurred, with a median recurrencefree survival (RFS) of 15 months (range: 3–123 months), and 35 (7.3%) advanced into muscle-invasive disease, with a median progression-free survival (PFS) of 35 months (range: 5–123 months). Overall, 184 patients (38.4%) underwent adjuvant intravesical instillation with one or more cycles (doxorubicin or mitomycin), and the other 40 high-risk patients received the BCG therapy with or without maintenance. The main characteristics of the patients are shown in Table 1.

The results of univariate and multivariate Cox regression for recurrence and progression risks based on clinical and pathological factors are shown in Table 2. Prior recurrence rate, number of tumors, grade, and second TUR pathology were associated with a higher risk of recurrence. Age, prior recurrence rate, number of tumors, T category, grade, and second TUR pathology were associated with risk of progression. In the multivariate , prior recurrence rate, grade, and second TUR pathology were independent prognostic factors for the risk of recurrence. Similarly, age, prior recurrence rate, grade, and second TUR pathology were significant predictors of the risk of progression.

Table 3 compares the expected outcome probabilities according to the EORTC and CUETO risk tables with the

Table 2 Univariate and multivariate of prognostic factors of disease recurrence and progression

Variable	Recurrence			Progression		
	HR	95% CI	*p* value	HR	95% CI	*p* value
Uni-variate analysis						
Age (≤70 years vs > 70 years)	1.081	0.833–1.404	0.558	1.744	1.208–2.518	0.003
Gender (male vs female)	0.843	0.617–1.152	0.283	1.249	0.600–2.601	0.553
Prior recurrence rate (primary vs recurrence)	1.675	1.211–2.317	0.002	2.299	1.099–4.809	0.027
Number of tumors(solitary vs multiple)	1.258	1.001–1.580	0.049	1.782	1.068–2.972	0.027
Tumor size (< 3 cm vs ≥ 3 cm)	1.025	0.617–1.704	0.924	0.821	0.197–3.425	0.786
T category (Ta vs T1)	1.272	0.922–1.755	0.142	4.180	2.143–8.156	< 0.001
Grade (G1, G2, G3)	1.729	1.178–2.581	0.009	2.286	1.482–3.241	< 0.001
Second TUR pathology (negative vs positive)	1.469	1.059–2.037	0.027	2.349	1.127–4.895	0.023
Interval (≤ 42 days, >42 days)	1.022	0.768–1.361	0.879	0.923	0.441–1.930	0.831
Multi-varitate analysis						
Age (≤70 years vs > 70 years)	–	–	NS	1.523	1.047–2.215	0.028
Prior recurrence rate (primary vs recurrence)	1.678	1.208–2.329	0.002	2.258	1.113–5.432	0.026
T category (Ta vs T1)	–	–	NS	2.140	0.985–4.651	0.055
Grade (G1, G2, G3)	1.508	1.104–2.159	0.012	1.887	1.082–3.289	0.031
Second TUR pathology (negative vs positive)	1.433	1.033–1.989	0.031	2.245	1.062–4.744	0.034

observed outcomes at 1, 2 and 5 years in our cohort who underwent second TUR. In the intermediate risk groups (EORTC 1–4 and 5–9), the observed recurrence probability of 19% (95% CI 17–22) and of 26% (95% CI 20–31) at 1 year overestimated by applying the EORTC risk tables. In the same way, the results indicate that the CUETO recurrence risk table underestimated risks of disease recurrence at 1, 2 and 5 years for the three risk study groups and the risk of progression at 1, 2 and 5 years in the intermediatehigh risk group. Other EORTC and CUETO data show acceptable risk variability. However, the group with highest risk scores in the two models were not analyzed separately because they had only 1–2 patients, except the CUETO progression score 10–14 group.

In terms of the EORTC model, Kaplan–Meier survival curves for the risk groups were plotted for disease recurrence and progression (Fig. 1a, b). Risk of recurrence was associated with higher score ($P < 0.05$). The Harrell's concordance index based on the EORTC model was 0.563 for recurrence and 0.681 for progression, respectively.

Figure 1c, d show Kaplan–Meier survival curves of risk of recurrence and progression according to the CUETO scoring model. There was no significant difference between the recurrence score 0–4 and score 5–6 groups ($P = 0.968$) at 1 year and 5 years. A significant difference was found between the four groups using the CUETO progression score ($P < 0.05$). Similarly, the Harrell's concordance index using the CUETO model was 0.516 and 0.702 for recurrence and progression, respectively.

Table 3 Comparison of expected outcome and observed outcomes according to the EORTC and CUETO scoring model

Model	Probabilities at 1 year (%)	Probabilities at 2 year (%)	Probabilities at 5 year (s%)
EORTC			
Recurrence scores			
EORTC 0	15 (10–19)	–	31 (24–37)
Jena cohort 0	14 (12–17)	–	33 (29–37)
EORTC 1–4	24 (21–26)	–	46 (42–49)
Jena cohort 1–4	19 (17–22)	–	50 (46–54)
EORTC 5–9	38 (35–41)	–	62 (58–65)
Jena cohort 5–9	26 (20–31)	–	57 (51–64)
Progression scores			
EORTC 0	0.2 (0–0.7)	–	0.8 (0–1.7)
Jena cohort 0	0	–	2.7 (1.5–3.9)
EORTC 2–6	1 (0.4–1.6)	–	6 (5–8)
Jena cohort 2–6	1.7 (0.8–2.6)	–	8 (5 –10)
EORTC 7–13	5 (4–7)	–	17 (14–20)
Jena cohort 7–13	3 (1–5)	–	22 (15–28)
CUETO			
Recurrence scores			
CUETO 0–4	8 (6–11)	13 (10–15)	21 (17–25)
Jena cohort 0	18 (16–20)	32 (30–35)	45 (42–48)
CUETO 5–6	12 (8–16)	22 (17–28)	36 (29–42)
Jena cohort 5–6	16 (12–20)	32 (27–37)	43 (37–48)
UETO 7–9	25 (20–31)	40 (33–46)	48 (41–55)
Jena cohort 7–9	34 (26–42)	49 (41–57)	60 (51–68)
Progression scores			
CUETO 0–4	1.2 (0.2–2.2)	2.2 (0.8–3.5)	3.8 (1.9–5.6)
Jena cohort 0	0	1.2 (0.6–1.8)	3.5 (2.5–4.5)
CUETO 5–6	3 (0.8–5.2)	5 (2.3–7.6)	12 (7.6–16)
Jena cohort 5–6	2 (0–4)	6 (2.8–9.8)	12 (7–17)
CUETO 7–9	5.6 (2.7–8.4)	12 (8–16)	21 (16–27)
Jena cohort 7–9	10 (3.3–16.7)	15 (7–23)	43 (30–56)
CUETO 10–14	14 (6.6–21)	25(16–34)	34 (23–44)
Jena cohort 10–14	9 (3–15)	9 (3–15)	26 (14–39)

Discussion

An accurate estimation of disease recurrence and progression risks in the individual patient can facilitate the decision-making process regarding the optimal therapy, especially for high-risk tumors [10]. Furthermore, molecular research has not been accepted as a standard diagnostic procedure in clinical guidelines [2, 11]. Therefore, clinical and pathological variables still play important roles in predicting disease recurrence and progression. In the present study, we mainly analyzed second TUR pathology as a potential prognostic factor. Meanwhile, the interval was included as recommended by Baltaci and coworkers [12].

In our cohort, we found that the rate of residual tumor proven by second TUR was 16.7% less than the previous rate reported by Babjuk, who estimated that disease persisted in 27–72% of Ta and 33–78% of T1 tumors [13]. Moreover, we found that the positive pathology after second TUR was associated with higher risks of recurrence and progression. The other prognostic variables associated with risk of recurrence and/or progression in the multivariate are those recognized as such in EORTC and CUETO studies: age, prior recurrence rate, number of tumors, stage, and grade.

The EORTC risk tables have been accepted as a standard since their inclusion in EAU guidelines [2]. The CUETO model was more suitable for patients treated with BCG. Overall, our patient characteristics were similar to that of the EORTC system, but not to that of the CUETO system. External validation of these prognostic models in different populations is crucial to estimate their generalizability [14, 15]. To our knowledge, this study is the first to focus on NMIBC patients who have undergone second TUR to estimate the utility of the EORTC risk tables and CUETO scoring model. To assess the models' accuracy, we used Harrell's concordance index. We demonstrated

that the EORTC and CUETO risk tables exhibited poor discrimination in predicting disease recurrence (0.563 for EORTC model and 0.516 for CUETO model). The poor discriminative ability of the CUETO model is not surprising, considering only 8.4% of patients treated with BCG therapy in our study. For recurrence the CUETO evaluation underestimated the risk comparison to our data, which is similar the result reported by Ravvaz [16]. For the EORTC score we found that the model overestimated the risks in patients with recurrence score 5–9. This may have been due to the routine use of second TUR in our cohort. This result is similar to two previous external validations based on patients with similar characteristics [15, 17]. Interestingly, both EORTC and CUETO models showed better discrimination for predicting progression risk in our cohort (0.681 for EORTC risk tables and 0.702

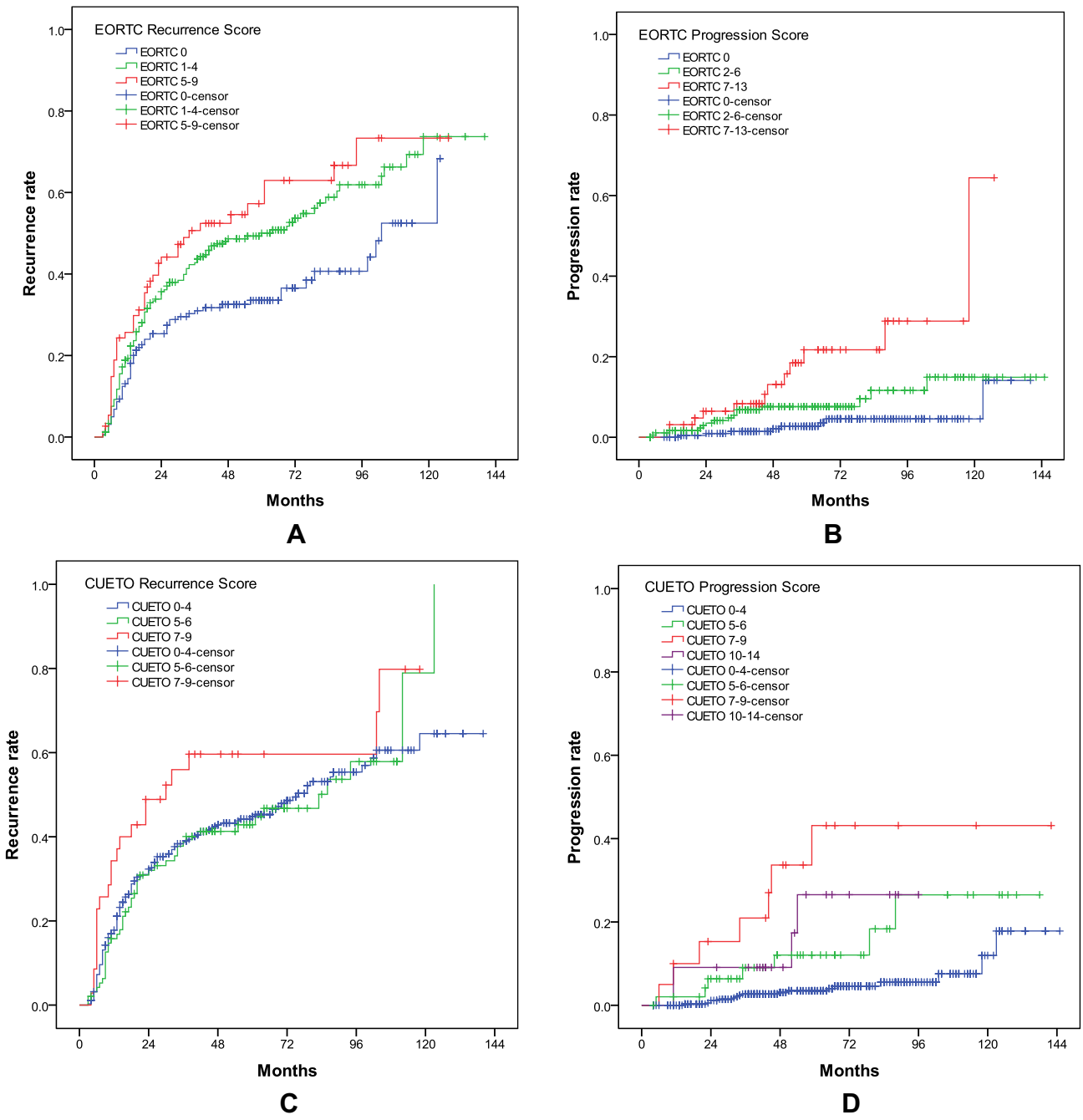

Fig. 1 Kaplan–Meier survival curves of risk of recurrence according to EORTC risk tables (**a**), risk of progression according to the EORTC risk tables (**b**), risk of recurrence according to the CUETO model (**c**), and risk of progression according to the CUETO model (**d**)

for CUETO model). This conclusion regarding predicting progression is also consistent with previous external validations regardless of the characteristics of the cohort [7, 14, 18, 19]. Thus, both the EORTC and CUETO models could discriminate tumor progression well in our cohort, especially the CUETO system, in contrast to the prediction of tumor recurrence. These results are also in line with Kohjimoto's findings [8]. The reason may be that the weighted score of tumor history has less effect on tumor progression than it did on tumor recurrence. Another study in the US population illustrates that EORTC and CUETO had poor discriminative ability to predict NMIBC recurrence and progression. The reasons include the fact that many predictive factors were imprecise and had poor interobserver agreement [16]. Therefore, patient characteristics are still crucial when deciding which scoring system should be applied.

The limitations of our study are its retrospective nature, its relatively small sample size, and the relatively large proportion of low- and intermediate-risk patients. On the other hand, our cohort lacked many high-risk NMIBC patients, which is also in accordance with the number of patients predicted by the EORTC and CUETO models to be at highest risk of recurrence or progression.

Conclusions

In our cohort treated with second TUR, positive pathology after second TUR was also considered an independent prognostic factor for disease recurrence and progression. The EORTC and CUETO risk models estimated progression better than recurrence, especially with higherscore groups. Improved predictive tools should be developed for optimal treatment selection.

Conflicts and interest

The authors declare that no conflicts of interest exist.

Acknowledgements We thank Frau Ulrike Burger in cancer center at Jena University hospital. Special thanks to Dr Birgit Wilski, Dr Christian Knöpfel, Dr Ekkehard Hofmann, Dr Carldieter Bothor, Dr Gerlinde Finke, Dr Matthias Kühnert, Dr Stefan Göckeritz, and Dr Stefan Kowalik, for helping us collect the data of up.

Author contributions Horstmann M,Grimm M–O and Zhang GX designed the research. Zhang GX and Steinbach D collected the data. Zhang GX and Horstmann M wrote the draft of the manuscript and performed the statistic works. Zhang GX, Horstmann M and Grimm M–O analyzed and interpreted the data. Horstmann M and Grimm M–O reviewed the article and made suggestions for revision. All authors reviewed the manuscript.

Funding No.

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