Validation of Two Preoperative Kattan Nomograms Predicting Recurrence After Radical Prostatectomy for Localized Prostate Cancer in Turkey: A Multicenter Study of the Uro-oncology Society

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OBJECTIVES To examine, in a multicenter validation study designed under the guidance of the Uro-Oncology Society, the predictive accuracies of the 1998 and 2006 Kattan preoperative nomograms in Turkish patients. These 2 preoperative Kattan nomograms use preoperative parameters to estimate disease recurrence after radical prostatectomy.

METHODS A total of 1261 men with clinically localized prostate cancer undergoing radical prostatectomy were included. The preoperative prostate-specific antigen level, biopsy Gleason score, clinical stage, number of positive and negative prostate biopsy cores, and postoperative recurrence status of all patients were studied. The predicted values using the Kattan nomograms and the observed values were compared.

RESULTS The patient characteristics in the cohort were comparable with those of the cohorts used to create the Kattan nomograms. The 5-year probability of freedom from recurrence was 73% using Kaplan-Meier analysis and was similar to that of the 1998 Kattan nomogram cohort. However, the 10-year probability of freedom from recurrence was 67%, slightly lower than the same estimate from the 2006 nomogram cohort. The predicted values of recurrence using Kattan nomogram and the observed rates in our cohort were similar. The estimated concordance index value was 0.698 and 0.705 for 1998 and 2006 nomograms, respectively.

CONCLUSIONS The Kattan preoperative nomograms can be used with adequate success in Turkey, because the predicted and observed rates in our cohort were similar. Our results have demonstrated satisfactory concordance index values, suggesting that both the 1998 and the 2006 Kattan preoperative nomograms can safely be used in Turkish patients with similar accuracy. Although the 2006 nomogram had slightly better discrimination, the 1998 nomogram was a little more calibrated. UROLOGY 74: 1289–1295, 2009. © 2009 Published by Elsevier Inc.

Given that prostate cancer is one of the most common malignancies, precise risk evaluation is crucial for the selection of therapy.[1] An insufficiency in the number of randomized trials of prostate cancer makes diagnostic and treatment decisions complex for the physicians.[1,2] Recently developed nomograms can provide more clear-cut predictions than physician judgment about the outcome of patients with localized prostate cancer.

In 1998, Kattan et al.[3] published a nomogram for the prediction of the probability of disease progression within 5 years after radical prostatectomy (RP) in patients with clinically localized prostate cancer. The basis for the Kattan preoperative nomogram was a statistical model derived from 983 men treated by a single surgeon at Baylor College of Medicine (Houston, TX). This preoperative Kattan nomogram combines the preoperative prostate-specific antigen (PSA) level, biopsy Gleason score, and clinical stage to estimate the probability of disease recurrence after RP. The preoperative Kattan nomogram was updated in 2006 with addition of the

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number of positive and negative prostate biopsy cores to the former preoperative parameters used in the 1998 Kattan nomogram.[4] Also, the 2006 Kattan preoperative nomogram is used to calculate the 10-year progression-free probability, instead of 5 years.

Although 3 external validations for the 1998 Kattan nomogram and 1 external validation for the 2006 Kattan nomogram have been performed, it has not been validated in Turkey.[4-7] However, the preoperative Kattan nomograms seemed to be the most-used nomograms to predict the outcome of patients with prostate cancer among uro-oncologists in Turkey. Also, Turkey is geographically important, because it is located between Europe and Asia, where the overall and aggressive prostate cancer incidence might be much lower than in the United States and Scandinavian countries. This could hypothetically hamper the effective use of the Kattan nomograms in Turkey. Accordingly, we decided to test the predictive ability of both the 1998 and the 2006 preoperative Kattan nomograms when applied to Turkish patients. A multicenter validation study with the participation of 18 clinics from Turkey was designed under the guidance of the Uro-Oncology Society (Istanbul, Turkey). The success and feasibility of the preoperative Kattan nomograms in predicting recurrence after RP in Turkish patients was explored.

MATERIAL AND METHODS

A total of 1261 men with clinically localized prostate cancer (Stage cT3a or less and N0M0) undergoing RP in 18 clinics in Turkey from 1992 to 2007 were included in the present study. Data, including preoperative PSA level, biopsy Gleason score, clinical stage, number of negative and positive biopsy cores, and postoperative recurrence status of all patients, were collected from each clinic. Those with missing information for the preoperative serum PSA level, Gleason score, clinical stage, or number of negative and positive biopsy cores and those who had undergone neoadjuvant endocrine treatment were excluded (n = 386). The serum PSA values, clinical stage, biopsy Gleason score, and number of negative and positive biopsy cores were evaluated by different physicians at each clinic. All biopsy specimens were graded histologically using the Gleason scoring system.[8] The clinical stage in all institutions was assigned using the 1992 American Joint Committee on Cancer TNM classification. The preoperative characteristics of our patients and those of the original Kattan study groups were compared. Disease recurrence was defined as biochemical failure (2 consecutive PSA values of ≥0.4 ng/mL after RP or secondary cancer treatment).[3] Because serial PSA data were not complete for all patients, treatment failure was assumed if the patient had received a second prostate cancer treatment >6 months after RP. Patients who had received neoadjuvant therapy (hormonal therapy or radiotherapy) before RP were excluded from the development of the nomogram. Men who had received adjuvant hormonal therapy or radiotherapy (but before documented recurrence) were treated as if the treatment had failed at the use of the second therapy.

All statistical evaluations were 2-sided and performed using the Statistical Package for Social Sciences, version 13.0, software (SPSS, Chicago, IL). The computation of actual progression-free probability was performed using Kaplan-Meier analysis. The 5-year probability of freedom from recurrence was calculated. To facilitate this analysis, 5 population groups were defined, with almost equal number of patients in each, according to the nomogram-predicted probability of recurrence for convenience in comparing the predicted and observed rates of freedom from recurrence. We compared the observed recurrence-free rate at 5 years calculated using Kaplan-Meier actuarial analysis to the predicted recurrence-free rate at 5 years calculated using the Kattan nomograms. In addition, the continuous nomogram scores were used to determine the concordance index (ie, the proportion of randomly paired patients for whom the patient with the greater probability of recurrence also had earlier disease recurrence).[3,6]

RESULTS

The patient characteristics (eg, age, preoperative serum PSA level, clinical stage, number of negative and positive biopsy cores, and biopsy Gleason score) of the entire Turkish cohort and the original Kattan cohorts were compared (Table 1). Differences were found between the patient groups. For example, the median pretreatment PSA level in our patient group was slightly greater than that in the original 1998 and 2006 Kattan cohorts (8.1, 6.8, and 6.1 ng/mL, respectively; Table 1). The percentage of patients with a PSA level <4 ng/mL was lower in our cohort than in the original 1998 Kattan cohort. Nonetheless, the proportion of patients with clinical Stage T1c in our patient group was greater than that in the 1998 Kattan group but almost the same as that for the 2006 cohort (Table 1).

Of our 1261 patients, 216 (17.1%) had ≥60 months of disease-free follow-up, and 16 (1.3%) had ≥120 months of disease-free follow-up; 201 (15.9%) had evidence of disease recurrence. The median follow-up of those patients with recurrence was 34 months (maximum 168), and the median follow-up of the patients without recurrence was 31 months (maximum 145).

For all patients, the 5-year probability of freedom from recurrence was calculated as 73% using Kaplan-Meier analysis (95% confidence interval 69.1-76.9). The 10-year probability of freedom from recurrence was 68.7% using Kaplan-Meier analysis (95% confidence interval 62.5-74.9). In the entire cohort, the 1998 preoperative Kattan nomogram scores (ie, the predicted probability of remaining recurrence free 5 years after surgery) were 7%-96% (mean ± SD 75.9% ± 17.2%, median 81%). The 2006 Kattan nomogram scores for our cohort (ie, the predicted probability of remaining recurrence-free 10 years after surgery) were 2%-96% (mean ± SD 75.1% ± 19.4%, median 81.6%).

The predicted values of PSA recurrence using the Kattan nomograms and the observed rates according to Kaplan-Meier analysis are presented in Figure 1 and Table 2. As expected, the lower the nomogram estimates, the less likely that patients would remain free of recurrence at 5 and 10 years after RP. Figure 2 shows the

Table 1. Comparison of patient characteristics between Turkish and Kattan cohorts

Variable	Turkish Cohort (n = 1261) (%)	Kattan Cohort* (1998) (n = 983) (%)	Kattan Cohort† (2006) (n = 1978) (%)
PSA category (ng/mL)			
<4	117 (9.3)	217 (22.1)	NA
4.1-10	674 (53.4)	472 (48)	
10.1-20	345 (27.4)	187 (19)	
>20	125 (9.9)	107 (10.9)	
PSA (ng/mL)			
Median	8.1	6.8	6.1
IQR	0.42-120	0.1-100	4.4-9.0
Gleason score			
1-2/1-2	152 (12.1)	108 (11)	Gleason 2-6: 1348 (68)
1-2/3	123 (9.8)	158 (16.1)	Gleason 3+4: 397 (20)
3/3 and 3/1-2	575 (45.6)	405 (41.2)	Gleason 4+3: 130 (7)
3/4-5	255 (20.2)	213 (21.7)	Gleason 8-10: 104 (5)
4-5/1-5	156 (12.4)	99 (10.1)	
Clinical stage			
T1a-T1b	61 (4.8)	83 (8.4)	—
T1c	548 (43.5)	148 (15.1)	803 (41)
T2a	433 (34.3)	266 (27.1)	509 (26)
T2b	156 (12.4)	246 (25.0)	335 (17)
T2c	26 (2.1)	182 (18.5)	244 (12)
T3a	37 (2.9)	—	88 (4)
Positive biopsy cores (n)			
Median	2	NA	2
IQR	1-4		2-4
Total biopsy cores (n)			
Median	8	NA	6
IQR	6-10		6-9

PSA = prostate-specific antigen; NA = not assessed; IQR = interquartile range.
* Data from Kattan et al.[3]
† Data from Stephenson et al.[4]

Kaplan-Meier curves for each Kattan prognostic group. The Kaplan-Meier curves were within, or very close to, the boundaries of the 5- and 10-year prediction, as desired (Fig. 2 and Table 2). The 1998 Kattan nomogram tended to underestimate the freedom from recurrence rate for the prognostic category of ≥88.8% and slightly overestimated the probability of freedom from recurrence for the prognostic category of 84.1%-88.7% (Table 2). The 2006 Kattan preoperative nomogram exhibited some degree of optimism (underestimation) for all groups (Table 2). Thus, the 2006 Kattan nomogram tended to minimally underestimate the incidence of PSA recurrence in our cohort.

The estimated concordance index value for entire cohort was 0.698 and 0.705 for the 1998 and 2006 Kattan nomograms, respectively.

COMMENT

The accurate risk estimate in patients with prostate cancer is important, not only to decide who requires treatment, but also to determine which therapy is likely to improve the cancer-specific outcomes. Traditionally, physician judgment has formed the basis of risk estimation in decision making for patients with prostate cancer. Clinicians' estimates, however, can be influenced by the subjective and objective confounders that exist at all stages of the prediction process.[1,2,9,10] Predictive and prognostic nomograms have been introduced to overcome the shortcomings of physician judgment and to complement the standard modeling techniques with the ability to predict the various risks for individual patients.[2,3,11-13] The traditional factors used in most of the predictive models are the serum PSA level, clinical tumor stage, and biopsy Gleason score. The widely used Partin tables are helpful for localized prostate cancer to some degree, allowing the prediction of the pathologic stage at RP using the combination of stage, PSA level, and Gleason score.[12] Nevertheless, the Partin tables do not provide information beyond the pathologic outcome; they cannot predict the clinical outcome, and also they are not ideal tools for additional treatment planning.[12,14] The prediction of recurrence and follow-up is gaining importance for the selection of therapy for prostate cancer. The Kattan preoperative nomograms, combining clinical prognostic factors and used for the preoperative prediction of disease recurrence after RP as the endpoint, are most commonly used nomograms worldwide and in Turkey.[2,3]

The predictive accuracy reported in an original nomogram study must be externally validated to confirm the nomogram is useful with other patient groups. Differences related to the geographic region can potentially affect the different steps of the diagnostic workup and the performance of the nomogram. However, in a steady

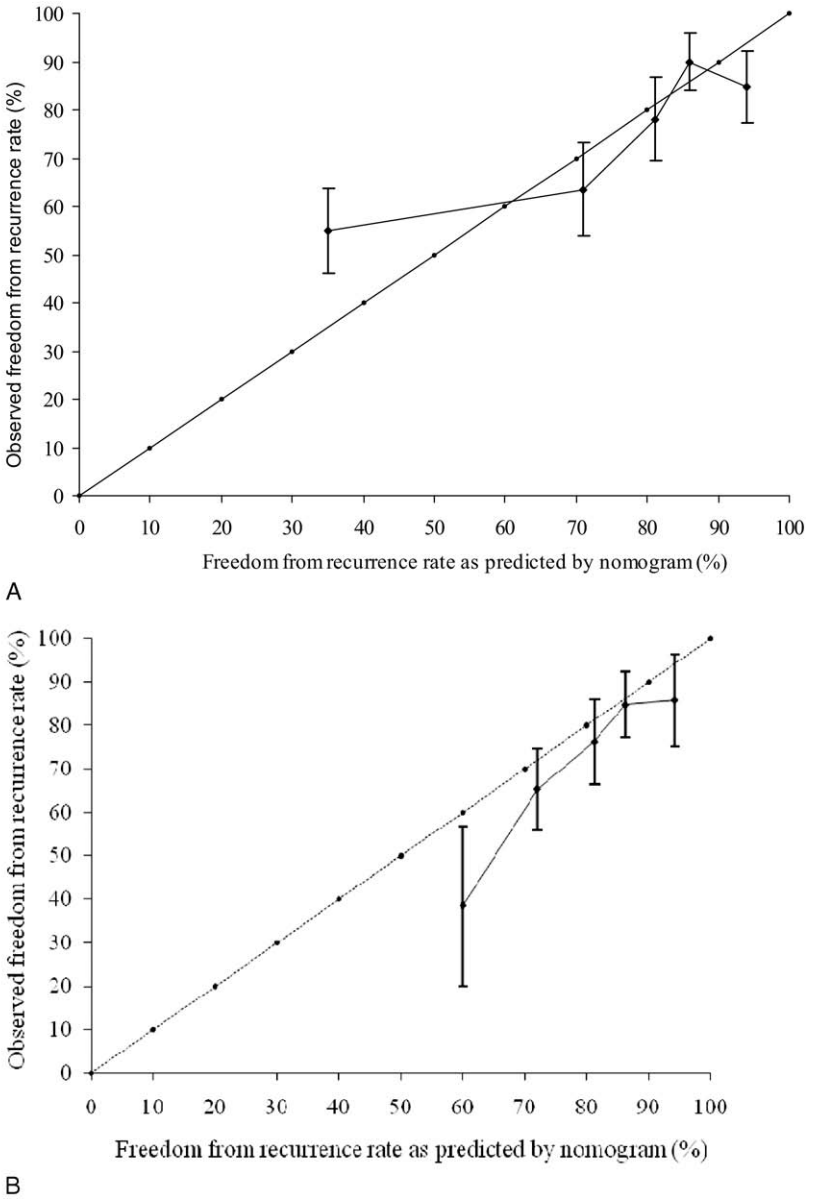

Figure 1. (A) Comparison of predicted and observed 5-year freedom from recurrence rates in entire cohort using 1998 Kattan nomogram. **(B)** Comparison of predicted and observed 10-year freedom from recurrence rates of entire cohort using 2006 Kattan nomogram. Dotted line indicates theoretical perfect agreement between prediction and observation.

nomogram, such differences would result in minimal variations in diagnostic accuracy. The 1998 Kattan preoperative nomogram has been validated with 3 different external data sets. However, the 2006 Kattan nomogram has been validated only using the original published series.[4-7] In our study, we performed a multicenter validation study of both preoperative Kattan nomograms (1998 and 2006) in Turkish patients. Our study population was heterogeneous, including patients from 18 clinics. The clinics varied from tertiary referral academic centers to community hospitals. Thus, no bias was present in the recruitment of the patients.

The original 1998 Kattan preoperative nomogram was created using the data from 983 patients with clinically localized prostate cancer treated with RP performed by 1 surgeon. The 1998 Kattan nomogram was internally validated using patients at the same institution.[3] Subsequent external validation at different academic centers confirmed the performance of the model for predicting freedom from recurrence.[5-7,15] This nomogram had concordance indexes of 0.68-0.83 when applied to external validation cohorts. The patients in those validation studies had been drawn from academic centers and treated by oncologic urologists, except for the Cancer of the Prostate Strategic Urological Research Endeavor (CaPSURE) study,[5] which contained a large, community-based patient cohort. The CaPSURE study cohort was similar to our study cohort, which was also community based and included patients who had undergone RP by surgeons with varying experience. The concordance index in our

Table 2. Observed and predicted rates of freedom from recurrence at 5 and 10 years

Kattan Nomogram Group	Patients (n)	Observed Freedom From Recurrence Rate (%)
1998 Kattan nomogram (5 y)		
0-64	260	54.9
64.1-78	262	63.5
78.1-84	238	78.1
84.1-88.7	252	89.9
≥88.8	249	84.7
2006 Kattan nomogram (10 y)		
0-65.5	199	38.5
65.6-78.4	237	65.3
78.5-84	211	76.2
84.1-88.4	192	84.8
≥88.5	230	85.9

cohort for the 1998 Kattan nomogram was 0.698, similar to concordance index (0.68) of the CaPSURE study. Thus, although the accuracy might be slightly lower than in the validation studies from academic centers, it remains reasonably applicable to a wide spectrum of patients and clinics.

The 2006 Kattan preoperative nomogram was internally and externally validated.[4] The concordance index in external validation was 0.77. Although the concordance index of 0.705 in our cohort was lower than the concordance index in the other external validation cohort, it was still reasonable to use the 2006 preoperative Kattan nomogram in our cohort. Moreover, the estimated concordance index of 0.698 proves that the 1998 Kattan preoperative nomogram could be used with adequate success in Turkish patients with prostate cancer. This finding was crucial, because many uro-oncologists in Turkey are using these tools for patients with localized prostate cancer. Although the 2006 nomogram uses an additional preoperative parameter (number of positive biopsy cores), our findings (concordance index) suggest that both 1998 and 2006 Kattan preoperative nomograms are have practically the same accuracy. Nevertheless, the 2006 nomogram has the advantage of providing the 10-year progression-free probability.

The predicted values of the 5-year PSA recurrence rates using the 1998 Kattan nomogram and the real observed rates in our cohort were mostly similar. As expected, the lower the nomogram estimate, the less likely that the patients would remain free of recurrence 5 years after RP (Fig. 1 and Table 2). The Kaplan-Meier curves were within, or very close to, the boundaries of the 5-year prediction, as desired (Fig. 1 and Table 2). However, the nomogram tended to underestimate the freedom from recurrence for the prognostic category of ≥88.8% and slightly overestimated the probability of freedom from recurrence for the prognostic category of 84.1%-88.7% (Table 2). The reasonable explanations for the nomogram underestimation in the prognostic group of 84.1%-88.7% could be pathologic and clinical stage assessment differences, disparity in the surgical techniques, or the length of follow-up in our patient group.

The 2006 Kattan preoperative nomogram tended to underestimate the PSA recurrence for all groups in our cohort (Table 2). That optimism of the 2006 Kattan nomogram was also demonstrated in the original external validation.[4] A part of that optimism can be explained because the model was developed using patients treated by high-volume surgeons and the validation cohort was treated by both high- and low-volume surgeons.[4] Nevertheless, the increased rate of positive surgical margin in the low-volume surgeon cohorts probably explains the greater PSA recurrence rate. This probable explanation was also true for our cohort.

Most of the patient characteristics in our cohort were comparable to those of the original Kattan nomogram cohort (Table 1). Our community-based patient population differed from the 1998 validation cohort with respect to the clinical T stage and serum PSA level distribution. The proportion of patients with clinical Stage T1c in our cohort was greater (43.5% vs 15.1%), which was probably because the original Kattan cohort was studied 10 years earlier. Accordingly, the newer 2006 nomogram cohort was similar to our cohort in this respect. However, the median PSA level was greater in our cohort and the proportion of patients with a PSA level <4 ng/mL was lower than in the original 1998 cohort, a finding that conflicts with the greater proportion of patients in our cohort having clinical Stage T1c. This could hypothetically be explained by inherited or geographic factors. However, the Gleason score distributions were similar between the groups.

In the 1998 report by Kattan et al.,[3] a single expert pathologist graded the biopsies, minimizing variability. In addition, the PSA level was determined using one assay type (Hybritech Tandem R, Perkin Elmer, Foster City, CA), and digital rectal examination was performed by a single practitioner. Because our study was a multicenter study, several types of PSA assays were used at each treatment center. In addition, the clinical stage was determined by different clinicians at each clinic. One could criticize our multicenter study cohort because it used many different PSA assays and differences were present in Gleason score, surgical experience, and number of surgeons and pathologists involved. Nevertheless, in a stable nomogram, such differences should result in minimal predictive accuracy variations, because a truly generalizable nomogram should adjust properly for any such differences.[2] It is likely that many of these factors accounted for the lower, but acceptable, concordance index of our study group and the CaPSURE study group.

Our study was limited by the lack of central pathologic review. Although some studies reported acceptable interobserver reliability among pathologists when reporting biopsy results, some variability could be present in the interpretation of the pathologic results.[16] Therefore, one

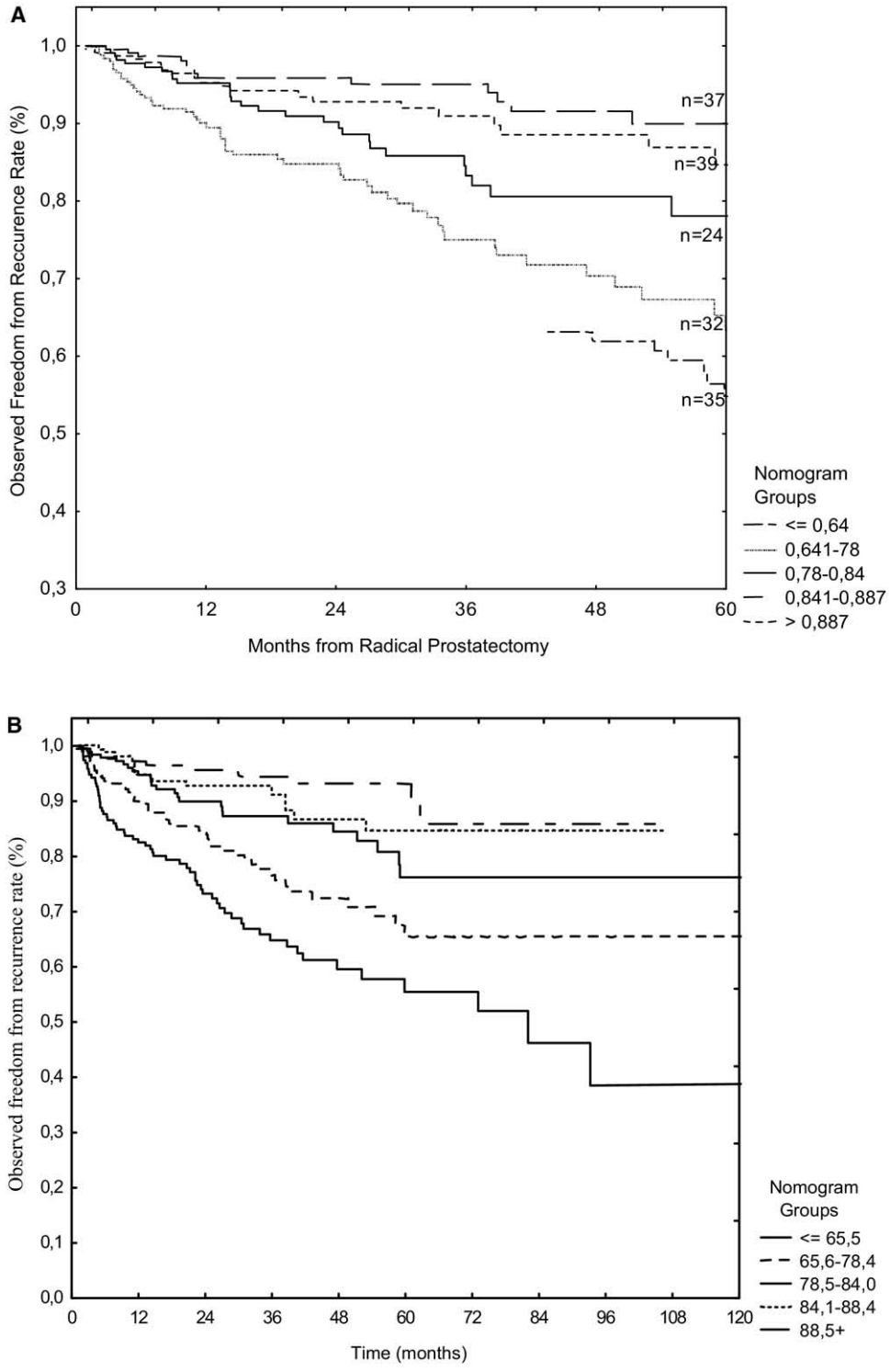

Figure 2. (A) Observed rates of freedom from recurrence according to 1998 Kattan nomogram prediction categories. **(B)** Observed rates of freedom from recurrence according to 2006 Kattan nomogram prediction categories.

might prefer a single pathologist to review each pathologic specimen. However, this would not reflect real world practice.[17]

The databases supplied by different institutions in our cohort were very important for determining the generalizability of the Kattan nomograms. The comparison of the predicted outcome and actuarial recurrence demonstrated a high degree of agreement, demonstrating the general applicability of the nomogram in the community-based setting.

Nevertheless, the results of the present study have demonstrated that both 1998 and 2006 preoperative Kattan nomograms have accuracy comparable to that in the previous validation studies of more homogeneous groups.

Furthermore, the Kattan preoperative nomograms revealed good performance in our cohort, which reflected real world practice.

Despite some differences between the study groups in the pretreatment variables, the preoperative Kattan nomograms were satisfactory in predicting recurrence in our Turkish patients. The differences in some of the preoperative parameters reflect the differences in patients' attitudes toward screening and the availability of serum PSA testing in the 2 countries.

In addition to the tremendous patient variability, the results from our validation study emphasize the robustness of both the 1998 and the 2006 preoperative Kattan nomograms to predict disease recurrence after RP. Our study is the first validation study of the 1998 and 2006 preoperative Kattan nomograms from this part of the world predicting the outcomes after RP. Accordingly, the present study has important implications for practicing physicians, as well as for patients who need a prediction of surgical efficacy.

CONCLUSIONS

The patient characteristics in our cohort were comparable with those of the original Kattan nomogram cohorts in most aspects. The predicted values of the 5- and 10-year PSA recurrence using the Kattan nomogram and the actual observed rates in our cohort were mostly similar. Although the estimated concordance index values of 0.698 and 0.705 were slightly lower than in most of the previous validation cohorts and both nomograms tended to slightly overestimate the 5- and 10-year probability of freedom from recurrence in most of the subgroups, both 1998 and 2006 Kattan preoperative nomograms were still strong and could be successfully used for Turkish patients with localized prostate cancer. Although the 2006 nomogram discriminated slightly better, the 1998 nomogram was a slightly more calibrated. Moreover, it was demonstrated by the satisfactory concordance index values, that both 1998 and 2006 Kattan preoperative nomograms could be used with similar accuracy.

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APPENDIX

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