Positive surgical margins after robot-assisted radical prostatectomy: Long-term oncologic consequences

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ABSTRACT

Introduction: We aimed to evaluate the prognostic significance of positive surgical margins (PSM) and associated clinicopathologic factors on long-term oncologic outcomes following robot-assisted radical prostatectomy (RARP).
Methods: We analyzed a prospectively maintained registry of patients undergoing RARP between 2003 and 2022, stratified by surgical margin status (positive vs. negative [NSM]). Primary outcomes were overall survival (OS) and biochemical recurrence-free survival (BCRFS). Multivariable Cox regression adjusted for age, prostate-specific antigen (PSA), Gleason grade group (GGG), pathologic stage, nodal status, and adjuvant therapy. A prognostic nomogram for OS was developed in the PSM cohort.
Results: Among 3969 patients, 459 (11.4%) had PSM, which was more common in the presence of adverse pathologic features. On unadjusted analysis, PSM was associated with worse OS

KEY MESSAGES

- Positive surgical margins (PSM) occur more often in patients with adverse pathologic features, reflecting underlying tumor biology rather than margin status alone.
- Although PSM is associated with worse unadjusted OS and BCR-free survival after RARP, it is not independently predictive after adjustment for clinicopathologic risk factors.
- Among patients with PSM, advanced pathologic stage and node-positive disease are the primary drivers of long-term mortality.
- A PSM-specific prognostic nomogram demonstrated moderate-to-high discriminative ability for long-term overall survival and may aid individualized postoperative risk stratification.

(hazard ratio [HR] 1.39, 95% confidence interval [CI] 1.02–1.90, p=0.036) and BCRFS (HR 2.20, 95% CI 1.62–2.97, p<0.001). After adjustment, PSM was not independently associated with OS (adjusted [a]HR 1.16, p=0.377) or BCRFS (aHR 0.86, p=0.343). In the PSM cohort, ≥pT3a disease, node-positive status, and advanced pathologic stage were strong predictors of mortality (HRs 3.91, 3.86, and 3.62, respectively), while adjuvant radiation therapy was associated with improved survival (HR 0.46, p=0.025). The PSM-specific nomogram demonstrated time-dependent area under the curves of 0.737 (three years), 0.713 (five years), 0.774 (10 years), and 0.932 (20 years).
Conclusions: PSMs are associated with worse unadjusted outcomes, largely driven by their association with high-risk pathologic features, but are not independently prognostic after accounting for tumor biology and disease stage. A PSM-specific nomogram may support individualized postoperative risk stratification and shared decision-making, pending external validation.

INTRODUCTION

In the United States, over 313,000 new prostate cancer (PCa) diagnoses are estimated in 2025,[1] and nearly 140,000 prostatectomies are performed annually.[2] Post-prostatectomy pathological features have important prognostic value, one of which is the status of surgical margins (SM). A positive surgical margin (PSM) indicates the presence of cancerous cells at the edge of the removed tissue, suggesting potential residual disease. Although robotic-assisted procedures generally have lower odds of PSM compared to open surgeries, PSMs still occur in approximately 14-24% of cases in high-volume centers with expert surgeons.[3]

In numerous other types of cancer, PSMs are closely linked to the success of the surgery, the patient's disease-free status, and overall mortality.[4] However, this link is somewhat less clear in prostatectomy. Guidelines and physicians' approaches to PSMs have evolved over time. Historically, adjuvant therapy was commonly recommended for high-risk patients, including those with PSM.[4] However, current guidelines often advocate for observation instead as the first choice,[5–7] while early salvage radiation therapy does not compromise cancer control.[8] This shift aims to balance the benefits of additional treatment against the potential impact on patients' quality of life, as adjuvant therapy can exacerbate urinary symptoms and affect overall well-being.

There is consensus that PSM significantly increases the risk of biochemical recurrence (BCR).[9,10] However, BCR in the context of PSM is regarded as a weak surrogate marker because it primarily indicates the likelihood of residual tissue rather than a predictor of PSA persistence or recurrence , and thus does not fully capture the long-term oncologic implications. Additionally, PSM status when assessed intraoperatively with frozen section influences key intraoperative decisions, such as the extent of nerve-sparing, In the postoperative setting it is often a source of anxiety for both patients and surgeons as the resection is perceived as potentially incomplete.[3] This ambiguity creates a major challenge in clinical decision-making, particularly in counseling patients and determining the need for adjuvant therapy. The prognostic significance of PSMs remains heterogeneous, likely influenced by a variety of pathological and clinical factors, emphasizing the potential value of prognostic tools, such as nomograms, to help quantify recurrence risk and guide treatment decisions.

This study seeks to comprehensively assess the impact of PSM on long-term survival after RARP utilizing a large database of patients compiled over 20 years. Additionally, by dissecting pre- and post-prostatectomy risk factors in patients with PSM, we assembled the first prognostic nomogram for assessing long-term survival in these patients.

METHODS

Study population and data collection

This study was conducted following approval from the institutional review board (protocol number RSRB #9984). De-identified patient data were obtained from our prospectively maintained Cancer Data Registry, which includes all PCa patients who underwent RARP (CPT code 55866) at our tertiary care center. All procedures were performed by a single experienced surgeon (J.V.J.) between July 1, 2003, and June 30, 2023. Additional data were retrieved from electronic medical records (EMR) using EPIC (Epic Systems Corporation, Madison, WI) when necessary. Two database managers are continuously in charge of data monitoring and integrity for this registry through periodic chart reviews and EMR monitoring during office visits. For patients lost to follow-up, survival status was obtained through national death registries and direct family contact, as EMR updates may be delayed. The last update of survival status was performed in December 2024 for the purpose of this study.

The following exclusion criteria were applied: (i) Non-PCa patients, identified by a negative preoperative biopsy; (ii) Patients with no post-operative follow-up after RARP; (iii) Patients with critical missing data, including those with indeterminate, or missing SM pathology reports; (iv) Patients who underwent salvage RARP following radiotherapy or RARP in the presence of distant metastases.

Variable and measurements

Collected data included patient and procedural characteristics: age, body mass index, and American Society of Anesthesiologists physical status score, approach (trans- versus extraperitoneal); preoperative tumor characteristics: PSA, clinical stage, prostate volume (measured via imaging), D'Amico risk classification and biopsy Gleason score (reported as Gleason Grade Group [GGG; 1–5]); surgical specimen pathologic characteristics: GGG, pathological stage, margin status, and nodal status. The follow-up protocol included PSA measurements at 3 months post-surgery, then at 6-month intervals for 4 years, followed by annual assessments. The use of radiotherapy (as adjuvant or salvage) with or without androgen deprivation therapy was recorded. BCR was defined according to American Urological Association criteria as a PSA $\geq$ 0.2 ng/mL, confirmed by a second PSA $\geq$ 0.2 ng/mL, and lastly survival status.

Outcomes and analysis

The primary analysis evaluated the impact of SM status on overall survival (OS) and biochemical recurrence-free survival (BCRFS), comparing patients with PSM to those with negative surgical margins (NSM).

Secondary outcomes focused on identifying potential predictors of OS within the PSM and NSM subgroups, assessed separately. These predictors included baseline clinical characteristics such as PSA and age at surgery, as well as postoperative pathological features

including GGG, pathologic stage (categorized as ≤ pT2, pT3a, or > pT3a), lymph node status, and use of subsequent radiation therapy.

Statistical analysis

Descriptive statistics were reported as medians and interquartile ranges (IQRs) for continuous variables and as frequencies with percentages for categorical variables. Kaplan-Meier survival analyses were conducted to estimate OS and BCRFS, with differences between groups assessed using log-rank tests and Cox proportional hazards models. Landmark survival rates at 5, 10, 15, and 20 years were calculated for the overall cohort and analyzed by margin status (PSM vs. NSM).

Univariable, unadjusted hazard ratios (uHRs) with corresponding 95% confidence intervals (CIs) were calculated for each covariate. Multivariable Cox proportional hazards models were developed to estimate adjusted hazard ratios (aHRs), accounting for age, PSA, GGG, pathologic stage, nodal status, and receipt of subsequent radiation therapy. Additionally, a separate multivariable Cox model was applied exclusively to the PSM vs. NSM subgroups to assess the independent prognostic impact of these variables on long-term oncologic outcomes. Kaplan-Meier survival analysis and Cox proportional hazards modeling were performed using Stata/MP version 16.1 (StataCorp, College Station, TX); while the nomogram was generated using the rms package in RStudio version 4.5.0 (Posit, Boston, MA). A two-sided p-value < 0.05 was considered statistically significant.

Prognostic nomogram development

An analysis was performed to develop a prognostic nomogram for long-term survival among patients with PSM following RARP. A multivariable Cox regression model was constructed incorporating key predictors identified from the prior analyses, including age, PSA, GGG, pathologic stage, lymph node status, and use of adjuvant therapy.

Each variable was assigned a weighted score based on its regression coefficient, and the cumulative total score was used to estimate patient-specific survival probabilities at multiple time points. The nomogram was internally validated using bootstrapping techniques to assess both calibration and discrimination. This tool was intended to assist clinicians in delivering individualized prognostic information and guiding shared decision-making in the postoperative setting.

RESULTS

Patient characteristics

Of 4,137 patients in the registry, 3,969 (96%) met the inclusion criteria. A total of 168 patients were excluded from the analysis due to missing margin status (n = 53), missing follow-up data (n = 39), missing other critical clinical variables (n = 56), or due to undergoing salvage RARP following radiotherapy (n = 8) or RARP after neoadjuvant systemic therapy (n = 12). The median age was 62.0 years (IQR: 57.0–66.8), and the median preoperative PSA was 5.5 ng/mL (IQR: 4.3–7.8). Based on the D'Amico risk classification, 40.3% were classified as low risk, 46.1% as intermediate risk, and 13.6% as high risk. A total of 55.6% of patients underwent a transperitoneal surgical approach, while 44.4% underwent the extraperitoneal approach. Pathological staging revealed ≥ pT3 disease in 32% of patients. Lymph node dissection was performed in 69.5% of the cohort, with node-positive disease (pN+) identified in 3.4% of

patients. PSM were present in 459 patients (11.4%). Detailed clinicopathological characteristics of the PSM and NSM cohorts are presented in Table 1.

Primary analysis: Long-term OS and BCRFS

Patients with PSM had significantly worse OS compared to those with NSM (uHRs = 1.39; 95% CI: 1.02–1.899; p = 0.036), as shown in Figure 1. The estimated 5-, 10-, and 15-year OS rates for the PSM group were 93.3%, 78.0%, and 73.5%, respectively, while the corresponding rates for the NSM group were 95.1%, 85.7%, and 73.6%, as detailed in Table 2. The median OS was not reached in either group. However, in multivariable Cox regression analysis, the prognostic significance of SM diminished (aHR = 1.16; 95% CI: 0.83–1.61; p = 0.377). In contrast, factors such as age, prostatectomy GGG, pT stage, and pN status remained independently associated with survival, as shown in Supplementary Table 1.

BCR was significantly more common in the PSM group during follow-up (uHR = 2.20; 95% CI: 1.62–2.97; p < 0.001, Figure 2). The estimated 5-, 10-, and 15-year BCRFS rates for the PSM cohort were 87.6%, 77.6%, and 66.2%, respectively, compared to 93.9%, 87.9%, and 83.1% in the NSM group. The median BCRFS was not reached in either cohort. On multivariable analysis, PSM status was no longer significantly associated with BCRFS (aHR = 0.86; 95% CI: 0.62–1.17; p = 0.343), as shown in Supplementary Table 2.

Predictors of mortality by margin status

In multivariable analyses, predictors of OS varied by SM status and are illustrated in the forest plot in Figure 3. Among patients with PSM, advanced pathologic stage was the most prominent predictor of mortality. Specifically, pT3a (HR 3.91, 95% CI 1.63–9.42, p = 0.002) and pT3b–pT4 (HR 3.86, 95% CI 1.45–10.24, p = 0.007) were significantly associated with worse OS. Positive lymph nodes also emerged as a strong predictor (HR 3.62, 95% CI 1.49–8.78, p = 0.005). Radiation therapy conferred a survival benefit (HR 0.46, 95% CI 0.23–0.91, p = 0.025).

In contrast, among patients with NSM, PSA ≥ 10 (HR 1.75, 95% CI 1.25–2.43, p = 0.001), GGG 4–5 (HR 2.04, 95% CI 1.30–3.21, p = 0.002), and age ≥ 70 (HR 1.82, 95% CI 1.29–2.55, p = 0.001) were independently associated with increased mortality. A trend was also observed for pathologic stage pT3b–pT4 (HR 1.63, 95% CI 1.00–2.66, p = 0.052). Adjuvant radiation was associated with improved survival (HR 0.52, 95% CI 0.34–0.80, p = 0.003).

The novel nomogram which was generated for long-term OS prognostication in the PSM cohort is illustrated in Figure 4. The model achieved a C-statistic of 0.68 (95% CI: 0.59–0.76). Time-dependent ROC analysis showed AUC values of 0.737 at 3 years, 0.713 at 5 years, 0.774 at 10 years, and 0.932 at 20 years (Supplementary Figure 1). These results reflect moderate discriminative performance of the nomogram across varying follow-up durations.

DISCUSSION

The role of SM in radical prostatectomy outcomes remains complex and frequently debated in PCa management. PSM remains a source of concern for both patients and physicians,[11] often interpreting such report as a failure to fully remove the tumor and a lost opportunity for a cure.[12] While PSMs are clearly associated with a higher risk of BCR, their impact on long-term outcomes remains uncertain, particularly given the typically indolent course of PCa following surgery. With this uncertainty the management of patients with a positive surgical margin is inconsistent and vary widely among practitioners. An extensive review of the literature did not

reveal any tool to assist clinicians in making prognostic assessments when discussing next steps with their patients after RARP with PSM.

Our findings indicate that patients with PSMs had approximately a 40% higher risk of long-term mortality; however, this association was attenuated after adjusting for tumor characteristics and use of adjuvant or salvage radiotherapy. This suggests that the presence of a PSM is not an independent predictor of survival but rather correlate with aggressive pathological features that more directly influence outcomes. This interpretation of our findings is supported by large-scale studies, such as Wright et al., who analyzed over 65,000 patients in the SEER registry and observed a 1.7-fold increased risk of PCa-specific mortality among men with PSMs.[13] Yet, this risk remained significant only in patients with high-grade or extraprostatic disease. Similarly, Chalfin et al. demonstrated a modest negative impact of PSMs on survival in over 4,500 patients but emphasized that Gleason score and pathological stage had far greater prognostic value.[14] Other studies have found no independent link between PSMs and systemic progression or mortality, consistent with our results.[9,15] However, most available data are limited to 7–10 years of follow-up. Given the indolent nature of prostate cancer, our study's ability to utilize 20 years of patient data to assess OS as a primary endpoint over a truly long-term follow-up period represents a unique contribution to the current knowledge base upon which everyday clinical decisions are made when PSM are identified postoperatively.

Several recent studies have attempted to refine the prognostic value of PSMs by analyzing margin length and extent.[16] A systematic review of 16 retrospective studies concluded that PSM length, whether continuous or dichotomized (<3 mm vs. >3 mm), independently predicted BCR-free survival.[17] Pellegrino et al. further showed that only multiple PSMs were associated with PCa-specific mortality in a cohort of 8,141 men.[18] However, Zeidan et al. reinforced the priority of core tumor features over margin status.[12] In their analysis of 1,552 patients undergoing RARP, those with high prostate tumor volume (PTV, 40–100%) were older, had higher grade and stage, and were more likely to have PSMs, BCR, PCa-specific mortality, and overall mortality. Notably, in multivariate models including PTV, multifocal PSMs lost prognostic significance. Kates et al. reported that a lower Gleason score at the positive surgical margin is independently associated with a shorter margin length and a decreased risk of early biochemical recurrence (5.6% in NSM vs. 22% in PSM).[19] The mean follow-up was 22 months (range: 12–48 months). Furthermore, in multivariable Cox models, having a lower-grade margin (< Grade Group 2) was associated with a decreased risk of biochemical recurrence (HR 0.50, 95% CI 0.25–0.97), highlighting the importance of nuanced documentation of PSM characteristics.

We developed what is, to our knowledge, the first prognostic nomogram specifically tailored for patients with PSM. This tool draws directly from our analyses, which demonstrated that long-term mortality in the PSM cohort was not uniformly driven by margin status itself, but rather by underlying aggressive tumor features—including GGG 5, extraprostatic extension (pT3+), and nodal positivity (pN+). These variables, which independently predicted adverse outcomes, formed the foundation of our model. By integrating these clinically significant driving factors, the nomogram offers a personalized, evidence-based framework for risk stratification—helping to contextualize the relatively modest influence of PSMs when considered apart from broader tumor biology. It challenges the traditional perception of PSMs as a direct marker of surgical failure and provides actionable insight to inform postoperative management, patient counseling, and shared decision-making. While a promising and novel tool, the nomogram still

requires external validation and further refinement, potentially incorporating additional surgical and molecular parameters, to enhance its precision and clinical utility.

Limitations

While our study provides valuable insights, it is important to acknowledge its limitations. Our nomogram demonstrated variable discriminative ability for survival in different timepoints, which likely reflects the complexity of interactions among prognostic factors rather than a single variable. Although internal bootstrapping demonstrated acceptable calibration and discrimination, external validation in independent, multi-institutional cohorts will be essential before routine clinical implementation. The nomogram should therefore be viewed as a decision-support tool rather than a definitive risk calculator.. We reported overall survival as the primary endpoint, which is more robust for long-term follow-up, recognizing that it is not cancer-specific and may be influenced by competing causes of death, and supplemented this with surrogate measures such as biochemical failure and need for radiation therapy, adjusted for clinicopathologic features. Moreover, all procedures were performed by a single high-volume surgeon, which enhances internal consistency but may limit generalizability across different surgical techniques and experience levels. Surgeon volume and technical variability may influence margin rates and downstream outcomes Finally, limited detail regarding margin characteristics (e.g., length, focality, and anatomic location) precluded more granular secondary analyses, and limits the interpretability of PSM heterogeneity.

CONCLUSIONS

While positive surgical margins are associated with an increased risk of biochemical recurrence, they are not independently predictive of long-term survival after accounting for adverse pathologic features. Our findings emphasize that tumor biology and disease stage, rather than margin status alone, drive oncologic outcomes following RARP. To support individualized risk stratification, we developed a PSM-specific prognostic nomogram derived from a large, contemporary institutional cohort, which demonstrated moderate-to-high discriminative performance. This data-driven tool may assist postoperative risk assessment and shared decision-making, and warrants external validation before broader clinical implementation.

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FIGURES AND TABLES

Figure 1. Kaplan-Meier curves illustrating long-term overall survival (OS) stratified by surgical margin status following robotic-assisted radical prostatectomy (RARP). Patients with negative margins demonstrated improved OS compared to those with positive margins over extended followup. Differences were assessed using the log-rank test. CI: confidence interval.

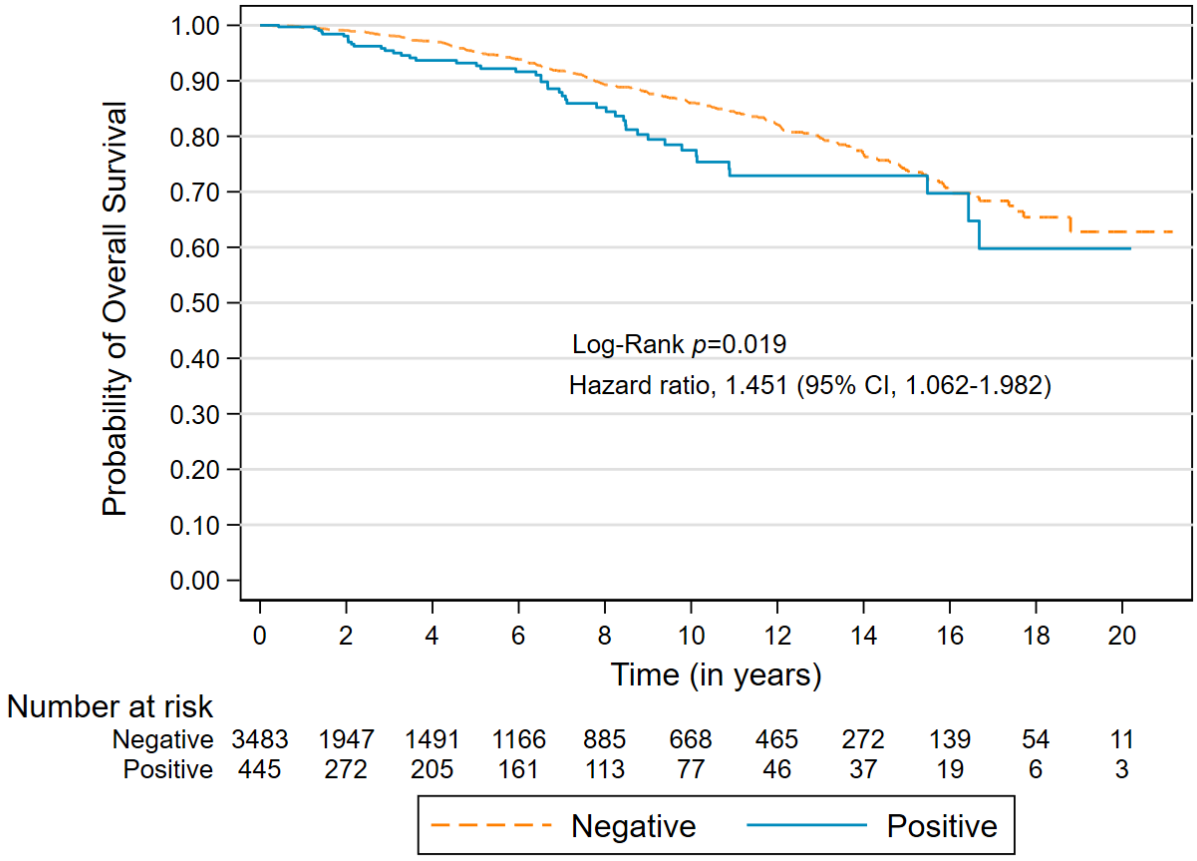

Figure 2. Kaplan-Meier curves showing biochemical recurrence-free survival (BCRFS) stratified by surgical margin status following robotic-assisted radical prostatectomy (RARP). Patients with negative margins had significantly improved BCRFS compared to those with positive margins. Survival differences were evaluated using the log-rank test. CI: confidence interval.

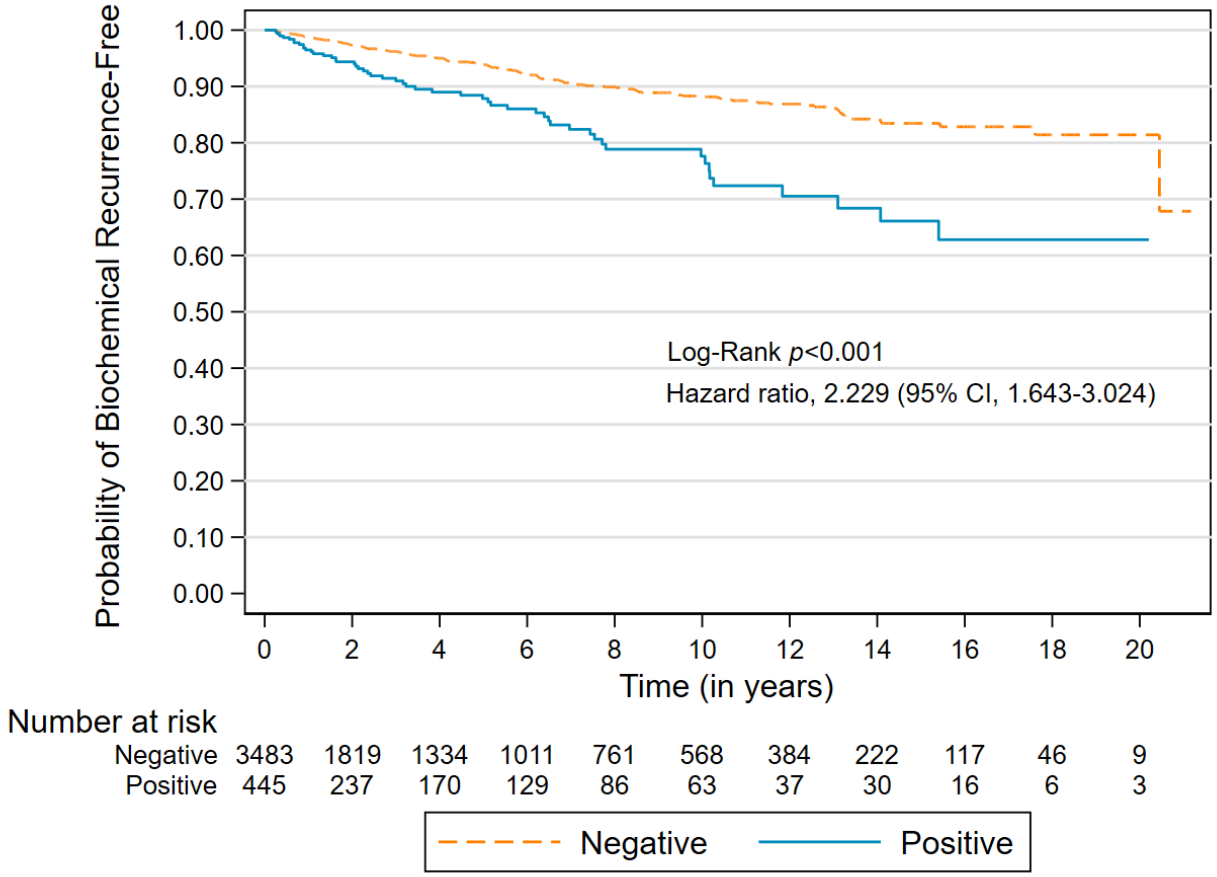

Figure 3. Multivariable Cox proportional hazards regression models assessing predictors of overall mortality among patients with positive and negative surgical margins following robot-assisted radical prostatectomy (RARP). Hazard ratios (HRs) with 95% confidence intervals (CI) are displayed for each covariate. Separate models were constructed for each margin status cohort to evaluate differential prognostic factors. GGG: Gleason grade group; OS: overall survival; PSA: prostate-specific antigen; RT: radiation therapy.

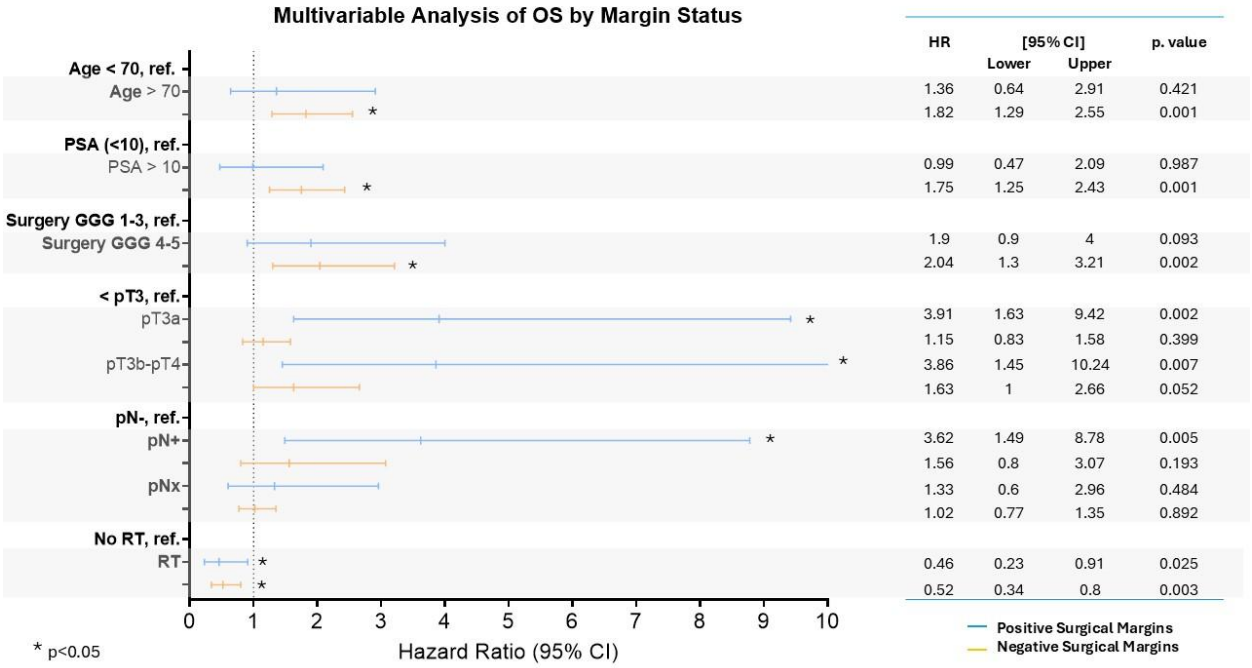

Figure 4. Prognostic nomogram for estimating long-term overall survival (OS) in patients with positive surgical margins (PSMs) following robotic-assisted radical prostatectomy. The model incorporates age, prostate-specific antigen (PSA) level, pathological Gleason grade group, pathologic stage, lymph node status, and receipt of adjuvant therapy. Each variable is assigned a point value, and the total score corresponds to predicted survival probabilities at defined time intervals.

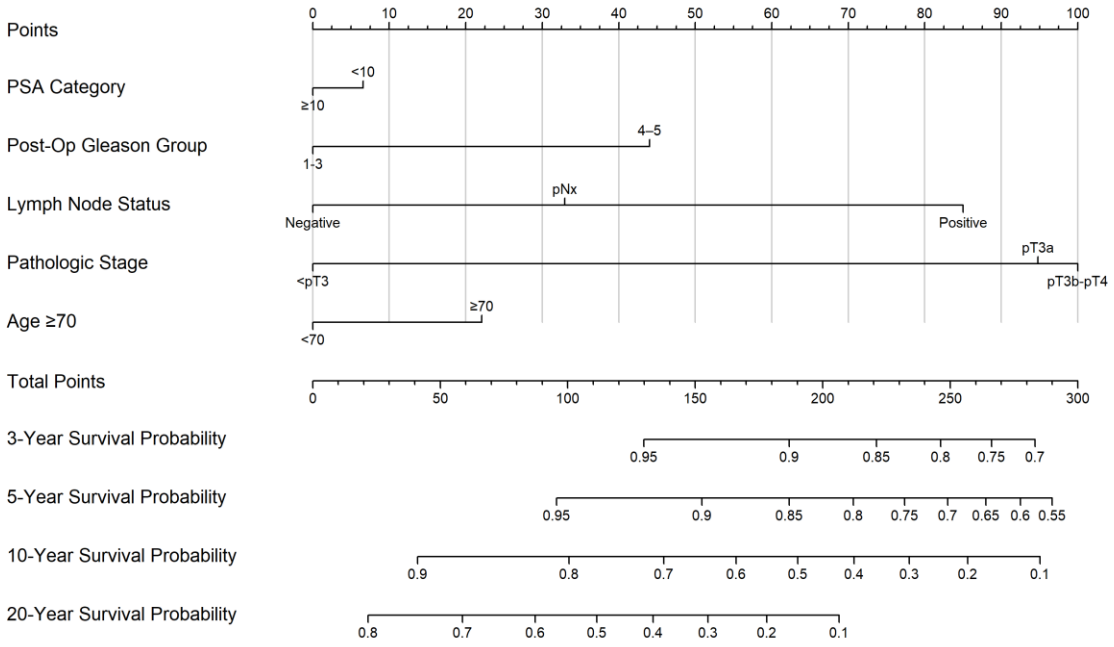

Table 1. Patient clinicopathologic characteristics by surgical margin (SM) status			
	Total	**Negative SM**	**Positive SM**
N	3969 (100.0%)	3519 (88.7%)	450 (11.3%)
Age at surgery, years, median [IQR]	62.0 [57.0, 66.8]	62.0 [57.0, 66.5]	63.0 [58.0, 68.0]
BMI, kg/m^2, median [IQR]	28.3 [25.7, 31.7]	28.3 [25.7, 31.7]	28.3 [25.7, 31.9]
Approach			
Extraperitoneal	1772 (44.6%)	1599 (45.4%)	173 (38.4%)
Transperitoneal	2197 (55.4%)	1920 (54.6%)	277 (61.6%)
PSA, ng/ml, median [IQR]	5.5 [4.3, 7.8]	5.4 [4.2, 7.5]	6.5 [4.9, 9.6]
Biopsy GGG			
1	1847 (46.5%)	1682 (47.8%)	165 (36.7%)
2	1217 (30.7%)	1083 (30.8%)	134 (29.8%)
3	487 (12.3%)	430 (12.2%)	57 (12.7%)
4	303 (7.6%)	241 (6.8%)	62 (13.8%)
5	115 (2.9%)	83 (2.4%)	32 (7.1%)
D'Amico risk			
Low	1600 (40.3%)	1476 (41.9%)	124 (27.6%)
Intermediate	1828 (46.1%)	1619 (46.0%)	209 (46.4%)
High	541 (13.6%)	424 (12.0%)	117 (26.0%)
Pathologic stage			
<pT3	2698 (68.0%)	2540 (72.2%)	158 (35.1%)
pT3a	996 (25.1%)	794 (22.6%)	202 (44.9%)
pT3b-pT4	275 (6.9%)	185 (5.3%)	90 (20.0%)
Prostatectomy GGG			
1	1216 (30.6%)	1149 (32.7%)	67 (14.9%)
2	1694 (42.7%)	1515 (43.1%)	179 (39.8%)
3	704 (17.7%)	595 (16.9%)	109 (24.2%)
4	177 (4.5%)	134 (3.8%)	43 (9.6%)
5	146 (3.7%)	98 (2.8%)	48 (10.7%)
Missing	32 (0.8%)	28 (0.8%)	4 (0.9%)
Pathologic lymph nodes			
pN-	2623 (66.1%)	2320 (65.9%)	303 (67.3%)
pN+	134 (3.4%)	84 (2.4%)	50 (11.1%)
pNx	1,212 (30.5%)	1,115 (31.7%)	97 (21.6%)
Adjuvant/salvage RT			

No radiation	3623 (91.3%)	3271 (93.0%)	352 (78.2%)
Radiation	346 (8.7%)	248 (7.0%)	98 (21.8%)

BMI: body mass index; GGG: Gleason grade group; IQR: interquartile range; pNx: pathologic lymph nodes not assessed; PSA: prostate-specific antigen; RT: radiotherapy; SM: surgical margin.

Table 2. Long-term survival outcomes by surgical margin status

Time (years)	**OS (%)**		**Biochemical failure-free survival (%)**	
	PSM (95% CI)	**NSM (95% CI)**	**PSM (95% CI)**	**NSM (95% CI)**
5	93.3 (89.54–95.75)	95.08 (93.94–96.02)	87.59 (82.80–91.12)	93.87 (92.65–94.90)
10	78.0 (70.62–83.73)	85.73 (83.58–87.61)	77.64 (70.45–83.28)	87.92 (85.95–89.64)
15	73.51 (65.14–80.17)	73.55 (69.88–76.86)	66.20 (55.39–74.97)	83.12 (80.11–85.71)
20	61.05 (44.95–73.75)	62.79 (55.19–69.47)	62.89 (50.55–72.96)	81.12 (76.71–84.78)

CI: confidence interval; NSM: negative surgical margin; OS: overall survival; PSM: positive surgical margin.