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Sentinel Lymph Node Biopsy for Nodal Staging in Node-Negative Penile Cancer: A 10-Year Cohort Study

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Abstract

Purpose

To evaluate the diagnostic performance, morbidity, and implementation factors of sentinel lymph node biopsy (SLNB) for clinically node-negative (cN0) penile cancer.

Patients and Methods

A retrospective study analyzed 71 consecutive patients (131 inguinal procedures) undergoing SLNB for intermediate- or high-risk penile cancer over 10 years at a French tertiary center. Performance was assessed against definitive histopathology and clinical follow-up (mean 31.5 months). Endpoints included sensitivity, false-negative rate (FNR), intraoperative frozen-section accuracy, postoperative morbidity, and success factors. We evaluated whether this technique can be safely implemented outside pioneering institutions.

Results

Sentinel lymph nodes were successfully identified in 89% of procedures, with bilateral identification in 80% of eligible patients. Sensitivity was 94.1% and specificity 100%, with a FNR of 5.9%. Intraoperative frozen-section analysis demonstrated limited sensitivity (64.7%). Complications occurred in 28.2% of patients (all Grade I–II) and were significantly more frequent after completion inguinal lymphadenectomy than after SLNB alone (71.4% vs 10.0%, $p < 0.001$). No inguinal recurrences were observed. Procedural failure was significantly associated with a longer tracer injection-to-procedure interval (OR 1.02 per 10-min increase, $p = 0.039$) and operator experience (40% reduction in failure risk per 10 additional procedures).

Conclusion

SLNB provides high diagnostic accuracy and a major morbidity benefit compared to radical dissection. Our findings demonstrate that while SLNB is influenced by a learning curve, it is highly reproducible outside of pioneering centers provided that procedural and logistical standardization is maintained. This supports the wider implementation of SLNB in tertiary referral centers to optimize oncological staging.

INTRODUCTION

Penile cancer is a rare malignancy [1], with a stable incidence of approximately 500 cases per year in France [2]. In clinically node-negative penile cancer, prognosis largely depends on the detection of occult lymph node metastases, present in approximately 25% of patients classified as intermediate or high risk according to current guidelines [3]. In the absence of early surgical excision, survival decreases from 84% with early treatment to 35% when excision is delayed by three years [4].

Lymph node assessment is necessarily surgical, as imaging-based strategies have not demonstrated sufficient diagnostic accuracy [5–7]. The historical surgical standard, modified inguinal lymphadenectomy [8], provides excellent diagnostic and therapeutic outcomes but is associated with substantial morbidity, with reported complication rates of up to 58%, including 10% severe complications[9–10]. Sentinel lymph node biopsy (SLNB) represents a less invasive alternative, combining lower morbidity with high diagnostic performance. Reported sensitivities range from 80% to 95%, with false-negative rates of 5–20% and complication rates of 6–14% [11–13]. Owing to its favorable morbidity profile, SLNB is now the recommended staging approach in international guidelines [14–15], nonetheless its adoption remains inconsistent.

This inconsistency often stems from the technical challenges and heterogeneous outcomes reported in the literature. High-volume, longitudinal data are essential to define the requirements for a reliable SLNB program. We report a ten-year, single-center experience evaluating the diagnostic performance and morbidity of SLNB in cN0 penile cancer. Beyond oncological outcomes, we specifically aimed to identify how procedural standardization and the learning curve influence procedural success and complication rates.

MATERIALS METHODS

Study design and population

This was a single-center retrospective study including consecutive patients scheduled for SLNB for primary penile cancer between May 2016 and May 2025. Indications for SLNB were based on guideline-defined risk criteria, corresponding to tumors at increased risk of nodal involvement (≥ pT1b and/or ≥G2). Patients were classified as clinically node-negative (cN0) in the absence of palpable nodal disease; selected patients with unilateral nodal involvement underwent contralateral SLNB. Patients without confirmed primary penile malignancy or who ultimately did not undergo surgery were excluded.

Surgical procedure and pathological assessment.

SLNB was performed according to a standardized institutional protocol. Preoperative lymphoscintigraphy was performed on the day of or the day before surgery. Intraoperatively, blue dye was injected at the primary tumor site, and sentinel lymph nodes were identified using a gamma probe and completely excised. Frozen-section analysis was systematically performed.

Completion inguinal lymphadenectomy was performed in cases of sentinel lymph node positivity on frozen section or definitive histopathological examination, failed tracer migration, or intraoperative failure to identify a sentinel lymph node. All lymphadenectomies followed the European Association of Urology–defined template, including superolateral, superomedial, and saphenous regions. Definitive histopathological findings, combined with clinical and imaging follow-up, were used to identify false-negative cases.

Data collection and endpoints

Data were retrospectively collected from electronic medical records. Variables included SLNB identification and retrieval rates, histopathological findings, postoperative complications graded according to the Clavien–Dindo classification, recurrence, and oncologic follow-up. The study was approved by the relevant ethics committees, and data were handled in accordance with applicable regulations.

The primary endpoint was diagnostic performance of SLNB, assessed by sensitivity, specificity, predictive values, and false-negative rate. Secondary endpoints included postoperative morbidity, predictive factors for procedural success and complications, and recurrence-free survival.

Statistical analysis

Medians (IQR) and counts (%) summarized variables. Groups were compared using chi-square, Fisher's, or t-tests. Logistic regression assessed diagnostic performance, success, nodal positivity, and complications. Recurrence-free survival (surgery to recurrence/last follow-up) lacked events, precluding Kaplan–Meier estimation. R (v4.5.2) generated analyses/graphics ($p < 0.05$). No data were missing. Supplementary Tables contain contingency tables.

RESULTS

1. Study population

A total of 76 patients met the inclusion criteria and were scheduled for SLNB. Three patients were subsequently excluded because the procedure was not performed: one due to refusal of surgery, one because of an anesthetic contraindication, and one due to metastatic progression occurring before surgery. Two additional patients were excluded after histopathological examination revealed diagnoses incompatible with primary penile cancer (one urothelial carcinoma recurrence and one melanoma).

Ultimately, 71 patients were included in the analysis, representing 131 procedures (Figure S1). 60 patients were classified as cN0 and underwent bilateral SLNB, whereas 11 patients were classified as cN1 and underwent a unilateral procedure on the contralateral groin.

Median age was 75 years (IQR 66.5–75.5), and median body mass index was 27 kg/m² (IQR 24.5–29.5). Most patients had an ASA score ≤2 (64%). A history of urological cancer was reported in 23% of patients, including 15% with penile recurrence at presentation; one patient (1%) had a prior HPV-related cancer. Tumors were predominantly located on the glans (69%). Squamous cell carcinoma accounted for 85% of cases, and HPV positivity was observed in 38% of tumors (Table S1).

2. Diagnostic performance

Sentinel lymph node identification was successful in 117 of 131 nodal mappings (89%), with bilateral identification achieved in 80% of eligible patients. Unilateral non-detection occurred in 12 cases (9.1%), predominantly on the right side (n = 10) compared with the left side (n = 2). Bilateral non-detection was observed in a single case (0.8%), occurring during the first third of the series (Table S2).

Sentinel lymph node retrieval was successful in 115 of these 117 procedures (98.3%), with no bilateral retrieval failures (Table S3).

Frozen-section analysis demonstrated moderate diagnostic performance. On a per-procedure basis, sensitivity was 64.7%, with six false-negative cases, while specificity remained 100%. Per-patient analysis confirmed these findings, with sensitivity decreasing to 60% due to six false-negative cases (Table S4, S5, S6).

In contrast, based on definitive histopathological examination, one false-negative result was observed among 17 node-positive procedures, corresponding to a false-negative rate of 5.9%. Sensitivity was 94.1% and specificity was 100%, yielding an overall diagnostic accuracy of 99.1%, with positive and negative predictive values of 100% and 99.0%, respectively. Similar results were observed in per-patient analyses, with a sensitivity of 93.3% (Table S7, S8, S9).

3. Follow-up and morbidity

Mean follow-up duration was 31.5 months, with a median follow-up of 25 months (IQR 6–49.5). The maximum follow-up was 106 months. No inguinal nodal recurrence was observed.

Overall, 20 patients (28.2%) experienced postoperative complications, all limited to Clavien–Dindo grade I–II. Complications were significantly more frequent after completion inguinal lymphadenectomy than after SLNB alone (71.4% vs. 10.0%). Lymphedema and lymphocele were more common in the lymphadenectomy group, while infectious complications were uncommon in both groups (Table S10).

4. Predictive factors

4.1. Factors influencing procedural success

Injection-to-procedure interval and migration failure

Longer injection-to-procedure intervals were associated with an increased risk of procedure failure. Procedures with complete success (n=56) had a shorter injection-to-procedure interval of 468 minutes (median 315; IQR 231–458.5) compared with procedures with failure (n=15), with an interval of 646 minutes (median 387; IQR 301.5–1110) (Table S11).

In logistic regression analysis, each 10-minute increase in the interval was associated with a statistically significant increase in the odds of failure (OR = 1.02, 95% CI 1.001–1.029; p = 0.039) (Figure 1).

Procedural experience and failure rate

Logistic regression analysis demonstrated a learning effect, with increasing procedural experience associated with a progressively reduced risk of failure. When modeled in increments of 10 procedures, each additional block of 10 procedures was associated with a 40% reduction in the odds of failure (OR = 0.60, 95% CI 0.41–0.83) (Figure 2).

4.2. Risk factors for sentinel lymph node positivity

Univariate analysis

In univariable logistic regression analysis, primary tumor size, vascular emboli, and perineural invasion were significantly associated with sentinel lymph node positivity. Tumor size, analyzed in 5-mm increments, was associated with an increased risk of nodal involvement, with each additional 5-mm increase in maximum tumor diameter increasing the odds of sentinel lymph node positivity by 32% (OR 1.32, 95% CI 1.07–1.67) (Figure 3A).

The presence of vascular emboli was associated with a markedly increased risk of nodal involvement (OR 12.71, 95% CI 3.83–48.78), as was perineural invasion, which was associated with a more than 15-fold increase in the odds of sentinel lymph node positivity (OR 15.31, 95% CI 4.12–68.11) (Tables S12 and S13).

Multivariable analysis

In multivariable logistic regression analysis including primary tumor size, vascular emboli, and perineural invasion, all three variables remained independently associated with sentinel lymph node positivity. Tumor size retained a significant effect, with each additional 5-mm increase independently increasing the odds of nodal involvement (OR = 1.32, 95% CI 1.01–1.78).

Vascular emboli (OR = 6.53, 95% CI 1.54–30.17) and perineural invasion (OR = 7.20, 95% CI 1.35–43.73) also remained independent predictors of sentinel lymph node positivity (Figure 3B).

4.3. Postoperative complications and associated risk factors

Inguinal lymphadenectomy and number of lymph nodes removed

Completion inguinal lymphadenectomy and postoperative complications were strongly associated. Complications occurred in 71.4% of patients undergoing lymphadenectomy, compared with 10.0% of patients who had only SLNB.

In univariable analysis, lymphadenectomy was associated with a markedly increased risk of postoperative complications (OR = 22.5, 95% CI 6.5–93.7; $p < 0.001$) (Table S14). Increasing extent of lymphadenectomy was also associated with a higher complication risk in logistic regression, with an odds ratio of 5.6 per additional five lymph nodes removed (95% CI 2.4–16.5) (Figure S2).

4.4. Contralateral sentinel lymph node involvement

Lymph node involvement was identified in 18 of the 71 included patients, considering both those undergoing SLNB and those managed with inguinal lymphadenectomy. 11 cases were unilateral (61%) and only 7 were bilateral (39%). The risk of bilateral involvement was significantly increased when one side was involved (OR = 13.25, 95% CI 3–57; p = 0.001). (Tables S15 and S16).

DISCUSSION

With 71 patients and 115 procedures, this is the largest French penile cancer SLNB cohort to date, demonstrating over ten years excellent diagnostic performance and reduced postoperative morbidity.

Our low false-negative rate (5.9%, one patient) compares favorably with contemporary series (5–20%) [16–21]. Historical higher rates likely reflected technical heterogeneity and lack of standardized protocols [22], whereas recent refinement improved accuracy. Sensitivity (94.1%) and negative predictive value (99%) align with recent meta-analyses (pooled sensitivities ~ 87–88%) [13, 23].

Morbidity remains crucial. SLNB substantially reduced complications versus lymphadenectomy (10% vs. 71.4%), all being Clavien–Dindo grade I–II. This major morbidity benefit outweighs the minimal sensitivity loss, a clinically acceptable trade-off provided patients are informed of false-negative risks and undergo adequate postoperative surveillance.

Intraoperative frozen-section analysis showed excellent specificity and positive predictive value, but sensitivity was clearly inferior to definitive histopathology. Thus, negative frozen sections cannot rule out nodal involvement or guide surveillance. They should only confirm positivity to enable immediate completion lymphadenectomy, with definitive histopathology remaining essential for accurate staging, in line with the limited available literature reporting similar findings. [24]

Several factors influenced procedural success and nodal involvement. Longer injection-to-procedure intervals correlated with higher failure rates, indicating that perioperative logistics impact performance, consistent with literature favoring shorter, same-day protocols [25]

Operator experience also emerged as a key determinant of SLNB success, with a progressive reduction in failure rates as experience increased, consistent with the presence of a learning curve described in previous studies [26]. Although no clear threshold could be identified, this finding underscores the importance of cumulative experience over a fixed learning plateau, supporting case centralization.

Regarding oncologic risk, primary tumor size, vascular emboli, and perineural invasion were independently associated with SLNB positivity, supporting risk-adapted selection [27]. Bilateral nodal involvement occurred in only 39% of positive cases (unilateral in 60%). Due to our small sample size, this does not challenge recommendations for bilateral lymphadenectomy in unilateral clinically positive disease. However, contralateral SLNB was feasible without adverse outcomes, warranting larger prospective evaluation given its lower morbidity.

Several limitations should be acknowledged. First, the median follow-up of 31.5 months may appear relatively short. However, available evidence indicates that most clinically relevant nodal recurrences in penile cancer occur within the first 48 months after inguinal lymph node dissection, with a median time to inguinal recurrence of approximately 12 months [28]. In this context, our zero-recurrence rate is unlikely due to insufficient follow-up, though longer surveillance is warranted.

Additional limitations include the retrospective design, the single-center setting, and the involvement of a single operator, which may limit generalizability. Nevertheless, our results indicate that high diagnostic accuracy with SLNB can be achieved outside pioneering centers when strict patient selection, standardized techniques, and sufficient procedural volume are ensured. Taken together, these findings support the referral of patients to expert centers to maintain adequate case volume and to guarantee optimal and reproducible outcomes. This single-center experience may therefore serve as a benchmark for optimal practice in the management of this rare malignancy.

CONCLUSIONS

In this ten-year single-center experience representing the largest French cohort to date, SLNB demonstrated high diagnostic accuracy with a low false-negative rate of 5.9% and substantially lower morbidity than inguinal lymphadenectomy in patients with clinically node-negative penile cancer. These findings confirm that SLNB allows reliable nodal staging while sparing most patients from unnecessary lymphadenectomy. Importantly, our results highlight that procedural standardization, operator experience, and perioperative logistics are key determinants of successful SLNB implementation, reflecting a meaningful learning curve.

Overall, SLNB represents the preferred nodal staging strategy in specialized centers, provided that strict patient selection and standardized techniques are applied. Future multicenter efforts should focus on defining minimal procedural volumes and structured training pathways to ensure reproducible outcomes in routine practice.

Declarations

Participant Consent Statement: In accordance with the hospital's ethics committee guidelines, an information sheet was sent to the patients, providing them with the opportunity to opt out of the study. No patient objected to the use of their data.

FUNDINGS / Conflict of interest

The authors declare that they have no conflict of interest to disclose.

There was no financial support for the research.

ETHICS / Ethics Approval:

The study was conducted in accordance with applicable regulations and was approved by the local hospital Ethics Committee, the Ethics Committee of the French Association of Urology (acting as a Comité de Protection des Personnes, submission no. CERU_2025018), and the National Data Protection Authority (CNIL; approval no. 2239718 v0).

All data were collected and processed in compliance with the General Data Protection Regulation (GDPR).

Author Contribution

MF was responsible for project development, data collection or management, data analysis, and manuscript writing. TM contributed to project development, data management, data analysis, and manuscript editing. PHS, RT, and SV participated in data management and manuscript editing. LC, NA, and IM contributed to manuscript editing. All authors read and approved the final manuscript.

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Data Availability

The datasets generated and analyzed during the current study are not publicly available due to data protection regulations (GDPR) and institutional restrictions but are available from the corresponding author upon reasonable request.

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Figures

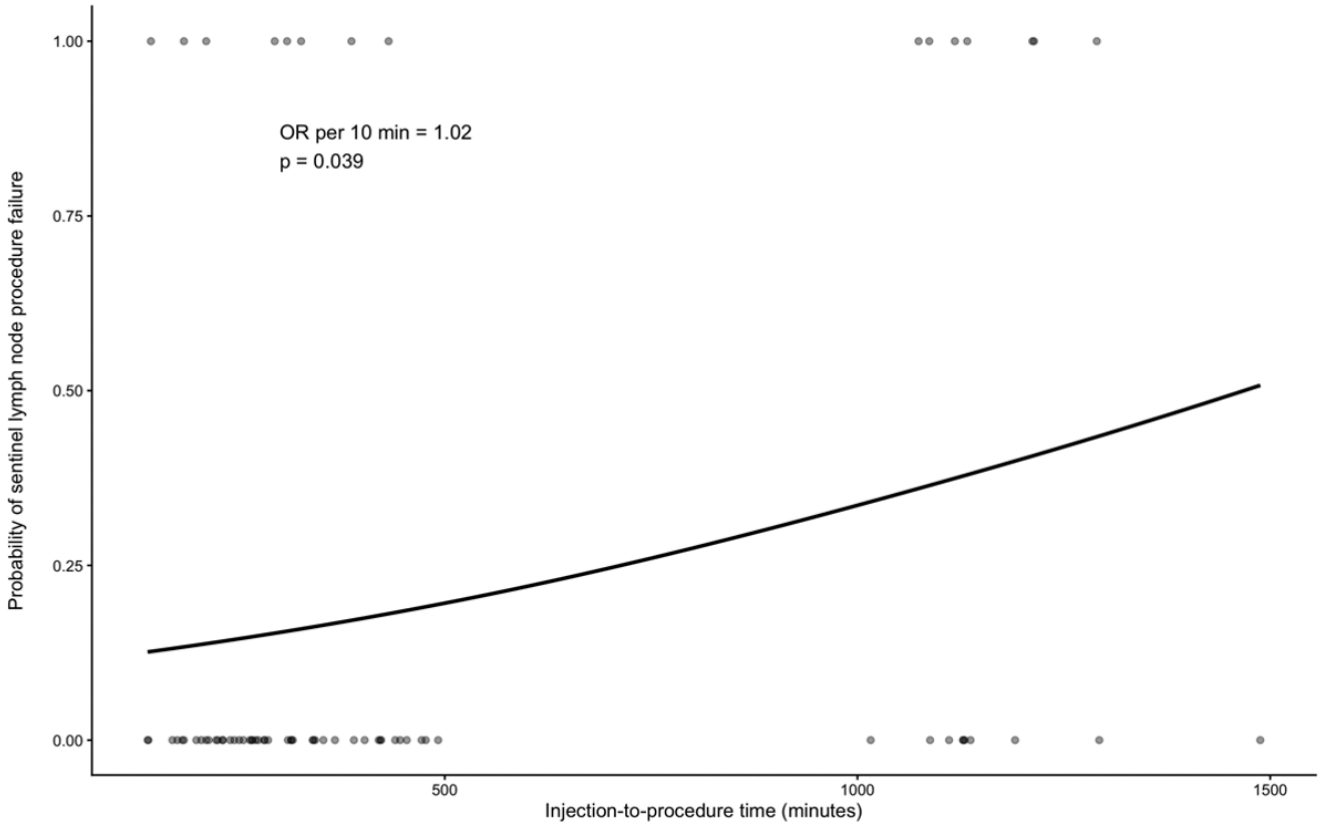

Figure 1

Probability of sentinel lymph node procedure failure according to injection-to-procedure time (logistic regression model).

Sentinel lymph node procedure failure was defined as either scintigraphic migration failure or failure of sentinel lymph node retrieval despite migration.

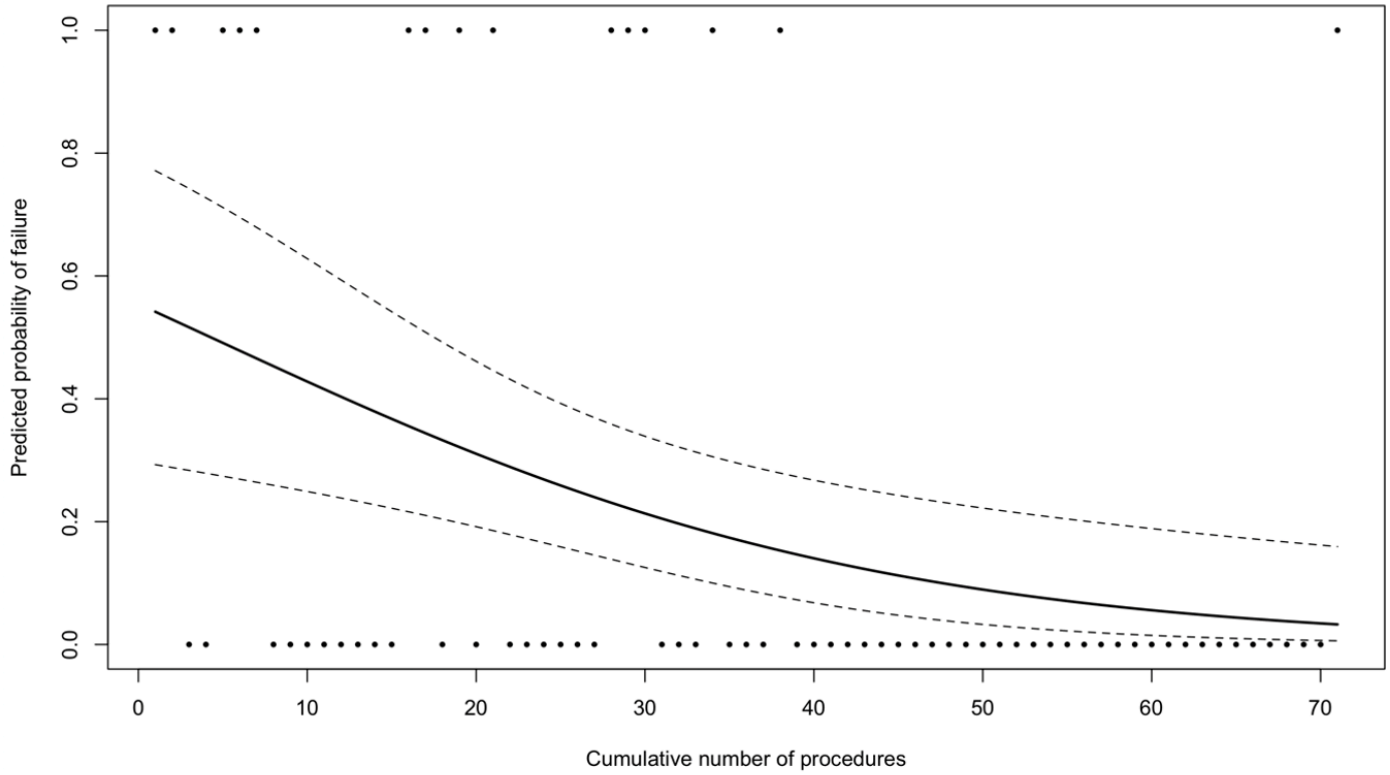

Figure 2

Learning curve of sentinel lymph node biopsy according to cumulative operator experience

Predicted probability of procedure failure according to cumulative operator experience. The solid line represents the estimated probability and dashed lines indicate the 95% confidence interval.

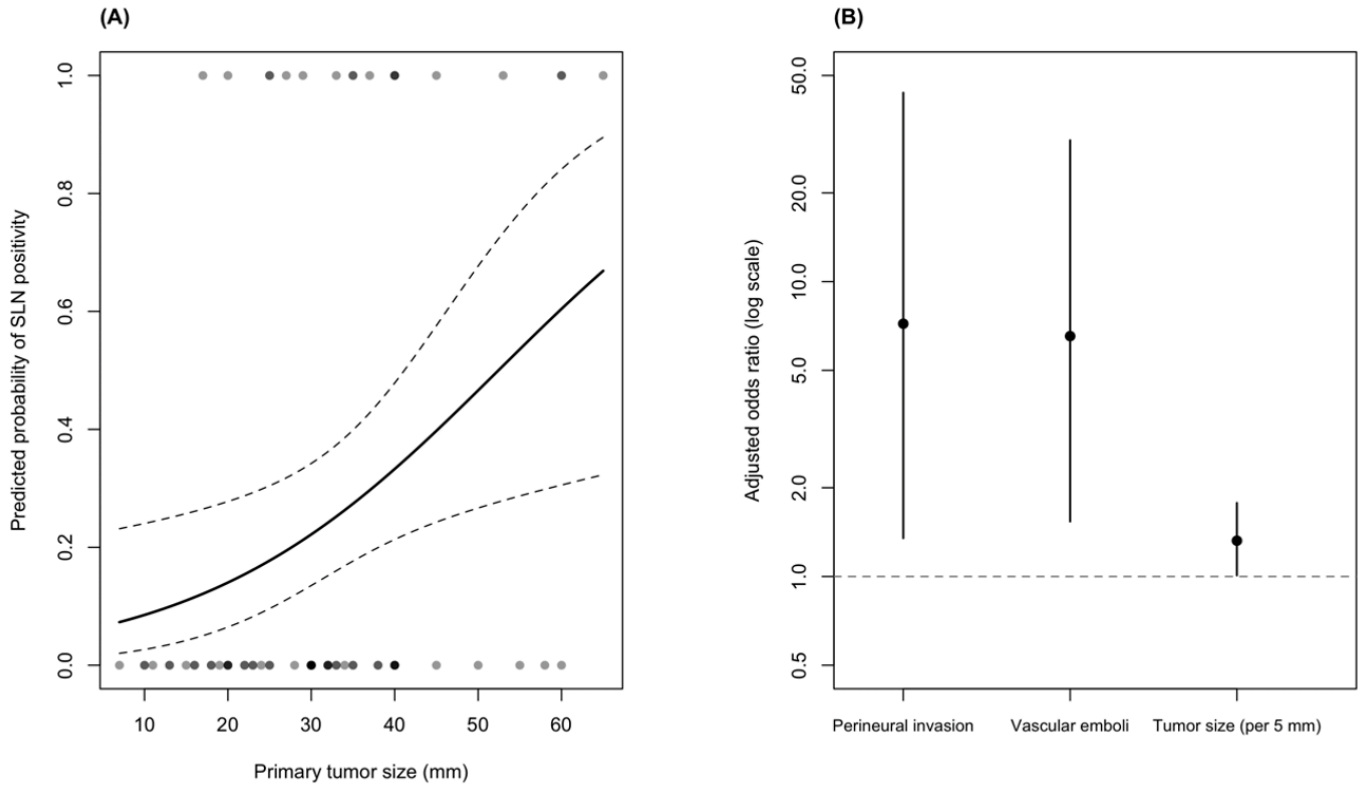

Figure 3

Logistic regression analyses of predictors of sentinel lymph node positivity.

(A) Univariable model showing predicted probability according to primary tumor size. Solid line indicates the estimated probability and dashed lines the 95% confidence interval. Dots represent observed results. (B) Multivariable model displaying adjusted odds ratios with 95% confidence intervals.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- WorldJUrol.SupplementaryData.SLNB.docx