

COMPARISON OF PERCENTAGE OF TOTAL PROSTATE NEEDLE BIOPSY TISSUE WITH CANCER TO PERCENTAGE OF CORES WITH CANCER FOR PREDICTING PSA RECURRENCE AFTER RADICAL PROSTATECTOMY: RESULTS FROM THE SEARCH DATABASE

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ABSTRACT

Objectives. Tumor volume in the prostate needle biopsy is an important prognosticator for patients with prostate cancer. However, the best method to measure tumor volume in the prostate needle biopsy is unknown. We compared the total percentage of biopsy tissue with cancer to the percentage of cores positive for their ability to predict adverse pathologic findings and biochemical failure after radical prostatectomy (RP).

Methods. A retrospective survey of 355 patients from the Shared Equal Access Regional Cancer Hospital database treated with RP between 1990 and 2002 was undertaken. Multivariate analysis was used to compare the percentage of cores and percentage of tissue with cancer to the standard clinical variables of age, prostate-specific antigen (PSA) level, biopsy Gleason score, and clinical stage for their ability to predict positive surgical margins, non-organ-confined disease, seminal vesicle invasion, and time to PSA recurrence after RP.

Results. On multivariate analysis, the percentage of tissue with cancer significantly predicted non-organ-confined disease and seminal vesicle invasion, but the percentage of cores did not significantly predict any of the pathologic features examined. In separate multivariate analysis, only the percentage of tissue with cancer, but not the percentage of cores with cancer, significantly predicted PSA failure. Moreover, when compared in the same multivariate analysis, only the percentage of tissue with cancer (hazard ratio 8.25, 95% confidence interval 3.06 to 22.22, $P < 0.001$) was a significant predictor. The area under the receiver operating curves for predicting PSA failure was significantly greater for the percentage of tissue with cancer (0.697) than for the percentage of cores (0.644, $P = 0.022$). Cutpoints for the percentage of tissue with cancer (less than 20%, 20% to 40%, and greater than 40%) and the percentage of cores (less than 34%, 34% to 50%, greater than 50%) both provided significant preoperative risk stratification for biochemical failure, although the percentage of tissue with cancer cutpoints provided better risk stratification (higher hazard ratios and lower P value). Cutpoints for the percentage of tissue with cancer but not the percentage of cores positive further stratified patients who were at low ($P = 0.041$), intermediate ($P = 0.002$), and high ($P = 0.023$) risk on the basis of the PSA level and biopsy Gleason score.

Conclusions. The percentage of tissue with cancer was better than the percentage of cores at predicting advanced pathologic features and PSA recurrence after RP. Unlike the percentage of cores, the percentage of tissue with cancer cutpoints further stratified low, intermediate, and high-risk patients on the basis of PSA level and biopsy Gleason score. Although the percentage of tissue with cancer is a slightly more cumbersome measurement than the percentage of positive cores, it provided statistically and clinically superior preoperative risk stratification for biochemical failure after RP. UROLOGY 61: 742–747, 2003. © 2003, Elsevier Science Inc.

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Prostate needle biopsy tumor volume, measured by the maximal percentage of a core involved with cancer,¹ the percentage of cores positive,²⁻⁴ or the percentage of biopsy tissue with cancer,⁵⁻⁷ significantly predicts advanced pathologic findings and prostate-specific antigen (PSA) recurrence after radical prostatectomy (RP). The cutpoints for the percentage of cores^{2,4} and the percentage of tissue with cancer⁸ both provide significant risk stratification for biochemical recurrence after RP, although which is the stronger predictor is unclear.^{5,9}

Using the Shared Equal Access Regional Cancer Hospital (SEARCH) database, we compared the percentage of cores with cancer and the percentage of tissue with cancer for their ability to predict advanced pathologic findings and PSA recurrence after RP.

MATERIAL AND METHODS

After obtaining institutional review board approval from each institution, data from consecutive patients undergoing RP at the West Los Angeles (WLAVA), Palo Alto (PAVA), and San Francisco Veterans Affairs (VA) Medical Center and San Diego Naval Medical Center were combined into the SEARCH database. Patients treated with preoperative hormonal or radiotherapy were excluded. Only the WLAVA and PAVA routinely reported data for the percentage of tissue with cancer, with PAVA not beginning to do so until 1996 for an initial cohort of 514 patients.

Patients with missing data regarding the percentage of tissue with cancer ($n = 120$) or the percentage of cores ($n = 23$), or patients with fewer than four cores ($n = 17$) were excluded, resulting in a study population of 355 patients, categorized as white ($n = 173$), black ($n = 134$), Hispanic ($n = 32$), Asian ($n = 15$), or other/unknown ($n = 1$).

Prostate needle biopsy was performed with ultrasound guidance (median 8, mean 8.2, range 4 to 18 cores obtained). The length of each core and the length of cancer in each involved core were recorded. The percentage of tissue with cancer was calculated by dividing the sum of the cancer length by the total core lengths. The percentage of cores positive was calculated by dividing the number of cores positive by the number of cores.

RP specimens were sectioned per each institution's protocol.¹⁰⁻¹³ A single PSA level greater than 0.2 ng/mL or two values at 0.2 ng/mL defined PSA recurrence. One patient had no follow-up data; this patient's data were only used for evaluating predictors of advanced pathologic features.

STATISTICAL ANALYSIS

Age, Gleason score, PSA level, and clinical stage (T1 versus T2 versus T3) were evaluated as continuous variables. The percentage of cores and percentage of tissue with cancer were examined as continuous and categorical variables. The percentage of cores was categorized as less than 34%, 34% to 50%, and greater than 50% because among the current patient population, these were the best cutpoints to divide patients into low, intermediate, and high-risk groups.⁴ Because the best cutpoints for the percentage of tissue with cancer among this patient population were unknown, we examined multiple cutpoints. Non-organ-confined disease was defined as pathologic Stage T3 or greater or lymph node involvement. Predictors of adverse pathologic features and the time to biochemical recurrence were determined using logistic regression analysis and Cox proportions hazard analysis, respectively. For multivari-

TABLE I. Preoperative clinical and pathologic characteristics of men undergoing radical prostatectomy

| | |
|----------------------------------|----------------|
| Patients (n) | 355 |
| Mean age \pm SD (yr) | 61.8 \pm 6.6 |
| PSA (ng/mL) | |
| Mean \pm SD | 9.9 \pm 7.2 |
| Median | 7.9 |
| Clinical stage (%) | |
| T1 | 165 (47) |
| T2 | 184 (53) |
| T3 | 1 (0) |
| Biopsy Gleason score (%) | |
| 2-6 | 264 (74) |
| 7 | 64 (18) |
| 8-10 | 27 (8) |
| Mean \pm SD | 5.9 \pm 1.1 |
| Median | 6 |
| Percentage of cores positive | |
| Mean \pm SD | 36 \pm 23 |
| Median | 33 |
| Percentage of tissue with cancer | |
| Mean \pm SD | 14 \pm 16 |
| Median | 8 |
| Pathologic Gleason score (%) | |
| 2-6 | 188 (53) |
| 7 | 142 (40) |
| 8-10 | 25 (7) |
| Mean \pm SD | 6.4 \pm 1.0 |
| Median | 6 |
| Pathologic stage (%) | |
| T2 | 268 (75) |
| T3 | 77 (22) |
| T4 | 10 (3) |
| Positive surgical margins (%) | 129 (36) |
| Capsular perforation (%) | 61 (17) |
| Seminal vesicle invasion (%) | 33 (9) |
| Positive lymph nodes (%) | 6 (2) |

KEY: PSA = prostate-specific antigen.

ate analysis, we used a forward stepwise model, with $P < 0.15$, determining which variables to enter into the model at each step. If the generated model contained variables with $P > 0.1$, the least significant variable was successively deleted until only variables with $P < 0.1$ remained. A comparison of the area under the receiver operating curves (AUC) was also used to compare variables for predicting PSA failure. The log-rank test was used to compare the Kaplan-Meier survival curves. Patients were stratified into low (PSA less than 10 ng/mL and biopsy Gleason score less than 7), intermediate (PSA 10 or greater to 20 ng/mL and biopsy Gleason score of 7 or less), and high (PSA greater than 20 ng/mL or biopsy Gleason score greater than 7) risk groups for biochemical failure using a modification of a prior risk-grouping system.¹⁴ Data were examined separately for each institution, as well as combined. All statistical analyses were performed using STATA, version 7.0 (Stata, College Station, Tex).

RESULTS

Table I demonstrates the clinical and pathologic characteristics of the study population. The per-

TABLE II. Logistic regression analysis of factors predicting adverse pathologic findings after radical prostatectomy

| | Odds Ratio | 95% CI | P Value |
|----------------------------------|------------|--------------|---------|
| Positive surgical margins | | | |
| Univariate analysis | | | |
| Serum PSA | 1.06 | 1.02–1.09 | 0.001 |
| Biopsy Gleason score | 1.12 | 0.92–1.37 | 0.266 |
| Age | 0.99 | 0.96–1.02 | 0.537 |
| Clinical stage | 1.19 | 0.77–1.83 | 0.440 |
| Percentage of tissue with cancer | 4.93 | 1.33–18.29 | 0.017 |
| Percentage of cores positive | 2.67 | 1.07–6.66 | 0.035 |
| Multivariate analysis | | | |
| Serum PSA | 1.05 | 1.01–1.08 | 0.006 |
| Percentage of tissue with cancer | 3.93 | 0.94–16.44 | 0.061 |
| Non-organ-confined disease | | | |
| Univariate analysis | | | |
| Serum PSA | 1.06 | 1.02–1.09 | 0.001 |
| Biopsy Gleason score | 1.67 | 1.33–2.11 | <0.001 |
| Age | 1.00 | 0.96–1.03 | 0.838 |
| Clinical stage | 1.32 | 0.82–2.14 | 0.253 |
| Percentage of tissue with cancer | 6.52 | 1.68–25.37 | 0.007 |
| Percentage of cores positive | 2.29 | 0.85–6.17 | 0.103 |
| Multivariate analysis | | | |
| Biopsy Gleason score | 1.56 | 1.23–1.98 | <0.001 |
| Serum PSA | 1.04 | 1.00–1.07 | 0.030 |
| Percentage of tissue with cancer | 4.90 | 1.08–22.16 | 0.039 |
| Seminal vesicle invasion | | | |
| Univariate analysis | | | |
| Serum PSA | 1.07 | 1.03–1.12 | <0.001 |
| Biopsy Gleason score | 1.97 | 1.40–2.78 | <0.001 |
| Age | 1.02 | 0.96–1.08 | 0.476 |
| Clinical stage | 2.46 | 1.14–5.32 | 0.022 |
| Percentage of tissue with cancer | 66.05 | 12.35–353.15 | <0.001 |
| Percentage of cores positive | 20.18 | 5.02–81.07 | <0.001 |
| Multivariate analysis | | | |
| Percentage of tissue with cancer | 59.25 | 8.92–393.74 | <0.001 |
| Biopsy Gleason score | 1.81 | 1.25–2.61 | 0.002 |
| Serum PSA | 1.05 | 1.00–1.09 | 0.045 |

KEY: CI = confidence interval; PSA = prostate-specific antigen.

centage of cores positive and the percentage of tissue with cancer correlated significantly (Spearman $r = 0.778$, $P < 0.001$).

Only PSA independently predicted all three pathologic features examined (Table II). Biopsy Gleason score and the percentage of tissue with cancer independently predicted non-organ-confined disease and seminal vesicle invasion. Although the percentage of cores positive significantly predicted positive surgical margins and seminal vesicle invasion in univariate analysis, in multivariate analysis, it did not significantly predict any of the pathologic features examined.

With a median 34-month follow-up (mean 38), 89 patients (25%) developed biochemical recurrence. The AUC for predicting PSA failure was significantly greater for the percentage of tissue with cancer (0.697) than for the percentage of cores

(0.644, $P = 0.022$). We examined three separate multivariate models for predicting PSA failure: first using the percentage of tissue with cancer, second using the percentage of cores, and third comparing the two (Table III). Biopsy Gleason score and PSA independently predicted biochemical recurrence in all three models. In the first model, the percentage of tissue with cancer was the strongest predictor of biochemical recurrence ($P < 0.001$). In the second, a trend was noted for the percentage of cores to be associated with PSA failure ($P = 0.057$). In the third model, the percentage of tissue ($P < 0.001$), but not the percentage of cores positive, significantly predicted PSA failure.

The percentage of tissue with cancer cutpoints of less than 20%, 20% to 40%, and greater than 40% provided the greatest overall risk stratification while maintaining significant risk stratification

TABLE III. Cox proportional hazards analysis of factors predicting time to biochemical recurrence after radical prostatectomy

| | Hazards Ratio | 95% CI | P Value |
|--|---------------|------------|---------|
| Univariate analysis | | | |
| Serum PSA | 1.04 | 1.02–1.06 | <0.001 |
| Biopsy Gleason score | 1.45 | 1.20–1.75 | <0.001 |
| Age | 1.01 | 0.98–1.05 | 0.412 |
| Clinical stage | 1.20 | 0.78–1.83 | 0.405 |
| Percentage of tissue with cancer | 9.34 | 3.64–23.96 | <0.001 |
| Percentage of cores positive | 2.59 | 1.12–5.96 | 0.025 |
| First multivariate model using percentage of tissue with cancer | | | |
| Percentage of tissue with cancer | 8.25 | 3.06–22.22 | <0.001 |
| Biopsy Gleason score | 1.34 | 1.11–1.62 | 0.003 |
| Serum PSA | 1.03 | 1.01–1.05 | 0.003 |
| Second multivariate model using percentage of cores positive | | | |
| Biopsy Gleason score | 1.33 | 1.10–1.61 | 0.003 |
| Serum PSA | 1.03 | 1.01–1.05 | 0.007 |
| Percentage of cores positive | 2.27 | 0.98–5.27 | 0.057 |
| Third multivariate model using percentage of tissue with cancer and percentage of cores positive | | | |
| Percentage of tissue with cancer | 8.25 | 3.06–22.22 | <0.001 |
| Biopsy Gleason score | 1.34 | 1.11–1.62 | 0.003 |
| Serum PSA | 1.03 | 1.01–1.05 | 0.003 |

Abbreviations as in Table II.

among the low, intermediate, and high-risk groups. Although cutpoints for both the percentage of cores (hazard ratio 1.31, 95% confidence interval 1.03 to 1.66, $P = 0.028$, Fig. 1) and the percentage of tissue with cancer (hazard ratio 1.91, 95% confidence interval 1.44 to 2.52, $P < 0.001$, Fig. 2) provided significant risk stratification for PSA recurrence, the percentage of tissue with cancer cutpoints were stronger predictors (higher hazard ratio and lower P value). The percentage of tissue with cancer cutpoints further stratified patients who were low ($P = 0.041$), intermediate ($P = 0.002$), and high ($P = 0.023$) risk for PSA failure on the basis of PSA and biopsy Gleason score. The percentage of cores positive cutpoints could not further stratify patients who were low ($P = 0.064$), intermediate ($P = 0.740$), or high ($P = 0.221$) risk.

The cutpoints for the percentage of tissue and the percentage of cores positive were compared for their ability to predict PSA failure separately at each center. The cutpoints for the percentage of tissue with cancer provided significant risk stratification to patients at both the WLAVA ($P = 0.001$) and PAVA ($P < 0.001$). However, when the centers were examined separately, the cutpoints for the percentage of cores positive did not significantly predict PSA failure at either center ($P > 0.15$).

We sought to determine whether using the percentage of tissue with cancer improved the preop-

erative risk assessment relative to using PSA and biopsy Gleason score alone. The multivariate model containing PSA, biopsy Gleason score, and the percentage of tissue with cancer had a significantly higher AUC for predicting PSA failure than the model containing just PSA and biopsy Gleason score (0.722 versus 0.653, $P = 0.020$).

COMMENT

Biopsy tumor volume, as measured by either the percentage of cores or the percentage of tissue with cancer, significantly predicts outcome among men with newly diagnosed prostate cancer.^{1–7,15} Whether a more detailed quantitative measurement such as the percentage of biopsy tissue with cancer improves risk stratification relative to the simpler measurement of the percentage of cores positive is unclear. In the present study, when compared in the same multivariate analysis, the percentage of tissue with cancer, but not the percentage of cores, significantly predicted non-organ-confined disease and seminal vesicle invasion and PSA recurrence after RP. Additionally, the percentage of tissue had a significantly higher AUC for predicting PSA failure than did the percentage of cores. Although cutpoints for both measurements significantly risk-stratified patients, only the percentage of tissue with cancer could further stratify

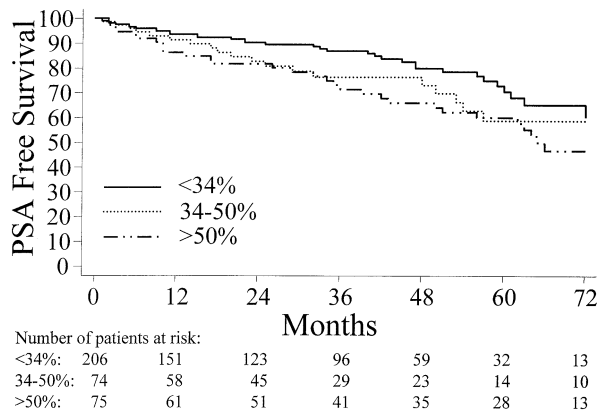


FIGURE 1. Six-year Kaplan-Meier estimates of PSA failure-free survival of patients treated with RP stratified by percentage of cores positive. Pairwise log-rank P values: less than 34% versus 34% to 50%, $P = 0.161$; less than 34% versus greater than 50%, $P = 0.015$; and 34% to 50% versus greater than 50%, $P = 0.462$.

patients who were already stratified into risk groups by PSA and biopsy Gleason score. When each center was examined separately, the percentage of tissue with cancer, but not the percentage of cores, significantly predicted PSA recurrence. Moreover, the percentage of tissue with cancer significantly improved the preoperative prediction of PSA failure relative to using just PSA and biopsy Gleason score. Although the percentage of tissue with cancer is a slightly more cumbersome measurement than the percentage of cores, it provided both statistically and clinically superior risk stratification for all patients in the current study.

In the present study, the percentage of tissue with cancer was determined by linear measurement of the cumulative fragments, which adds approximately 5 minutes of pathologic analysis time per case. Given the amount of time involved in patient counseling and accurate preoperative risk assessment, the added pathologic analysis time is justified by the significant improvement in risk stratification provided by using the percentage of tissue with cancer. Whether a visual inspection of the percentage of tissue with cancer, which can be performed in approximately 1 minute, provides similar prognostication remains to be determined.

Contrary to the current findings, Linson *et al.*⁹ found that among intermediate-risk patients (based on PSA, Gleason score, and clinical stage), the percentage of cores was a stronger predictor of PSA failure after RP than was the percentage of tissue with cancer. Differences between this prior study and the current one may lie in the use of different cutpoints for the percentage of tissue with cancer; we used cutpoints of less than 20%, 20% to 40%, and greater than 40%, and Linson *et al.* dichotomized the percentage of tissue with cancer using a 25% cutpoint. It is unclear how the 25%

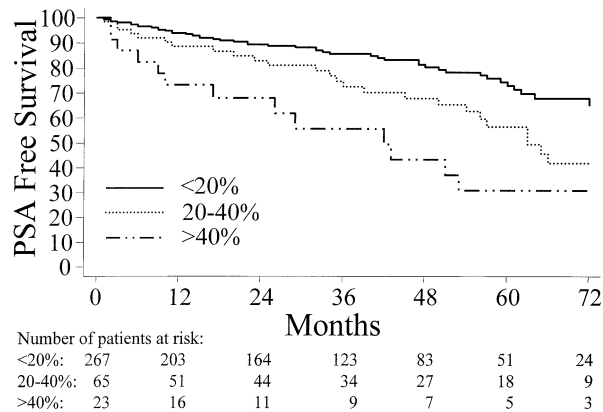


FIGURE 2. Six-year Kaplan-Meier estimates of PSA failure-free survival of patients treated with RP stratified by the percentage of biopsy tissue with cancer. Pairwise P values: less than 20% versus 20% to 40%, $P = 0.042$; less than 20% versus greater than 40%, $P < 0.001$; and 20% to 40% versus greater than 40%, $P = 0.036$.

cutpoint was chosen. It would be interesting to reanalyze the data of Linson *et al.*⁹ using the current cutpoints.

In the present study, the percentage of tissue with cancer cutpoints of less than 20%, 20% to 40%, and greater than 40% provided the greatest preoperative risk stratification. Previously, we identified 55% or more as the best cutpoint between intermediate and high-risk populations.⁸ The current study differs from our prior report by the inclusion of patients from the PAVA, additional patients from the WLAVA, and longer follow-up of our original cohort. The use of this larger data set allowed the identification of new cutpoints, which significantly stratified low-risk patients, who could not be stratified using our previous cutpoints.⁸

In the current study, we excluded patients with fewer than four cores to minimize the impact of lesion-directed biopsies. Thus, even though the number of cores obtained varied, the biopsies were generally performed in a systematic fashion and therefore accurately reflect tumor volume, which explains the strong relationship between the percentage of tissue with cancer and clinical outcome.

The limitations of the current study were its retrospective nature and the short follow-up. Longer follow-up with larger and different patient populations are needed to confirm these findings. Moreover, whether the examination of other biopsy tumor burden measurements would result in greater risk stratification than the percentage of tissue with cancer remains to be determined.^{1,7}

CONCLUSIONS

The percentage of tissue with cancer, but not the percentage of cores positive, independently pre-

dicted PSA failure. Moreover, only the percentage of tissue with cancer further stratified patients who were at low, intermediate, or high risk on the basis of PSA level and Gleason score. The percentage of tissue with cancer significantly improved the preoperative risk assessment relative to using just PSA and biopsy Gleason score alone. Consideration should be given to incorporating the percentage of tissue with cancer into nomograms and models for predicting biochemical failure after RP.

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