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Poorly Differentiated Prostate Cancer Treated With Radical Prostatectomy: Long-Term Outcome and Incidence of Pathological Downgrading

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Abstract

Purpose: Patients with high grade (Gleason score 8 to 10) prostate cancer on biopsy are at high risk for cancer recurrence after local treatment, such as radiation therapy and radical prostatectomy. We examined long-term outcomes in patients with high grade prostate cancer on biopsy who were treated with radical prostatectomy alone. We also investigated the impact on outcomes of changes in the radical prostatectomy Gleason score.

Materials and Methods: Of 5,662 patients who underwent radical prostatectomy during 20 years 238 had a biopsy Gleason score of 8 to 10. We analyzed the rate of biochemical recurrence in this subgroup according to the Gleason grade of cancer in the radical prostatectomy specimen.

Results: Ten-year biochemical recurrence-free probability in the cohort was 39%. However, 45% of patients (95% CI 38 to 51%) with Gleason score 8 to 10 cancer on biopsy had a Gleason score of 7 or less in the radical prostatectomy specimen. These patients had a 10-year biochemical recurrence-free probability of 56% compared to 27% in those with a final Gleason score that remained 8 to 10 ($p = 0.0004$). On multivariate analysis neither prostate specific antigen nor biopsy features, including total number of cores, number of cores with cancer and percent of cancer in the cores, was a significant predictor of downgrading. However, clinical stage and biopsy Gleason score were significant with 58% of cT1c and 51% of biopsy Gleason score 8 cancers downgraded. Almost 65% of cT1c Gleason score 8 cancers were downgraded compared to 11% of cT3 Gleason score 9 cancers.

Conclusions: Patients diagnosed with poorly differentiated prostate cancer (Gleason score 8 to 10) on biopsy do not uniformly have a poor prognosis. Of the patients 39% remain free of cancer recurrence 10 years after radical prostatectomy. Of these cancers 45% have a lower Gleason score in the radical prostatectomy specimen and a correspondingly more favorable long-term outcome. Predictors of downgrading are lower clinical stage (cT1c) and Gleason score 8 in the biopsy specimen.

Keywords

prostate; prostatic neoplasms; prostatectomy; mortality; biopsy

*Financial interest and/or other relationship with Oncovance.

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Study received Institutional Review Board approval.

In men with prostate cancer pathological stage and prognosis can be predicted by clinical cancer stage, PSA and Gleason score (primary plus secondary Gleason grade) in the biopsy specimen.^{1,2} Higher Gleason score (8 to 10) is a poor prognostic factor regardless of treatment.³ While RP is among the most widely used treatments for clinically localized prostate cancer, some investigators have argued that poorly differentiated cancers are cured infrequently with RP and they should not be treated with surgery. Rioux-Leclercq et al reported unfavorable outcomes even for pathologically organ confined Gleason score 8 to 10 cancer and the outcomes could not be predicted using preoperative clinical and pathological data.⁴

However, the Gleason score of cancer in a patient biopsy specimen often underestimates and may sometimes overestimate the score in the RP specimen.^{5,6} Since prognosis is more strongly associated with the Gleason score in the RP specimen than with the Gleason score in the biopsy,⁷ the rate of downgrading, that is a lower grade in the RP specimen than in the biopsy specimen, could affect prognosis and recommendations for treatment, especially for poorly differentiated cancer. We examined a large cohort of men with poorly differentiated prostate cancer (Gleason score 8 to 10) in the diagnostic needle biopsy to determine the probability of long-term cancer control with RP alone. We were especially interested in the chance that biopsy proven, poorly differentiated cancer would be downgraded to Gleason score 7 or less in the final surgical specimen. We assessed the degree to which the risk of recurrence after RP was affected by downgrading and we identified variables predicting the probability of downgrading in an individual.

METHODS

Patient Population

Our cohort was derived from a prospective database of men with clinically localized prostate cancer treated with RP by all surgeons at Memorial Sloan-Kettering Cancer Center and by 1 surgeon (PTS) at Baylor College of Medicine from June 1983. Informed consent was obtained from our Institutional Review Board to use an anonymous data set for the proposed analyses. The database was queried in July 2004. We identified patients who had clinical stage T1c to T3 prostate cancer with Gleason score 8 to 10 on biopsy. The operating surgeon preoperatively assigned clinical stage according to the 1992 UICC TNM system. Prostate cancer diagnosed by transurethral resection of the prostate (cT1a or b) was not included. Patients who received neoadjuvant hormonal therapy, neoadjuvant chemotherapy or prior radiation treatment to the pelvis were excluded from analysis since these treatments can alter pathological features of the cancer. Followup included measurement of serum PSA and digital rectal examination every 3 months for year 1 after surgery, at 6-month intervals for the next 4 years and annually thereafter. Cancer recurrence was defined as serum PSA 0.2 ng/ml or greater and increasing, clinical local or distant disease or secondary therapy begun at least 3 months after RP.

Needle Biopsy Specimens

All prostate biopsies were obtained using transrectal ultra-sound guidance and they reviewed by dedicated uropathologists. Each core containing cancer was assigned a primary and secondary Gleason grade. Patients referred from elsewhere underwent in-house review of prostate biopsies. The reviewed grade was used for this analysis. An overall Gleason score was given to each case by identifying the core with the highest Gleason score. The total number of cores obtained, the number of cores containing cancer and the percent of cancer in the cores were recorded.

RP Specimens

Whole mount prostate sections were prepared as previously described.⁸ The location and extent of invasive cancer were identified and precisely mapped in each section. Overall Gleason score

was defined by the Gleason score of the cancer with the highest score. Pathological parameters included in this study were the presence or absence of ECE, SVI and LN metastasis. We routinely recorded the level of extension as none, invasion into the capsule, focal ECE or established ECE with the latter 2 defining ECE. Organ confined cancer was defined as cancer with no evidence of ECE, SVI or LN involvement. Cancer cells at the inked resection level was considered a positive surgical margin.

Statistical Analysis

Downgrading was defined as Gleason score 7 or less in the RP specimen when cancer in the biopsy specimen was Gleason score 8 to 10. Progression-free probability was determined using Kaplan-Meier methodology. Two patients who received immediate adjuvant radiotherapy were excluded from survival analysis. The effect of downgrading on progression-free survival was assessed using the Cox proportional hazards model. Predictors of downgrading were evaluated by logistic regression. We pre-specified that stage 1 vs 2 vs 3, Gleason grade 8 vs 9 or 10 and PSA would be entered into a multivariate model. Because data on cancer in biopsy cores were not available in all patients, we pre-specified that variables related to cores would only to include if they were significant on univariate analysis. All analyses were done using Stata® 8.2 software.

RESULTS

During the study period 5,662 patients with clinically localized prostate cancer were treated with RP. Excluded from analysis were 153 patients with cancer recurrence after prior radiotherapy to the prostate, 130 who received neoadjuvant chemotherapy and 707 treated with neoadjuvant hormone therapy. Of the remaining 4,672 cases Gleason score in the biopsy specimen reviewed at our institution was 8 to 10 in 246 (5.3%). Three cases diagnosed by transurethral resection of the prostate (cT1a/b) were excluded and in 5 clinical stage information was not available, leaving 238 available for analysis.

Biochemical relapse was documented in 93 patients. Median followup in patients without relapse was 4.1 years (IQR 2.1 to 7.2). Two patients received adjuvant radiotherapy for a positive surgical margin and they were excluded from analysis. Neither had experienced cancer recurrence at last followup. Table 1 shows the distribution of cases by clinical stage (T1c to T3) and by biopsy Gleason score. There was 1 case of biopsy Gleason score 10 and three-quarters of the remainder were biopsy Gleason score 8. There were similar distributions of biopsy Gleason scores in each clinical stage group.

Gleason score in the RP specimen was lower, ie 7 or less, than in the biopsy in 106 patients (45%, 95% CI 38 to 51). The probability of downgrading to Gleason 7 or less increased with lower clinical stage (chi-square test $p = 0.009$) and lower biopsy Gleason score (Fisher's exact test $p = 0.001$). Of the cases 51% with biopsy Gleason 8 and 58% with cT1c were downgraded (table 2). Most downgraded cases had pathological Gleason score 4 + 3. Table 3 shows the probability of a final Gleason score of 7 or less by clinical stage and biopsy Gleason score, which was 64% in patients with cT1c and biopsy Gleason 8, and 11% for cT3 and biopsy Gleason 9 or 10.

Five and 10-year bRFP in the entire cohort was 51% and 39%, respectively (fig. 1). A patient with a Gleason score of 8 to 10 in the RP specimen had 5 and 10-year bRFP of 38% and 27%, respectively (fig. 2). Cases downgraded to a Gleason score of 7 or less had significantly better bRFP (HR 0.46, 95% CI 0.29 to 0.71, $p = 0.0004$). While most cases were downgraded to Gleason 4 + 3, this group still had significantly better biochemical outcomes than the pathological Gleason 8 to 10 group (HR 0.59, 95% CI 0.35 to 0.98, $p = 0.03$, fig 3).

After comparing individual biopsy Gleason score and clinical stage with RP Gleason score we examined other known preoperative variables (table 4). When comparing the downgraded and not downgraded groups, we found no important differences in preoperative PSA, the number of biopsy cores, the number of cores containing cancer or the percent of cancer in the cores. We examined preoperative predictors of downgrading (table 5). Biopsy Gleason score and clinical stage were significant predictors on univariate and multivariate analysis. The number of positive cores ($p = 0.079$) and percent cancer in cores ($p = 0.067$) approached statistical significance on univariate analysis but not after adjusting for stage and Gleason score ($p = 0.6$ and 0.9 , respectively). To allow for the increasing number of core biopsies in recent years we included year of surgery on univariate and multivariate analysis. There was no apparent association between year of surgery and downgrading on univariate analysis or on multivariate analysis adjusting for stage, PSA and biopsy Gleason grade ($p = 0.4$ and 1 , respectively). On exploratory analysis we created an interaction term between date of surgery and Gleason grade, and added this to a model incorporating stage, grade, PSA and date. There was some evidence of a temporal change in grading ($p = 0.035$). Grade 8 cancers were more likely to be downgraded with time, while grade 9 cancers were less likely to be downgraded in recent years.

We examined pathological variables to ascertain if there were any differences in cancer characteristics between the downgraded and final Gleason score 8 to 10 groups (table 6). Cancer volume was significantly lower in the group with a final pathological Gleason score of 7 or less (3.7 vs 7.3 cc, $p = 0.004$). There was no statistically significant difference between the groups with regard to organ confined rates, or ECE, SVI or LN involvement. The rate of positive surgical margins in the downgraded group was 25% compared to 38% in the group not downgraded ($p = 0.02$). This was presumably related to the larger volume of cancer in the latter.

DISCUSSION

Patients diagnosed with poorly differentiated prostate cancer (Gleason score 8 to 10) on biopsy do not have a uniformly poor prognosis since 39% remain free of cancer recurrence 10 years after RP alone. Patients with clinical stage T1c and biopsy Gleason score 8 do best with 64% free of biochemical or clinical recurrence. These results demonstrate that select patients with high risk cancer do well with surgery alone and they should be considered candidates for RP.

In our analysis 45% of patients had cancer downgraded to a Gleason score of 7 or less in the RP specimen. On multivariate analysis clinical stage and Gleason score in the prostate biopsy were significant predictors of downgrading with 58% of cT1c and 51% of biopsy Gleason score 8 cancers downgraded. Our results are consistent with those in earlier studies. Manoharan et al described 79 cases of biopsy Gleason 8 to 10 cancer treated with RP, of which 31% were downgraded to Gleason score 7 or less.⁹ Other studies of the association between biopsy and pathological Gleason scores showed a 39% to 53% rate of downgrading.^{5,10}

As expected, patients in our series with a Gleason score of 7 or less in the RP had a more favorable prognosis than those in whom disease was not downgraded (fig. 2) Even patients with modest downgrading to a final Gleason score of 4 + 3 had significantly better 10-year bRFP than those in whom Gleason score remained 8 to 10 (59% vs 27%). These findings emphasize the difficulty in comparing outcomes by grouped biopsy Gleason score alone among cohorts treated with RP or radiotherapy since clinical stage and RP Gleason score can influence prognosis.

Patients with a final Gleason score of 8 to 10 in our series had a 10-year bRFP of 27%, which is similar to outcomes reported in other surgical series. Lau et al reported 5 and 10-year bRFP rates of 49% and 36%, respectively, for pathological Gleason score 8 to 10, although 45% of patients received adjuvant therapy, which improved biochemical progression but not overall

survival.¹¹ Similar results were reported by Oefelein¹² and Tefilli¹³ et al with 10-year bRFP rates of 28% and 33%, respectively, although the former study began in the pre-PSA era and included Gleason score 7 cancers. However, Mian et al reported 5 and 7-year recurrence-free survival of 71% and 55%, respectively, for pathological Gleason score 8 to 10 cancer,¹⁴ which appears to be better than in our and other published studies. Interestingly the proportion of eligible cases in their total RP series was relatively high at 16% and the rate of lymph node metastasis in their series was only 6% compared to 20% in our group. This difference may be due to patient selection and it highlights the care required in comparisons of surgical series.

Our patient cohort spans 20 years that have seen substantial changes in the diagnosis and treatment of prostate cancer. An aspect is the increasing number of biopsies in patients suspected of having prostate cancer. Increasing the number of cores may improve the correlation between biopsy and pathological Gleason scores.¹⁵ Differences that we noted between the downgraded and unchanged Gleason score groups are unlikely to have been influenced by changing biopsy practices since we found no significant differences between the groups with regard to median PSA, the number of biopsy cores, the number of cores containing cancer or the percent of cancer in the cores. In pathological specimens there was no difference between the groups in pathological stage (organ confined, ECE, SVI or LN involvement) or prostate volume. However, there was a difference in some cancer characteristics. The volume of cancer was significantly higher in the group in which final grade remained at Gleason score 8 to 10, which may explain the significant difference that we noted in the rate of positive surgical margins, which was 25% in downgraded cases and 38% in those not downgraded. While there was a difference in cancer size, there was no difference between the groups in preoperative PSA, perhaps because poorly differentiated cancers tend to produce less PSA per gm of cancer.¹⁶

Many patients diagnosed with high grade prostate cancer on biopsy have a favorable prognosis when treated surgically. Regardless of clinical stage patients with downgraded disease had an advantage in bRFP over those in whom Gleason score remained 8 to 10. If a patient had clinical stage T1c cancer with a biopsy Gleason score of 8, there was a 64% chance that cancer would be downgraded. In stage cT2 cases the difference between those that were and were not downgraded was statistically significant (5-year bRFP 65% vs 43%, $p = 0.03$). However, in the other groups the difference was not significant, although it was present. In clinical stage T1c cases 5-year bRFP was 78% in the downgraded group compared to 57% in the group that was not downgraded ($p = 0.09$). Patients with clinical stage T3 disease that was not downgraded had biochemical recurrence within 5 years but in the 28% with downgrading 5-year bRFP was 42%.

We are currently assessing the potential of magnetic resonance imaging accompanied by MRSI to predict more accurately which cases will be downgraded. MRSI readings are assessed on the ratio of choline and creatine to citrate, which is altered proportionately with increasing Gleason score.¹⁷ The addition of MRSI to magnetic resonance imaging improves the sensitivity of preoperative detection of pathological Gleason score 8 to 10 cancers to 89%¹⁸ and it enhances cancer volume determination.¹⁹ Further study is required to determine whether this radiological approach is useful for predicting final Gleason score or pathological stage in these patients.

CONCLUSIONS

Patients presenting with Gleason score 8 to 10 prostate cancer on biopsy should still be considered for RP because their overall freedom from biochemical recurrence is 39% 10 years after surgery alone. Patients, especially those with clinical stage T1c and Gleason score 8 cancers, should be counseled that there is a distinct probability that the final histological grade

will be lower. Patients in whom cancer is downgraded are at significantly lower risk for biochemical recurrence than those with an RP Gleason score of 8 to 10.

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Abbreviations and Acronyms

bRFP, biochemical recurrence-free probability; ECE, extracapsular extension; LN, lymph node; MRSI, magnetic resonance spectroscopic imaging; PSA, prostate specific antigen; RP, radical prostatectomy; SVI, seminal vesicle invasion.

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Fig. 1.
PSA recurrence-free probability in men with biopsy Gleason score (*GS*) 8 to 10 prostate cancer.

Fig. 2. PSA recurrence-free probability in patients with final Gleason score (GS) 8 to 10 and those downgraded to final Gleason score 7 or less ($p = 0.0004$).

Fig. 3.
PSA recurrence-free probability according to final Gleason score (GS).

Table 1

Clinical stage and biopsy Gleason score

Biopsy Gleason Score	No. Clinical Stage (%)			Total No. (%)
	cT1c	cT2	cT3	
8	58 (76)	104 (78)	19 (68)	181 (76)
9	18 (24)	30 (22)	8 (29)	56 (24)
10	0	0	1 (4)	1 (0.5)
Total	76 (32)	134 (56)	28 (12)	238

Table 2

Final Gleason score by biopsy Gleason and clinical stage

		No. Final Gleason Score (%)			
		6 or Less	3 + 4	4 + 3	8-10
Biopsy Gleason score:	8	181	6 (3)	60 (33)	89 (49)
	9	56	3 (5)	8 (14)	42 (75)
	10	1	0	0	1
Clinical stage:	cT1c	76	12 (16)	28 (37)	32 (42)
	cT2	134	15 (11)	34 (25)	80 (60)
	cT3	28	2 (7)	6 (21)	20 (71)
	Totals	238	29 (12)	68 (29)	132 (55)

Table 3

Biopsy Gleason score 8 to 10 cancer downgrading by initial Gleason score and clinical stage

Clinical Stage	No. Pts	Biopsy Gleason Score/Total No. (%)	
		8	9 or 10
cT1c	76	37/58 (64)	7/18 (39)
cT2	134	48/104 (46)	6/30 (20)
cT3	28	7/19 (37)	1/9 (11)
Totals	238	181	57

Table 4

Final pathological Gleason score by other known preoperative variables

Variable	Pathological Gleason score 7 or Less		Pathological Gleason score 8–10	
	Median (IQR)	No. Pts	Median (IQR)	No. Pts
PSA (ng/ml)	7.6 (5.6–13.2)	104	9.6 (6.5–18.1)	127
Total No. cores	7 (6–10)	82	6 (6–9)	88
No. pos cores	2 (1–3)	82	2 (1–4)	88
% Ca core	30 (20–50)	82	30 (30–50)	88

Table 5 Univariate and multivariate analysis of preoperative variables to predict biopsy Gleason score 8–10 downgrading to pathological Gleason 7 or less

Variable	Univariate			Multivariate		
	P Value	OR	95% CI	P Value	OR	95% CI
Clinical stage: T2 vs. T1	0.015	0.49	0.28–0.87	0.016	0.48	0.26–0.87
T3 vs. T1	0.010	0.29	0.11–0.74	0.037	0.35	0.13–0.94
Biopsy Gleason score 9 or 10 vs. 8	0.001	0.31	0.16–0.62	0.001	0.32	0.16–0.63
PSA	0.2	0.98	0.97–1.01	0.3	0.99	0.97–1.01
Total No. cores	0.6	1.02	0.93–1.11			
No. pos cores	0.079	0.87	0.74–1.02			
% Ca core	0.067	0.26	0.06–1.10			

Table 6

Pathological variables in group downgraded to Gleason score 7 or less and group that remained at Gleason score 8 to 10

Variable	Gleason Score		p Value
	7 or Less	8–10	
No. pts	106	132	
No. organ confined	41 (39)	40 (30)	0.18
No. ECE	57 (54)	84 (64)	0.12
No. SVI	23 (22)	40 (30)	0.14
No. LN metastasis	16 (15)	27 (20)	0.3
No. pos surgical margin	26 (25)	50 (38)	0.03
Prostate vol:			0.12
Mean $\pm$ SD (cc)	36 $\pm$ 12	41 $\pm$ 12	
No. pts	24	30	
Ca vol:			0.004
Mean $\pm$ SD (cc)	3.7 $\pm$ 4.0	7.3 $\pm$ 7.3	
No. pts	44	51	