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The Journal of Urology

Volume 165, Issue 1, Pages 56-61 (January 2001)

COMBINATION CISPLATIN, 5-FLUOROURACIL AND RADIATION THERAPY FOR LOCALLY ADVANCED UNRESECTABLE OR MEDICALLY UNFIT BLADDER CANCER CASES: A SOUTHWEST ONCOLOGY GROUP STUDY

MAHA H.A. HUSSAIN, TRACY R. GLASS , JEFFREY FORMAN, WAEEL SAKR, DAVID C. SMITH , MUHYI AL-SARRAF, JEFFREY JONES, STANLEY P. BALCERZAK, E. DAVID CRAWFORD, H. BARTON GROSSMAN

Accepted 14 July 2000.

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Purpose

Patients with locally advanced bladder cancer or who are not medically fit for surgery are a therapeutic dilemma. Radiotherapy with or without single agent cisplatin has been the major therapeutic modality. A phase II Southwest Oncology Group trial investigated the efficacy and feasibility of 5-fluorouracil, cisplatin and radiation in this patient subset.

Materials and Methods

Eligible patients had muscle invasive bladder cancer (clinical stages T2-T4) with nodal involvement at or below the level of bifurcation of the iliac vessels, were medically or surgically inoperable, or refused cystectomy. Patients underwent pretreatment cystoscopy and detailed tumor mapping, and were treated with 75 mg/m² cisplatin on day 1 and 1 gm/m² daily, 5-fluorouracil on days 1 to 4 and definitive radiotherapy. Chemotherapy was repeated every 28 days, twice during and twice after radiation.

Results

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From October 1993 to April 1998, 60 patients were enrolled in study. Of the 56 eligible patients 34% had unresectable tumors, 21% were not medically fit for surgery and 45% refused cystectomy. Overall, 68% of the patients had clinical T3 tumors or greater and 22% had nodal metastasis. Treatment was completed as planned in 32 of 56 (57%) patients. The most frequent grade 3 or 4 toxicities were neutropenia, stomatitis or mucositis, diarrhea, neuropathy and nausea. There were 53 patients who were evaluable for response, although response was not determined for 18. The overall response rate was 51% (95% confidence interval [CI] 37 to 65) based on intent to treat with a complete response rate of 49% (95% CI 35 to 63). Estimated median survival of the 56 patients was 27 months (95% CI 21 to 40 months) with an overall 5-year survival of 32%. The 5-year survival of the 25 patients who refused surgery was 45%.

Conclusions

Concurrent 5-fluorouracil, cisplatin and radiation therapy is feasible. Despite a promising complete response rate, the overall 5-year survival suggests the need for more effective systemic therapy. The 5-year survival of patients who refused cystectomy suggests that this combined modality may provide another alternative to cystectomy for these patients.

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The Journal of Urology

Volume 169, Issue 1, Pages 164-169 (January 2003)

**Metastatic Carcinoma of the Prostate:
Identifying Prognostic Groups Using
Recursive Partitioning**

TRACY R. GLASS, CATHERINE M. TANGEN, E. DAVID CRAWFORD,
IAN THOMPSON

Accepted 2 August 2002.

ABSTRACT

Purpose

While in patients with metastatic prostate cancer median survival is approximately 30 months when treated with hormonal therapy, there is substantial interpatient variation. To explain better the outcome in patients with advanced disease we developed a set of prognostic groups within a large-scale clinical trial.

Materials and Methods

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Southwest Oncology Group Study 8894 was a randomized prospective clinical trial that compared orchiectomy and flutamide to orchiectomy and placebo. Using the technique of recursive partitioning we analyzed 5-year survival outcomes using a substantial number of patient, treatment and disease related variables to develop a set of prognostic groups with significant differences in survival.

Results

Of 1,286 eligible patients 1,076 had sufficient data for analysis. The patient data set was split to allow prognostic group development in the first half of patients, followed by validation in the second half of patients accrued to the study. After pruning the regression tree 4 factors had a major impact on outcome, namely appendicular versus axial disease, performance status 0 versus 1 to 3, prostate specific antigen less than 65 versus 65 ng./ml. or greater and Gleason score less than 8 versus 8 or greater. Using these criteria 3 prognostic groups were developed, including a good (hazards ratio 1), intermediate (hazards ratio 1.8) and poor (hazards ratio 2.8) group. Five-year survival estimates in the 3 groups were 42%, 21% and 9%, respectively. Using the validation test set similar 5-year survival estimates for the 3 groups of 46%, 25% and 14%, respectively.

Conclusions

These data from a large-scale randomized clinical trial provide a validated set of easily applied prognostic groups. We hope that our results may be validated by other investigators and we would encourage the future reporting of outcomes in patients with advanced prostate cancer using these prognostic groupings. Risk stratification is helpful for designing clinical trials and individual treatment, and it should be incorporated into future reports of outcomes of patients with metastatic disease.

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The Journal of Urology

Volume 177, Issue 5, Pages 1727-1731 (May 2007)

Patterns of Recurrence and Outcomes Following Induction Bacillus Calmette-Guerin for High Risk Ta, T1 Bladder Cancer

Seth P. Lerner^a, Catherine M. Tangen^b, Heidi Sucherew^b, David Wood^c, & David Crawford^d

Received 4 October 2005

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Purpose

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The standard approach to treatment for patients with high risk Ta, Tis, or T1 bladder cancer that persists or recurs after bacillus Calmette-Guerin is radical cystectomy in medically fit patients. Maintenance bacillus Calmette-Guerin has been shown in both SWOG (Southwest Oncology Group) and EORTC (European Organization for Research and Treatment of Cancer) studies to reduce the probability of disease worsening events. As new drugs come on line and experience with maintenance and combination immunotherapy increases, there may be a tendency to delay definitive local therapy and thereby expose patients to a higher risk of progression to invasive and potentially metastatic disease. We explored a large prospective data set from the SWOG 8507 randomized trial of maintenance bacillus Calmette-Guerin to better understand this risk and specifically to assess the impact of timing of recurrence on survival.

Materials and Methods

The database includes 501 evaluable patients who were treated with induction bacillus Calmette-Guerin and then were randomized to maintenance bacillus Calmette-Guerin or observation. Recurrence patterns were defined as early (less than 12 months following randomization) or late (12 or more months after randomization). Patients were identified who underwent cystectomy at any time after induction bacillus Calmette-Guerin. All patients were followed for life for determination of vital status. Outcome measure of overall survival was assessed using Kaplan-Meier analysis and adjustment for covariates was done with proportional hazards models. Survival was defined from date of randomization to death from any cause.

Results

A total of 501 patients were randomized after induction bacillus Calmette-Guerin, of whom 251 had recurrence and 229 died. Of the patients who died 59% had recurrence following randomization. Early recurrence was not associated with a higher risk of death compared to late recurrence ($p = 0.68$). There was no evidence that bacillus Calmette-Guerin affected the relationship of timing of relapse and survival. There was no difference in progression to T2 or greater between early and late recurrence (38 of 117, 32% vs 34 of 134, 25%; $p = 0.21$). Cystectomy was performed infrequently as 56 of 251 patients who had recurrence underwent the operation. Patients who had early recurrence had a slightly higher cystectomy rate than those with late recurrence (32 of 117, 27% vs 24 of 134, 18%; $p = 0.07$). Among 394 patients with no evidence of disease at randomization those who underwent cystectomy for T2 or greater disease had a higher risk of death compared to patients who underwent cystectomy for Tis or T1 disease (HR 1.76; 95% CI 0.77, 4.00; $p = 0.18$).

Conclusions

There was no association of the timing of recurrence after induction bacillus Calmette-Guerin on long-term survival probability. When patients had early recurrence there was a slightly higher probability of cystectomy but not progression to muscle invasive cancer. When cystectomy was performed the 5-year postoperative survival probability was lower than that reported in contemporary series.

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The Journal of Urology

Volume 168, Issue 5, Pages 2016-2019 (November 2002)

Neoadjuvant Therapy Before Radical Prostatectomy For Clinical T3/T4 Carcinoma of the Prostate: 5-Year Followup, Phase II Southwest Oncology Group Study 9109

ISAAC J. POWELL, CATHERINE M. TANGEN, GARY J. MILLER[†], BRUCE A. LOWE, GABRIEL HAAS, PETER R. CARROLL[‡], MICHAEL B. OSSWALD, RALPH deVERE WHITE, IAN M. THOMPSON JR.[‡], E. DAVID CRAWFORD

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ABSTRACT

Purpose

Several investigators have examined the role of hormonal therapy before definitive local therapy for locally advanced prostate cancer to improve outcome. We evaluated the resectability rate and clinical response rate to 16 weeks of total androgen blockage therapy for clinically locally prostate cancer before radical prostatectomy, and progression-free survival in this multi-institutional study.

Materials and Methods

Southwest Oncology Group 9109 was a phase II feasibility study designed to treat patients with clinical stage C prostate cancer (T3, T4, N0 and M0). Cases were classified by stage T3 versus T4 and bulky (greater than 4 cm.) versus nonbulky (or less 4 cm.) disease. The neoadjuvant agents used were goserelin and flutamide before radical prostatectomy.

Results

A total of 62 patients were accrued to the study and 1 patient was ineligible. There were 2 protocol deviations and these patients refused to undergo prostatectomy after hormonal therapy. Four patients went off protocol treatment because they were not considered surgical candidates. The racial distribution was 72% white, 20% black, 7% Hispanic and 2%

Asian. Clinical stage at diagnosis was T3 in 97% and T4 in 3% of cases. Of the patients 39% were diagnosed with bulky disease. Of the 61 eligible patients 55 (90%) underwent a prostatectomy. The 5-year progression-free survival estimate was 70% (24 of 61 cases failed) and the 5-year survival estimate was 90% (11 of 61 deaths). Most of the patients in this trial would have been considered inoperable and referred to radiation oncology.

Conclusions

Neoadjuvant hormonal therapy followed by radical prostatectomy is reasonable and appropriate for clinical stage T3 prostate cancer. A progression-free and overall 5-year survival of 70% and 90%, respectively, compares favorably to Radiation Therapy Oncology Group neoadjuvant trial outcomes for this stage of prostate cancer.

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The Journal of Urology

Volume 159, Issue 4, Pages 1265-1269 (April 1998)

MORPHOLOGICAL ANALYSIS AND CLASSIFICATION OF LATENT PROSTATE CANCER USING A 3-DIMENSIONAL COMPUTER ALGORITHM: ANALYSIS OF TUMOR VOLUME, GRADE, TUMOR DOUBLING TIME AND LIFE EXPECTANCY

DAISAKU HIRANO, PRIYA N. WERAHERA, E. DAVID CRAWFORD, M. SCOTT LUCIA, EDWARD P. DeANTONI, GARY J. MILLER

Accepted 31 October 1997.

Abstract

Purpose

We estimate the potential clinical significance of prostate cancers found at autopsy provided the individual had lived to the projected lifespan based on life expectancy tables.

Materials and Methods

We used 3-dimensional computer models of 59 autopsy prostates that contained clinically undetected carcinoma to determine tumor volumes. Using doubling times of 2, 3, 4 and 6 years, carcinoma volumes at autopsy were extrapolated through patient projected lifespans. The carcinomas were then classified as clinically insignificant or significant

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according to Mayo Clinic criteria.

Results

In 13 patients less than 60 years old, using doubling times of 2, 3, 4 and 6 years, clinically significant tumors were identified in 13 (100%), 10 (77%), 7 (54%) and 7 (54%), respectively. In 46 patients 60 years old or greater significant tumors were identified in 32 (70%), 22 (48%), 21 (46%) and 18 (39%), respectively. A statistical difference ($p < 0.0001$) was found between the mean tumor volume (0.20 ± 0.10 cc) of 43 organ confined carcinomas and the mean tumor volume (3.26 ± 3.58 cc) of 16 extracapsular tumors. No capsule perforation was found in tumors with Gleason sums of 4 or less. However, capsule perforation was present in 8 of 31 tumors (25.8%) with Gleason sums of 5 or 6, and 8 of 11 tumors (72.7%) with Gleason scores of 7 or 8.

Conclusions

Prostatic carcinomas that remain clinically insignificant throughout life are likely to have doubling times greater than 4 years. The subset of carcinomas that emerge as clinically significant are likely to have doubling times less than 3 years. Therefore, an accurate method to measure doubling time at diagnosis could, provide an objective indicator to guide clinical management.

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The Journal of Urology

Volume 161, Issue 1, Pages 350-351 (January 1999)

Treatment With Finasteride Preserves Usefulness of Prostate-Specific Antigen in the Detection of Prostate Cancer: Results of a Randomized, Double-Blind, Placebo-Controlled Clinical Trial

G.L. Andriole, H.A. Guess, J.I. Epstein, H. Wise, D. Kadmon, E.D. Crawford, P. Hudson, C.L. Jackson, N.A. Romas, L. Patterson, T.J. Cook, J. Waldstreicher

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The Journal of Urology

Volume 171, Issue 2, Supplement, Pages S3-S4 (February 2004)

**First International Conference on
Chemoprevention of Prostate Cancer**

[IAN M. THOMPSON](#) , [DEMETRIUS ALBANES](#), [JOSEPH W. BASLER](#), [E. DAVID CRAWFORD](#), [LOUIS J. DENIS](#), [BOB DJAVAN](#), [NEIL FLESHNER](#), [TERESA L. JOHNSON-PAIS](#), [ERIC A. KLEIN](#), [ALAN R. KRISTAL](#), [M. SCOTT LUCIA](#), [HOWARD L. PARNES](#), [GARY A. PIAZZA](#), [ELIZABETH A. PLATZ](#), [BRAD H. POLLOCK](#), [DOUGLAS K. PRICE](#), [JUERGEN K. REICHARDT](#), [CATHERINE M. TANGEN](#), [ANTHONY W. TOI](#), [QHER, MARY CAROLE McMANN](#)

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The Journal of Urology

Volume 157, Issue 3, Pages 805-808 (March 1997)

**Treatment of Advanced Bladder Cancer With
Combined Preoperative Irradiation and Radical
Cystectomy Versus Radical Cystectomy Alone:
A Phase III Intergroup Study**

[Joseph A. Smith Jr.](#), [E. David Crawford](#), [Jorge C. Paradelo](#), [Brent Blumenstein](#), [Barry R. Herschman](#), [H. Barton Grossman](#), [Debra W. Christie](#)

Accepted 13 September 1996.

ABSTRACT

Purpose

Our study was designed to compare the effects of preoperative irradiation and cystectomy to surgery alone in patients with transitional cell carcinoma of the bladder.

Materials and Methods

A total of 140 patients with documented invasive bladder

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cancer or rapidly recurring superficial high grade tumors was randomized to receive 2,000 rad of pelvic irradiation followed by cystectomy within 1 week or surgery alone.

Results

The 5-year survival rate was 53% (95 confidence intervals 41 to 65%) in the surgery only group and 43% (95% confidence intervals 30 to 56%) in the irradiation plus surgery group. The p value for the log rank statistic comparing the survival distributions was 0.23.

Conclusions

Although this trial showed no benefit for preoperative irradiation and cystectomy, the confidence intervals were wide. This finding does not exclude the possibility of a favorable effect of radiation in a subset of patients with high stage tumors. Overall, however, the dominant effect of distant disease as a cause of treatment failure diminishes any potential impact of radiation on results.

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The Journal of Urology

Volume 176, Issue 2, Pages 548-553 (August 2006)

Locally Advanced Prostate Cancer Treated With Concomitant Radiation and 5-Fluorouracil: Southwest Oncology Group Study 9024

Gregory P. Swanson^a, James Faulkner^{bcdf}, Stephen R. Smalley^a, Mark J. Noble^f, Ronald L. Stephens^a, Timothy J. O'Rourke^{abcdf}, Geoffrey R. Weisse^a, Donald P. Quick^c, Ian M. Thompson Jr^a, E. David Crawford^a

Received 8 November 2005

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Purpose

Radiation is considered the standard treatment for locally advanced (T3 and T4) prostate cancer but cure with radiation alone is infrequent. Studies have shown that adding androgen ablation improves the results but there is still much room for improvement. We performed a phase II multi-institutional study to explore the feasibility of concomitant chemoradiotherapy.

Materials and Methods

Eligible patients had prostate cancer with clinical evidence of invasion through the prostatic capsule or into the seminal vesicles without evidence of nodal or distant metastasis. Prior prostatectomy was not allowed and patients could not be candidates for surgical resection due to medical reasons or refusal of surgery. Radiation consisted of 7,020 cGy in 39 fractions. Continuous infusion 5-fluorouracil at a dose of 200 mg/m² daily was started on day 1 and continued 7 days weekly until the last day of radiation.

Results

All 30 eligible patients were evaluated for toxicity. Diarrhea was the most common toxicity with grade 3 and 4 diarrhea in 2 and 1 patients, respectively. The only other grade 4 toxicity was hemorrhagic cystitis in 1 patient. There was 1 incident each of grade 3 stomatitis, congestive heart failure, edema, proctitis and hematuria. No patient with grade 3 or 4 toxicity required treatment delay. Ten patients (33%) achieved a negative biopsy and 13 (43%) achieved prostate specific antigen less than 1.0 ng/ml. Six patients (20%) achieved a complete response, defined as negative biopsy and prostate specific antigen less than 1.0 (95% CI 8 to 39). Patients without any biopsies or without prostate specific antigen followup were assumed to be nonresponders.

Conclusions

Toxicity was acceptable. The modest response rate indicates that better chemotherapy that improves local and systemic failure is necessary to improve the results. This study confirms the feasibility of a combined chemoradiotherapy approach.

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The Journal of Urology

Volume 161, Issue 4, Page 1394 (April 1999)

Bilateral Orchiectomy With or Without Flutamide for Metastatic Prostate Cancer

M.A. Eisenberger, B.A. Blumenstein, E.D. Crawford, G. Miller, D.G. McLeod, P.J. Loehrer, G. Wilding, K. Sears, D.J. Culkln, I.M. Thompson Jr., A.J. Bueschen, B.A. Lowe

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The Journal of Urology

Volume 171, Issue 2, Supplement, Pages S5-S9 (February 2004)

Prostate Cancer Chemoprevention: An Overview of United States Trials

ALBAHA BARQAWI, IAN M. THOMPSON, E. DAVID CRAWFORD 

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ABSTRACT

Purpose

We review the current status of clinical trials investigating the use of interventions designed to reduce the risk of prostate cancer.

Materials and Methods

A comprehensive review of the literature was conducted, which included the Ovid database and recent abstract proceedings from national meetings relevant to chemoprevention trials in prostate cancer. All clinical trials sponsored by the National Institutes of Health and National Cancer Institute in the United States were included.

Results

A total of 11 randomized controlled trials were found to be currently recruiting patients in the United States. These randomized controlled trials are designed to investigate the efficacy of a variety of agents ranging from dietary supplements to laboratory manufactured drugs, such as finasteride and cyclooxygenase-2 inhibitors, for the primary chemoprevention of prostate cancer.

Conclusions

Chemoprevention of prostate cancer is currently being tested in a wide range of clinical trials. These studies have the potential to fundamentally alter the current approach to prostate cancer management.

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The Journal of Urology

Volume 175, Issue 4, Pages 1422-1427 (April 2006)

Baseline Factors as Predictors of Clinical Progression of Benign Prostatic Hyperplasia in Men Treated With Placebo

E. David Crawford^a, Shandra S. Wilson^a, John D. McConnell^b, Kevin M. Slawin^c, Michael C. Lieber^d, Joseph A. Smith^e, Alan G. Meehan^f, Oliver M. Bautista^g, William R. Noble^h, John W. Kusekⁱ, Leroy M. Nyberg^j, Claus G. Roehrborn^{k*}, MTOPS RESEARCH Group

Received 2 June 2005

Purpose

We analyzed data from the placebo arm of the MTOPS trial to determine clinical predictors of BPH progression.

Materials and Methods

A total of 3,047 patients with LUTS were randomized to either placebo, doxazosin (4 to 8 mg), finasteride (5 mg), or a combination of doxazosin and finasteride. Average length of followup was 4.5 years. The primary outcome was time to overall clinical progression of BPH, defined as either a confirmed 4-point or greater increase in AUA SS, acute urinary retention, incontinence, renal insufficiency, or recurrent urinary tract infection. We analyzed BPH progression event data from the 737 men who were randomized to placebo.

Results

The rate of overall clinical progression of BPH events in the placebo group was 4.5 per 100 person-years, for a cumulative incidence (among men who had at least 4 years of followup data) of 17%. The risk of BPH progression was significantly greater in patients on placebo with a baseline TPV of 31 ml or greater vs less than 31 ml ($p < 0.0001$), a baseline PSA of 1.6 ng/dl or greater vs PSA less than 1.6 ng/dl ($p = 0.0009$), a baseline Qmax of less than 10.6 ml per second vs 10.6 ml per second or greater ($p = 0.011$), a baseline PVR of 39 ml or greater vs less than 39 ml ($p = 0.0008$) and baseline age 62 years or older vs younger than 62 years ($p = 0.0002$).

Conclusions

Among men in the placebo arm, baseline TPV, PSA, Qmax, PVR and age were important predictors of the risk of clinical progression of BPH.

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Volume 171, Issue 3, Pages 1071-1076 (March 2004)

Cytoreductive Nephrectomy in Patients With Metastatic Renal Cancer: A Combined AnalysisROBERT C. FLANIGAN*, G. MICKISCH, RICHARD SYLVESTER, CATHY TANGEN†, H. VAN POPPEL, E. DAVID CRAWFORD**ABSTRACT****Purpose**

Metastatic renal cancer is associated with a poor prognosis. Recent advances in immunotherapy for this problem have rekindled interest in cytoreductive nephrectomy. We report a combined analysis of 2 prospective randomized trials that used an identical study protocol.

Materials and Methods

A total of 331 patients were randomized to 2 identical protocols comparing cytoreductive nephrectomy plus interferon α -2b vs interferon α -2b alone in patients with metastatic renal cancer, in whom the primary tumor was present and believed to be resectable. The primary end point for each trial was overall survival with a secondary end point of the response rate. Patients were stratified at pre-randomization by performance status (0 or 1), site of metastases (lung only vs other) and disease measurability. All results were analyzed by intent to treat criteria. Assuming a median survival of 1 year for interferon only, the Southwest Oncology Group trial was designed to detect a 50% improvement in median survival duration and a 15% improvement in response rate with a power of 0.85. The European Organization for the Research and Treatment of Cancer accrued an additional 80 patients in that study.

Results

The combined analysis of these 2 trials yielded a median survival of 13.6 months for nephrectomy plus interferon vs 7.8 months for interferon alone. This difference represents a 31% decrease in the risk of death ($p = 0.002$). There was no evidence of a difference in the size of the treatment effect according to pre-randomization stratification factors.

Conclusions

Cytoreductive nephrectomy appears to improve significantly overall survival in patients with metastatic renal cancer treated with interferon immunotherapy independent of patient

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performance status, the site of metastases and the presence of measurable disease. Although it is highly statistically significant, the overall survival advantage is only 5.8 months for the entire group. These data emphasize the need to determine if this survival advantage can be further improved using more aggressive immunotherapy or other novel agents in the setting of cytoreductive nephrectomy.

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The Journal of Urology

Volume 178, Issue 5, Pages 1946-1951 (November 2007)

Association of Body Mass Index With Response and Survival in Men With Metastatic Prostate Cancer: Southwest Oncology Group Trials 8894 and 9916

R. Bruce Montgomery¹, Bryan Goldman², Catherine M. Tangen³, Maha Hussain⁴, Daniel P. Petrylak⁵, Stephanie Page⁶, Eric A. Klein⁷, E. David Crawford⁸

Received 5 March 2007 published online 14 September 2007.

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Purpose

We evaluated the effect of body mass index on prostate specific antigen response, and progression-free and overall survival in men with androgen dependent or androgen independent metastatic prostate cancer.

Materials and Methods

We examined the prognostic impact of body mass index in patient cohorts from phase III randomized studies coordinated by the Southwest Oncology Group. The first study included 1,006 men treated with androgen deprivation for metastatic prostate cancer. The second study included 671 patients treated with chemotherapy for metastatic, androgen independent prostate cancer.

Results

Among men with androgen dependent disease, higher body mass index was associated with longer overall (p <0.001) and progression-free (p = 0.009) survival, as well as with an increased likelihood of achieving a prostate specific antigen nadir less than 4 ng/ml (p = 0.008). In multivariate analysis adjusting for risk factors, increasing body mass index was positively correlated with overall survival (p <0.01) and overweight but not obese patients (body mass index 27 to 29.9) had a significantly improved outcome compared to

normal weight patients, with hazard ratios for risk of progression and death of 0.82 (95% CI 0.69, 0.98) and 0.75 (95% CI 0.63, 0.89), respectively. Among men with androgen independent prostate cancer, no clear association could be detected between body mass index and progression-free survival, overall survival or prostate specific antigen response.

Conclusions

This study revealed higher body mass index to be associated with better overall and progression-free survival in patients with androgen dependent metastatic prostate cancer. Among men who had androgen independent disease, no significant association was found between body mass index and survival.

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The Journal of Urology

Volume 161, Issue 4, Pages 1394-1395 (April 1999)

Quality of Life in Advanced Prostate Cancer: Results of a Randomized Therapeutic Trial

C.M. Moinpour, M.J. Savage, A. Troxel, L.C. Lovato, M. Eisenberger, R.W. Veith, B. Higgins, R. Skeel, M. Yee, B.A. Blumenstein, E.D. Crawford, F.J. Meyskens Jr.

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The Journal of Urology

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Adjuvant Radiotherapy for Pathological T3N0M0 Prostate Cancer Significantly Reduces Risk of Metastases and Improves Survival: Long-Term Followup of a Randomized Clinical Trial

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Purpose

Extraprostatic disease will be manifest in a third of men after radical prostatectomy. We present the long-term followup of a randomized clinical trial of radiotherapy to reduce the risk of subsequent metastatic disease and death.

Materials and Methods

A total of 431 men with pT3N0M0 prostate cancer were randomized to 60 to 64 Gy adjuvant radiotherapy or observation. The primary study end point was metastasis-free survival.

Results

Of 425 eligible men 211 were randomized to observation and 214 to adjuvant radiation. Of those men under observation 70 ultimately received radiotherapy. Metastasis-free survival was significantly greater with radiotherapy (93 of 214 events on the radiotherapy arm vs 114 of 211 events on observation; HR 0.71; 95% CI 0.54, 0.94; p = 0.016). Survival improved significantly with adjuvant radiation (88 deaths of 214 on the radiotherapy arm vs 110 deaths of 211 on observation; HR 0.72; 95% CI 0.55, 0.96; p = 0.023).

Conclusions

Adjuvant radiotherapy after radical prostatectomy for a man with pT3N0M0 prostate cancer significantly reduces the risk of metastasis and increases survival.

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The Journal of Urology

Volume 171, Issue 4, Pages 1513-1519 (April 2004)

LONG-TERM SURVIVAL PROBABILITY IN MEN WITH CLINICALLY LOCALIZED PROSTATE CANCER: A CASE-CONTROL, PROPENSITY MODELING STUDY STRATIFIED BY RACE, AGE, TREATMENT AND COMORBIDITIES

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ABSTRACT

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Purpose

We used a propensity risk scoring approach to model long-term survival for men with clinically localized prostate cancer. We developed comprehensive lookup tables for estimating survival probability stratified by patient age, race, readily available clinical variables, comorbidities and treatment type.

Materials and Methods

We retrospectively identified a cohort of 1,611 men with clinically localized prostate cancer (patients) and 4,538 age, race and comorbidity matched controls. Based on demographic and clinical variables propensity risk scoring was used to develop smoothed survival prediction models for patients and controls. Based on these models tables were created to provide 10-year overall survival estimates. The tables are stratified by patient age, race, comorbidity, prostate specific antigen, cancer grade, and treatment type when applicable.

Results

Mean patient age was 67.0 years and median baseline prostate specific antigen was 8.5 ng/ml. Of the patients 68% had biopsy cancer grade 2, 39% were black, 29% received conservative treatment, 43% underwent radical prostatectomy and 27% were treated with radiation therapy. Crude and cancer specific 10-year survival rates were 67% and 93%, respectively. Validation C-index values were 0.63 for the cancer specific model and 0.69 for the overall survival model.

Conclusions

These lookup tables provide physicians and patients with realistic estimates of 10-year survival and allow them to compare the impact of cancer vs noncancer factors on patient mortality.

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Predictors of Survival of Advanced Renal Cell Carcinoma: Long-Term Results From Southwest Oncology Group Trial S8949

[Primo N. Lara Jr.](#)^a, [Catherine M. Tangen](#)^b, [Sarah J. Conlon](#)^a, [Robert C. Flanigan](#)^c, [E. David Crawford](#)^d

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Purpose

S8949 demonstrated improved overall survival for debulking nephrectomy in interferon treated patients with advanced renal cell carcinoma. We present an updated analysis of S8949, now with a median followup of 9 years. We explored clinical predictors of overall survival.

Materials and Methods

Univariate and multivariate Cox regression analysis was performed to evaluate the impact of clinical variables potentially influencing survival.

Results

Of 246 patients 241 were eligible and randomized to interferon with or without nephrectomy. Patients randomized to nephrectomy continued to have improved overall survival (HR 0.74, 95% CI 0.57–0.96, $p = 0.022$). Multivariate analysis showed that performance status 1 vs 0 (HR 1.95, $p < 0.0001$), high alkaline phosphatase (HR 1.5, $p = 0.002$) and lung metastasis only (HR 0.73, $p = 0.028$) were overall survival predictors. There was no evidence of an interaction of performance status, measurable disease or lung metastases with nephrectomy (each $p > 0.30$). In a patient subset that survived at least 90 days after randomization early progressive disease within 90 days was prognostic of overall survival in a multivariate model (HR 2.1, $p < 0.0001$), as was performance status (HR 1.7, $p = 0.0006$).

Conclusions

Nephrectomy prolonged long-term overall survival in this updated analysis, supporting its role as standard therapy in patients with advanced renal cell carcinoma. A nephrectomy benefit was seen across all prespecified patient subsets. Early progressive disease and performance status were strong predictors of overall survival. These results support efforts to identify biomarkers of renal cell carcinoma resistance to treatment and early progressive disease to facilitate rational patient selection for systemic therapy.

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Re: Patterns of Recurrence and Outcomes Following Induction Bacillus Calmette-Guerin

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for High Risk Ta, T1 Bladder Cancer: S. P. Lerner, C. M. Tangen, H. Sucharew, D. Wood and E. D. Crawford J Urol 2007; 177: 1727-1731

Donald L. Lamm

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The Journal of Urology

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GnRH Analogues: The State of the Art 2001

GnRH Analogues: The State of the Art 2001

Siam Oottamasathien, M.D., E. David Crawford, M.D.

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The Journal of Urology

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The Prognostic Impact of Seminal Vesicle Involvement Found at Prostatectomy and the Effects of Adjuvant Radiation: Data From Southwest Oncology Group 8794

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Purpose

From the randomized study Southwest Oncology Group 8794 we evaluated the effect of seminal vesicle involvement on outcomes and whether those patients benefited from post-prostatectomy adjuvant radiation therapy.

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Materials and Methods

Southwest Oncology Group study 8794 randomized high risk patients (with seminal vesicle positive disease and/or capsular penetration and/or positive margins) to radiation vs observation after prostatectomy. A total of 431 subjects with pathologically advanced prostate cancer were randomized.

Results

Median followup was 12.2 years. Of the patients 139 had seminal vesicle involvement with or without capsular penetration and/or positive margins. Compared to the 286 patients with seminal vesicle negative disease there was poorer 10-year biochemical failure-free survival (33% for seminal vesicle negative and 22% for seminal vesicle positive, $p = 0.04$), metastasis-free survival (70% and 56%, respectively, $p = 0.005$) and overall survival (10-year overall survival 74% and 61%, respectively, $p = 0.02$) for those with seminal vesicle positive disease. Patients with seminal vesicle positive disease who received adjuvant radiation compared to observation realized an improvement in 10-year biochemical failure-free survival from 12% to 36% ($p = 0.001$), in 10-year overall survival from 51% to 71% ($p = 0.08$) and in metastasis-free survival from 47% to 66% ($p = 0.09$), respectively.

Conclusions

Although seminal vesicle involvement is a negative prognostic factor, long-term control is possible especially if patients are given adjuvant radiation therapy. This therapy appears to be effective in patients with seminal vesicle involvement.

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