## **Supplementary Online Content**

Bosland MC, Kato I, Zeleniuch-Jacquotte A, et al. Effect of soy protein isolate supplementation on biochemical recurrence of prostate cancer after radical prostatectomy: a randomized trial. *JAMA*. doi:10.1001/jama.2013.7842

**eTable.** Estimates for 3-Year Recurrence (Biochemical Failure) Rates by High Risk Characteristic From the Literature and Data From NYU

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**eTable.** Estimates for 3-Year Recurrence (Biochemical Failure) Rates by High Risk Characteristic From the Literature<sup>1</sup> and Data From NYU<sup>2</sup>

Parameter	Failure Rate (range)	Best Estimate (Subjective)	References <sup>a</sup>	NYU Data <sup>b</sup>
Overall failure rate (all cases) <sup>c</sup>	15 - 36%	20% (median)	1-11, 15, 16, 18	8 - 12% <sup>d</sup>
Preoperative PSA ≥ 20 ng/mL	49 - 70%	~ 50%	2, 4, 5, 7, 9-11, 15-18	56% (9/16) <sup>e</sup>
Positive surgical margins	20 - 50%	~ 40% (variable)	1, 2, 6, 10, 12-16	38% (18/48)
Seminal vesicle invasion	40 - 57%	≥ 50%	6, 10, 15, 16	57% (13/23)
Extracapsular extension	16 - 33%	~ 25%	4, 6, 8, 10, 11, 15, 16	35% (23/65)
Gleason sum ≥ 8	40 - 50%	≥ 45%	1, 2, 4-6, 8-18	39% (12/31)
Lymph node metastases	50 - 80%	≥ 60%	2, 6, 10	n/a
No. high risk characteristics				
One or more	n/a	n/a		27% (32/118)
Two or more	n/a	n/a		47% (22/47)
One	n/a	n/a		14% (10/71)
Two	n/a	n/a		41% (12/29)
Three	n/a	n/a		58% (7/12)
Four	n/a	n/a		50% (3/6)

<sup>a</sup> The estimates were derived by review in 1997 and again in 2003 from references 1-18. A PSA cut-off at 0.1-0.2 ng/mL was used to determine recurrence at NYU and in the reviewed literature. The initial estimate in 1997 of the recurrence rate was 40%, which lowered in 2003 to 30% and the sample size adjusted to maintain the same statistical power.

<sup>b</sup> For the period 1997-2001 (n = 690).

<sup>c</sup> This includes both cases with high risk of recurrence and low risk cases.

- <sup>d</sup> 11.6% (53/455) for the period 1997-1999 and 7.7% (18/235) for the period 2000-2001.
- In parentheses is the number of recurrence cases over the number of participants with that characteristic.
  n/a = not available or not applicable.

## References

- 1. Haese A, Huland E, Graefen M, Hammerer P, Noldus J, Huland H. Ultrasensitive detection of prostate specific antigen in the followup of 422 patients after radical prostatectomy. *J Urol.* 1999;161(4):1206-1211.
- 2. Graefen M, Noldus J, Pichlmeier U, et al. Early prostate-specific antigen relapse after radical retropubic prostatectomy: prediction on the basis of preoperative and postoperative tumor characteristics. *Eur Urol.* 1999;36(1):21-30.
- 3. Han M, Partin AW, Piantadosi S, Epstein JI, Walsh PC. Era specific biochemical recurrence-free survival following radical prostatectomy for clinically localized prostate cancer. *J Urol.* 2001;166(2):416-419.
- Han M, Partin AW, Zahurák M, Piantadosi S, Epstein JI, Walsh PC. Biochemical (prostate specific antigen) recurrence probability following radical prostatectomy for clinically localized prostate cancer. J Urol. 2003;169(2):517-523.
- 5. Partin AW, Piantadosi S, Sanda MG, et al. Selection of men at high risk for disease recurrence for experimental adjuvant therapy following radical prostatectomy. *Urol.* 1995;45(5):831-838.
- Roberts WW, Bergstralh EJ, Blute ML, et al. Contemporary identification of patients at high risk of early prostate cancer recurrence after radical retropubic prostatectomy. Urol. 2001;57(6):1033-1037.
- D'Amico AV, Whittington R, Malkowicz SB, Schultz D. A method for determining a prostate-specific antigen cure after radiation therapy for clinically localized prostate cancer. Int J Rad Oncol Biol Phys. 1995;32(2):473-477.
- Ohori M, Goad JR, Wheeler TM, Eastham JA, Thompson TC, Scardino PT. Can radical prostatectomy alter the progression of poorly differentiated prostate cancer? J Urol. 1994;152(5 Pt 2):1843-1849.
- 9. Catalona WJ, Smith DS. Cancer recurrence and survival rates after anatomic radical retropubic prostatectomy for prostate cancer: intermediate-term results. *J Urol.* 1998;160(6 pt 2):2428-2434.
- 10. Kattan MW, Wheeler TM, Scardino PT. Postoperative nomogram for disease recurrence after radical prostatectomy for prostate cancer. *J Clin Oncol.* 1999;17(5):1499-1507.
- 11. Bauer JJ, Connelly RR, Sesterhenn IA, et al. Biostatistical modeling using traditional variables and genetic biomarkers for predicting the risk of prostate carcinoma recurrence after radical prostatectomy. *Cancer.* 1997;79(5):952-962.
- 12. Grossfeld GD, Chang JJ, Broering JM, et al. Does the completeness of prostate sampling predict outcome for patients undergoing radical prostatectomy?: data from the CAPSURE database. *Urology*. 2000;56(3):430-435.
- Cheng L, Darson MF, Bergstralh EJ, Slezak J, Myers RP, Bostwick DG. Correlation of margin status and extraprostatic extension with progression of prostate carcinoma. *Cancer*. 1999;86(9):1775-1782.
- 14. Tefilli MV, Gheiler EL, Tiguert R, et al. Prognostic indicators in patients with seminal vesicle involvement following radical prostatectomy for clinically localized prostate cancer. *J Urol.* 1998;160(3 Pt 1):802-806.
- 15. Sofer M, Savoie M, Kim SS, Civantos F, Soloway MS. Biochemical and pathological predictors of the recurrence of prostatic adenocarcinoma with seminal vesicle invasion. *J Urol.* 2003;169(1):153-156.
- Amling CL, Blute ML, Bergstralh EJ, Seay TM, Slezak J, Zincke H. Long-term hazard of progression after radical prostatectomy for clinically localized prostate cancer: continued risk of biochemical failure after 5 years. J Urol. 2000;164(1):101-105.
- 17. Kupelian PA, Buchsbaum JC, Elshaikh M, Reddy CA, Zippe C, Klein EA. Factors affecting recurrence rates after prostatectomy or radiotherapy in localized prostate carcinoma patients with biopsy Gleason score 8 or above. *Cancer.* 2002;95(11):2302-2307.
- Mian BM, Troncoso P, Okihara K, et al. Outcome of patients with Gleason score 8 or higher prostate cancer following radical prostatectomy alone. J Urol. 2002;167(4):1675-1680.