

PSA Variability Versus Velocity

TO THE EDITOR:

The article "Variability of Repeated Serum Prostate-Specific Antigen (PSA) Measurements Within Less than 90 Days in a Well-Defined Patient Population" by Roehrborn *et al.* (Urology 47: 59–66, 1996) confirms our previous observations that PSA variability between measurements is substantial, and that the variability is similar regardless of the sampling interval.¹ However, in the article, the authors confuse the concepts of variability and velocity. They state in the discussion that "it appears at least equally possible to have an increase of 0.75 ng/mL or more by chance alone when the two measurements are obtained 1 year apart compared with less than 90 days apart. Thus, using the rate of change concept, there is also a great risk of triggering a diagnostic procedure based on a random variation rather than on a true change." The change or variability in PSA is not equivalent to the rate of change in PSA. Variability is only one part of the rate of change concept. Rate of change or PSA velocity is the PSA variability corrected for the elapsed time between measurements. The authors are correct that a given change is as likely when the interval between measurements is 1 year, or less than 90 days. However, if the change is corrected for an elapsed time of 1.5 years or more, less than 5% to 10% of men with benign prostatic hyperplasia will have a rate of change that exceeds 0.75 ng/mL per year.^{1,2}

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2. Carter HB, Pearson JD, Morrell CH, Brant LJ, Gruer PJK, and Guess HA: What is the shortest time interval over which PSA velocity should be measured?(abstract 764). J Urol 153: 419A, 1995.

Reproducibility of Pressure-Flow Variables in Patients with Symptomatic Benign Prostatic Hyperplasia

TO THE EDITOR:

I read with great interest the article by Madsen *et al.* (Urology 46: 816–820, 1995) addressing important questions regarding use of pressure-flow studies in patients with benign prostatic hyperplasia (BPH). Based on a small

sample of the nonrandomized study of 25 patients (17 with suprapubic tube and 8 with urethral catheter) who had repeated testing, the authors concluded that while a single pressure-flow test is sufficient and reproducible for large clinical trials, it is of limited value in the individual patient for BPH diagnosis. This is because of a finding of considerable (within patient) variation of the test.

Pressure-flow studies are performed in patients with BPH to decide if they are obstructed or not. Although the design of the present work is to study reproducibility, it did not answer the question. In fact, all patients were unobstructed according to the authors' data, whether they were initial or repeated. The real question is what to do with these patients who fell in a borderline situation.

Although this study is timely, it unfortunately has a small number of patients in each group that probably had different inclusion/exclusion criteria for medical BPH protocol studies. For example, in the transurethral group, there was only 1 patient who, on repeated study, changed classification from obstructed to borderline. Even in this patient (see Fig. 4), an error of reading pressure of -1 cm H₂O or in reading Q_{max} of $+0.5$ mL/s, would have made him stay borderline. These minute variations in urodynamic numbers are certainly common, and clinical judgment should prevail.

Using the same data of the transurethral group, can we conclude that transurethral urodynamic measurements in BPH are more accurate than suprapubic urodynamics? Certainly, it would be a welcomed conclusion decreasing cost, morbidity, time, and effort. Unfortunately, the small number of patients studied in this group (eight) precludes such a desired conclusion, and a larger study is needed.

The authors did not tell us why they concluded that multiple consecutive tests are more appropriate. Does it mean that the third test on the suprapubic study or the second test on the transurethral study are the only reliable tests, and initial tests should be discarded, or should we base our classification on the average of all repeated tests?

A contributing factor to variable urodynamics could be related to presence or absence of residual urine, as well as the volume at which the test was performed. These data are missing from the article. Another factor possible for different results and repeated testing would be the individual variability in responding to test environment. Patient anxiety, inhibitory reflexes, and lack of complete relaxation of external sphincter would produce artifacts.

The authors performed "sequential" testing for repeated studies. Repeated studies without time to recover could be less reproducible, secondary to decreased resting activity of the contractile component of the detrusor muscle, which makes stretch receptors less sensitive to filling. Other factors, such as hysteresis, metabolic, and nerve changes, can contribute to changes in variability of results.

A time interval has to be allowed before repeated urodynamic studies are performed to have reproducible results. We performed a total of 340 urodynamic studies to address and show the effect of time interval and mild over-

distention of the bladder (+20% of cystometric capacity) on reproducibility of urodynamic parameters (capacity, filling pressure, compliance, and isometric detrusor contraction) in a subhuman primate model.¹ The parameters were reproducible after a 30-minute waiting period. In case of mild overdistention, 45 minutes were required.

The exact waiting interval to repeat a human urodynamic study is not known, but necessary. A 20 to 30-minute waiting period before repeating a crucial study is, in our opinion, worthwhile.

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Transperineal Prostate Needle Biopsy Guided by Transurethral Ultrasound in Patients Without a Rectum

TO THE EDITOR:

We read with interest the article by Seaman *et al.* (*Urology* 47: 353–355, 1996).¹ We agree that using endoluminal ultrasound to facilitate prostate biopsy in patients without rectums is a useful and promising technology. We also use this technique with some minor modifications.²

The use of a flexible cystoscope to place a 5F ultrasound probe within the prostatic fossa is far less invasive than utilizing a 26F resectoscope sheath as described by the authors. We also have found that biopsies can then be done under local anesthesia exclusively without the necessity of intravenous sedation. Using less invasive techniques can modify endoluminal-guided biopsy so that it may also be used in the office setting in the same fashion transrectal ultrasound biopsies are currently performed.

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2. Kirby KA, *et al.*: Intraluminal ultrasound-guided biopsy of the prostate: case report. *J Endourol* 9: 323–324, 1995.

REPLY BY THE AUTHORS:

We would like to thank Dr. Kirby for his comments. We agree that the use of flexible cystoscopy and small-sized ultrasound probes is a significant improvement on the technique replacing the 26F ACMI resectoscope sheath. After submitting our man-

uscript for publication, we had experience with the smaller-sized ultrasound as well as with local anesthesia. Our preliminary experience with this has been very encouraging. We have recently performed two procedures under local anesthesia exclusively. These improvements further advance the concept of utilizing transurethral ultrasound for the imaging of the prostate as well as for guidance of needle biopsies.

On behalf of the authors,

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Diagnosis of Advanced or Noncurable Prostate Cancer Can Be Practically Eliminated by Prostate-Specific Antigen

TO THE EDITOR:

Labrie *et al.*¹ state that the screen-detected prostate cancer rate observed in their study of 12% is “not too different from” the 10% lifetime risk of developing prostate cancer in the absence of screening, suggesting the conclusion that little or no overdiagnosis occurs from screening. However, the comparisons cited may not be very meaningful. The 12% detection rate is based on screening a population with an average age of 55 years at the beginning of screening and with 15 years of follow-up. Using the DEVCAN² software program and SEER incidence data from 1981 to 1983 (years when screening for prostate cancer was relatively low), we computed the probability that a 55-year-old man would develop prostate cancer in the next 15 years, the next 20 years, and in his remaining life expectancy. The answers are 2.9%, 4.9%, and 10.2%, respectively. The first estimate is probably too low to provide a valid comparison with the screen-detected rate because it does not count the clinically significant prostate cancer cases that would be detected early due to the lead time effect of screening. The second estimate allows for an average 5-year lead time for prostate cancer screening. In this case, the 12% detection rate reported by Labrie *et al.* is about 2.5-fold greater than the cumulative incidence of prostate cancer expected in the unscreened population. We conclude that the comparisons offered by Labrie *et al.* do not provide persuasive evidence that overdiagnosis is absent.

The most definitive way for evaluating the potential of overdiagnosis from screening is to compare the cumulative incidence of cancer in a screened and comparable unscreened population (from a controlled trial if possible), with follow-up after the termination of screening.^{3,4} Therefore, it would be of great interest for Labrie *et al.* to report the cumulative incidence of prostate cancer in both the screened group and the control group of their study.

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REPLY BY THE AUTHORS

Our randomized screening study for prostate cancer (the first to be performed) included more than 8000 men at the time of last analysis.¹ It should be mentioned that the 0.8% annual incidence rate leading to a 12% detection rate over a 15-year period ($15 \times 0.8\%$) is not calculated from incidence data obtained only in 55 to 70-year-old men but over the whole 45 to 80-year-old range, thus including the highest incidence rate found in 70 to 80-year-old men. The results recently published¹ are the actual data obtained from these patients, and they do not suffer from any assumption related to any model. It seems somewhat difficult to compare such actual experimental data with the estimate derived from a model having its intrinsic assumptions. It should be added that, with a lead time of 5 years, screening for 15 years starting at the age of 55 years should cover prostate cancers diagnosed in the absence of screening up to 75 years of age, or up to 5 years after last screening.

It should also be mentioned that the estimates of Brown and Feuer are based upon 1981 to 1983 data. Despite this limitation, they come up to the estimate of a 10.2% probability of developing prostate cancer during the remaining lifetime expectancy. This conclusion by Brown and Feuer that a 55-year-old man has 10.2% risk of being diagnosed with prostate cancer during his lifetime expectancy is certainly close to our calculation of 12%.¹ In other words, their modeling supports our conclusion that overdiagnosis did not occur with screening performed as described in our study.¹⁻³

It is clear, however, that the final answer will come from the incidence of prostate cancer found in both the screened and control groups. Such a randomized study started at our Prostate Cancer Research Clinic in November 1988, as well as others more recently started, should be able to provide this much-needed answer.

On behalf of the authors,

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The Scrotal Hitch for Hemostasis and Edema Prevention and Scrotal Surgery

TO THE EDITOR:

The article by Drs. Griffin and Canning (*Urology* 47: 918, 1996) is of extreme interest to me.

Since the original publication by Dr. Mandler, in the *Journal of Urology* in 1966, I have been using this method, both as a resident and a practicing urologist, for almost 30 years.

I have found it an extremely helpful method of controlling hemostasis and edema following scrotal surgery for hydrocelectomy. I do not use it for simple orchiectomy since I have never had a problem with hemostasis or edema following this procedure. I think it is a major advance in minimizing problems usually encountered with hydrocele surgery.

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REPLY BY THE AUTHORS

I appreciate the insightful comments and endorsement of the scrotal hitch from a surgeon with almost 30 years of experience, Dr. Rudolph Talarico. Dr. Talarico commented that for simple orchiectomy he has never had a problem with hemostasis or edema. Although this may very well be the case, we opted to perform the scrotal hitch on orchiectomies. The reason being, our orchiectomies were performed in a subcapsular fashion, requiring more dissection and potential for complication. It is our belief, since the morbidity from the scrotal hitch is negligible, that it can be used for most any scrotal surgery.

On behalf of the authors,

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