

On the Status of the Prostate Disease Assessment Team

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Thanks to the generous support of the Hartford, Commonwealth, and Johnson Foundations, the Prostate Disease Assessment Team (PDAT) at the Dartmouth Medical School has been working for several years prior to establishment of the new federal effectiveness initiative and the receipt of support from the Agency for Health Care Policy and Research.

PRACTICE STYLE VARIATIONS AND THEORIES FOR TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

Epidemiologic studies of surgical practice showed that the chance of having a prostatectomy varied remarkably, depending on place of residence and, by inference, on the practice styles of physicians: in some communities 10 percent of men underwent the operation by age 85, while in others the chances were in excess of 50 percent (Wennberg and Gittelsohn 1982). Our Prostate Disease Assessment Team (PDAT), comprised of an interdisciplinary group of researchers and practicing physicians (see Table 1), was formed to study the practice style-related reasons for variation in treatments of benign prostatic hyperplasia (BPH), a condition that causes difficulty in urination for most men as

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they grow older. At the time of our initial work, treatment options were restricted to surgery (transurethral or open prostatectomy) or watchful waiting; the variations indicated that surgical treatment theories were more commonly subscribed to by clinicians living in high-rate areas while the medical theory (watchful waiting) was preferred by physicians practicing in low-rate areas.

The initial task was to find out why physicians held different practice theories and what these theories were. We accomplished this through using a systematic, structured review of the medical literature and holding group meetings with practicing physicians in Maine who

Table 1: Members of the Prostate Disease Assessment Team

<i>Discipline</i>	<i>Members</i>	<i>Location</i>
Biostatistics	Klim McPherson	Oxford, England
	Frederick Mosteller	Boston, MA
	Frederick Whaley	Hanover, NH
Clinical decision making	Michael J. Barry	Boston, MA
	Albert G. Mulley	Boston, MA
Computer science/interactive videodisc technology	Eric Baumgartner	Hanover, NH
	Joseph V. Henderson	Hanover, NH
	Harold C. Lyon, Jr.	Hanover, NH
	Barbara Sasso	Hanover, NH
	Coralea Wennberg	Hanover, NH
Medical care epidemiology/ Claims data studies	Nicolas Black	London, England
	Thomas Bubolz	Hanover, NH
	Marsha M. Cohen	Manitoba, Canada
	Elliott S. Fisher	Hanover, NH
	E. Robert Greenberg	Hanover, NH
	David J. Malenka	Hanover, NH
	Dale McLerran	Hanover, NH
	Leslie L. Roos	Manitoba, Canada
	Noralou P. Roos	Manitoba, Canada
	John E. Wennberg	Hanover, NH
Medical ethics	Charles Culver	Hanover, NH
Psychometrics/Survey research	Tavs Folmer Andersen	Copenhagen, Denmark
	Floyd J. Fowler	Boston, MA
Urology	Reginald Bruskewitz	Madison, WI
	Abraham Cockett	Rochester, NY
	John A. Heaney	Hanover, NH
	H. Logan Holtgrewe	Annapolis, MD
	Michael O'Leary	Boston, MA
	Ernest Ramsey	Manitoba, Canada
	Ian Thompson	San Antonio, TX
	Robert P. Timothy	Portland, ME
Richard Williams	Iowa City, IA	

lived in low- and high-rate areas. The literature review, as is so often the case, illustrated the great gaps in the scientific basis of clinical medicine: although prostatectomy is the most common major operation on men in the Medicare program, not a single randomized clinical trial could be found comparing surgical and nonsurgical treatment theories or studies testing the theory that a transurethral procedure is superior to an open prostatectomy (even though by the 1980s most urologists had adopted the transurethral or "TURP" approach to surgery). The group meetings with urologists revealed an important division of opinion on the role of surgery.

THE PREVENTIVE THEORY OF EARLY SURGICAL INTERVENTION

Some urologists subscribed to the preventive theory of surgery, arguing that since BPH is a progressive disease that leads in most cases to life-threatening obstruction of the kidneys, it was in the best interest of patients to operate early in the course of the disease because such early intervention would increase life expectancy. Waiting would mean that patients would be older and sicker when they had the operation and that they would therefore experience higher operative mortality.

THE QUALITY OF LIFE THEORY OF SURGERY

Other urologists were skeptical of the preventive theory largely on the basis of their different assessment of the natural history of the BPH patient. In this view, BPH is not necessarily progressive; operations performed early in the course of disease will include a number of patients whose conditions might not worsen under medical management. Operative mortality incurred by operating on all patients with early symptomatic disease might actually decrease life expectancy. According to this theory, for patients who do not have obstruction of the upper urinary tract, the operation should be undertaken to reduce symptoms and improve the quality of life.

ASSESSING WATCHFUL WAITING VERSUS PROSTATECTOMY

Our assessment team set out to test these theories and to obtain estimates for all of the outcomes that patients and physicians thought were relevant. The strategies we used included (1) a systematic review of the literature; (2) the use of focus groups with patients and physicians to

identify the relevant outcomes; (3) the use of large claims data bases to develop probability estimates for such outcomes as operative mortality, reoperation, and other treatment failures; (4) interviews with patients before and after treatment to ascertain changes in symptoms and quality of life in response to treatment; and (5) the use of decision analysis to test the preventive and quality of life theories.

The results of our first assessment are published in a series of articles in leading medical journals (Fowler, Wennberg, Timothy, et al. 1988; Barry et al. 1988; Wennberg, Mulley, Hanley, et al. 1988). In brief, we show that the preventive theory is not sustained by an actuarial analysis; for all patient subgroups who do not evidence chronic obstruction of the upper urinary tract, implementation of the preventive theory appears to result in a slight decline in life expectancy. About 80 percent of men can expect marked improvement in their symptoms and those with severe symptoms gain in quality of life. However, the benefit of surgery can be gained only by taking some risks, including the chance of incontinence, impotence, and operative mortality. About 20 percent of those who choose watchful waiting may expect some reduction in symptoms, while for most men symptoms seem to stay the same, and for 20 percent they get worse. Those who do not have the operation also may face an increased probability of becoming acutely obstructed. This is a painful but non-life-threatening condition for which precise estimates of the probability cannot be obtained from the literature or from our studies.

Another very important conclusion of our assessment is that for the individual patient, rational choice depends on his attitudes about the risks and benefits of the treatment options. We found (not surprisingly) that men differ in their degree of concern about their symptoms and the impact their symptoms have on their quality of life. We found that some men who were severely symptomatic were not bothered very much by their condition and would presumably prefer watchful waiting over surgery. Indeed, we found no objective data based on physical examination, history, or the careful quantification of symptoms that accurately predicts the preferences of patients for surgery or for watchful waiting. Rational choice *depends* on the active involvement of the patient in the decision because the patient's attitudes and values concerning the symptoms and risks of BPH are key to making the right decision. The only way to find out the treatment a patient actually wants is to ask him.

Our assessment thus reached the conclusion that the practice style-related reasons for small-area variations were an erroneous belief in the preventive theory of surgery and a failure to involve patients actively in

the decision process to assure that the choice of treatment was based on preferences of the patient regarding risks and benefits, rather than those of the physician. Our remedy is to make information about the treatment options available to patients and physicians in a way that communicates the nature and probabilities of the relevant outcomes.

THE SHARED DECISION-MAKING PROCEDURE

Our strategy for ensuring better information for clinical decision making and for activating the involvement of patients is the “shared decision-making procedure,” or SDP. This integral part of our assessment strategy is based on a new technology wedding computers with video in an interactive environment that permits viewers to see presentations tailored to their circumstances, for instance, their level of symptoms and operative risk. They can move interactively and iteratively through the presentation by exercising a series of options. The SDP includes information on the nature and chances for the outcomes that our focus groups indicated are of concern to patients. It contains video clips of patients who have chosen either watchful waiting or surgery, and who have experienced good results as well as complications. The objective is to provide both data about the chances for particular outcomes and video presentations about the outcomes themselves in order to help the patient understand vicariously his predicament and options. To help the patient understand that he actually does have a choice, interviews are presented with two physician-patients, both with severe symptoms, one of whom chose watchful waiting, the other surgery. This heuristic has been very successful in establishing in the viewer’s mind that he really does have a choice. After all, if physicians choose differently, so can patients.

The SDP serves three purposes.

First, we believe it meets the ethical and the legal requirements for informed patient decision making.

Second, it provides an important research tool for outcomes research. The potential of the MEDTEP program will be met best if assessment teams can develop more effective ways to capture information generated in everyday clinical practice in formal, prospective clinical studies. The SDP serves as a tool for undertaking such studies by providing a uniform presentation of information and facilitating the follow-up of patients. We are now undertaking studies to improve estimates of the probabilities of outcomes following either surgery or

watchful waiting by filling in the key gaps in the data base, such as the chances for acute retention in patients who have chosen watchful waiting.

Third, the SDP provides a new tool for studying the impact of information on patient choices and for understanding and modeling the role of the physician as cognitive advisor to the patient. We are pursuing these issues collaboratively with other researchers around the country.

COLLABORATION WITH THE AMERICAN UROLOGICAL ASSOCIATION/ NEW TREATMENTS FOR BPH

In the course of our work, we noted a disturbing elevation in mortality rates over a five-year period for patients undergoing a transurethral prostatectomy compared to open prostatectomy (Roos, Wennberg, Malenka, et al. 1989). Although additional data for severity adjustment obtained through a retrospective review of medical charts suggested that the finding is not explained by differences in patient selection (Malenka, Roos, Fisher, et al. 1990), most clinicians and many members of our assessment team believe that the observation will ultimately be explained by patient factors: that severity adjustment is imperfect; and that patients who have transurethral resection are sicker, and our adjustment for comorbidity is not adequate to show this as the reason for the elevated mortality. While the report of a randomized clinical trial, first available in 1988, is consistent with the higher mortality finding, the trial had too few patients. We believe that the uncertainty surrounding the use of these two surgical treatments can be removed only by a randomized clinical trial. We have recommended that such a trial take place.

Our results are having an impact on the profession (Wennberg, Freeman, and Culp 1987). Over the past year, our group has been meeting on a regular basis with senior officers of the American Urological Association (AUA) to plan a prospective randomized clinical trial to clarify the theory that transurethral prostatectomy may cause an elevation in mortality in the years following surgery. The AUA, working with our team, submitted a proposal to the Agency for Health Care Policy and Research (AHCPR) in June 1990 to fund a multicentered randomized clinical trial. The trial is being designed to test new ideas that have not as yet been evaluated. We have noted that the last two

years have been extremely productive of new treatment theories for BPH (Winslow 1990). The AUA is rightly concerned that past strategies for the evaluation of BPH treatments have not worked and is anxious to access the new technologies that are "coming on line," including drug treatments, balloon dilations, and microwave treatments. The research design of the AUA-PDAT proposal will include these new treatments. Our group, in keeping with its philosophy of seeking to establish a balanced assessment strategy that brings all relevant treatment theories under the evaluative network, is pleased with this development. We believe this collaborative network will provide an effective, ongoing, and nonregulatory basis for bringing new technologies and their treatment theories under evaluation.

EARLY PROSTATE CANCER ASSESSMENT

During the recent year, our group has begun an assessment of treatment theories for early cancer of the prostate using the methods that we employed in our assessment of BPH treatments. We anticipate preliminary results from these efforts within the next year.

REFERENCES

- Barry, M. J., A. G. Mulley, F. J. Fowler, and J. E. Wennberg. "Watchful Waiting vs Immediate Transurethral Resection for Symptomatic Prostatism." *Journal of the American Medical Association* 259, no. 20 (1988):3010-17.
- Fowler, F. J., J. E. Wennberg, R. P. Timothy, M. J. Barry, A. G. Mulley, and D. Hanley. "Symptom Status and Quality of Life Following Prostatectomy." *Journal of the American Medical Association* 259, no. 20 (1988):3018-22.
- Malenka, D. J., N. Roos, E. S. Fisher, D. McLerran, F. S. Whaley, M. J. Barry, R. Bruskewitz, and J. E. Wennberg. "Further Study of the Increased Mortality following Transurethral Prostatectomy: A Chart-Based Analysis." *The Journal of Urology* 144 (August 1990):224-28.
- Roos, N. P., J. E. Wennberg, D. J. Malenka, E. W. Fisher, K. McPherson, T. F. Anderson, M. M. Cohen, and E. Ramsey. "Mortality and Reoperation after Open Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia." *New England Journal of Medicine* 320, no. 27 (April 1989):1120-24.
- Wennberg, J. E., J. L. Freeman, and W. J. Culp. "Are Hospital Services Rationed in New Haven or Over-Utilized in Boston?" *Lancet* no. 1 (1987):1185-88.

- Wennberg, J., and A. Gittelsohn. "Variations in Medical Care Among Small Areas." *Scientific American* 246, no. 4 (1982):120-34.
- Wennberg, J. E., A. G. Mulley, D. Hanley, R. P. Timothy, F. J. Fowler, N. P. Roos, M. J. Barry, K. McPherson, E. R. Greenberg, D. Soule, T. Bubolz, E. Fisher, and D. Malenka. "An Assessment of Prostatectomy for Benign Urinary Tract Obstruction." *Journal of the American Medical Association* 259, no. 20 (1988):3027-30.
- Winslow, R. "Avoiding the Knife, Prostate Patients Get Choice of Treatments that Obviate Surgery." *Wall Street Journal* 215, no. 27 (7 February 1990).