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Helping Patients Make Treatment Choices for Localized Prostate Cancer

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1. Introduction

One in six men in the U.S. will be diagnosed with prostate cancer in his lifetime; however, only one in 35 men will die from the cancer.[1] As prostate-specific antigen (PSA) screening has become widespread, about 90 percent of patients are diagnosed with localized prostate cancer which will not lead to death in the majority of patients.[2] As a result, over treatment of localized prostate cancer (LPC) has been an increasing concern. [3] However, prostate cancer is the second most common cause of cancer-related death in U.S. men, after lung cancer. Therefore not treating aggressive cancers which are detected early carries a grave risk.

Treatment of localized cancer by surgery or radiotherapy can be curative; however, in about one-half to three-fourths of patients, the risk of death from screening-detected prostate cancer is very low, even if they choose observation. [4,5] A large U.S. retrospective study found that about 20 percent of low-risk patients who chose observation died from prostate cancer over 20 years of follow-up.[6] A Swedish randomized controlled trial also found a survival benefit after eight years of treatment in low-risk patients.[7] However, patients in both of these studies had higher-stage cancer at diagnosis (i.e., their cancer was clinically diagnosed and was not detected by PSA screening). The Swedish trial also found that prostate cancer–specific mortality was only 2.4 percent at 10 years in low-risk patients who were randomized to active surveillance.[8] A large study of 44,630 low-risk U.S. patients found a survival benefit of treatment, [9] but only 2.1% of the patient sample had died because of prostate cancer.

Treatment is associated with urinary, sexual, and bowel dysfunction, and enhances the quality-adjusted survival of low-risk patients by only 1.2 months. [10] Five years after treatment in 3,533 patients, 79.3% of surgery patients and 63.5% of radiotherapy patients had erectile dysfunction, 15% of surgery patients and 4% of radiotherapy patients had at least frequent urinary leakage, and 19% of surgery patients and 29% of radiotherapy patients had bowel urgency.[11] Side effects are unpredictable and vary very widely,[12] and decisional regret is common.[13] In addition, the cost of each potentially unnecessary prostatectomy or radiation treatment was about $10,000 to $25,000 in 2000 dollars. [14] Despite these concerns, about 94 percent of patients with localized prostate cancer choose treatment.[15] In patients treated from 2000 to 2002, the rate of overtreatment (i.e., treatment in low-risk patients) was estimated to be about 55 percent.[16]

Under-treatment of localized prostate cancer has also been a concern for over two decades. The incidence and mortality of the cancer are two to three times higher in black men.[17]

However, black and Hispanic men are more likely to be monitored instead of receiving treatment, possibly because they are more likely to present late, have poorer access to care, and sometimes a cultural preference for conservative treatment but many of these factors are not well evidenced.[18]

Few randomized controlled trials have compared outcomes of different treatments for localized prostate cancer. A survey of 504 urologists and 559 radiation oncologists found that for the same hypothetical patient, 93 percent of urologists would recommend surgery, and 72 percent of radiation oncologists would recommend radiotherapy. [19] Although treatment of localized prostate cancer is unlikely to improve the survival of low-risk patients and has potentially negative effects on health-related quality of life, about 70 to 90 percent of patients choose a treatment during the first visit to a urologist after a positive biopsy.[20]

In our survey of 184 men with newly diagnosed prostate cancer, more than one-half significantly overestimated the survival benefit of treatment. [21] Education, income, and health literacy did not affect the results; 60 percent of the survey respondents were college educated and had an annual income more than $50,000, and more than 90 percent had at least a ninth-grade health literacy. [22] Although these patients had been counseled by their urologists and had already elected treatment or observation, more than 50 percent incorrectly answered more than one-half of the 18 items in a questionnaire designed to test their knowledge, understanding, and judgment about the advantages and disadvantages of treatment options for prostate cancer. This questionnaire[22] can be used to identify patients who need further counseling about treatment choices.

Over-, and Under-treatment occur because without the use of guidelines, it is extremely difficult for even the most intelligent LPC patient to make a good decision. Patients must choose from treatments with marginally different HRQOL outcomes, and without clear numerical probabilities of the frequency, severity, and duration of side effects. Finding the HRQOL outcome that can best match the patient's preference can eclipse the bigger question of whether any treatment will enhance survival. Urologists are unsure too, which is reflected in their need to develop newer nomograms to predict survival even though 40 nomograms already exist. [23] Most urologists recommend definitive treatment for low risk young patients. [24] Observation is inappropriate in many patients, and until better evidence is obtained, a balanced decision-aid with numerical probabilities is recommended. [25] This could be very difficult, given that for LPC patients, urologists have more than 69 tools to predict prognosis, [26] and more than 800 articles [27] about HRQOL outcomes have been reported.

Dahm et al [83] have suggested that such a complex decision should not be left to expert opinion alone, and that national guidelines can help in preventing over-, or under-treatment because guidelines are developed by panels of individuals who have the access and time to understanding and balance the available evidence. Guidelines aim to maximize both survival and HRQOL, are freely available on the Internet, are likely without much bias, and can give a point of reference from where patients may deviate by personal preference. However, in the literature, we found 160 articles with combinations of search terms and Medical Subject Headings including "prostate cancer, practice guidelines, NCCN, medical oncology/standards, evidence-based practice, urology/standards, and neoplasms/ therapy". Except for a Japanese study on the outcomes of brachytherapy, [29] and a case report by Walsh [30] suggested that any named guideline was used in choosing a treatment for LPC. Our publication in 2010 was the first to show the use of guidelines; we have described a new method to estimate co-morbidity adjusted life expectancy that makes the use of guidelines feasible.[31]

Among ten guidelines published for choosing a treatment for LPC, the guideline by the National Comprehensive Cancer Network (NCCN)[32] was rated as the most evidenced-based. [28] NCCN risk categories use the D'Amico criteria for survival prediction in LPC patients, [33] all NCCN guidelines require continuous review, and their recommendations are level 2A or better (either high level evidence or uniform consensus). The goal of NCCN guidelines is "to extend life expectancy while minimizing excess morbidity," and the guidelines are based on the thinking that "despite differences in values, most patients would make the same choice." An algorithm based on the NCCN guideline is presented in Figure 1. Four factors are used in determining the recommended treatment. These are: the cancer's stage, its grade i.e, the Gleason score, the PSA level, and the estimated baseline co-morbidity adjusted life expectancy of the patient.

Stages T1 (not palpable) and T2 (palpable but limited to the prostate) are considered localized if there are no lymph nodes involved and no distant metastasis.

The Gleason score is determined by adding the grades of the two most common histologic patterns seen in each biopsy core. Each pattern is scored from 1 to 5, with 5 being most poorly differentiated. For example, if grade 3 is the most common pattern and grade 4 is the

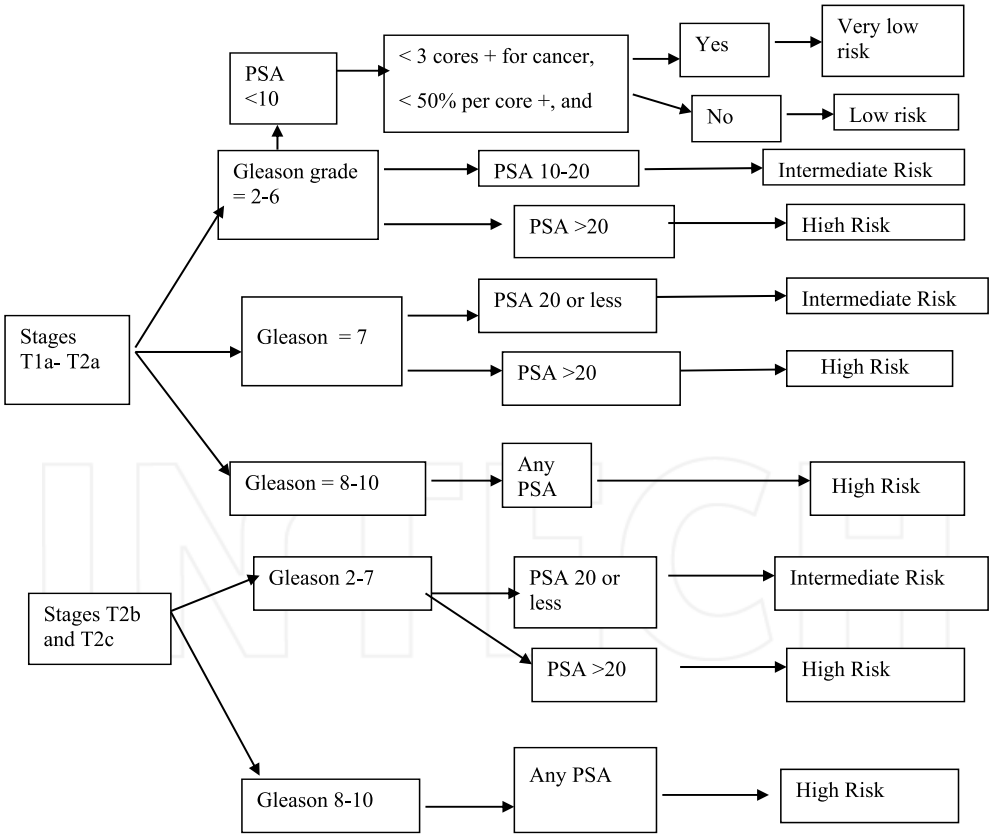

Fig. 1a.

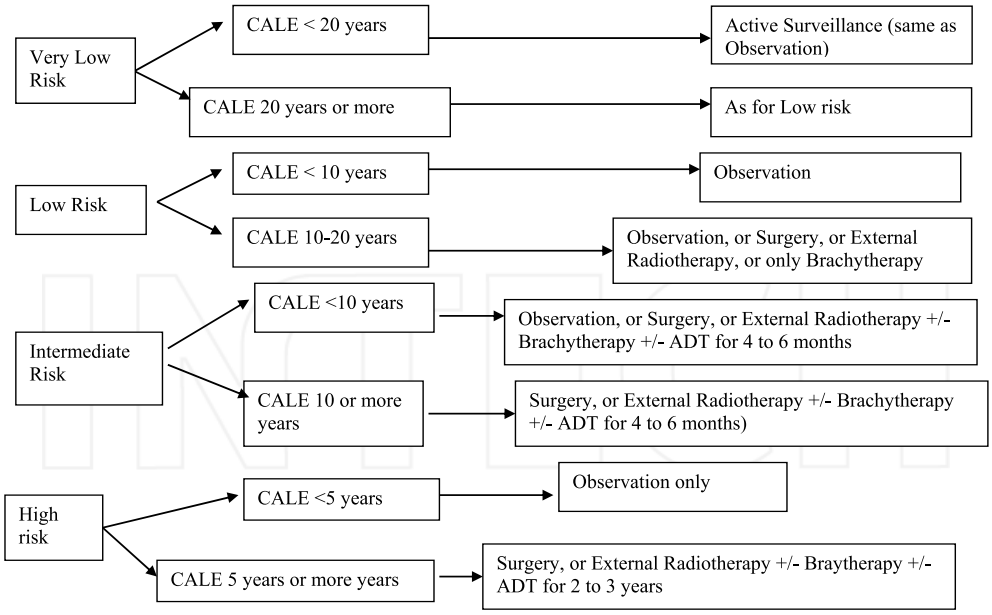

Fig. 1b.

Fig. 1a and 1b. Algorithm based on guideline by National Comprehensive Cancer Network for selection of treatment for localized prostate cancer.

next most common pattern, the Gleason score would be 7 (3+4). The most common grade is 6, whereas grades 2 to 5 are uncommon. Grade 6 identifies a tumor with well-differentiated histology; grade 7 has intermediate differentiation; and grades 8 to 10 are the most poorly differentiated and have the worst prognosis. A grade 7 cancer is more aggressive if its scoring is 4+3 instead of 3+4.

PSA levels of 4 to less than 10 ng per mL, 10 to20 ng per mL (10 to 20 mcg per L), and greater than 20 ng per mL are associated with a low, intermediate, and high risk of prostate cancer recurrence after treatment, respectively.

The factor of Comorbidity-adjusted Life Expectancy is particularly important because the number of comorbid diseases is the most significant predictor of survival after treatment of prostate cancer. [34] Prostate cancer is usually slow growing, and the survival benefit of treatment may present only after 10 years or longer. This is the basis of the "10-year rule": a patient with prostate cancer should be treated only if the patient has a comorbidity-adjusted life expectancy of at least 10 years. Age alone is not accurate in estimating life expectancy. To estimate comorbidity-adjusted life expectancy, the NCCN recommends the use of health status quartiles that match corresponding quartiles of life expectancy at each year of age. Tables 1a [35] and 1b [31] give a short patient-administered Charlson Comorbidity Index that can be used for a quick estimation of comorbidity-adjusted life expectancy.

After deciding in favor of treatment, patients can choose between surgery and radiotherapy based on the side-effect profile of treatments. A systematic review did not find any good-quality head-to-head trials comparing surgery and radiotherapy. [36] The review found that surgery and external beam radiation therapy (EBRT) are equivalent in controlling the

cancer, especially if the baseline PSA level is greater than 10 ng per mL.[36] Many trials studied biochemical progression but not long-term survival, and some trials were conducted before the advent of PSA testing. No trial has compared treatment outcomes by race or ethnicity, and most trials do not provide baseline racial characteristics. Among patients in whom cancer was detected clinically (not by PSA screening), those who underwent radical prostatectomy (RP) had fewer prostate cancer–related deaths than patients who chose watchful waiting, although this benefit was limited to patients younger than 65 years. [36] Patients who were operated on by surgeons who performed more than 40 RPs per year had fewer urinary adverse effects. Laparoscopic RP performed with or without the use of robotic technology is associated with less blood loss and shorter hospital stays, but all long-term outcomes are similar to open RP. In robotic laparoscopic RP, surgeons with more experience were more likely to achieve complete resection of the cancer.[36]

Which medical problems have you had?		Has this condition limited your activities, or do you need to take prescription medicine?	
		Yes	No
Inflammatory bowel disease	O	O	O
Liver disease	O	O	O
Stroke	O	O	O
Ulcer	O	O	O
Arthritis	O	O	O
Chest pain	O	O	O
Chronic lung disease	O	O	O
Depression	O	O	O
Diabetes mellitus	O	O	O
Heart attack	O	O	O
Heart failure	O	O	O
High blood pressure	O	O	O

Note: Inflammatory bowel disease, liver disease, stroke, and ulcers are scored as one disease each, regardless of severity. The remaining eight conditions are scored as one disease each only if the conditions limit the patient's activity or require prescription medications.

Table 1a. Patient-Administered 12-item Charlson Comorbidity Index

EBRT is given over eight to nine weeks and is associated with more bowel adverse effects than surgery. Surgery is more difficult if cancer recurs after EBRT. The review found one trial in which proton therapy was more effective than EBRT. [36] In patients with low-risk cancer, brachytherapy using iodine-125 or palladium-103 pellet implantation is recommended as monotherapy.[32] It is a preferred option in these patients because it controls the cancer as effectively as surgery or EBRT, and patients experience much less urinary incontinence and erectile dysfunction. Implantation may be difficult in patients who have bladder outlet obstruction or a very large or very small prostate, and in those who have had previous prostate surgery.

Hormone therapy (also known as androgen deprivation therapy) as an adjunct to surgical treatment is discouraged in low-risk patients because it does not increase treatment effec-

tiveness and is associated with gynecomastia and erectile dysfunction. [32, 36] Cryotherapy and high-frequency ultrasound are not recommended as routine monotherapies.

Age (years)	Life expectancy (years)		
	Top percentile of health (no disease)*	Middle two percentiles of health (1 or 2 diseases)*	Bottom percentile of health (3 or more diseases)*
50	42.69	28.46	14.23
51	41.43	27.62	13.81
52	40.18	26.79	13.39
53	38.94	25.96	12.98
54	37.71	25.14	12.57
55	36.49	24.33	12.16
56	35.28	23.52	11.76
57	34.06	22.71	11.35
58	32.88	21.92	10.96
59	31.69	21.13	10.56
60	30.54	20.36	10.18
61	29.4	19.6	9.8
62	28.27	18.85	9.42
63	27.16	18.11	9.05
64	26.07	17.38	8.69
65	25.00	16.67	8.33
66	23.94	15.96	7.98
67	22.90	15.27	7.63
68	21.88	14.59	7.29
69	20.89	13.93	6.96
70	19.90	13.27	6.63
71	18.96	12.64	6.32
72	18.01	12.01	6.00
73	17.11	11.41	5.70
74	16.21	10.81	5.40
75	15.36	10.24	5.12
76	14.52	9.68	4.84
77	13.71	9.14	4.57
78	12.93	8.62	4.31
79	12.16	8.11	4.05
80	11.43	7.62	3.81

*—Number of diseases refers to the conditions listed in the Charlson Comorbidity Index.

Table 1b. Comorbidity-Adjusted Life Expectancy in U.S. Men

Adverse effects vary depending on the treatment modality used; the specialist's experience; the criteria used to assess the frequency, severity, and duration of symptoms and their baseline status; and the medications or devices used to treat the symptoms. Table 2 shows the incidence of adverse effects two years after surgery and EBRT. [37] Adverse effects noted five years after treatment include no urinary control or frequent urinary leakage (14 percent after surgery

versus 5 percent after EBRT, with pad use in 29 percent of surgical patients and 4 percent of EBRT patients). [36] After adjusting for baseline factors, dripping or leaking urine was noted six times more often after surgery than after EBRT.[36] Erections insufficient for intercourse occurred in approximately three-fourths of patients after surgery or EBRT.[36] Despite these adverse effects, less than 5 percent of patients reported dissatisfaction with treatment, and more than 90 percent of patients said they would make the same decision again.[36] Patients who underwent surgery were most satisfied. Patient satisfaction was highly related with adverse effects, but also with the perception of freedom from prostate cancer.

Adverse effect	Watchful waiting (%)	Surgery (%)	External beam radiation (%)	Hormone therapy (%)
Bowel problems (urgency)	16	14	29	16
Erectile dysfunction (no erections at all)	33	58	43	86
Urinary problems (leaking)	7	35	12	11

Adapted from Agency for Healthcare Research and Quality. Treating prostate cancer. A guide for men with localized prostate cancer. http://www.effectivehealthcare.ahrq.gov/ehc/products/9/98/ProstateCancerConsumer.pdf Accessed June 4, 2010.

Table 2. Adverse Effects Two Years After Prostate Cancer Treatment

Compared with observation and watchful waiting, active surveillance is a more structured program to track the progression of prostate cancer, allowing for earlier intervention if the patient's risk is found to increase on follow-up. A protocol used in Canada is shown in Table 3 [10]; with the use of this protocol, patient survival is similar to that after treatment (99.2 percent at eight years in 299 patients).[10] About 25 percent of patients in this protocol proceed to intervention.9 Patient survival in a European study was 100 percent at 10 years in 616 patients. [38] In this ongoing study, patients continue with active surveillance only if their PSA level (checked every three months) doubles in more than three years; if cancer is present in only one or two biopsy cores; and if their Gleason score remains 6 (3+3) or lower (biopsy is done if the PSA doubling time is three to 10 years, and routinely at one, three, five, and seven years, then every five years thereafter). Active surveillance is recommended for low- and very low-risk patients. Drawbacks include the potentially increased difficulty of curative or nerve-sparing surgery in patients for whom intervention is delayed despite increasing risk, and mild anxiety. However, men following this protocol have been found to have favorable levels of anxiety and distress.[39]

In summary, with the use a new, easy and quick method that we have described to estimate a newly-diagnosed patient's co-morbidity adjusted life expectancy, physicians can help patients in choosing treatment or observation according to evidence-based national guidelines. This may reduce reluctance among patients and physicians in getting PSA screening and may reduce worry regarding over-diagnosis of low-risk cancers and the potential damage to the patient's health-related quality of life through unnecessary treatment of such cancers. We have recently published our algorithm in the journal American Family Physician, [40] which is the most widely read journal in primary care; this

may help primary care physicians in counseling newly-diagnosed patients; until now patients return to primary care physicians after they have chosen a course of treatment as recommended by the urologist who had done the biopsy. [41] Although in October 2011 the United States Preventive Services Task Force has recommended against PSA testing,[42] this recommendation is based on the potential harms that can result from treatment of low-risk cancers. However, to not screen for prostate cancer- which is the second most common cause of cancer death in American men, will inevitably lead to even more deaths from untreated advanced cancer. A more prudent approach might be to screen for the cancer, but to use the approach in this article to convince low-risk patients to choose active surveillance instead of immediate treatment.

Eligibility criteria • PSA level ≤ 10 ng per mL (10 µg per L), Gleason score of 6 or lower, and stage T1c or T2a cancer • For men with more than 15-year life expectancy: fewer than three cores and less than 50 percent of any one core involved
Follow-up schedule • PSA testing and digital rectal examination every three months for two years, then every six months as long as PSA level is stable • 10 to 12 core biopsies at one year, then every three years until 80 years of age • Optional: transrectal ultrasonography on alternate visits
Indications for intervention • PSA doubling time less than three years (based on at least eight determinations; required in about 20 percent of patients) • Progression to Gleason score of 7 (4+3) or higher (required in about 5 percent of patients)

PSA = prostate-specific antigen. Adapted with permission from Klotz L. Active Surveillance for prostate cancer: for whom? J Clin Oncol 2005; 23(32): 8167

Table 3. Canadian Protocol for Active Surveillance of Prostate Cancer

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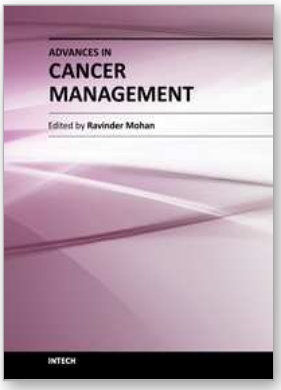

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Cancer is now the most common cause of death in the world. However, because of early diagnosis, better treatment, and advanced life expectancy, many cancer patients frequently live a long, happy, and healthy life after the diagnosis- and often live as long as patients who eventually do not die because of cancer. This book presents newer advances in diagnosis and treatment of specific cancers, an evidence-based and realistic approach to the selection of cancer treatment, and cutting-edge laboratory developments such as the use of the MALDI technique and computational methods that can be used to detect newer protein biomarkers of cancers in diagnosis and to evaluate the success of treatment.

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