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Treating Prostate Cancer

*t*here is controversy about the optimal treatment for clinically localized prostate cancer (i.e., cancer that appears not to have spread beyond the prostate based on information available without performing surgery).[1] In the United States, the preference is for aggressive treatment, with urologists generally preferring radical prostatectomy (203, 318). However, recent research has revealed considerable variability in stage-specific treatments actually administered (219, 238, 247). In other developed countries, urologists have tended to be more conservative regarding both early detection (78, 302, 303) and treatment (5, 175, 364).

Although observational studies exist to determine the outcomes of men who receive different treatments and to measure their risks of adverse outcomes, few well-designed trials exist to determine whether observed outcomes are actually the result of the treatment or due to some other uncontrolled and unmeasured factor. As shown in chapter 5, this uncertainty about treatment effectiveness is the greatest impediment to evaluating the cost-effectiveness of a potential Medicare prostate screening benefit.

STRATEGIES TO DETERMINE CANCER STAGE

One problem with current strategies for early detection of prostate cancer is that screening will detect some cancers that are not destined to cause morbidity or mortality and do not need treatment, as well as some cancers that have already spread through the prostate capsule and are less likely to be cured or slowed by treatment. Unfortunately, many patients may need to undergo a surgical staging procedure such as pelvic lymphadenectomy, or even radical prostatectomy itself, to establish the true stage of their cancer. Better, less invasive staging tests might allow physicians to withhold treatment from patients unlikely to benefit, sparing both the risks and costs of these procedures.

In terms of determining preoperatively whether cancers are likely to be insignificant (which this background paper defines as well-differentiated and less than 0.5 mL in volume), clinicians have developed some algorithms using data from systematic biopsies, and if necessary, rebiopsies (338). Unfortunately, however, other investigators have documented that these algorithms

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[1]As discussed in the preceding chapters, unless otherwise indicated, cancers that are confined within the prostate, less than 0.5 mL in volume, and well differentiated are assumed not to pose any threat to a patient's health and would not require treatment unless they grow or change in grade.

predict incorrectly in a quarter to a third of cases (98, 191, 192).

As far as predicting preoperatively which tumors have spread to other parts of the body, detection of metastasis to bone by using radiographic bone scans is relatively straightforward, and algorithms do exist to help identify low-risk subsets of men in whom bone scans are unlikely to be helpful (84, 357). However, the use of other diagnostic technologies (e.g., computerized tomography (CT), magnetic resonance imaging (MRI), transrectal ultrasound (TRUS)) have not yet replaced operative pathological examinations to determine if the cancer has spread to the pelvic lymph nodes (76, 164, 281) or to determine if the cancer is extracapsular (97, 137, 285). Models that use the results of multiple tests to assess the probability of organ confinement and lymph node involvement also result in substantial misclassification rates for most patient groups (1, 191, 192, 267, 283, 369).

While better staging techniques, such as molecular staging strategies currently under active investigation (185), may allow better prediction of which tumors are likely to be dangerous enough to threaten a patient's longevity but still potentially curable, selective treatment of only those tumors most likely to benefit may still be practically difficult. As shown later in this chapter, evidence establishing the effectiveness of treatment is currently weak. Once a clinician finds cancer, in the absence of data that there is not at least some net benefit from treating even apparently inconsequential or unconfined cancers, patients and physicians may have difficulty in forgoing therapy, even when the expected net benefits are clearly less than for other types of cancers.

Many patients with negative bone scans undergo a dissection of the pelvic lymph nodes to determine if the cancer has spread in the region of the prostate prior to a radical prostatectomy, one type of treatment with curative intent.[2] Most clinicians would not proceed with a radical prostatectomy in light of the discovery of involved pelvic nodes, although a minority feel that aggressive surgical treatment of node positive disease improves outcomes (254, 375). Recently, some urologists have begun to question the need for a pelvic lymph node examination prior to radical prostatectomy among men with better differentiated tumors, or in men with lower prostate-specific antigen (PSA) values (38, 102, 126, 138).

Another new strategy sometimes employed before radical prostatectomy is the use of hormonal drugs to decrease the likelihood that the cancer is found to extend beyond the outside of the prostate capsule or beyond the surface of the surgically removed specimen (known as *surgical margin positivity*). Controversy exists about whether this treatment (known as *androgen ablation therapy*) actually causes a shrinking of the tumor (*regression*) as opposed to only decreasing PSA levels (223, 259, 321). Although a recently presented clinical trial suggests that preoperative androgen ablation therapy actually does cause some regression (202), there is no evidence such treatment improves patient outcomes with prolonged followup.

THE EFFECTIVENESS OF TREATMENT

This chapter examines three strategies for treating prostate cancer: 1) expectant management (or "watchful

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[2]This examination can be done as a traditional, open surgical procedure or less invasively using a laproscope that requires only a small incision (188, 290, 304). It can be done as a separate procedure, or as the first stage of a combined pelvic lymph node examination and radical prostatectomy.

waiting"), 2) radiation therapy, and 3) radical prostatectomy.

Expectant Management

Expectant management, a commonly used strategy for clinically localized cancer worldwide (367), can take two basic forms: 1) only monitoring the patient for symptoms related to cancer progression and treating these symptoms as necessary or 2) monitoring for disease progression and attempting cure with radiation treatment or prostatectomy in that circumstance. Even in the United States, where the approach to prostate cancer is much more aggressive, a 1990 study by the American College of Surgeons Commission on Cancer found that almost two-thirds of Stage A cancers were not actively treated (238).

Many men with prostate cancer treated expectantly will have evidence of local progression by digital rectal examination (DRE) over time (342). Local progression of prostate cancer can cause symptoms from bladder outlet obstruction or invasion of surrounding tissues. Bladder outlet obstruction can be treated mechanically (by transrectal resection of the prostate (TURP)[3] or, less commonly, stenting).

Treatment involving deprivation of the male hormone testosterone (an androgen) is often used as part of an expectant management therapy when the disease becomes symptomatic (168) or, more recently, for evidence of cancer progression in asymptomatic men.[4] Clinicians can accomplish androgen deprivation therapy by orchiectomy (surgical removal of the testes) or by medical means with other hormones or drugs (301). The latter option is more common despite considerably higher costs and the risk of patient noncompliance, at least partially because of patient preference (53, 65, 311).[5] Although the initial response to hormonal therapy for advanced prostate cancer is often gratifying, it is also frequently short-lived, with the results of subsequent chemotherapy generally disappointing (94, 108).

What Is the Effect of Expectant Management?

Although the outcomes of expectant management have been studied around the world (3, 4, 114, 135, 175, 176, 249), few investigators in the United States have done so (178, 366).

A number of case series of men with clinically localized prostate cancer in "watchful waiting" strategies have been reported from around the world. As shown in table 4-1, a recent structured literature review and synthesis of 23 nonexperimental studies showed that receiving expectant management for localized prostate cancer had rates of metastasis and death no different from radical prostatectomy and lower than radiation therapy (362). However, these comparisons are inferior to well-controlled, experimental results (333, 362). This literature synthesis has been criticized for the inclusion of series describing predominantly the outcomes of early, inconsequential Stage T1a/A1 cancers, and for including series using early androgen deprivation therapy (132, 360). In addition, patients receiving radiation therapy had more poorly differentiated patients than those receiving other treatment options.

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[3]TURP does not seem to have an unfavorable impact on the prognosis of prostate cancer (372).

[4]The effect of early androgen deprivation on the natural history of clinically localized prostate cancer is not well defined; some nonexperimental studies demonstrated little effect (23, 114).

[5]Recently, clinicians have increasingly used combination therapy involving two agents, a GnRH agonist and an androgen blocker (flutamide), with some evidence from clinical trials that this approach increases median survival time to a degree (94, 108).

TABLE 4-1: PATIENT CHARACTERISTICS AND OUTCOMES OF LOCALIZED PROSTATE CANCER TREATMENT

	Watchful waiting		Radiation therapy		Radical prostatectomy	
	Median (CI)	n	Median (CI)	n	Median (CI)	n
Patient characteristics						
Age	71		66		63	
	(69-73)	27	(64-66)	49	(61-64)	33
Percent of cancers poorly differentiated	7		21		11	
	(6-11)	19	(13-24)	45	(6-25)	22
Outcomes						
Annual mortality rate						
All causes	.060		045		.032	
	(.050-.04)	27	(.040-.052)	45	(.020-.044)	27
Cancer-specific	.009		.023		009	
	(.006-.012)	23	(.010-.030)	22	(.007-.013)	23
Metastatic rate	.017		.050		.023	
	(.011-.043)	15	(.030-.095)	17	(.014-.025)	18

KEY: CI = 95% confidence interval; n = number of studies, which varies since not all studies supply all data of interest.

SOURCE: Office of Technology Assessment, 1995. Data from J.H. Wasson, C.C. Cushman, R.C. Bruskewitz, et al, "A Structured Literature Review of Treatment for Localized Prostate Cancer," *Archives of Family Medicine* 2:487-493, 1993.

A literature synthesis of seven studies (586 patients) of outcomes of men with *palpable*, clinically localized cancers (Stage T2) reported since 1980 yielded rates of metastasis, overall mortality, and prostate cancer-specific mortality higher than those presented in the Wasson review described above (6). However, one would expect these higher rates in an analysis restricted to palpable cancers. Only two studies provided data on cancer-specific survival at 10 years among men treated expectantly with a mean of 84 percent. In this analysis, the results of studies reporting outcomes of radical prostatectomy were better, while studies reporting outcomes for radiation therapy were worse.

One of these expectant management studies enrolled men with localized prostate cancer from a well-defined geographic area in Sweden between 1977 and 1984 and has an unusually long duration of followup (175, 176, 177). It excluded men with moderately or poorly differentiated cancer or a few men receiving curative treatment, leaving a sample of 223 with a mean age of 72. At 12.5 years of average followup, there have been 23 prostate cancer deaths in the cohort (10 percent), and 148 deaths from other causes (66 percent). Ten-year metastasis-free survival (corrected for deaths from other causes) was 83 percent. Tumor grade was the dominant predictor of prognosis.[6]

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[6]Although this study has been criticized for enrolling too many older men and too many with insignificant cancers discovered during TURP and for having insufficient followup to detect a late upsurge in hazard of prostate cancer death, neither age nor stage (controlling for grade) was an independent predictor of the prostate cancer death rate in this study. In addition, the study's "T0I" tumors (a unique stage different from T1a or A1) included tumors encompassing up to 25 percent of the volume of the TURP specimen (as opposed to up to 5 percent for T1a or A1 tumors in the United States), and there has been no increase in hazard rate noted with followup to 12.5 years. Moreover, a subset analysis for men who would be considered candidates for radical prostatectomy yielded similar results. Concerns have also been raised about identification of prostate cancer by means of aspiration cytology, as was generally the mode of diagnosis in this study (214, 296); however, this method had similar results to core biopsy in one Scandinavian study (358).

Another recent study with long-term followup showed similar results. It presented data from men diagnosed with clinically localized prostate cancer in Connecticut between 1971 and 1980, and treated with immediate or delayed hormonal therapy when necessary. Again, grade, but not age, predicted cancer-specific survival. For men over 65, cause-specific 15-year survivals were: well differentiated, 82 to 93 percent; moderately differentiated, 67 to 78 percent; and poorly differentiated, 46 to 53 percent (194).

Chodak and colleagues have recently conducted a meta-analysis including 828 men (mean age 70) enrolled in expectant management studies from six centers with 10-year adjusted cancer survival rates: well differentiated, 87 percent; moderately differentiated, 87 percent; and poorly differentiated, 34 percent (82, 83). Grade was once again the dominant independent determinant of the rate of prostate cancer mortality. The predicted metastasis-free survival at 10 years was lower than the survival statistics would indicate: 81, 58, and 26 percent for well, moderately, and poorly differentiated disease, respectively.[7]

The Risks of Expectant Management

The risks of expectant management for clinically localized cancer include any higher rate of the development of metastases and prostate cancer-specific mortality that this strategy imposes over and above the rates seen with active treatment.[8] The magnitude of these added risks, if any, has not been defined. More clearly, men managed expectantly have increased risks of local cancer progression compared with men treated with radical prostatectomy; however, the clinical significance and quality-of-life implications of local cancer progression have not been well studied (343). Johansson reported that 22 percent of the men in his study developed evidence of progression by DRE to Stage T3 over 10 years; however, he recently reported that in only six cases were local problems "substantial" and resistant to treatment (176).[9]

Radiation Therapy

Radiation therapy administered for cure (also known as radiotherapy) usually involves x-rays from an external source delivered in maximal doses to the prostate, lesser doses to the seminal vesicle (located above the prostate), and minimal radiation to the small bowel, rectum, anal canal, and urethra (270). Adjustments are made in the dose and targets based on the specific tumor and host. Much less commonly, radioactive "seeds" are placed in the prostate as primary therapy, or in combination with external beam radiotherapy, to increase the dose delivered to the prostate while better protecting nearby tissues. Patients usually receive external beam radiotherapy in five weekday treatments over six or seven weeks (20). Research is actively underway to identify new methods of radiotherapy, such as three-dimensional conformal therapy, that may avoid underdosing the prostate while more effectively excluding surrounding normal tissues, reducing the associated risks (209).

The relatively little attention given to radiation therapy in the recently published literature on prostate cancer detection and treatment may reflect the fact that urol-

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[7]The reason for the discrepancy between the rate of metastatic disease and prostate cancer mortality, particularly for men with moderately differentiated cancer, is not well understood; to some degree, early detection of a low burden of asymptomatic metastatic disease with periodic bone scans in these series may explain some of the apparent delay between the development of metastases and cancer death implicit in these results (278).

[8]Waiting for signs of clinical progression will result in fewer cancers being pathologically localized at the time clinicians attempt curative treatment.

[9]Thirty patients did undergo TURP for obstructive symptoms, only about half of whom had cancer in the removed tissue (176).

ogists, who most often recommend radical prostatectomy for localized prostate cancer, have conducted these studies (362). However, as recent as 1990, a study by the American College of Surgeons Commission on Cancer found that radiotherapy was used more commonly than radical prostatectomy in the United States for *every stage* of prostate cancer (238).[10] In addition, a recent study suggested that prostate cancer patients in health maintenance organization settings were more likely to receive radiotherapy rather than surgery compared with patients in fee-for-service settings (152).[11]

How Effective Is Radiation Therapy?

The effectiveness of radiotherapy, compared with either expectant management or radical prostatectomy, for reducing mortality and morbidity among men with clinically localized cancer has not been well studied. A single randomized clinical trial of 97 men with Stage A2 or B cancers found a significant improvement in time-to-recurrence with surgery compared with radiation, but no mortality difference (269, 359). However, because many patients "crossed-over" to the other treatment after randomization and the analysis was based on "treatment given" rather than "intention to treat," these conclusions may not be valid.

Although the results of only one imperfect clinical trial are available, some additional evidence is available from two cohort studies[12] of patients with clinically

localized cancer treated with radiotherapy for cure -the Patterns of Care Studies (PCS) (161, 197) and the Radiation Therapy Oncology Group (RTOG) study (#7706) (15). At 10 years, overall survival among patients receiving radiation was no different than expected survival for age-matched men without cancer (63 percent in PCS and 64 percent in RTOG). In the 1978 PCS, about 83 percent of the 10 year survivors had no evidence of disease. For men with palpable, clinically localized T2 cancers, overall survival at 10 years was 46 percent (i.e., about 20 percent lower than for cancer-free men of similar age), with about 74 percent of the survivors classified as disease-free (165). Radiation oncologists argue that, out to 10 years, these outcomes are equivalent to radical prostatectomy, particularly given the unknown nodal status of the radiotherapy patients (87, 117, 161, 163, 165, 184, 208). In fact, for a subset of men in RTOG study with negative lymph node dissections, most of whom had T2 cancers, cancer-specific survival was 86 percent after 10 years, with 79 percent metastasis-free survival (162).

In one of the literature reviews mentioned in the section on expectant management, only one study was found to have stratified patient outcomes following radiotherapy by grade and stage of disease (362). In all the available cases of patients treated with radiotherapy, these men had higher median rates of development of distant metastases and cancer- specific mortality than men treated with radical prostatectomy and expectant management, but they also had more men with poorly

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[10]Presumably, some patients who underwent a surgical examination of the pelvic lymph nodes prior to radical prostatectomy subsequently underwent radiotherapy instead because of nodal involvement.

[11]However, registry data indicate that for the U.S. population as a whole, this trend reversed itself in 1991 with radical prostatectomy becoming the more commonly used treatment strategy (166).

[12]Cohort studies are often used to compare the outcomes of two groups of patients similar in important characteristics other than the outcome of interest -in this case, treatment strategy. Because of the inability to control retrospectively for all factors that might be related to treatment choice and outcome, the results of such a study are inferior to a prospectively randomized clinical trial.

differentiated cancers than series of either of the other treatments (table 4-1). These nonexperimental comparisons may also be invalid because of the older age of radiotherapy patients, and the fact that patients with lymph node involvement are included in radiotherapy series but excluded from surgical series.

Many urologists worry that evidence of residual cancer in many men following radiotherapy augurs poorly for the prognosis of men treated this way (51, 75, 183, 210, 294, 297, 327, 359). On the other hand, rates of biopsies after radiotherapy have been lower in some recent small series of Stage T1 and T2 disease (cancers confined to the prostate) given radiation treatment in a particular manner (125), and the prognosis for men with positive biopsies after radiotherapy is debated (275).

Risks of Radiation Therapy

Injury from radiotherapy to the radiosensitive tissues of the bladder and urethra can cause cystitis[13] and incontinence. Injury to the rectum can cause proctitis,[14] and injury to the nerves and blood vessels adjacent to the prostate can cause impotence (205). Table 4-2 provides estimates of these risks based on a structured review of the medical literature published since 1981 (362).[15] This literature does not allow estimation of the hazards of radiotherapy specifically among Medicare-age men. However, preliminary analysis of a survey of complications of external beam radiotherapy among Medicare-aged men suggests that about 5 percent of men use pads to deal with incontinence and that 35 percent had noted

no partial or full erections since their treatments (27). These results compare favorably to published data on the complications of radical prostatectomy collected using the same methods and discussed below (127).

Radical Prostatectomy

The third treatment strategy, radical prostatectomy, entails removing the entire prostate with the tissues that cover it and the seminal vesicles that sit above the gland. In recent years, modification of the procedure by Walsh and colleagues and a better understanding of the anatomy of the area (50) has allowed wider excision around the prostate, but with special attention to nearby nerves and blood vessels to reduce blood loss and post-operative incontinence and impotence. However, attempts to preserve these nerves in cases of capsular penetration increases the risk of surgical margin positivity[16] (267, 287).

How Effective Is Radical Prostatectomy?

Observational data indicate that men who undergo radical prostatectomy tend to do well with prognosis dependent on disease stage (331). Those with organ-confined cancer have a low risk of recurrence and normal life expectancies. For men with unconfined disease, one recent study noted localized recurrence in 8 percent of men within five years as opposed to metastases in 30 percent.[17] This suggests that prostatectomy improves cancer control in the area around the prostate, even in situations when the rate of development of metastatic disease elsewhere in the body may be unchanged (50, 248).

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[13]Cystitis is an inflammation of the bladder.

[14]Proctitis is inflammation of the rectum.

[15]As with radical prostatectomy, complications from radiotherapy may depend on the expertise of the radiotherapist and treatment center. While some radiation oncologists at major referral centers may have better outcomes than reflected in table 4-2, as reported recently by Shipley (312), a nationwide prostate cancer early detection program may outstrip the capacity of these centers.

[16]Margin positivity refers to the discovery of cancerous tissue right up to the edge of the surgically removed tissue, raising the possibility that the operation may not have removed all of the cancer.

[17]This is the opposite of the pattern described earlier for men who are treated by expectant management.

TABLE 4-2: PERSISTENT ADVERSE OUTCOMES OF LOCALIZED PROSTATE CANCER TREATMENT
(from literature published since 1981)

	Radical prostatectomy	External beam radiation
Mortality		
Weighted mean	1.1%	0.2%
Sample size (number of men)	400.0	496.0
Median probability[a]	2.0%	0.0%
Number of studies	6.0	8.0
Any incontinence		
Weighted mean	26.6%	6.1%
Sample size (number of men)	301.0	443.0
Median probability[a]	16.0%	6.5%
Number of studies	8.0	6.0
Complete incontinence		
Weighted mean	6.8%	1.2%
Sample size (number of men)	719.0	739.0
Median probability[a]	6.0%	1.0%
Number of studies	11.0	11.0
Any bowel injury		
Weighted mean	2.7%	11.4%
Sample size (number of men)	407.0	1,148.0
Median probability[a]	1.5%	13.5%
Number of studies	4.0	12.0
Bowel injury (requiring long-term treatment or colostomy)		
Weighted mean	1.3%	2.3%
Sample size (number of men)	551.0	1,680.0
Median probability[a]	1.0%	1.0%
Number of studies	6.0	17.0
Stricture requiring long-term treatment		
Weighted mean	12.4%	4.5%
Sample size (number of men)	542.0	959.0
Median probability[a]	9.0%	2.5%
Number of studies	9.0	12.0
Impotence		
Weighted mean	84.6%	41.5%
Sample size (number of men)	374.0	415.0
Median probability[a]	62.0%	44.0%
Number of studies	7.0	5.0

[a] Median probability across reported studies.

SOURCE: Office of Technology Assessment, 1995. Data from J.H. Wasson, C.C. Cushman, R.C. Bruskewitz, et al., "A Structured Literature Review of Treatment for Localized Prostate Cancer," *Archives of Family Medicine* 2:487-493, 1993.

However, the *attributable* benefit of radical prostatectomy is less clear.[18] The structured literature synthesis of prostate cancer treatment, already described in the discussion of expectant management, found rates of death and metastasis that were not statistically different for radical prostatectomy and expectant management (table 4-1) (362). The good outcomes for men receiving radical prostatectomy noted in observational studies are in part due to better preoperative staging, and the exclusion of men whose cancer is found preoperatively to have spread to the pelvic lymph nodes. Hence, nonexperimental comparisons of outcomes of expectant management, radiation therapy, and radical prostatectomy are potentially confounded by different mixes of cancer among these studies.

Only one clinical trial has compared expectant management and radical prostatectomy directly. In a Veterans Administration Cooperative Research Group (VA-CURG) clinical trial, 61 men with clinically localized prostate cancer were randomized to radical prostatectomy and 50 men to expectant management; about half had cancers found at TURP and half palpable cancers. After seven years and again after 15 years, there is no statistically significant difference in survival between the two treatment strategies (54, 147). However, the trial's small sample size impedes detection of any real difference that may exist.[19]

The Risks of Prostatectomy

As indicated in table 4-2, Wasson's synthesis of the medical literature since 1981 indicates that the median risk of death associated with radical prostatectomy itself is about 1.1 percent; any incontinence, 27 percent; complete incontinence, 7 percent; impotence, 85 percent (31 percent in two studies of the never-sparing procedure); and stricture (obstruction or narrowing of the urethra) requiring long-term treatment, 12 percent. However, the definitions of adverse outcomes vary considerably among the studies, and as with radiation therapy, the likelihood of these outcomes are likely to vary with the experience and skill of the surgeon and hospital (50, 69, 276). On the other hand, these may be a lower-bound of the risks faced by typical patients since publication bias may lead to underestimates (27). Furthermore, Medicare patients may face higher risks because of age and comorbidities.

A recent survey that used Medicare claims data to choose a national probability sample of men who have received radical prostatectomy provides more generalizable estimates of the risks associated with this procedure for Medicare beneficiaries (127).[20] The results are presented in table 4-3 and stand in contrast to the less frequent adverse outcomes suggested by the preliminary analysis mentioned earlier of a similar survey of Medicare-age men (albeit older ones) who underwent radiation therapy. Within this cohort of men over 65, the risk of these complications was not related to age at surgery.

FOLLOWUP TREATMENT AFTER CURATIVE THERAPY

After initial treatment by radiation or radical prostatectomy, clinicians often consider additional therapy if

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[18]The attributable benefit is that portion of the total observed benefit in the treated population (i.e., extra years of life) actually due to radical prostatectomy as opposed to other causes.

[19]After seven years, patients undergoing radical prostatectomy had a probability of death 0.01 higher than those receiving expectant management. However, calculation of a 95-percent confidence interval around this figure indicates that the data are actually consistent with a probability of death with radical prostatectomy as much as 0.07 *lower* than that for expectant management as well as a probability as much as 0.09 *higher* than that for expectant management.

[20]The researchers analyzed Medicare claims data and performed a survey based on a national probability sample of 1,070 men who had radical prostatectomies under Medicare between 1988 and 1990; they oversampled Massachusetts for a subexperiment to determine whether mode of interview (personal, mail, or phone) gave different results. The method of interview did not affect any of the data presented in this paper (127).

TABLE 4-3: ADVERSE OUTCOMES OF RADICAL PROSTATECTOMY AMONG MEDICARE BENEFICIARIES

Condition	Percent of men reporting
Attributable 30-day post-operative mortality[a]	0.6%
Cardiopulmonary complications[b]	4.0-5.0
Incontinence	
▪ Wore pads or other devices for incontinence[c]	31.0
▪ Dripped more than a few drops daily	23.0
▪ Underwent surgical treatment for incontinence	6.0
▪ Had a catheter	2.0
Impotence	
▪ Had ability to have erections prior to surgery	90.0
▪ No full or partial erections since surgery	61.0
▪ Had erections firm enough for intercourse in previous month	11.0
Underwent medical/surgical treatment for stricture,	
2-4 years after surgery	20.0

[a] Total 30-day post-operative mortality (1%) minus probability of death for other causes.

[b] Congestive heart failure, myocardial infection, pulmonary embolism, or respiratory failure.

[c] Over 80% of these men reported dripping every day, indicating these pads and devices were not just used prophylactically.

SOURCE: Office of Technology Assessment 1995. Data from F.J. Fowler, M.S. Barry, A. Roman, et al. "Patient-Reported Complications and Follow-up Treatment After Radical Prostatectomy, The National Medicare Experience: 1988-1990 (Updated June 1993), " *Urology* 42(6):622-629, 1993.

there is evidence of recurrence, spread, or indications that the patients are at high risk of such problems. For men who have had radiation treatment, the clinician can consider "salvage" radical prostatectomy with evidence of local progression (297, 370), but the results are usually disappointing (67).

After initial treatment by radical prostatectomy, clinicians often consider adjuvant radiation or androgen deprivation therapy for men at higher risk of harboring residual cancer, particularly those with positive surgical margins or PSA test values that do not fall to female levels, although it is controversial whether these adjuvant treatments improve survival (77, 373). Furthermore, clinicians follow patients closely for evidence of recurrent disease with periodic DRE and PSA testing (35, 289). Men with evidence of recurrence are often considered for additional treatment with radiation. As is the case for men treated expectantly, androgen deprivation therapy may be instituted for men with locally symptomatic cancer recurrence, for men who develop distant metastases, or for some men without symptoms but a progressive abnormality on DRE or a rising PSA.

In the survey of Medicare-age men who underwent radical prostatectomy between 1988 and 1990 discussed above, 5 percent reported followup radiation therapy within the first year (probably for residual disease), and another 13 percent underwent radiation therapy between the beginning of the second and the end of the fourth year of followup (probably for evidence of recurrence). Ten percent of men had hormonal therapy prescribed in the four years following their operation, and 15 percent had an orchiectomy.