

PATIENT-REPORTED COMPLICATIONS AFTER CRYOABLATION THERAPY FOR PROSTATE CANCER

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ABSTRACT

Objectives. To define the patient-reported complications after cryoablation therapy for prostate cancer and to compare these results to previously published patient-reported complications for radical prostatectomy and external beam irradiation.

Methods. A questionnaire similar to previously published patient-reported complication studies was sent to the first 290 patients treated by cryoablation therapy at our institution. The questionnaire was returned by 267 patients. Forty-four patients were excluded from analysis because of prior irradiation, transurethral prostatectomy, or cryoablation, resulting in a study group of 223 patients.

Results. Of the 208 patients with good urinary control preoperatively, 9 (4.3%) patients used incontinence pads after cryoablation. Seven of the 8 patients who used one pad daily reported leakage of only a few drops. Impotency, defined as an inability to obtain erections adequate for vaginal penetration, occurred in 85% of men who were potent preoperatively. Urethrorectal fistula occurred in 1 patient (0.4%). Bladder outlet obstruction caused by stricture or sloughed necrotic prostatic tissue required dilation or transurethral resection in 10% of patients. Scrotal swelling, penile tingling, and pelvic pain occurred in 18%, 15%, and 12% of patients, respectively; typically, these resolved spontaneously within 3 months.

Conclusions. Patient-reported complications for cryoablation compared favorably to those reported for radical prostatectomy and external beam irradiation. Patient satisfaction was high; 96% of patients reported that they would choose cryosurgery as a treatment option again. *UROLOGY* 54: 295–300, 1999. © 1999, Elsevier Science Inc.

Recently, Onik and associates^{1,2} have reintroduced cryoablation as a primary treatment option for localized prostate cancer. Preliminary results concerning the efficacy and complications associated with cryotherapy have been variable.^{3,4} We believe that this inconsistency may be related to the experience and technique of the team performing the cryoablative procedure. Establishment of the efficacy of the primary treatment for localized prostate cancer typically requires 10 to 15 years of follow-up. However, accurate assessment of morbidity is currently available.

Most published studies reporting complications after radical prostatectomy and external beam irra-

diation are based on retrospective analysis of patients' medical records; only a handful of studies are based on patient-reported complications. Yet, the latter type of report may minimize the investigator bias typically seen with retrospective analyses. A questionnaire was developed for our patients undergoing cryotherapy by slightly modifying existing questions developed by Fowler and associates⁵ and subsequently used by others.^{6–8} In the present study, the results of the patient-reported complications after cryoablation of the prostate are reported from our survey and compared with previously published patient reports on the complications of radical prostatectomy and external beam irradiation.

MATERIAL AND METHODS

PATIENT POPULATION

Between February 1993 and December 1994, 290 consecutive patients with prostate cancer were treated with cryoablative therapy at Crittenton Hospital. Of the 290 patients, 84 (29%) had Stage T2a, 113 (39%) Stage T2b, and 55 (19%)

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TABLE I. Comparison of treatment options for prostate cancer and patient-reported complications

Author	Treatment	Patients (n)	Mean Age (yr)	Incontinence (% Using Pads)	Impotency* (%)	Urinary Obstruction† (%)	Intestinal Complications
Fowler <i>et al.</i> , ⁵ 1993	RRP	757	70	31	89	20	—
Widmark <i>et al.</i> , ⁶ 1994	ERT	181	67	19	—	—	17% moderate to severe
Crook <i>et al.</i> , ⁸ 1996	ERT	192	70	2	35	—	29% moderate to severe
Jonler <i>et al.</i> , ⁷ 1994	ERT	98	71 [‡]	11	16	5	18% moderate to severe
Present study	Cryoablation	223	65	4.3	85	10	0.4% fistula

KEY: RRP = radical retropubic prostatectomy; ERT = external beam radiation therapy.

* Defined as erections not satisfactory for vaginal penetration.

† Urinary obstruction requiring dilation or surgery.

‡ Median age.

Stage T3 disease, and in 38 (13%) radiation failed. A questionnaire was developed based on questions originally developed by Fowler and associates⁵ (see Appendix). This questionnaire was mailed to all 290 patients and returned by 267 patients (92%). No direct personal or phone contact was made with patients concerning this questionnaire. Forty-four patients (16%) were excluded because of prior external beam irradiation (31 patients), transurethral prostatectomy (9 patients), or cryoablation of the prostate (4 patients). Patients who underwent cryoablation were followed up for a mean of 2.3 years (range 1.3 to 3.1).

The remaining 223 constitute the study group used in the current analysis. The average age was 65.2 years (range 46.4 to 91.7). Of the 223 patients, 15 (6.7%) had a variable degree of incontinence before cryotherapy; only the remaining 208 patients were considered in the analysis of incontinence. Of the 223 patients, 198 (89%) were potent before cryoablation and were considered in that analysis. Occasionally, a question was left unanswered in the returned questionnaire; these unanswered questions were excluded from analysis.

TECHNIQUE OF CRYOABLATION OF THE PROSTATE

Our technique has been previously described.^{9,10} In brief, cryoablation was performed by a urologist working in conjunction with a radiologist specializing in interventional ultrasound. All patients were treated with neoadjuvant combination hormonal therapy (luteinizing hormone-releasing hormone agonist and flutamide) for 3 to 6 months to downsize tumors to 40 cc or less. An AccuProbe (Cryomedical Sciences, Rockville, Maryland) system and a modified five-cryoprobe pattern, as described by Onik and associates, were used. The geometry of the prostatic apex was an important factor in the cryoprobe placement. A flat gland with a wide apex required the cryoprobes to be inserted farther apart than a triangular-shaped gland with a narrow apex. In the latter instance, cryoprobe placement required a free-hand technique, resulting in the cryoprobes actually crisscrossing externally, being close to each other in the prostatic apex, and diverging toward the prostatic base. Positioning the cryoprobes close to each other at the midline of the prostatic apex allowed for the coalescing of the apical iceball and more uniform cytotoxic temperatures (-20°C or less) from base to apex. This was monitored by five thermosensors strategically positioned around the periphery of the prostate. A two-freeze technique was employed and often required pullback of the cryoprobes for treatment of the prostatic apex.

The urethral warming catheter manufactured by Cryomedical Sciences was used until removed from the market by the Food and Drug Administration (FDA) in May 1994. Subsequently, a slightly modified urethral warming catheter was used. The FDA approved a later version of the urethral warmer, which is now in use. Since the FDA approval of this device occurred in October 1995, it does not apply to data in this study.

RESULTS

URINARY INCONTINENCE

Urinary incontinence was defined as the use of one or more pads per day. Of the 208 patients with preoperative continence, 9 (4.3%) used one or more pads (Table I). Of the 9 patients using pads, 8 used only one pad per day. Seven of these 8 patients reported leakage of only a few drops daily. One patient used 3 to 5 pads per day.

SEXUAL DYSFUNCTION

Potency was defined as having erections firm enough for vaginal penetration. Of the 198 men potent before cryoablation, only 30 (15%) were potent after cryoablation. An additional 46 patients (23%) reported partial erections that were not firm enough for vaginal penetration. In 168 patients with impotency or partial potency, 42 (25%) used a vacuum pump, 39 (23%) used intracorporeal injection therapy, and 3 (2%) underwent implantation of a penile prosthesis.

URETHRORECTAL FISTULA

Urethrorectal fistula was noted in 1 patient (0.4%). This patient was treated early in our experience before the use of thermosensors. His fistula closed after prolonged urethral and suprapubic catheter drainage. However, he subsequently developed a bladder neck contracture and became

incontinent. He was the only patient in this study who used more than one pad daily.

BLADDER OUTLET OBSTRUCTION

Bladder outlet obstruction, which was caused by bladder neck contracture or sloughing of necrotic tissue, required dilation(s) or transurethral resection(s) in 10% (22 of 223 patients). These interventions were performed once in 12 patients, twice in 6 patients, three times in 3 patients, and was not specified in 1 patient. This problem occurred when the freezing temperatures exceeded the capacity of the warming device to maintain the viability of the prostatic urethral mucosa.

MINOR COMPLICATIONS

Virtually all minor complications resolved spontaneously within 3 months of the cryoablative procedure. Of 223 patients with previously untreated prostate cancer undergoing cryoablative therapy, 41 (18%) noted scrotal swelling, 34 (15%) described having a penile tingling sensation, and 27 (12%) reported pelvic pain. The scrotal swelling was the result of serosanguinous drainage around the prostate, which follows the cryoprobe tracks to the most dependent position. Typically, maximum enlargement of the scrotum occurs between the seventh to tenth day after the procedure and then steadily recedes thereafter. Penile tingling and pelvic pain are thought to be caused by the effect of extraprostatic extension of the iceball on sensory nerve fibers.

OVERALL PATIENT SATISFACTION

Of the 223 patients with prostate cancer treated initially by cryoablation of the prostate, 213 (96%) responded that they would choose cryosurgery again as their treatment preference. Ten patients (4%) stated that they would not choose cryosurgery again. The questionnaire revealed that of these 10 patients, 3 had cancer recurrence, 2 were incontinent and used pads, and 6 were impotent.

PATIENT MEDICAL INSURANCE COVERAGE

Financial considerations may also play a role in a patient's decisions concerning the choice and satisfaction of cryotherapy. Until July 1, 1999 Medicare did not recognize cryoablation as a reimbursable procedure. The vast majority of patients had to pay out of pocket for this procedure.

COMMENT

In the late 1960s, cryoablation was first used as a treatment for localized prostate cancer.¹¹ The technique, crude by today's standards, used a perineal incision to expose the prostate gland. Proper positioning of the cryoprobe was ascertained by inspec-

tion and palpation. A single cryoprobe was used, and the flow of the liquid nitrogen through the cryoprobe was inconsistent, leading to erratic temperatures. Despite these limitations, the University of Iowa reported favorable results in a retrospective study.^{12,13} An analysis of 229 patients treated by cryoablation reported 10-year survival rates that stage for stage were similar to patients treated by radical prostatectomy. Unfortunately, the complication rate limited the use of cryotherapy as a treatment option for prostate cancer. Of the 215 patients studied by Loening and Lubaroff,¹² fistulas occurred in 26 (12%), stress incontinence in 16 (7%), bladder neck obstruction in 15 (7%), and death in 4 (2%).

Technical advances led the group at Allegheny General Hospital to reintroduce cryoablation of the prostate.^{1,2} A percutaneous transperineal approach was made possible by the use of transrectal ultrasound. Use of five cryoprobes permitted accurate probe placement and monitoring. At our institution, we emphasize a urologist-radiologist team approach, preoperative hormonal therapy to decrease prostate volume and, we hope, to downstage tumors, and the use of thermocouples to monitor freezing temperatures. The use of thermocouples was initiated after we treated our first 47 patients.

Demonstration of the true efficacy of the modern cryoablative technique to treat prostate cancer awaits long-term studies. However, our available follow-up data provide sufficient information concerning the morbidity of the procedure. A current analysis includes all patients treated at Crittenton Hospital. Our first group of patients, who had a higher morbidity rate due to our learning curve, was not eliminated. Also, our study was of patient-reported complications rather than retrospective interpretations of patient records. The questionnaire used in this study is similar to that used initially by Fowler *et al.*⁵ and later by others.⁶⁻⁸ As Crook and associates⁸ have noted, "retrospective reviews are dependent on the diligence of the observer." We believe that the patient himself is best suited to assess the severity of his symptoms.

The current study appears to be similar to the previous studies summarized in Table I. Minor differences are apparent. The mean follow-up of our patients was shorter than that of the other studies. The shorter follow-up may permit both favorable and unfavorable biases. Although shorter follow-up may preclude reporting long-term complications, it has been our clinical experience that most patients experience gradual improvement of adverse symptoms with time. The longer follow-up of Jonler and associates⁷ could theoretically result in reporting more favorable results for patients treated by radiotherapy. Fourteen percent of pa-

tients in their study died before collection of the questionnaire; it is possible that these patients had more complications from their external beam irradiation than the living group who responded to the questionnaire. Additionally, because of longer follow-up, the death of some patients, comorbid diseases (such as Alzheimer's disease), and unknown addresses, only 98 (74%) of the 133 patients treated were actually included in the analysis.

The mean age of our patients, 5 to 6 years younger than in the other studies, may appear to represent a potential bias. However, a separate analysis demonstrated that the incontinence rate for patients was not related to age grouping by decade. Also, the studies by Fowler *et al.*,⁵ Jonler and associates,⁷ and Widmark and coworkers⁶ similarly did not find age to be related to incontinence. These studies suggest that the younger age of our patients probably did not introduce a substantial bias.

After cryoablation, 4.3% of our patients required incontinence pads. This rate compares favorably with the 31% after radical prostatectomy⁵ and the 19% to 2% after external beam irradiation (mean rate 11%) who required incontinence pads.⁶⁻⁸ The current study attempted to quantify the degree of incontinence by the number of pads used daily. Of the 9 patients using pads, 1 wore 3 to 5 pads daily and 8 used 1 pad daily. The number of pads used per day per patient was not noted in earlier studies. However, the earlier studies did try to quantify the degree of incontinence with the amount of urine lost. Only 2 (1%) of 208 patients treated by cryoablation noted the loss of more than a few drops of urine per day. After radical prostatectomy, 23% in the study by Fowler *et al.*⁵ reported dripping urine daily and usually more than a few drops. After external beam irradiation in the studies by Jonler *et al.*⁷ and Crook *et al.*,⁸ 8% to 13% of patients (mean rate 10%) lost more than a few drops of urine daily.

Bladder outlet obstruction caused by stricture and, in the case of cryoablation, prostatic urethral sloughing, was not uncommon. Among patients treated by radical prostatectomy, 20% required at least one surgical procedure to treat strictures and 11% required multiple procedures.⁵ Jonler *et al.*⁷ reported that after radiotherapy, 5% required dilation or surgery for stricture and 2% required multiple interventions. After cyroablation, 10% required at least one procedure and 5% required multiple procedures to treat bladder outlet obstruction.

It is our experience that prostatic urethral sloughing after cryoablation should be treated conservatively. It may take 3 to 12 months for the sloughed tissue to pass completely. Transurethral resection should be performed only after catheterization and a failed trial of voiding. During trans-

urethral resection, aggressive resection of necrotic tissue may result in fistula formation and/or incontinence. Resecting the floor of the prostatic fossa requires extreme care; the only viable tissue in this area may be the rectum itself. It is far better to perform multiple limited resections. Among patients who develop bladder neck contractures, we have found that neodymium:yttrium-aluminum-garnet laser urethrotomy using a contact laser tip is particularly useful.

The impotency rate after cryoablation of the prostate in our study appears to be similar to that noted for radical prostatectomy (85% versus 89%, respectively).⁵ Potency preservation after external beam irradiation appears to be superior to both cryotherapy and radical prostatectomy. After radiotherapy, impotency rates ranged between 16% and 35% (mean rate 29%).^{6,7} It has been our general experience that impotency rates have slowly increased as we became more aggressive in extending the iceball laterally outside the prostate in the attempt to treat possible extraprostatic disease.

Perhaps the most feared nonfatal complication after cryoablation is rectourethral fistula. In the present study, only 1 patient reported a fistula (0.4%). Since the data for this study have been collected, we have performed a total of 461 cryoablative procedures in patients without prior radiotherapy, and we have had a total of two fistulas (0.43%). Fowler's questionnaire to patients who underwent radical prostatectomy did not inquire about intestinal problems. A 1993 meta-analysis for prostate cancer reported a colostomy rate of 3%.¹⁴ However, most recent retrospective studies have shown that serious rectal injury requiring colostomy occurs very infrequently. Lerner and associates¹⁵ from the Mayo Clinic reported six rectal injuries in 1000 patients treated by radical prostatectomy, all were closed primarily, and no substantial morbidity was noted. After radiotherapy, moderate to severe longstanding intestinal side effects may occur in 17% to 29% of patients.⁶⁻⁸ Intestinal sequelae after irradiation may include bleeding, cramps, mucus, and fecal soiling.

CONCLUSIONS

At our institution, patient-reported complications for cyroablation compare favorably to those reported for radical prostatectomy and external beam irradiation. Urinary incontinence rates after cryoablation seem to be slightly lower than those reported after external beam irradiation and much lower than those after radical prostatectomy. Intestinal side effects of cryoablation appear to be similar to those of radical prostatectomy; both appear to be more favorable than the intestinal side effects caused by external beam irradiation. Both cryoab-

lation and radical prostatectomy result in very unfavorable impotency rates compared with external beam irradiation. Urinary tract obstruction is least common after external beam irradiation, intermediate after cryoablation, and most common after radical prostatectomy.

Traditional treatment modalities for prostate cancer have limited effectiveness. Approximately 55% of patients treated by radical prostatectomy have positive surgical margins and about 15% have clinically insignificant tumor volumes.¹⁶ Furthermore, 15% of patients with pathologically localized cancer based on the radical prostatectomy specimen have biochemical (prostate-specific antigen) failure by 10 years.¹⁷ Among patients treated by external beam irradiation, those with a pretreatment prostate-specific antigen level of 0 to 4 ng/mL, 4.1 to 10 ng/mL, and greater than 10 ng/mL have a 10-year biochemical failure rate of 41%, 82%, and 100%, respectively.¹⁸ Thus, it appears reasonable to investigate alternative treatment options. Although the patient-reported complication rates for cryoablation compare favorably to traditional treatment modalities, long-term efficacy studies will determine the ultimate role of cryotherapy in the treatment of prostate cancer.

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APPENDIX: QUESTIONNAIRE

Questions Regarding Postoperative Incontinence

1. Before you had cryosurgery,
 - 1a. Did you leak any urine? Yes___, No___.
 - 1b. If yes, how many pads did you wear daily? 0___, 1-2___, 3-5___, More than 5___.
2. After cryosurgery, some men find they have a problem with dripping or leaking urine. Did you have:
 - 2a. That problem to any degree either right after or at any time since? Yes___, No___.
 - 2b. Any additional surgery to help stop dripping or leaking? Yes___, No___.
 - 2c. Did you do the Kegel exercise? Yes___, No___.
 - 2d. Do you still have any problem at all with dripping or leaking? Yes___, No___.
3. Dripping or leaking urine can happen at different times. For example, in the past month have you:
 - 3a. Dripped or leaked urine when you coughed or sneezed? Yes___, No___.
 - 3b. Dripped or leaked urine when your bladder was full before you could get to the bathroom? Yes___, No___.
4. When you drip urine, about how much usually comes out? A few drops___, Less than a tablespoon___, More than a tablespoon___.
5. How often do you drip or leak urine? More than once a day___, About once a day___, Less than once a day___.
6. Some men wear pads, rubber pants, adult diapers, or a clamp to help with wetness.
 - 6a. Do you wear anything like that now? Yes___, No___.
 - 6b. If you wear pads, how many pads do you wear daily? 1-2___, 3-5___, more than 5___.

Questions Regarding Postoperative Sexual Function

7. Before you had cryosurgery,
 - 7a. Could you have sexual erections when you were stimulated? Yes___, No___.
 - 7b. Were your erections rigid enough for vaginal penetration? Yes___, No___.
 - 7c. For the 5 years immediately before you had cryosurgery, was the rigidity of your erections: Same___, Decreasing___.
8. Since your cryosurgery, have you had any full erections? Yes___, No___.
 - 8a. (If no) Have you been able to have any partial erections? Yes___, No___.
 - 8b. (If yes) Have you been able to have erections rigid enough for vaginal penetration? Yes___, No___.
9. Over the past month or so, how often have you had sexual erections when you were sexually stimulated in any way? Not at all___, A few times___, Fairly often___, Usually or always___.
10. Over the past month or so, when you had erections, how often were they firm enough to have intercourse? Not at all___, A few times___, Fairly often___, Usually or always___.
11. Since your cryosurgery, have you tried treatments of any kind to help your sexual function? Yes___, No___. If yes,
 - 11a. Did you try a vacuum erection device? Yes___, No___.
 - 11b. Did you try shots or penile injections? Yes___, No___.
 - 11c. Did you try implant surgery (penile prosthesis)? Yes___, No___.

Questions Regarding Postoperative Strictures/Tissue Sloughing/Fistula Formation/Pain

12. Problems after cryosurgery are strictures or sloughing of tissue. The scar tissue or sloughed tissue can make it hard to urinate. Since your cryosurgery, has a doctor had to dilate your urinary tract or perform any surgery to treat stricture or to remove sloughed tissue? Yes___, No___. If yes, how many times was that done? ___times.
13. One of the major complications after cryosurgery is fistula formation (connection between prostate and

rectum). Did you have this complication? Yes___, No___.
If no, skip to question 14.

- 13a. If it happened, how many months after cryosurgery did it develop?___ months.
- 13b. What was the treatment for this condition? Conservative treatment___, Surgical repair___ (what type? _____).
14. Other common complications:
 - 14a. Pelvic pain? Yes___, No___. If yes, for how long? ___months.
 - 14b. Scrotal swelling? Yes___, No___. If yes, for how long?___months.
 - 14c. Tingling sensation of penis? Yes___, No___. If yes, for how long?___months.

Questions Regarding the Presence of, or Follow-up Treatment for, Cancer

15. As far as you know, do you have cancer anywhere now? Yes___, No___.
 - 15a. Where do you have cancer? Prostate___, Bones___, Lymph node___, Other___ (please specify: _____).
16. Since your cryosurgery, have you had
 - 16a. Any pills or injections of estrogens or hormones for prostate cancer? Yes___, No___.
 - 16b. Surgery to remove the testes? Yes___, No___.
 - 16c. Radiation treatment? Yes___, No___.
 - 16d. Repeated cryosurgery? Yes___, No___.
17. If you do have a record of a recent PSA result performed at another facility, please let us know. Date of test ___/___/___, PSA result ___ng/mL.
18. Did you have any follow-up biopsies at another institution? Yes___, No___. If yes, please make every effort to send us a copy of the result.
19. Did you have any other treatment before cryosurgery at Crittenton Hospital such as transurethral resection of the prostate ___, radiation therapy___, another cryosurgery___, radical prostatectomy___?
20. If you were to choose treatment options for your cancer today, would you choose cryosurgery again? Yes___, No___.

Other complications: Please specify the nature and duration.

Thank you very much for your time and continued support.