Active surveillance failure for prostate cancer: does the delay in treatment increase the risk of urinary incontinence?

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Introduction: *Active surveillance for low risk prostate cancer has become an acceptable management strategy. However, a percentage of these patients in active surveillance move on to active treatment. Our aim was to examine urinary incontinence (UI) rates in men who move on to treatment from active surveillance and compare it to quoted rates in the literature. We examined the question that a potential delay in the treatment of prostate cancer in those on active surveillance may result in an increase in incontinence rates.*
Materials and methods: *From July 1992 to June 2009, 443 men at our institution entered into active surveillance for newly diagnosed prostate cancer. We reviewed their medical records and data was abstracted from physician-reported medical records. The mean age of the entire group was 64.1 years old (range 40-80). Their mean prostate-specific antigen (PSA) was 7.65 (range 0.21-36) and their mean Gleason score was 6.2 (range 4-8). Of these patients on active surveillance, 150/443 (33.3%) went on to active treatment. Median time to active treatment was 31.5 months (range 3-180 months). Only 5 patients went onto active treatment less than 1 year after starting active surveillance. Of these patients who went onto active treatment, 85 had radiation alone, 48 had a radical prostatectomy (RP), 7 had a RP and radiation, 7 had HIFU alone, 2 had focal ablation and 1 had HIFU followed by salvage RP. Of those undergoing radiation (92 patients), 66 had external beam and 26 had brachytherapy.*
Results: *Prior to active treatment 25/443 (5.6%) patients had UI documented in their history. Of those 25 patients only 3 went on to a RP and all had persistent UI after surgery. Two of the 25 patients went on to radiation therapy and their UI resolved. In the active treatment groups, after RP alone, 14/48 (29.2%) patients had new onset UI that persisted at a mean of 47.2 months (range 11-149 months) postoperatively. Of these 14 patients, 7 patients (14.6%) had significant leakage (> 1 pad/day). After radiation therapy alone 2/85(2.4%) had new onset persistent UI at 34 and 49 months post radiation. Only 1/7 (14.3%) patients that had high intensity focused ultrasound (HIFU) alone had persistent UI at 38 months after HIFU. Of the 7 patients that had both a RP and radiation, 2 had persistent significant UI at 49 and 153 months after surgery. One patient that had HIFU and a RP had persistent UI at 23 months post surgery. The 2 patients that had focal ablation were dry.*
Conclusions: *The UI rates in our cohort of active surveillance patients who move on to active treatment are similar to patients who undergo treatment immediately after prostate cancer is diagnosed as quoted in the literature. This suggests that active surveillance, as an initial mode of therapy, does not increase the risk of UI if active treatment occurs at a later date.*

Key Words: prostate cancer, active surveillance, urinary incontinence

Introduction

Active surveillance for low risk prostate cancer has become an acceptable management strategy since surgery and radiation have an adverse impact on quality of life.[1-3] Active surveillance involves close monitoring of patients with the initiation of curative treatment should there be any indication that the disease is progressing.[4] Urinary incontinence (UI) after treatment due to prostate cancer (radical prostatectomy (RP), radiation or high intensity focused ultrasound (HIFU)) can be devastating.

There is a wide range in the incidence of incontinence after RP, radiation and HIFU. Litwin et al found that

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TABLE 1. **Patient characteristics of active surveillance cohort (n = 443)**

Mean age	64.1 years old (range 40-80)
Mean PSA	7.65 (range 0.21-36)
Mean Gleason score	6.2 (range 6-8)
Mean PSA active treatment cohort (n = 150)	8.97 (range 0.43-48.2)
Mean Gleason score active treatment cohort (n = 150)	6.60 (range 6-9)

PSA = prostate-specific antigen

40% of patients had long term UI after RP though it was mild in most cases.[5] However, only 4% of patients complain of significant leakage requiring pads.[5] For external beam radiation 12%-23% of patients, depending on the dose of radiation, have UI.[6] Benoit et al found that 6.6% of patients undergoing brachytherapy have UI.[7] The prevalence of UI after HIFU ranges between 0.5%-15.4%.[8] The delay in treatment of prostate cancer in those men who fail active surveillance may result in a higher incidence of UI. Some reasons maybe the following. Delay in treatment may result in progression of the disease such that a more extensive/aggressive (non-nerve sparing) surgical procedure needs to be performed. Similarly, radiation or HIFU fields may need to be widened if a delay in treatment occurs. Furthermore, some patients may need combination therapies due to more aggressive disease. All of these have the potential to increase the incidence of UI.[9] Our aim was to examine UI rates in men who move on to prostate cancer treatment from active surveillance and compare it to quoted rates in the literature. Our hypothesis was that if active treatment was delayed, some patients may need more aggressive treatment or even combination therapy which may result in increased rates of UI. This paper is a descriptive report of the risk of incontinence in men who undergo active surveillance and then move on to active treatment.

Methods and materials

An ethics-approved-prospectively maintained database of all prostate biopsies performed at the Princess Margaret Hospital along with clinical records were used to construct a database of all men undergoing active surveillance. The criteria for men to enter active surveillance and progression at our institution has been documented previously.[10]

From July 1992 to June 2009, 443 men at our institution entered into active surveillance for newly diagnosed prostate cancer. We reviewed their medical records retrospectively and data was extracted from physician-reported medical records. Median time to active treatment was 31.5 months (range 3-180 months). Only 5 patients went onto active treatment less than 1 year after starting active surveillance. Specifically we looked at UI before and after treatment. UI was determined by documented history. Every patient was questioned about incontinence before and after initiating active surveillance and after they underwent active treatment at each follow up visit. Mild UI was considered to be 0-1 pads/day and significant UI was considered to be > 1 pad/day. The mean age of the entire group was 64.1 years (range 40-80). Their mean prostate-specific antigen (PSA) was 7.65 (range 0.21-36) and their mean Gleason score was 6.2 (range 4-8), Table 1. Of the patients on active surveillance, 150/443 (33.3%) went on to active treatment. Of these patients, 85 had radiation alone, 48 had a RP, 7 had a RP and radiation, 7 had HIFU alone, 2 had focal ablation and 1 had HIFU followed by RP, Figure 1. Of those undergoing radiation (92 patients), 66 had external

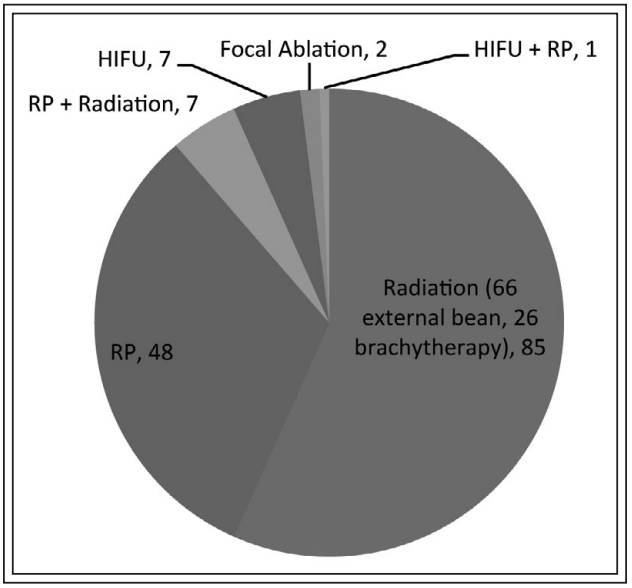

Figure 1. Active treatment (n = 150).

TABLE 2. **Incontinence prior to active treatment (n = 25)**

Treatment	Post treatment incontinence (number of patients)
Radical prostatectomy (n = 3)	3
Radiation (n = 2)	0

beam and 26 brachytherapy. Of those 150 patients who entered active treatment the mean PSA was 8.97 (range 0.43-48.2) and the mean Gleason score was 6.60 (range 6-9), Table 1.

Results

Prior to active treatment 25/443 (5.6%) patients had UI documented in their history. Of those 25 patients only 3 went on to a RP and all had persistent UI after surgery, Table 2. Two of 25 patients went on to radiation therapy and their UI resolved, Table 2. Of those patients that went onto active treatment (n = 150), after RP alone, 14/48 (29.2%) patients had new onset UI that persisted at a mean of 47.2 months (range 11-149 months) postoperatively, Table 3. Of these 14 patients, 7 patients (14.6%) had mild or minimal leakage (no pads or 1 pad/day) and 7 patients (14.6%) had significant leakage (> 1 pad/day). Of these 14 patients 6 had bilateral nerve sparing surgery, 3 had unilateral nerve sparing surgery, 2 non-nerve sparing surgery and in 3 it was unknown. After radiation therapy 2/85 (2.4%) had new onset persistent UI at 34 and 49 months post radiation. Only 1/7 (14.3%) patients that had HIFU alone had persistent significant UI at 38 months after HIFU. Of the 7 patients that had both RP and radiation, 2 had persistent significant UI at 49 and 153 months after surgery (one bilateral nerve sparing surgery and one unknown). One patient that had HIFU and a RP (non-nerve sparing surgery) had persistent UI at 23 months post surgery. The 2 patients that had focal ablation had no incontinence whatsoever documented.

Discussion

The overall prevalence of incontinence in the male population is 3%-11%.[11-15] Diokno and associates reported a 19% prevalence rate of incontinence in men older than 60 years of age.[16] Urge incontinence being the most common (40%-80%) with mixed incontinence (10%-30%) and stress incontinence (< 10%) being less common.[15-19] UI may be present before surgery (RP) and has been reported in 0%-21% of patients.[20-23] In our group of patients 5.6% (25 patients) had documented UI in their histories prior to any prostate cancer treatment. This is in keeping with above reports. Of these 25 patients, 3 underwent a RP and remained incontinent, while 2 underwent radiation and their UI resolved. It is unclear as to why those that had radiation had their incontinence resolve. It is possible that behavioral modification (less fluids, less caffeine or alcohol, timed voiding etc) or urethral stricture formation may have caused resolution of the incontinence. Goluboff et al showed no correlation between preoperative and postoperative incontinence.[20] In fact, McCammon et al reported that continence status improved postoperatively in a subset of patients with preoperative incontinence.[24]

Reported rates of incontinence range from 2%-57% after RP depending on the definition used.[25-29] Even higher rates have been reported. Rudy et al reported an 87% incidence of incontinence after RP.[30] However, this was only with a small number of patients at 1year postoperatively and many of these men had mild incontinence.[30] The incidence of incontinence has been reported after radiation and HIFU to be 6.6%-23% and 0.5%-15.4%, respectively.[6-8]

TABLE 3. **Incontinence post active treatment**

Treatment	Number of patients
Radical prostatectomy	14/48 (29.2%) (7/14 significant) (7/14 mild)
Radiation	2/18 (2.4%)
Radical prostatectomy and radiation	2/7 (29%)
HIFU	1/7 (14.3%)
HIFU and radical prostatectomy	1/1 (100%)
Focal ablation	0/2 (0%)

HIFU = high intensity focused ultrasound

After RP the distal urethral sphincter can be damaged by direct injury or injury to the nerve supply or supporting structures.[31] However, after RP, along with sphincteric dysfunction, there can be bladder dysfunction (26%-46%).[32-37] Bladder dysfunction is rarely the sole cause of incontinence after RP.[32-37] The cause of incontinence after radiation and HIFU is not exactly known but is likely related to sphincteric dysfunction and/or bladder dysfunction.[38]

The incidence of incontinence after combination therapy is not as clearly documented. Sia et al showed worsening of significant incontinence after radiation in those who had a RP, when radiation was given at a median of 14 months after surgery.[39] The incidence of postoperative incontinence after salvage RP in failed radiation patients has been reported as high as 44%.[44] In our series 7 patients had a RP followed by radiation and 2 had persistent incontinence. However, these are small numbers and hence conclusions cannot be drawn from this.

Studies have reported that patient age at surgery, stage of disease, surgical technique and preoperative continence status were risk factors for incontinence after RP.[31] A number of studies have shown that advancing age to be a risk factor for postoperative incontinence.[41-46] However, Steiner et al found no correlation between age and continence but they had a small number of patients 70 years or older.[47] Most large series have found no association between stage of disease and incontinence rates after RP.[43,44,48,49] However, in certain cases, the stage of the disease may affect surgical technique (e.g. advancing disease may negate a nerve sparing procedure) and rates may be higher. However, Eastham et al felt this may be related to surgical technique and not disease stage.[43] It is still unclear if there is any difference between those having a nerve sparing RP and non-nerve sparing RP. A number of authors feel that a nerve sparing RP does not provide better continence.[47,50,51] Other authors have shown the opposite outcome.[52,53] It has been suggested that more careful dissection around the sphincter required for the nerve-sparing technique is responsible for improved continence.[31] We also did not find any correlation between nerve-sparing RP and incontinence, as 6/14 had bilateral nerve-sparing surgery, 3 had unilateral nerve-sparing surgery, 2 non nerve-sparing surgery and 3 were unknown, although the numbers were small. In our series 29.2% of active surveillance patients who had a RP had any degree of incontinence with 14.6% having significant leakage (> 1pad/day). This is similar to patients who undergo immediate RP after diagnosis.[25-29] Similarly, 2.4% of patients in our series had de novo incontinence after radiation which is comparable to studies of patients undergoing immediate radiation therapy.[6,7] With HIFU alone and those that had combined RP and radiation who failed active surveillance their incontinence rates of 14.3% and 28.6%, respectively, are also comparable to documented incontinence rates in those patients who do not undergo active surveillance.[8,39] The concern is that ultimately delaying active treatment may result in an increasing age of the patient and advancing stage of the disease. As a result of this it may not be possible to perform a nerve-sparing procedure which may potentially increase the incidence of incontinence. Our results suggest that this does not hold true. Median time to active treatment was just over 2.5 years with only 5 patients moving onto active treatment less than 1 year after starting active surveillance. This is not an insignificant time interval for the disease to progress or advance thereby potentially increasing the incidence of incontinence. In our cohort of patients there appears to be no increased risk for worsening incontinence if active surveillance is selected initially and then patients move on to active treatment.

There are a number of limitations in our study. This was a retrospective chart review documenting incontinence. No questionnaires were used in regards to assessing incontinence after active treatment. Furthermore, as has been documented previously, physician reported incontinence rates are less then patient questionnaire reporting.[54,55] A lack of a control group, comparison to existing literature that has wide variations in outcomes and definitions of UI, physician reported outcomes without standardized questionnaires are the main limitations of this study. Lastly, the difference in incontinence rates between immediate active treatment and delayed active treatment after active surveillance may be subtle and require large numbers of patients with pre and post treatment validated questionnaires to document a significant difference. It is possible that a prolonged interval to reach the active treatment phase (i.e. > 2.5 years) may have shown different results. Nonetheless, delaying active treatment, at least in our patients, did not appear to result in excessive incontinence rates. In the future a prospective study with standardized questionnaires and a control group with at least a 2 year follow up after active treatment would give us optimal outcomes.

Conclusions

The UI rates in our cohort of active surveillance patients who move on to active treatment are similar to patients who undergo treatment immediately after prostate cancer is diagnosed as reported in the literature. Our results suggest that active surveillance, as an initial

mode of therapy, does not increase the risk of UI if active treatment occurs at a later date. Further studies with pre and post incontinence questionnaires and longer median intervals to active treatment are needed to confirm our findings. □

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EDITORIAL COMMENT

In this well-annotated cohort of patients on active surveillance for prostate cancer, one third eventually underwent treatment. Theoretically, delayed treatment may pose an increased risk of urinary incontinence compared to immediate treatment, potentially due to increasing age, multiple previous biopsies, more advanced cancer requiring multimodal therapy, or need for non-nerve sparing surgery.[1, 2] This study is suboptimal since it lacks a control group, uses non-standardized questionnaires, and has physician-reported outcomes. Nevertheless, it is reassuring urinary continence rates are consistent with previous reports of patients undergoing immediate treatment, suggesting that active surveillance does not compromise urinary continence among those patients subsequently requiring whole-gland treatment.

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