Changing management of localized prostate cancer: a comparison survey of Ontario radiation oncologists

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Background and purpose: *Annual genitourinary radiation oncology meetings aim to assist in the dissemination of knowledge that may affect current practice. We aim to measure changes in practice approaches that have occurred while these meetings have been conducted.*

Materials and methods: *A previously published survey from 2002 was sent to all genitourinary radiation oncologists in Ontario. Six prostate cancer patient scenarios were used: three definitive (low risk, intermediate risk, high risk), and three post-operative (extracapsular extension, margin positive, slowly rising PSA). There were 21 responders from seven cancer centers.*

Results: *Using biological equivalent dose (BED), there is significant dose escalation in 2005, particularly for intermediate risk patients (mean BED 73.0 Gy_2 in 2002 versus 76.1 Gy_2 in 2005, p=0.0003). There has been a corresponding move away from the use of neoadjuvant hormones in these patients (2002: 62% versus 2005: 24%, p=0.0097). More accurate prostate localization using fiducials is more common, leading to less use of rectal barium and urethrograms in the simulation process. In the definitive settings there is more utilization of rigid immobilization and more complex treatment delivery including intensity modulated radiotherapy. There is also greater use of multileaf collimation, electronic portal imaging and dose volume histograms in 2005 compared with 2002.*

Conclusions: *There have been significant changes in the way that prostate cancer is managed with radiotherapy in Ontario between 2002 and 2005. Dose escalation and more complex treatment planning is widely evident.*

Key Words: radiation oncology, physician's practice patterns, prostatic neoplasms, combined modality therapy

Introduction

The management of prostate cancer across a large geographic area introduces the potential for heterogeneous practice. Information disseminates from clinical trials and regional guidelines, which offers the potential to standardize practice to some degree. The evidence may not be adhered to for many reasons, which can include ongoing debate of result validity, changing trends and equipment availability.

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Ontario is the most populated province in Canada, with the 2001 census showing over 11.4 million people.[1] There are ten university-affiliated centers that deliver radiation therapy under an exclusively public healthcare system. An annual genitourinary radiation oncology retreat (GROR) aims to help disseminate clinical information and to maintain a consistent standard of practice across the province. Each year, before holding the GUOR, a needs assessment is performed, topics of interest determined, as well as an assessment of the overall interest level in continuing to hold the retreat.

A survey was performed in 2002, which reported a snapshot of the clinical management of prostate cancer in six common clinical scenarios.[2] Given the new evidence that has become available in the intervening years, we decided to repeat the survey in order to chart the evolution of the radiotherapeutic management of prostate cancer in Ontario.

Methods

The sixth annual GROR, financially supported by Sanofi-Aventis, was held in Huntsville, Ontario in October 2005. Prior to the retreat, the same survey that was distributed prior to the 2002 meeting was e-mailed to all eligible oncologists. Table 1 summarizes the scenarios. At the end of the manuscript we show the questions asked specifically for case 1. For the definitive scenarios, the Canadian consensus guidelines were used for risk stratification.[3] A summary is presented below.

1. Definitive: low risk
2. Definitive: intermediate risk
3. Definitive: high Risk
4. Post-operative: pT3a (extracapsular extension, but margin negative)
5. Post-operative: margin positive
6. Post-operative: rising PSA after 4 years

All scenarios were designed for curative intent

TABLE 1. **Scenario details**

Case	Details
1. Definitive: low-risk	70-year old Baseline PSA 8 ng/ml Gleason score 6/10 (3+3, 1/6 cores positive) cT1cN0M0
2. Definitive: intermediate-risk	65-year old Baseline PSA 15 ng/ml Gleason score 7/10 (3+4, 3/6 cores positive) cT2aN0M0
3. Definitive: high-risk	60-year old Baseline PSA 25 ng/ml Gleason score 8/10 (3+5,4/6 cores positive) cT3aN0M0
4. Post-prostatectomy: adjuvant margin negative	55-year old Baseline PSA 8 ng/ml, PSA nadir 0.2 ng/ml Gleason score 7/10 (3+4) pT3aN0M0 (margin negative)
5. Post-prostatectomy: adjuvant margin positive	57-year old Baseline PSA 8 ng/ml, PSA nadir 0.2 ng/ml Gleason score 7/10 (3+4) pT3aN0M0 (margin positive)
6. Post-prostatectomy: salvage rising PSA	58-year old Baseline PSA 8 ng/ml, PSA nadir 0.2 ng/ml PSA rise to 0.5 ng/ml over 4 years Gleason score 7/10 (3+4) pT2aN0M0 (close positive margin)

management, with the definitive settings reflecting single modality treatment with the prostate in situ. The survey was modified slightly to capture more information on treatment options, hormone delivery, and dose fractionation in different phases. A total of four reminders were sent out, and individual coordinators at each center were asked to encourage local participation.

Twenty-one completed surveys were returned out of 39 sent out, giving a response rate of 54% from 7 out of 10 centers in Ontario. This compared with 26 responses in 2002, also from seven centers. All of the original questionnaires from 2002 were obtained.

All data was entered into an Excel spreadsheet to generate descriptive statistics. Biological Equivalent Doses (BED) were calculated for all regimens to a dose of 2 Gy per fraction assuming an alpha/beta ratio for prostate cancer of 1.5.[4,5] Analysis of the data was performed on Excel. Figures in tables are given as a percentage, unless otherwise specified. Contingency tables had categories combined so no cell had a value of less than five, and were then analyzed using a Chi-square statistic. For hypothesis generation, a statistically significant p-value of 0.05 was used.

Results

Demographics

Table 2 gives background information on the respondents in 2002 and 2005. The vast majority of respondents had written guidelines available at their center. The majority had trained in Ontario, and had also performed a period of post-fellowship advanced training in any sub-specialty.

Investigations

For the definitive scenarios there is a significant trend for increased investigation of progressively higher risk scenarios ($p<0.0005$), but no difference between 2002 and 2005 ($p=0.76$). This is particularly marked for the imaging studies (CXR, CT and bone scan). For example, in 2005 the incidence of CT recommendation for low, intermediate and high-risk patients was 5%, 43% and 100% respectively.

Options

Table 3 shows the treatment options recommended in 2005 (this information was not available from 2002). Responders were allowed to select as many options as they thought appropriate. Note that low dose rate brachytherapy and watchful waiting are popular options for low risk disease only, with radical prostatectomy considered an option by around half of respondents for both low and intermediate risk disease. Mainly due to this, the median number of potential treatment options is highest in the low risk scenario (3), and progressively lower in the higher risk stratifications (2 for intermediate risk and 1 for high risk, ANOVA for comparisons of means $p<0.0001$).

For post-operative patients, a larger proportion of respondents would recommend external beam radiotherapy (EBRT) in 2005 than in 2002. This was most evident in the margin positive scenario, where 72% and 100% of respondents recommended EBRT as an option in 2002 and 2005 respectively (Chi-Square $p=0.031$).

TABLE 2 **Information on respondents**

	2002	2005	Chi-square
Responses	26 (70%)	21 (54%)	
Centers	7 (70%)	7 (70%)	
Residency			
Ontario	69	76	
Other	31	24	0.60
Fellowship			
Yes	62	71	
No	38	29	0.48
Years in practice			
<10	58	62	
>10.1	42	38	0.77
Proportion of practice treating prostate cancer			
<40%	31	43	
>40.1%	65	57	0.45
Written guidelines			
Yes	85	95	
No	15	5	0.24

TABLE 3 **Treatment options recommended in 2005**

	Low	Intermediate	High
Watchful waiting	81	0	0
LDR brachytherapy	86	0	0
EBRT	86	100	100
HDR boost	0	14	14
Radical prostatectomy	52	48	14

LDR=low dose rate; EBRT=external beam radiotherapy; HDR=high dose rate brachytherapy

Fields treated

Responders were asked to define if the seminal vesicles and whole pelvis would be treated in a multiphase technique.

If the whole pelvis radiotherapy (WPRT) was used, it was always to between 44 Gy and 46 Gy. The upper margin was variable, with the majority using either L5/S1 (43%) or the bottom of the sacroiliac joints (48%). The high-risk category saw 85% use in WPRT in 2002, and 100% in 2005. WPRT was only rarely used in the low risk, intermediate risk and post-operative scenarios in 2005(8%-15%).

The seminal vesicles were similarly more frequently included as a separate boost volume with increasing risk of the disease. If treated separately, they were boosted to a median dose of 56 Gy_2. Their frequency of inclusion in the two surveys ranged from 5%-12% for low risk disease to 35%-52% for high-risk disease.

Dose prescribed

Figure 1 shows the mean prescribed BED in each scenario in the definitive settings. There is significant dose escalation occurring for intermediate risk patients in both 2002 (ANOVA p=0.0098) and 2005 (ANOVA p<0.0001). There is also dose escalation occurring between 2002 and 2005 for both low (p=0.0397) and intermediate risk patients (p=0.0003), with a non-significant difference in the high-risk scenario (p=0.139). This is emphasized for the intermediate risk scenario by the minimum BED prescribed in 2005 (74 Gy) exceeding the mean BED (73.1 Gy) in 2002.

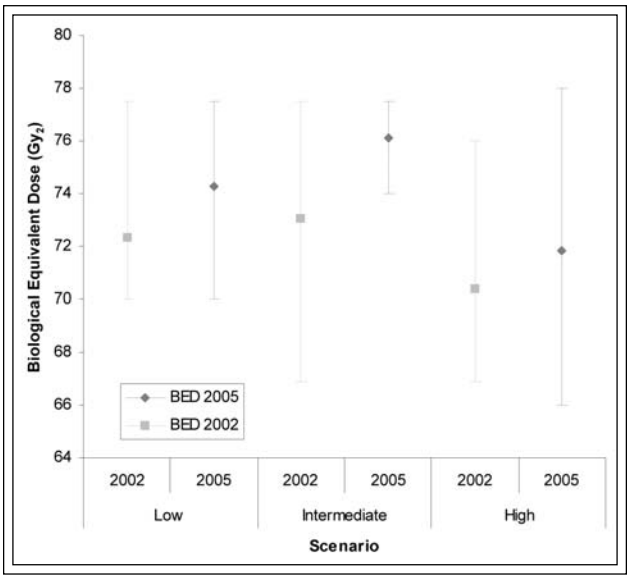

Figure 1. Mean prescribed BED for patients treated in the definitive scenarios with vertical bars indicating the range of responses.

In the post-operative setting median BED has remained essentially stable between 63 Gy-65 Gy.

Hormones

Neoadjuvant hormones for intermediate risk disease are less commonly recommended in 2005 (24%) than in 2002 (62%) (Chi Square p=0.0097). The duration ranged from 3-6 months (median 4 in 2002, 6 in 2005) in the form of a LHRH agonist, usually with an antiandrogen for a median of 1 month initially (range 1-6).

In high risk disease adjuvant hormonal deprivation using a LHRH agonist was uniformly recommended by all responders in 2002 and 2005 for a median of 36 months (range 24-36). This often included a neoadjuvant component (38% in both 2002 and 2005). Oral antiandrogens were frequently given at the commencement of LHRH agonist therapy for a median of 1 month (85% in 2002 and 76% in 2005). For both the low risk and post-operative scenarios, adjuvant hormones were rarely recommended in either 2002 or 2005 (range of 0%-9.5%).

Simulation

In the definitive scenarios, all would use CT simulation with the exception of one respondent treating the high-risk patient in 2002. Conventional simulation is much less frequent in 2005 (5%-9%) compared with 2002 (27%-50%) in the post-operative scenarios.

In the 2005 definitive scenarios, intraprostatic fiducials are more often used for prostate localization, especially in the intermediate risk setting (2002: 27%, 2005: 52%). Rectal barium and urethrograms are less popular in all scenarios. In particular, in the post-operative setting rectal barium use has gone from between 38%-63% in 2002, to zero in 2005.

For all scenarios in 2002 and 2005, supine positioning is by far the most popular, being used in between 81%-100% of responses. Rigid forms of immobilization (hip-fix, aquaplast, Vac-Loc and Alpha Cradle) are more frequently recommended in the 2005 definitive scenarios, especially in the intermediate risk cases (2002: 27%, 2005: 48%). Leg immobilization is generally the most popular method used, especially in the post-operative scenarios (37%-67%).

In all three definitive scenarios in 2002, 35% of respondents recommended the patient attend simulation and treatment with an empty rectum, with the remainder offering no instructions. This completely reversed in 2005, with 72%, 71% and 58% for low, intermediate and high-risk disease respectively instructing for an empty rectum.

There was great variety in bladder instructions, which varied little across scenarios or years.

Technique

It was more common for a DVH not to be performed in the post-operative setting (60%-100%) compared with the definitive setting (0%-38%). This difference was significant (t-test p=0.0002). Particularly noteworthy was that all respondents in 2005 would use a DVH in the intermediate risk scenario.

There was some consistency with rectal dose parameters recommended, with the majority of responders quoting a critical V70 of between 20%-30%. For bladder there was more heterogeneity, with a variety of parameters used:

- V60 <40%
- V70 <30%
- RTOG p0126
- V80 <15%, V65 <50%
- V75 <25%, V70 <35%, V65 <50%
- V55 <50%

In all three definitive scenarios in 2002, 31% would use greater than four-fields, none of whom were using IMRT. In 2005, greater than four fields were being used in 52%, 52% and 33% in the low, intermediate and high risk scenarios respectively. Furthermore, in 2005 the range of respondents using IMRT was from 14%-33% in these three scenarios. All post-operative beam arrangements were four-field.

For shielding, multileaf collimation (MLC) was recommended by all respondents in all scenarios in 2005. In 2002 MLCs were used by 85% in all three definitive scenarios, but between 50%-77% in the post-operative settings.

The frequency of film portal imaging decreased from a range of 73%-88% in 2002 to between 38%-50% in 2005, with a corresponding rise in electronic portal imaging use (paired t-test p=0.0003).

Discussion

Over the relatively short time period of 3 years, there have been definite shifts in the way survey responders would manage the presented scenarios. We must remember that this is only a sample of all genitourinary radiation oncologists in Ontario. However, given that responses were received from 70% of all centers, and that management is often shaped by the departmental resources and guidelines, we believe that this survey will reflect Ontario practice in 2005.

The challenge of affecting practice in a geographically disparate setting is large. The survey results, however, demonstrate not only that practice changes, but that it changes relatively consistently over a short time period. Part of the motivation of continuing to run the retreat is the potential for smaller and more isolated centers to help achieve this. In this era of rapidly advancing technology, oncologists who have being in long-term practice (between 38%-42% had been practice >10 years) need guidance and encouragement to implement changes. Workshops and retreats provide a forum for this type of continuing medical education activity.

Dose escalation is a significant trend shown by this survey. This is evident both for intermediate risk disease compared with the other definitive scenarios, but also compared with the 2002 responses both for low and intermediate risk scenarios. There have now been two fully published trials showing improved biochemical control with dose escalation.[6,7] Further confirmatory evidence has been presented in abstract form.[8] We should note that these trials all had doses of at least 78 Gy in the experimental arm, which is rarely approached in the Ontario surveys. Indeed, phase 2 evidence from Ontario shows that 75.6 Gy given in 42 fractions (BED 71.3 Gy_2) has only a 55% 5-year biochemical control rate.[9]

Concurrently with dose escalation, more sophisticated radiotherapy planning is in evidence in 2005 compared with 2002. More precise prostate localization with fiducials and CT simulation is matched with more rigid immobilization, complex plans (especially the utilization of IMRT), shielding with multileaf collimation and treatment verification using electronic portal imaging.[10-12] This has allowed greater confidence for dose escalation, which is a trend that should continue with wider availability and implementation of new technology.[13]

Neoadjuvant hormone deprivation was popular in 2002, largely based on data predating the dose escalation era.[14] The move away from neoadjuvant hormones in the intermediate risk scenario in 2005 suggests greater belief in the dose escalation evidence. Several of the 2005 respondents indicated that they would only prescribe hormones as a means of managing waiting time for radiotherapy. Newer evidence may sway this, such as the recently published TROG trial, although, once again, relatively low doses of radiation were used in this cohort.[15] Trials are currently ongoing to try to determine the impact of hormones in conjunction with dose-escalated radiotherapy.[16] Prolonged long course adjuvant hormone deprivation remains widely used for high risk disease based on level one evidence of a survival benefit.[17]

The post-operative setting has also seen some significant changes in practice approaches. EBRT is

now more commonly recommended, particularly in the margin positive scenario. Since 2002 the Bolla trial has been published, and the SWOG and German trials presented in abstract form.[18-20] Collectively they offer level one evidence to support the use of EBRT in the margin positive setting, with a biochemical control advantage compared with no adjuvant management.

Dose prescribed in the post-operative setting had a median of 63 Gy-65 Gy. This is in contradistinction to the Bolla trial which used a dose of 60 Gy. One reason for this may be the overall poor biochemical control rates post-operatively (particularly for a rising PSA), and dose escalation extrapolation from the definitive setting.[21] The ASTRO consensus statement recommends a dose of at least 64 Gy.[22] There is also debate on the use of adjuvant versus salvage radiotherapy.[23] The use of lower doses than in the definitive scenarios are associated with less sophisticated planning and treatment.

Many treatment options are recognized by radiation oncologists for low risk disease. It would be interesting to elicit the responses from a group of urologists across all scenarios, as there is likely to be some bias from the specialty concerned regarding the use of their own modality. Investigations continue to be titrated against the likely yield.[24]

Patient positioning is generally supine. There is a small randomized study which compared prone with supine positioning, and found that the former was more comfortable for the patients and resulted in less variability in prostate motion.[25] The diversity of bladder DVH parameters represents a general paucity of evidence. Variation in patient instructions was similar to that seen in the Australian survey.[26] Given the impact of rectal filling on prostate motion, the greater use of such instructions in 2005 may decrease interfraction organ motion.[27]

WPRT was popular in the high-risk scenario. WPRT was used in many randomized trials in the 1980s in both the control and experimental arms.[14,17] RTOG 9413 used a two by two randomization that included WPRT that seemed to initially confirm a biochemical control advantage for those at >15% calculated risk of nodal failure.[28] However, an update of this data shows a less convincing effect.[29] More sophisticated planning may allow dose escalation to nodes at risk, which may supercede the relatively low dose WPRT used in RTOG 94-13.[30] The effects of this ongoing debate on clinical practice remains to be seen.

Technology is now becoming available to administer image-guided radiotherapy (IGRT), with the potential for truly adaptive radiotherapy. The body of level one evidence also continues to grow, including the integration of multimodality treatment.[31] Given the significant changes in practice demonstrated over the last 3 years and momentum from the above factors, we look forward to repeating this survey in the years to come in order to track the evolution of the clinical management of prostate cancer with radiotherapy. □

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See next page for questions asked specifically for case 1

Questions asked specifically for case 1

A 70 year old male with an elevated prostate-specific antigen of 8 ng/ml has TRUS-guided sextant biopsy-proven adenocarcinoma of the prostate (1/6 cores positive for Gleason grade 6 (3+3)). Clinical examination does not demonstrate any detectable prostatic lesion. The remaining history and physical examination is non-contributory. Prostate size is 35 cc and voiding function is good.

1. Please indicate investigations (if any) that you would routinely obtain (check all that apply).
2. Assuming all investigations are negative and that the patient is to receive radiation therapy, please provide details of the hormonal and radiation treatment that you would routinely recommend.
3. Please describe the technical simulation and delivery process that you would utilize, assuming RT were recommended.

1. Preferred Treatment Options
- ☐ Watchful Waiting
- ☐ External Beam RT
- ☐ LDR Brachytherapy
- ☐ HDR Brachytherapy
- ☐ Radical Prostatectomy
- ☐ Hormone Therapy
- ☐ Other

2. Investigations

a) Hematology/biochem:
- ☐ CBC
- ☐ Repeat PSA
- ☐ Alkaline phosphatase
- ☐ Other Biochemistry eg LFT, Electrolytes, Renal

Other _____

b) Pathology:
- ☐ Pathology review

c) Imaging:
- ☐ Chest xray
- ☐ CT abdomen
- ☐ CT pelvis
- ☐ Abdominal ultrasound
- ☐ MRI pelvis
- ☐ MRI prostate
- ☐ MRS prostate
- ☐ Prostascint
- ☐ Bone scan

Other _____

d) Other tests: _____

3. Treatment Plan

a) Hormonal management:
- ☐ None
- ☐ LHRH agonist
- ___ months NeoAdj
- ___ months Adj
- ☐ Antiandrogen
- ___ months NeoAdj
- ___ months Adj

b) Radiation management:
- ☐ Whole Pelvis

Dose: ___ Gy in ___ fractions

Upper Margin: L5/S1 ☐
Bottom SI Joints ☐

Other _____ ☐
- ☐ Seminal Vesicles

Dose: ___ Gy in ___ fractions
- ☐ Prostate / Fossa

Dose: ___ Gy in ___ fractions

4. Simulation and Treatment

Simulation **Please Select** Immobilization **Please Select**

Prostate Localisation **Please Select**

Other: _____

Bladder Instructions **Please Select** Position **Please Select**

DVH
- ☐ None
- ☐ Prostate
- ☐ Normal Tissues

Dose Constraints (tick none, or please list maximum of 3 dosimetry constraints)

Rectum None ☐

_____
_____
_____

Bladder None ☐

_____
_____
_____

Femur None ☐

_____
_____

Rectum Instructions **Please Select** Field Arrangement **Please Select**

Other: _____

Shielding **Please Select** Treatment Verification **Please Select**