Results from a Canadian consensus forum of key controversial areas in the management of advanced prostate cancer: Recommendations for Canadian healthcare providers

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Abstract

Introduction: Rapid progress in diagnostics and therapeutics for the management of prostate cancer (PCa) has created areas where high-level evidence to guide practice is lacking. The Genitourinary Research Consortium (GURC) conducted its second Canadian consensus forum to address areas of controversy in the management of PCa and provide recommendations to guide treatment.

Methods: A panel of PCa specialists discussed topics related to the management of PCa. The core scientific committee finalized the design, questions, and analysis of the consensus results. Attendees then voted to indicate their management choice regarding each statement/topic. Questions for voting were adapted from the 2019 Advanced Prostate Cancer Consensus Conference. The thresholds for agreement were set at ≥75% for "consensus agreement," >50% for "near-consensus," and ≤50% for "no consensus."

Results: The panel was comprised of 29 PCa experts, including urologists (n=12), medical oncologists (n=12), and radiation oncologists (n=5). Voting took place for 65 predetermined questions and three ad hoc questions. Consensus was reached for 34 questions, spanning a variety of areas, including biochemical recurrence, treatment of metastatic castration-sensitive PCa, management of non-metastatic and metastatic castration-resistant PCa, bone health, and molecular profiling.

Conclusions: The consensus forum identified areas of consensus or near-consensus in more than half of the questions discussed. Areas of consensus typically aligned with available evidence, and areas of variability may indicate a lack of high-quality evidence and point to future opportunities for further research and education.

Introduction

Prostate cancer (PCa) is the most common type of cancer among Canadian men, accounting for 20% of all new cancer cases.[1] Five-year survival rates range from nearly 100% for localized to 30% for metastatic PCa,[2] and treatment and management strategies evolve considerably over the disease course.[3] Careful decision-making is required to choose between treatments that can be effective but carry adverse effects. Regular adaptation of clinical guidelines that incorporate recent evidence is important to support decision-making. Rapid development of therapeutics and diagnostics have introduced more options for treatment and management but have created areas lacking high-level evidence to guide decision-making.

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In 2018, the Genitourinary Research Consortium (GURC) conducted a consensus initiative to synthesize evidence and expert opinion to address areas of controversy in the management of PCa, and identified areas where additional research is needed.[4] Building off the success of the first consensus forum, the GURC recently conducted its second Canadian Consensus Forum (CCF). The aim of this initiative was to address controversial areas in the management of PCa patients, particularly in areas of limited evidence, to guide treatment practices.

Methods

This was a consensus forum to ascertain the extent of agreement for various aspects of the management and treatment of PCa in an expert panel of PCa specialists from Canadian academic institutions. The panel was a select group of multidisciplinary physicians who are members of the GURC.

A core scientific committee of eight physicians identified topics for discussion and developed questions adapted and updated from the 2019 Advanced Prostate Cancer Consensus Conference (APCCC) 2019,[5] which were then voted upon by the expert panel. Janssen authors did not participate in the consensus voting. Questions were administered in two formats: an online component (responses collected via the online platform, Qualtrics[6]), and a subsequent live virtual forum. Through a voting procedure, 65 questions were chosen for live voting and discussion, and 51 were subject to online voting prior to the forum by the expert panel. The forum took place on November 27, 2020. The predetermined thresholds were set at ≥75% for "consensus agreement," >50% for "near-consensus," and ≤50% for "no consensus," and were applied for both the live forum and online questions. All voting was analyzed descriptively as counts and percentages of total panel size. No hypothesis testing was performed.

Results

The expert panel included 29 PCa specialists, comprised of urologists (n=12, 41%), medical oncologists (n=12, 41%), and radiation oncologists (n=5, 17%), with geographic representation from Ontario (n=15, 52%), British Columbia and Alberta (n=8, 28%), and Quebec and Atlantic provinces (n=6, 21%). Areas of consensus and near-consensus from live voting are herein described. Further results from the forum and online questions are described in the online Appendices (available at *cuaj.ca*).

Questions from the live forum covered six topic areas, one of which was further split into subtopics:

1. Biochemical (i.e., prostate-specific antigen [PSA]) recurrence after local therapy
2. Treatment of newly diagnosed metastatic castration-sensitive PCa (mCSPC)
    a. Imaging modality to guide treatment
    b. Oligometastatic PCa (no prior systemic therapy for metastatic disease)
3. Management of non-metastatic CRPC (nmCRPC)
4. Management of metastatic CRPC (mCRPC)
5. Bone and bone metastases
6. Molecular characterization and genomic profiling: Tissue and blood

Voting took place for 65 predetermined questions and three ad hoc questions. Consensus was reached for 34 questions, with unanimous agreement on four questions (Table 1).

Reporting areas of consensus, simple majority, and variability

1. Biochemical recurrence after local therapy

Consensus was reached on which imaging modality participants most often use for patients with rising PSA after radical prostatectomy (RP), with 82% of physicians ordering conventional computed tomography (CT) and bone scintigraphy (± pelvic magnetic resonance imagining [MRI]). There was near-consensus (71%) that positive prostate-specific membrane antigen positron emission tomography (PSMA PET) findings should change the treatment and monitoring plan.

2. Treatment of newly diagnosed mCSPC

Patient stratification to guide initial systemic therapy

Almost all (90%) of physicians agreed high-/low-volume disease prognostic stratification is still needed to select patients for docetaxel use. There was 100% consensus that androgen receptor axis targeted agents (ARATs), apalutamide or enzalutamide, can be used in all-comer populations (i.e., not stratified by prognosis).

Preferred treatment for patients with low-volume disease

A number of recent clinical trials have investigated the addition of chemotherapy or ARATs to androgen deprivation therapy (ADT) for patients with mCSPC.[7-11] For de novo low-volume disease without symptoms from the primary tumor, 97% recommended an ARAT plus treatment of the prostate. Following relapse after local treatment, 100% recommended an ARAT. An ad hoc question asked whether metastasis-directed therapy (MDT) should be considered for patients with low-volume disease if they are experiencing bothersome side effects from their ARAT or systemic therapies, and 79% indicated they would consider MDT for a low-volume patient while acknowledging limited data and a need for further research.

For patients with de novo, high-volume mCSPC without symptoms from the primary tumor, near-consensus (59%) indicated an ARAT is preferred, while 41% indicated either an ARAT or docetaxel is acceptable. An ad hoc question

indicated 93% considered docetaxel an option for these patients, albeit not necessarily the preferred choice. Similar results were observed for patients with high-volume disease relapsing after local treatment of the prostate.

Limited role of docetaxel as up-front treatment prior to ARAT therapy

Just over three-quarters (76%) of panelists recommended against the use of docetaxel prior to ARAT in mCSPC, and 20.7% felt ARAT use should sequentially follow docetaxel (as per the TITAN[8] and ARCHES[12] trials) as opposed to combined therapy (as per the ENZAMET study).

Preferred treatment for high-volume/high-risk disease in patients with PSA <20 ng/mL

In mCSPC patients with de novo, high-volume and/or high-risk disease based on criteria from CHAARTED or LATITUDE, with a PSA value <20 ng/mL but no histopathological evidence of small cell carcinoma, docetaxel was the preferred treatment (86% agreement).

2a. Imaging modality to guide treatment

Nearly all participants (97%) ordered CT/bone scan to guide treatment for newly diagnosed, low-volume mCSPC. Most (83%) agreed with the need for additional imaging beyond just baseline and disease progression, such as at 6–12 months or the expected timing of a nadir response.

2b. Oligometastatic PCa (no prior systemic therapy for metastatic disease)

Definition of oligometastatic PCa to guide MDT

A number of different definitions of oligometastatic PCa exist in the literature.[13] The panel reached consensus that the most useful definition to guide MDT was "Limited bone and/or lymph node metastases, excluding visceral metastases," with 79% agreement. Some clinicians felt that PCa oligometastases also included patients with lung, but not liver, metastases.

Importance of distinguishing lymph node-only disease

For treatment decisions in untreated de novo oligometastatic PCa, 76% of the panel said it was important to distinguish lymph node-only disease from disease that includes metastatic lesions at other sites. However, 69% said it was not necessary to distinguish de novo oligometastatic PCa (synchronous) from a recurrent oligometastatic PCa patient (metachronous).

Treatment with ARAT together with treatment of the primary and use of MDT for all lesions

ARAT plus treatment of the primary tumor was preferred among 86% of physicians. The panel was also in consensus (86%) that they would not use (or only rarely consider) MDT *instead* of systemic therapy (ADT ± ARAT) in patients with oligometastatic prostate cancer. On further discussion, the panel felt that the more appropriate use of MDT was to *add* it to systemic therapy (ADT ± ARAT) in a minority of patients (59% of votes) or the majority of patients (14% of votes). Although most physicians did not recommend MDT as a primary therapy for mCSPC, 83% expressed that the treatment goal when adding MDT to systemic therapy is to prolong progression-free survival (PFS) and 86% felt there is "some" evidence that MDT confers benefit to ADT-free survival or PFS. These results generated much discussion and the closing comments focused on clarifying that the existing evidence for MDT resides in a different setting, the oligorecurrent setting, and further research is needed, especially with regards to the benefit of MDT for de novo oligometastatic disease.

Use of advanced imaging for patients without metastases on conventional imaging

Most (86%) panelists felt a positive PSMA PET result showing low-volume metastatic disease in a patient without metastases on conventional imaging would lead them to change their management strategy and treat the patient as having metastatic disease. However, consensus was not reached on whether management strategy should change if PSMA PET showed high-volume disease in patients who appeared to have low-volume disease on conventional imaging.

3. Management of non-metastatic CRPC (nmCRPC)

Imaging modality to use to distinguish nmCRPC from mCRPC

All participants agreed that CT and/or bone scintigraphy are sufficient to determine if patient is nmCRPC and to guide treatment decisions.

Timing of imaging in nmCRPC

Among asymptomatic nmCRPC patients on ADT with a PSA doubling time (PSADT) ≤10 months, 83% of physicians recommended imaging at a total PSA level >2 ng/mL; 72% agreed there may be a rationale to lower the PSA threshold to <2 ng/mL but further study is needed at these lower levels.

Treatment preference when PSADT ≤10 months

Ninety percent of the panel indicated they would recommend any of apalutamide, darolutamide, or enzalutamide, in addition to ADT. This aligns with the positive results seen in the SPARTAN,[14] PROSPER,[15] and ARAMIS[16] trials.

Sequencing ARAT to ARAT in nmCRPC to mCRPC

Ninety-three perecnt of participants would not recommend back-to-back ARAT sequencing for the majority of patients who progress from nmCRPC to mCRPC but most (86%) would recommend its use in a minority (i.e., ineligible or refuse other options). For this minority of patients for whom back-to-back sequencing could be recommended, most

(72%) respondents said they would recommend changing AR pathway treatment at occurrence of metastases alone.

4. Management of mCRPC

Waiting for progression beyond PSA progression alone to switch treatments

In the absence of other signs of progression, 79% of physicians did not recommend switching treatments at PSA progression alone.

Sequencing ARAT to ARAT in mCSPC to mCRPC

There was consensus agreement (79%) that back-to-back ARAT sequencing could be considered in a minority of patients (i.e., ineligible or refuse other options). Although not recommended for the majority of patients, when ARAT sequencing is used, the preference was abiraterone acetate + prednisone followed by enzalutamide.

Sequencing ARAT to ARAT in a minority of cases within the mCRPC setting

Ninety-three percent of panelists said there is a role for back-to-back ARAT sequencing within the mCRPC setting in a select minority of patients (ineligible for or refuse other options), for which 62% preferred abiraterone acetate + prednisone followed by enzalutamide.

Definition of oligoprogressive PCa

Most (76%) physicians agreed the most useful definition for oligoprogressive PCa was, "A limited number of progressing pre-existing or new lesion(s) in a patient with metastatic disease that is otherwise stable/treatment-responsive." When treating disease progression for oligoprogressive chemotherapy-naive mCRPC on a combination of ADT and ARAT, 65% said they would consider switching from the current ARAT to another systemic therapy but acknowledged the lack of evidence to support this.

5. Bone and bone metastases

Consensus was reached (86% agreement) on using denosumab or a bisphosphonate at the dose and schedule used for osteoporosis for patients with mCSPC starting on long-term ADT plus ARATs, and only for nmCRPC patients with an increased risk of fracture starting ADT plus ARATs, in order to prevent cancer treatment-induced bone loss (CTIBL) and fractures.

6. Molecular profiling

Testing for BRCA1/2 and other DNA repair gene alterations

Most (83%) participants recommended that the majority of PCa patients with metastatic disease get germline and somatic testing for BRCA1/2 and other relevant gene alterations. When asked which specialty should order genetic/genomic testing and lead treatment and management (including hereditary cancer referrals) for those with a positive result, 86% said all specialists with experience in genetic/genomic screening and treating PCa should be able to order and plan optimum treatment for patients with a positive result.

Relevance of BRCA1/2 aberrations in treating low-risk, localized PCa

In the presence of a BRCA1/2 germline aberration, 83% of physicians recommended radical therapy (either surgery or radiation) over surveillance in patients with low-risk, localized PCa.

PARP inhibitors (PARPis) for patients with BRCA1/2 (and other homologous recombination repair [HRR] gene)-mutated cancers

Most (97%) participants recommended that men with cancers with a pathogenic BRCA1/2 mutation (or other HRR gene mutation) and metastatic disease receive a PARPi during the course of their disease.

Preferred treatment for metastatic PCa with a pathogenic BRCA1/2 (or other HRR gene) aberration

Eighty-six percent of physicians recommended a PARPi or platinum therapy during disease course, when available, in patients with metastatic PCa with a pathogenic BRCA1/2 aberration (somatic and/or germline).

Discussion

To support clinical decision-making in the management of men with PCa, this consensus forum aimed to address areas of controversy by collecting and synthesizing expert opinion and develop recommendations.

In men with mCSPC, consensus aligned with evidence from the ARCHES,[12] ENZAMET,[17] and TITAN[8] trials showing the benefit of enzalutamide and apalutamide regardless of metastatic volume. Participants were unanimous in recommending that both agents could be used in an all-comer population, and were the preferred treatment choices following metastatic relapse in those that originally present with local disease only. Docetaxel and abiraterone acetate plus prednisone continued to be recommended for high-risk/high-volume patients (defined by the CHAARTED[7] and LATITUDE[10] trials), as supported by evidence from the STAMPEDE[9] trial. Recommendations for patients with BRCA 1/2-mutated cancers reflected the promising results for PARPis, such as olaparib, seen in the PROfound[18] trial. Lastly, recommendations across several clinical states indicated that current evidence does not inform fully on the value of PSMA PET when compared with the evidence for conventional standard imaging modalities.[11]

Voting results also indicated new trends in management and areas of consensus opinion despite a lack of level 1 evidence. For mCSPC patients, there was consensus or near-consensus that PCa treaters are moving away from chemotherapy in favor of ARAT for high-volume disease,

though chemotherapy was still considered an option. This was echoed for low-volume disease, where there was almost unanimous agreement that an ARAT plus ADT and treatment of the primary tumor was the recommended approach in patients with oligometastatic mCSPC with an untreated primary. This is a compelling message on an otherwise controversial issue, as there is no level 1 evidence that has directly assessed the addition of radiation therapy to the prostate primary with standard ARAT + ADT . Similarly, despite ongoing debate regarding an oligometastatic PCa definition to guide MDT, there was consensus agreement that "limited bone and/or lymph node metastases, excluding visceral metastases" was a useful definition; however, there was debate on whether patients with limited lung metastases could also be included in the oligometastatic group.

With some exceptions, questions for which voting did not reach consensus were often reflective of unclear evidence, though near-consensus was still achieved in some of these areas. There was near-consensus that de novo, synchronous, oligometastatic patients need not be distinguished from metachronous, oligometastatic patients in treatment decisions. A majority of panelists said they would recommend MDT in addition to systemic therapy in at least a minority of oligometastatic patients with no prior systemic treatment, but also highlighted that there is need for better clinical trial data to support that adding MDT extends PFS.

Voting also showed increased interest and advocacy for biomarker and genomic testing. The majority recommended tumor genomic testing, though there was some disagreement on when it should first be offered. Most agreed that larger panel testing, for example, homologous recombination deficiencies, mismatch repair evaluations, and tumor mutation burden, were all relevant to metastatic PCa. There was also agreement on an unmet need for biomarker testing for selecting potential responders to a second ARAT, at least in a minority of cases. That said, discussion highlighted that most do not have access to genomic testing outside of clinical trials, and further education and improved availability could produce stronger recommendations.

Compared to the results of the 2018 consensus forum, there were several noticeable shifts in expert opinion.[4] In nmCRPC patients, there was a shift to lowered thresholds for changing treatment, with near consensus agreement that treatment should be changed at occurrence of metastases alone, rather than waiting for multiple signs of progression. Similarly, for mCSPC, there was a trend towards more regular monitoring/imaging, rather than simply in response to PSA or clinical progression. The consensus on a definition of oligometastatic PCa for guiding MDT, mentioned previously, represents increased recommendation for treating oligometastatic patients relative to the 2018 forum. Lastly, there was increased confidence on recommendations for patients with BRCA1/2 and other HRR gene-mutated cancers, with physicians now routinely recommending PARPis for mCRPC patients and shifting away from the option of active surveillance in patients with localized disease.

This methodology has some limitations. First, the ability to make strong recommendations is dependent on available evidence, which can evolve rapidly. The recommendations derived from this initiative are based on the synthesis of expert opinion and the current state of evidence at the time of the forum; therefore, these recommendations may conflict with newer, incoming evidence, particularly in areas where recommendations were founded on lower level evidence. Second, although a multidisciplinary panel is useful for capturing expert opinion across clinical areas, certain questions may have had variable relevance across the panel. Similarly, opinions may have varied depending on the therapies and technologies to which each physician has access, and different interpretations of each question. However, a strength of the live forum was the opportunity for further clarification and discussion, and followup questions or re-voting.

Conclusions

The consensus recommendations provided from this forum represent an important initiative to identify and address controversial topics in the management of PCa patients in Canada. Consensus was reached for almost half of questions voted on at the live forum, and near-consensus was reached for an additional 25 questions. Areas of consensus mostly aligned with the available evidence, though consensus was still reached on topics where a need for further research was acknowledged. Areas of variability may highlight where high-quality evidence is lacking and point to future topics for further research.

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