Canadian consensus algorithm for erectile rehabilitation following prostate cancer treatment

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Abstract

Introduction: The present descriptive analysis carried out by a pan-Canadian panel of expert healthcare practitioners (HCPs) summarizes best practices for erectile rehabilitation following prostate cancer (PCa) treatment. This algorithm was designed to support an online sexual health and rehabilitation e-clinic (SHARe-Clinic), which provides biomedical guidance and supportive care to Canadian men recovering from PCa treatment. The implications of the algorithm may be used to inform clinical practice in community settings.

Methods: Men's sexual health experts convened for the TrueNTH Sexual Health and Rehabilitation Initiative Consensus Meeting to address concerns regarding erectile dysfunction (ED) therapy and management following treatment for PCa. The meeting brought together experts from across Canada for a discussion of current practices, latest evidence-based literature review, and patient interviews.

Results: An algorithm for ED treatment following PCa treatment is presented that accounts for treatment received (surgery or radiation), degree of nerve-sparing, and level of pro-erectile treatment invasiveness based on patient and partner values. This algorithm provides an approach from both a biomedical and psychosocial focus that is tailored to the patient/partner presentation. Regular sexual activity is recommended, and the importance of partner involvement in the treatment decision-making process is highlighted, including the management of partner sexual concerns.

Conclusions: The algorithm proposed by expert consensus considers important factors like the type of PCa treatment, the timeline of erectile recovery, and patient values, with the goal of becoming a nationwide standard for erectile rehabilitation following PCa treatment.

Introduction

Prostate cancer (PCa) is the second most frequent cancer found in men, accounting for 21% of the estimated new annual cancer cases.[1,2] A number of treatment options are available to patients with PCa, including active surveillance (AS), radiotherapy (RT), and radical prostatectomy (RP). Treatment options are chosen based on a number of factors, such as clinical stage, patient's age, and the presence of comorbid diseases in the patient.[3,4]

PCa treatments, regardless of modality, increase the likelihood of erectile dysfunction (ED).[5] Rates for ED lasting two years or more following RP range from 66–75%.[5,6] Similar results are reported in men following RT at three years (37–81%).[7] ED rates have been found to be 10- to 15-fold higher in men with PCa than their similarly aged peers.[8] ED is a significant threat to the quality of life of men diagnosed with PCa, as 60% of affected men experience severe distress from ED.[9-11] The loss of sexual activity and resultant challenge to masculinity have been shown to negatively affect quality of life.[12]

Currently, there remains a gap in the systematic and comprehensive care of sexual dysfunction after PCa treatment. This presents a significant barrier to continuity of care for PCa survivors across Canada. The TrueNTH SHARe Clinic was developed to provide sexual health support to men across Canada. The present manuscript incorporates research evidence, patient perspectives, and clinical expertise from experts in the field. To address the lack of consistency in care of sexual dysfunction after PCa treatment, a meeting was held. The TrueNTH Sexual Health and Rehabilitation Initiative Consensus Meeting was held with the purpose of developing an ED therapy algorithm following PCa treatment. The algorithm would be disseminated and used in the TrueNTH SHARe Clinic. The present manuscript describes the development of an ED therapy algorithm that uniquely

accounts for patient and partner values and goals for erectile recovery, type of PCa treatment, time since treatment, nerve-sparing status, and also includes thematic recommendations for psychosocial support

Methods

A pan-Canadian panel of men's sexual health experts convened for the TrueNTH Sexual Health and Rehabilitation Initiative Meeting to develop a consensus in managing ED in patients treated for localized PCa. The consensus panel meeting was held on October 31, 2016 in Toronto. A limited peer esteem snowballing technique (PEST) was used to identify expert opinion panellists based on research or clinical expertise in sexual dysfunction post-PCa treatment.[13] A 17-member expert opinion panel provided commentary on variation in ED treatment approaches through various programs and services across Canada. The group represented a wide range of backgrounds, including nursing, urology, urologic oncology, radiation oncology, psychology, psychiatry, and patient advocates.

The meeting involved several key decision-making components. Before the consensus meeting, all panelists reviewed the evidence-based medical literature on ED, particularly concerning physiology, pathophysiology, diagnosis, and treatment of ED following PCa treatment. The meeting began with a discussion of various cancer-related sexual health rehabilitation programs that exist across the country. Special attention was paid to patients' concerns about the current practice of ED therapy and management following PCa treatment, specifically the advantages and disadvantages of existing practices. Subsequently, the latest clinical guidelines on sexual rehabilitation after PCa treatment were reviewed and summarized.[14-16]

Patients' perspectives and feedback regarding gaps in current practice and desired practice were incorporated into the development of the TrueNTH SHARe Clinic algorithm. Possibilities for content and structure were outlined and discussed. Proposed strategies for the uptake of the algorithm to the medical community were also outlined.

Results

The TrueNTH Sexual Health and Rehabilitation Initiative Consensus Meeting established that a tailored, comprehensive ED therapy algorithm for patients (and their partners) after localized PCa treatment should recognize the following:

1. Real-life results are often more modest than reported in the literature.
2. Patients are overly optimistic about the likelihood that they will be in the minority of patients who do not experience ED and about the ease with which they will adapt to use of pro-erectile therapies.[17,18]
3. Poorly managed patient expectations can be demotivating in sustaining use of pro-erectile therapies.
4. While the best time to introduce erectile rehabilitation remains unclear, pre-PCa treatment psychoeducation on sexual dysfunction and available ED therapies is a necessity.[19-22]
5. Post-PCa treatment ED recovery typically occurs over a minimum of two (or more) years.[23]
6. Desired pace of return of ED function and willingness to engage in invasive treatment varies across patients and partners.[24,25]
7. Exclusive focus on achieving erections via any means may overlook the values or goals of patients and their partners.
8. The uptake and adherence to pro-erectile therapies is generally poor.[26-28]
9. Detailed education on the systematic use of pro-erectile therapies is often lacking in post-PCa sexual health care.[19]
10. Inclusion of the partner in the recovery process is optimal.[24,29-31]
11. The process of ED therapy re-challenging over the recovery period is necessary to achieve optimal erectile functioning and to manage perceived treatment failure.[32]
12. Maintaining regular sexual activity (penetrative or non-penetrative) during the course of erectile recovery is advantageous for individual's and couple's well-being.[33,34]

Algorithm

The algorithm for managing ED is illustrated in Table 1. The algorithm focuses on therapeutic strategies to erectile recovery, with psychosocial considerations at each stage of treatment. The focus of the algorithm is split based on patients' values or goals for erectile recovery. Further considerations are offered based on the cancer treatment (radiation or surgery), nerve-sparing status, preference for less invasive vs. more aggressive treatment approach, and inclination for a pharmaceutical vs. mechanical approach to pro-erectile therapy.

Section 1: Algorithm process

Patients will choose a management pathway (Table 1) based on the type of PCa treatment received (surgery or radiation), followed by the patients desired level of invasiveness (low or high), and the nerve-sparing status (bilateral nerve-sparing [BNS], unilateral nerve sparing [UNS], and non-nerve sparing [NNS]), and lastly if they prefer a pharmaceutical vs. mechanical approach to pro-erectile therapy**.** Thus, vacuum erection devices (VED) are available in each quadrant for a non-biomedical approach. The inflatable penile prosthesis is available for patients who are refractory to both biomedical

Table 1. Pro-erectile therapy algorithm

Patient preference		Low invasiveness			High invasiveness		
Patient goal		**Long-term penile health**			**Short-term erectile function**		
PCa treatment status		**BNS**	**UNS**	**NNS**	**BNS**	**UNS**	**NNS**
Surgery	Pharmaceutical approach	Daily and PRN full-dose PDE5i	PRN use of full-dose PDE5i	MUSE	ICI	ICI	ICI
	Mechanical approach	VED	VED	VED	VED	VED	VED
Radiation	Pharmaceutical approach	Daily and PRN full-dose PDE5i				ICI	
	Mechanical approach	VED				VED	

Baseline recommendation for all patients: Regular sexual activity (at least once a week). When applicable, patient's partners should be included in the treatment plan. BNS: bilateral nerve sparing; ICI: intracavernous injection; NNS: non-nerve sparing; PC: prostate cancer; PDE5i: phosphodiesterase type 5 inhibitors; UNS: unilateral nerve sparing; VED: vacuum erection devices.

and non-biomedical approaches, however, as this strategy is often reserved later in the treatment trajectory (beyond two years) to allow sufficient time for natural recovery and sufficient retrial with first-line treatments, it is not presented in the algorithm.[35] Patient preferences are also taken into account in terms of tolerance of degree of treatment invasiveness and the patient's goals for erectile recovery (articulated further below). In addition to the specific recommendations for pro-erectile therapy, patients are recommended to maintain regular sexual activity (at least weekly), whether penetrative or non-penetrative, and/or masturbation. Clinicians may also consider combination therapies if necessary, depending on the patient's desire to challenge ED over time.[36,37]

Section 2: Patient goals for erectile recovery and psychosocial considerations

As a supplemental document to the algorithm, Table 2 outlines patient values and goals for erectile rehabilitation and should be used as a resource to guide treatment planning. The panel agreed that there were essentially two pathways that the patient might choose. The primary goals of "long-term penile health" (i.e., optimizing changes for natural recovery of erections with a relatively non-invasive approach) vs. "short-term erectile function" were identified in the algorithm. Clinicians are encouraged to assess the patient's goals for outcomes, as this may change with time. Furthermore, partners may also wish to provide input into these goals.

Section 3: Benchmarking and normalization

In addition to the algorithm based on patient treatment and preference for ED rehabilitation (pharmaceutical vs. mechanical), the panel noted the importance of providing patients with a point of reference for their progress in terms of expected timeline of erectile function recovery. This attempt at typical response benchmarking is intended to help patients manage their expectations and normalize their recovery process. The panel determined that sufficient empirical evidence for typical response benchmarking was only available for the post-RP patient population (Table 3). More research is needed to determine the timeline for patients treated with RT.[38]

Discussion

Developing a treatment plan for ED after PCa involves balancing a number of factors, including different trajectories for radiation vs. surgical treatment, nerve-sparing status, and the degree of invasiveness of various pro-erectile therapies, along with determining patient and partner's goals for erectile recovery.[20-23] Other patient-related factors must all be considered to ensure that pro-erectile therapies are optimally successful, including patient expectations of pro-erectile therapy and timeline of recovery; the role of the partner in erectile recovery; and the patient's sexual beliefs, masculine values, possible grief in response to sexual losses, and potential performance anxiety.[39-41]

Sub-algorithms were proposed for each group of patients (e.g., those treated with radiation vs. surgery), as the panel recognized advantages to more accurately capture between-group differences, such as different trajectory of impact of PCa treatment on erectile function. Consensus on structures of the sub-algorithms was achieved; the structure would include consideration for timeline benchmarks, long-term penile health vs. short-term erectile function, as well as additional sexual concerns, all while integrating patient preferences.

Suggested timeline benchmarks for the sub-algorithms were 1–3, 6, 12, 18, and 24 months from baseline, for surgical outcomes only. The suggested benchmarks were based on historical practice adopted in clinical trials and the expected success rates of relevant treatment approaches. However, a significant limitation is the limited empirical evidence due to heterogeneity in treatment timelines and a low risk of external validity in clinical studies. Further discussion is required to establish outcome benchmarks for patients with a delayed response to treatment and also for patients receiving RT.

The sub-algorithm structure for penile rehabilitation (i.e., long-term care of penile health) was designed to focus on

Table 2. Timelines and patient goals for erectile recovery

Timeline	Long-term penile health	Short-term erectile function
Prior to treatment	– Treatment flow post-treatment focused on the patient's desire to maintain penile health over the long-term	– Treatment flow post-treatment focused on the patient's desire to achieve functional erections in the short-term
	Psychosocial focus: Normalize use of pro-erectile aids, education on timeline of recovery, and success with use of pro-erectile therapies exploring patient's goal for erectile recovery*	
6 weeks post-treatment	– PDE5i first-line; dosage daily vs. PRN – Include penile stimulation in treatment flow	– Include penile stimulation in treatment flow – If immediate erection is the goal, consider ICI therapy first-line, or possibly PDE5i full-dose if responsive
	Psychosocial focus: Importance of regular sexual activity (penetrative or non-penetrative), education on timeline of recovery, manage expectations for erectile recovery and success with use of pro-erectile therapies; encourage couples to maintain sexual intimacy (penetrative or non-penetrative)	
10 weeks post-treatment	– PDE5i first-line; dosage daily vs. PRN – Include penile stimulation in treatment flow	– Include penile stimulation in treatment flow – If immediate erection is the goal, consider ICI therapy first-line, or possibly PDE5i full-dose if responsive
	Psychosocial focus: Assessment and treatment of partner concerns, encouraging adherence to pro-erectile treatment plan; encourage couples to maintain sexual intimacy (penetrative or non-penetrative)	
4 months post-treatment	– For patients who do not respond initially to PDE5i, introduce ICI or MUSE or VED	– Depending on response to PDE5i, consider continued use of effective PDE5i or ICI or MUSE or VED
	Psychosocial focus: Recognition of grief response to sexual losses or performance anxiety, acknowledge impact on masculinity; encourage couples to maintain sexual intimacy (penetrative or non-penetrative)	
6 months post-treatment	– For patients who do not respond initially to PDE5i, introduce ICI or MUSE or VED	– Depending on response to PDE5i, consider continued use of effective PDE5i or ICI or MUSE or VED
	Psychosocial focus: Re-visit expectations and goals, and explore level of patient's bother due to ED; sexual desire and fantasy; encourage couples to maintain sexual intimacy (penetrative or non-penetrative)	
12 months post-treatment	– Re-challenge with PDE5i as needed – For patients who do not respond to PDE5i, introduce ICI or MUSE or VED	– Depending on response to PDE5i, consider continued use of effective PDE5i or ICI or MUSE or VED
	Psychosocial focus: Redefining sex life and building on success	
18 months post-treatment	– Re-challenge with PDE5i as needed – For patients who do not respond to PDE5i, introduce ICI or MUSE or VED	– Depending on response to PDE5i, consider continued use of effective PDE5i or ICI or MUSE or VED
	Psychosocial focus: Confirming goals and expectations	
24 months post-treatment	– Re-challenge with PDE5i as needed – For patients who do not respond to PDE5i, introduce ICI or MUSE or VED	– Depending on response to PDE5i, consider continued use of effective PDE5i or ICI or MUSE or VED
	Psychosocial focus: Long-term goal setting and management; adaptation and acceptance; satisfaction with pro-erectile therapy	

Consider time since treatment an expectation management. *Patient goals should be continually evaluated. ICI: intracavernous injection; PDE5i: phosphodiesterase type 5 inhibitors; VED: vacuum erection devices.

treatment flow, with emphasis placed on the patient's desire to engage in strategies that would promote penile health and improve capacity for natural return of erections with time. This sub-algorithm also considers the patient's tolerance of treatment invasiveness. Consistent with treatment guidelines, phosphodiesterase type 5 inhibitors (PDE5is) were identified as first-line treatment for ED post-RP with either daily or as-needed dosing.[35] Daily PDE5i dosing has been demonstrated to be an effective alternative to as-needed dosing in patients who had an incomplete response to therapy with maximum-dose as-required PDE5i.[42] If patient response to PDE5i is poor at three months, the introduction of intracavernous injection (ICI) treatment can be introduced as an option, with the possible retrial of PDE5i. Alternatively, treatment with VED can be used in place of ICI or PDE5i at any point in the recovery timeline, thus patient treatment preference should be prioritized to guide long-term clinical management.

In response to direct feedback from patients and clinicians on the panel, patient preference for expedient recovery of erections was identified as an alternative goal to long-term penile health. In this scenario, the short-term erectile function component of the algorithm should be followed (right column). The first increment of the treatment timeline should be 1–3 months. Patients motivated to achieve an erection immediately should initiate ICI therapy as first-line treatment. Otherwise, if treating with PDE5i, a higher dose is

Table 3. Timelines and benchmarks post-surgery

Timeline	Benchmarks using the Erectile Firmness Scale (1–10; 1=flaccid, 6=just hard enough to achieve penetration, 10=full erection)
Prior to treatment	Evaluate baseline erectile function (poorer function at baseline may require more aggressive approach)*
6 weeks post-treatment	1–3: Lack of natural sex function to be expected
10 weeks post-treatment	1–3: Lack of natural sex function to be expected
4 months post-treatment	1–4: Some early recovery of mild to moderate tumescence in <10% of patients
6 months post-treatment	2–6: Some early recovery of mild to moderate tumescence in <10% of patients
12 months post-treatment	3–7: 20–40% recover natural erectile function hard enough for penetration
18 months post-treatment	4–7: 20–40% recover natural erectile function hard enough for penetration
24 months post-treatment	5–8: 30–50% recover natural erectile function hard enough for penetration

Use of pro-erectile aids or devices encouraged at all time points. Consider time since treatment and expectation management. *Some men experience ED post-diagnosis/pre-treatment due to stress and anxiety. ED: erectile dysfunction.

recommended, with the possibility of combined treatment with ICI and/or VED.[36]

The following considerations were identified for inclusion in the content of the sub-algorithms: climacturia, dysorgasmia, alterations to penile anatomy, and reduced sexual desire. Other psychosexual factors that interact with patient preferences were considered for inclusion, such as the importance of sexual activity and intimacy, expectations for recovery with pro-erectile therapy, performance anxiety, and recognition of the impact of loss and grief. Important highlights included interventions to communicate the importance of persistence to therapy; these are required to ensure patients can realize the full benefits of clinical therapy. Psychosocial interventions are required to redefine a patient's sex life, integrate the sexual partner(s) when possible, and to focus on building on therapeutic gains.

Patients should be counselled about the likelihood of natural recovery of erections and timelines for recovery, including the significant role of baseline erectile function prior to PCa treatment. In fact, baseline erectile function may have even more influence on erectile recovery than use of pro-erectile therapies.[43] Age is also a major predictor, with younger men showing better natural erectile recovery;[23,44] the percent probability of erectile recovery by 24 months, for men who have full erections at baseline is 63% in men ≤60 years vs. 37% in men ≥65 years. In contrast, in men with recently diminished erectile function at baseline, the percent probability is lower at 48% in those ≤60 years vs. 26% in those ≥65 years, and even worse for men who had partial erectile function at baseline (35% in men ≤60 years vs. 18% in men ≥65 years). Rates in all categories increase slightly at 36 months.[23]

Additional insights from the literature should be considered when counselling patients about erectile recovery in order to promote adherence to and acceptance of the use of pro-erectile therapies. For example, in the general population, sustained use of PDE5i is better when prescribed with the knowledge and involvement of the patient's partner.[45] Given the overly optimistic mindset of patients about the probability of experiencing ED and the ease of treatments for ED, patients need adequate preparation before starting pro-erectile therapy. The algorithm was designed with the explicit purpose of being embedded in sexual health programming for PCa patients.[18]

The most common reason for discontinuation of PDE5i is lack of treatment efficacy (e.g., hardness of erection);[27] therefore, in a context when the need to re-challenge is the norm, patients need to be forewarned that PDE5i may not work for all patients immediately and that the likelihood of effectiveness increases the further out the patient is from surgery.[16,46] In the context of RT, the opposite effect is observed. Patients often do not understand that tactile stimulation is necessary to prompt an erectile response even with the use of PDE5i, and that spontaneous erections are unlikely.[47] Furthermore, patients should be informed that none of the pro-erectile therapies promote sexual desire or interest.

In addition, a variety of psychosocial factors are listed throughout the Table 2. Ideally, good erectile rehabilitation should be provided in a bio-psychosocial context. Where this is not possible, clinicians may wish to read the evidence-based literature for suggestions on enhancing the likelihood of successful sexual recovery.

The long-term goal is to use the treatment algorithms in the development of the web-based TrueNTH SHARe-Clinic. The opinion of the panel was that the application of a personalized clinical treatment tool with the TrueNTH SHARe-Clinic will improve treatment for ED in PCa patients by tailoring individualized therapies in a clinical environment that promotes patient participation in decision-making. The web-based clinic features tailored content, including personalized sexual health coaching, a multimodal virtual library, and symptom monitoring with feedback mechanisms. Thus, the TrueNTH SHARe-Clinic uniquely combines web-based sexual health counselling with an ED therapy algorithm designed to provide patients and their partners with accessible, personalized, post-PCa long-term sexual healthcare.

Conclusions

Because of the significantly high rate of ED after PCa treatment, it is critical to establish practices guidelines for the management of ED in this patient population. There exist a number of clinical guidelines to inform first-line through fourth- or fifth-line therapies, however, to date, none of these guidelines attempt to directly incorporate patient values into

the treatment decision-making process. Instead, they seem to focus on a linear progression of pro-erectile aids, from least invasive to most invasive. Ideal clinical management must be tailored to patient (and partner) preferences, including specific goals for erectile recovery. In addition, considerations from the diverse representation on our multidisciplinary panel highlighted the inclusion of patient experiences directly identified by patient advocates, as well as psychosocial recommendations to enhance patient and partner efficacy, acceptance, and compliance with pro-erectile aids. Furthermore, sensitivity to the discrepancies in trajectory of ED development after RT vs. RP need to be accommodated when making recommendations in order to maximize applicability. Further work is required to define subsequent clinical management benchmarks, particularly in the context of RT. The development of an algorithm that incorporates these many different facets should prove a novel and useful tool for clinicians wishing to support patient's erectile recovery after PCa treatment.

Competing interests: Dr. Elterman has been an advisory board and speakers' bureau member for Allergan, Astellas, Boston Scientific, Duchesnay, Ferring, Medtronic, and Pfizer; has received grants/honoraria from Boston Scientific and Pfizer; and has participated in clinical trials supported by Astellas, Boston Scientific, and Medtronic. Dr. Walker has received unrestricted educational grants from Abbvie and Astellas. Dr. Brock has been an advisory board member for Boston Scientific, Lilly, and Paladin; a speakers' bureau member for Astellas, Ferring, Lilly, and Pfizer; holds investments in Lilly and Pfizer; and has participated in clinical trials supported by Astellas and Ferring. Dr. Finelli has been an advisory board member for Abbvie, Astellas, Bayer, Ipsen, Janssen, Sanofi, and TerSera; and has participated in clinical trials supported by Astellas, Bayer, and Janssen. Dr. Gajewski has been an advisory board member for Astellas, Ferring, and Pfizer; and has received grants/honoraria from Laborie, Medtronic, and Pfizer. Dr. Jarvi has been a consultant for Lilly; received a grant from Allergan; and participated in a clinical trial supported by Allergan. Dr. Robinson has received grants from Abbvie and Astellas to support an ADT online program. The remaining authors report no competing personal or financial interests related to this work.

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