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Original Research

A Treatment Algorithm for High-Tone Pelvic Floor Dysfunction

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OBJECTIVE: To develop evidence- and consensus-based clinical practice guidelines for management of high-tone pelvic floor dysfunction (HTPFD). High-tone pelvic floor dysfunction is a neuromuscular disorder of the pelvic floor characterized by non-relaxing pelvic floor muscles, resulting in lower urinary tract and defecatory symptoms, sexual dysfunction, and pelvic pain. Despite affecting 80% of women with chronic pelvic pain, there are no uniformly accepted guidelines to direct the management of these patients.

METHODS: A Delphi method of consensus development was used, comprising three survey rounds administered anonymously via web-based platform (Qualtrics XM) to national experts in the field of HTPFD recruited through targeted invitation between September and December 2021. Eleven experts participated with backgrounds in urology, urogynecology, minimally invasive gynecology, and pelvic floor physical therapy (PFPT) participated. Panelists were asked to rate their agreement with rated evidence-based statements regarding HTPFD treatment. Statements reaching consensus were used to generate a consensus treatment algorithm.

RESULTS: A total of 31 statements were reviewed by group members at the first Delphi round with 10 statements reaching consensus. 28 statements were reposed in the second round with 17 reaching consensus. The putative algorithm met clinical consensus in the third round. There was universal agreement for PFPT as first-

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Botulinum toxin A is widely used clinically for pelvic floor muscle spasms; however, is not approved by the U.S. Food and Drug Administration for the treatment of high-tone pelvic floor dysfunction. This is disclosed in the article and described as off-label use.

Each author has confirmed compliance with the journal's requirements for authorship.

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line treatment for HTPFD. If satisfactory symptom improvement is reached with PFPT, the patient can be discharged with a home exercise program. If no improvement after PFPT, second-line options include trigger or tender point injections, vaginal muscle relaxants, and cognitive behavioral therapy, all of which can also be used in conjunction with PFPT. Onabotulinumtoxin A injections should be used as third line with symptom assessment after 2–4 weeks. There was universal agreement that sacral neuromodulation is fourth-line intervention. The largest identified barrier to care for these patients is access to PFPT. For patients who cannot access PFPT, experts recommend at-home, guided pelvic floor relaxation, self-massage with vaginal wands, and virtual PFPT visits.

CONCLUSION: A stepwise approach to the treatment of HTPFD is recommended, with patients often necessitating multiple lines of treatment either sequentially or in conjunction. However, PFPT should be offered first line.
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Chronic pelvic pain is estimated to affect one-quarter of women, costing more than $5.8 billion annually.[1,2] High-tone pelvic floor disorder (HTPFD), characterized by tight, weakened, and/or painful pelvic floor muscles, is present in 60–90% of women with chronic pelvic pain.[1,3,4] Muscle tension interferes with dynamic physiologic action, preventing appropriate pelvic floor coordination, contraction, and relaxation. High-tone pelvic floor dysfunction alone can cause pain and a wide range of genitourinary complaints, but can co-exist with other pelvic pain disorders. It frequently goes both unrecognized and untreated, contributing to poor outcomes.

High-tone pelvic floor dysfunction can be idiopathic or incited by poor toileting habits, visceral dysfunction (eg, endometriosis or interstitial cystitis or bladder pain syndrome), or musculoskeletal injuries (eg, sacroiliac joint dysfunction or hip osteoarthritis). Clinical identification of increased pelvic floor tone is subjective, relying on practitioner vaginal examination to identify hypertonicity pelvic floor muscles.[5,6]

Beyond the diagnosis, there is little guidance on treatment pathways. While multiple studies have examined potential treatments for HTPFD, there is considerable variability in peer-reviewed evidence quality. Head-to-head studies of therapeutic approaches are lacking, making it challenging for many clinicians to determine treatment progression. Insufficient clinical guidance often leaves patients unable to access effective treatment or make informed decisions.

In the absence of guidelines or level I evidence, we sought to generate a treatment algorithm using the Delphi method, a formal, systematic qualitative methodology,[7] to compile expert opinion statements supported by available literature pertinent to HTPFD.

METHODS

The HTPFD treatment consensus was developed using a modified Delphi process. After IRB approval (UCLA IRB#21–001399), we identified practitioners with expertise in HTPFD. Ten to 15 experts are the minimum number for Delphi methodology to yield sufficient results and ensure validity.[8,9] Experts were identified as either having significant peer reviewed publications or a large volume of patient-facing publications denoting a high-volume practice and contribution to the field. Once identified they were asked about their patient population to confirm a high-volume practice. As this is an area lacking in level 1 evidence, we wanted to include not only academic clinicians but also clinicians with a high level of experience with these patients. Initial screening identified 32 practitioners: either academic clinicians with publications on HTPFD or experts who had published patient-facing informational materials on HTPFD. Twenty-five practitioners confirmed that HTPFD comprised at least 20% of their patients; 11 of these specialists agreed to participate, reflecting geographic diversity and balanced representation of specialties.

Prior to initiating the Delphi process, the intended scope of the practice algorithm was outlined; experts were asked to review specific literature containing pertinent clinical trials and systematic reviews. Web-based software Qualtrics was used to administer confidential surveys to participants.

The Delphi method, an iterative process using a systematic progression of repeated voting rounds, is used to determine expert group consensus where little definitive evidence exists.[7] The process was conducted in three phases between September and December 2021 (Appendix 1, available online at http://links.lww.com/AOG/D592). To develop the initial statements, a literature review identified current evidence regarding options and efficacy of treatments for HTPFD. The authors identified the panel of literature. Experts were allowed to bring forth pertinent research topics/papers for further evaluation by the entire group. Relevant information regarding best practices was formulated by the study team into 31 statements for the Round 1 questionnaire. Survey questions used a 5-point Likert scale for participants to rate their level of agreement with questions.[10] Consensus was defined as 70% or more members agreeing (strongly agree or agree; or strongly disagree and disagree).[11,12] Statements that did not meet consensus

were revised and reposed to experts in the next round. New concepts presented by at least three individual experts were incorporated into subsequent rounds. All responses were anonymous. After the second round of questions, a provisional treatment pathway was developed by the study team, which was presented to experts in the third round, and qualitative and quantitative agreement was captured.

RESULTS

A total of three American Board of Urology-certified urogynecology and reconstructive pelvic surgeons, three American Board of Obstetrics and Gynecology-certified urogynecology and reconstructive pelvic surgeons, two minimally invasive gynecologists, and three American Board of Physical Therapy Specialties-certified Women's Clinical Health Specialists participated in this effort. Thirty-one statements were reviewed by HTPFD expert group members in the first Delphi round with 10 statements reaching consensus. 21 statements that did not reach consensus were reviewed and revised to clarify ambiguities (Appendix 2, available online at http://links.lww.com/AOG/D592). In total, 28 statements were included in the second Delphi survey, 17 of which reached consensus (Table 1). A treatment pathway (Fig. 1) was generated and evaluated by the group members in the third Delphi survey, which met clinical consensus.

Experts reached consensus that HTPFD treatment should be arranged into four tiers based on available data and perceived effectiveness and invasiveness of the therapy. Experts unanimously agreed that HTPFD patients should be referred to pelvic floor physical therapy (PFPT) and counseled on home-based symptomatic control measures, such as yoga or stretching exercises aimed at pelvic floor relaxation. At diagnosis, evaluation should rule out any extra-pelvic myofascial contributions, such as lower extremity joint or spinal pathology; if identified, a referral should be made to the appropriate specialists for concurrent management.

Unanimous consensus recommended PFPT be the first-line treatment for HTPFD. Pelvic floor physical therapy should be employed for at least 8–12 weeks; patients with a longer symptom history may require more sessions to experience improvement. Pelvic floor physical therapy is aimed at pelvic floor relaxation, not strengthening, employing techniques such as myofascial release and dry needling. Specific techniques (eg, biofeedback) may be employed at therapist's discretion and do not need to be specifically requested by the clinician.

Following initial treatment, women who improve with PFPT may continue therapy until the symptoms stabilize or resolve. After 4–6 months of stable symptoms, patients may then be discharged with self-management techniques for symptom maintenance and treatment of minor flares. The goal of PFPT is to facilitate initial improvements and provide sufficient training to allow patients to manage symptoms and minor flares themselves. Experts agreed second-line therapies, such as tender point injection (TPI) and vaginal suppositories, can be added to PFPT in patients whose progress has plateaued without sufficient improvement or who are not able to tolerate therapy.

Diazepam, the most prescribed vaginal suppository, serves to relax pelvic floor muscles, however other viable options include baclofen, cyclobenzaprine and tizanidine. Vaginal administration was preferred by experts over oral administration.

A myofascial trigger point is a tender nodule within a taught muscle band, and is increasingly referred to as a tender point with increased tone.[13] Tender points often accompany HTPFD; however, not all hypertonic muscles have tender points. Thus, tender point injection (TPI) is most useful for patients with identifiable tender points. To identify an appropriate injection site, pelvic floor muscles are palpated perpendicular to fiber orientation for a taut band. The taut band is then palpated within its fiber direction for the most tender spot reproducing pain. Local anesthetic is injected at this site. Consensus was reached that plain local anesthetic (eg, 0.25–0.5% bupivacaine) without steroid should be used. This is helpful for patients who cannot tolerate PFPT due to high pain levels or who have plateaued with PFPT. The goal of TPI is to downregulate the guarding reflex, allowing for further relaxation of the muscle. While response to TPI can be a good prognostic sign, if a patient does not respond to an initial injection, repeated injections are not warranted. There was no consensus on the use of anesthesia with TPI.

Cognitive behavioral therapy (CBT) has been associated with clinically meaningful improvements in pain and psychosexual function in patients with vestibulodynia and other chronic pain conditions, supporting its use in HTPFD.[14,15]

Experts reached consensus that injection with onabotulinumtoxinA (BTXA) is helpful for women with refractory myofascial pelvic pain and can be considered as a third-line option for women who have been minimally responsive to other therapies. While BTXA is FDA-indicated for multiple other forms of muscle spasm, its use in HTPFD is off-label. Experts determined BTXA injections should be targeted at myofascial sources of hypertonicity or pain, not

Table 1. Statements That Met Consensus

Statement	No. (%) Agreement (n=11)
Pelvic Floor Physical Therapy	
Pelvic floor physical therapy should be tried for 8–12 weeks before reassessment. Optimal treatment schedule would be 1–2 sessions per week for at least 8 weeks, ideally 12 weeks	11 (100)
Women with improvement and stabilization on PFPT should be discharged with a home exercise program to maintain improvement	11 (100)
Women with improvement and stabilization on PFPT should be discharged with a home exercise program and follow up with MD or APP after 4–6 months to check for sustained response	8 (73)
There was a mixed response on the role of biofeedback. Some believe it is considered a standard part of pelvic floor physical therapy and some feel it should be requested specifically by the clinician. There are promising studies to support biofeedback's utility in HTPFD. The literature presents evidence for the efficacy and effectiveness of pelvic floor muscle training performed together with adjunctive therapies (biofeedback, vaginal cones, electrical stimulation) as being greater than pelvic floor exercises performed alone (or using behavioral therapy alone). Pelvic floor muscle surface electromyographic biofeedback does NOT need to be specifically requested by the clinician for patients with HTPFD.	10 (91)
Pelvic floor muscle surface electromyographic biofeedback should be performed at the discretion of the physical therapist and does not need to be called out specifically in the HPTFD treatment algorithm	11 (100)
OnabotulinumtoxinA	
Injection of onabotulinumtoxinA into hypertonic pelvic floor muscles should be used in conjunction to PFPT in women who do not achieve adequate improvement with PT alone	8 (73)
When using onabotulinumtoxinA in the pelvic floor, should a standard template injection or a targeted injection at hypertonic muscles be used? Targeted	9 (82)
Should injections of onabotulinumtoxinA be performed unilateral or bilateral? Bilateral	8 (73)
If no improvement with onabotulinumtoxinA after how many sessions do you move on to another therapy? 1-2	10 (91)
There was a wide variation in the amount of botuliumtoxin per muscle group used from 10 to 50 units per muscle group. Units per muscle group depends on how many muscle groups are being targeted but is somewhere between 10 and 40 units per muscle group not to exceed 360 units in 3 months	8 (73)
Vaginal Muscle Relaxants	
Vaginal administration of benzodiazepines, such as diazepam, may reduce pelvic floor muscle tone. Although individual response is variable, it is worth a trial given low risk and invasiveness of therapy	8 (73)
Studies have shown that vaginally administered diazepam results in lower peak serum plasma concentrations, and longer half-life, resulting in fewer side effects. Thus, vaginal administration is preferred over oral administration	8 (73)
Which of the following vaginal muscle relaxants do you use? Diazepam	8 (73)
Cognitive Behavioral Therapy	
80% of respondents believed that psychological counseling or CBT should be offered at some point in the treatment algorithm. Do you feel patients should be offered CBT or psychological counseling as part of the initial assessment after diagnosis of HTPFD is made, OR should it be a second-line option if no improvement is made with PFPT. Second line	8 (73)
Tender Point Injections (TPI)	
There was a mixed response on the use of pudendal blocks in HTPFD. Respondents felt that pudendal blocks should only be used if there are signs of pudendal neuralgia or as a diagnostic tool to see if the process is peripheral or sympathetically maintained. Others felt this is to treat a different pathophysiology that HTPFD. Pudendal blocks do not have role in pure high-tone pelvic floor dysfunction	8 (73)
Sacral Neuromodulation	
There was a mixed response to the use of sacral neuromodulation (SNM) for HTPFD. 60% of respondents believed it should be included in the treatment algorithm in some capacity however due to the invasiveness of the procedure it should be reserved as a "last resort" option, after trial of less invasive options. Studies have shown the utility of SNM in patients with chronic pelvic or bladder pain with improvement in pelvic pain and urgency with 80% satisfaction (Marinkovic et al[28]). The goal of SNM is to target LUT symptoms as well as pelvic pain. Do you agree with the use of SNM as a fourth-line option for HTPFD after other options have been tried?	9 (82)

(*continued*)

Table 1. Statements That Met Consensus (*continued*)

Statement	No. (%) Agreement (n=11)
Therapies Not to Include	
Home therapies such as stretching, heating pads and yoga should be used as first-line therapy for HTPFD.	9 (82) disagreement
At home TENS units can be considered as an alternative to PFPT for treatment of HTPFD.	10 (91) disagreement
Order of therapy	
Pelvic floor physical therapy should be first-line therapy for high-tone pelvic floor dysfunction	11 (100)
Vaginal muscle relaxants, TPI, and BTX-A should all be considered second-line therapies	8 (73)
Second-line treatment options for HTPFD should include (choose 3) vaginal muscle relaxants, TPIs	8 (73)
Third-line treatment options for HTPFD should include (choose 3) BTX-A	8 (73)
Fourth-line treatment options for HTPFD should include (choose 3) sacral neuromodulation	8 (73)
Based on consensus opinions determined from questionnaire 1, the treatment algorithm should include PFPT as first-line option	9 (82)

administered in a single template fashion. Bilateral injection is preferred over unilateral. Repeat injection is not recommended if there is no response to the first injection.

Experts anecdotally reported that patients with co-existing HTPFD who underwent sacral neuromodulation (SNM) for urinary urgency and frequency may report improvement in pelvic pain. Use of SNM primarily for HTPFD would be off-label use; therefore, experts felt it should only be used in patients with co-existing urinary urgency and frequency, and HTPFD refractory to other therapies, with thorough counseling of expectations and indications.

DISCUSSION

This paper describes an expert-derived treatment algorithm for HTPFD. While the first-line option of PFPT easily met consensus among our panel of national experts, specifics regarding technique and dosing of second- and third-line therapies did not meet consensus due to poor quality evidence and heterogeneity in practice patterns, highlighting the need for further research to improve HTPFD care.

While PFPT has the highest-quality supporting data, there are challenges in its application. Most patients cannot identify an appropriate physician, experience long waits, or undergo inadequate or inappropriate treatment. Finding a skilled pactitioner is challenging; less experienced therapists may focus on muscle strengthening, which exacerbates HTPFD.[16] Uptake and attendance with prescribed PFPT for HTPFD is poor (15–40%).[17,18] Even when delivered by well-trained personnel, PFPT is only effective for two-thirds of patients.[5] In addition, patients need to be physically and cognitively intact to participate. These barriers to starting and completing PFPT make having alternative therapeutic options important.[19]

Despite limited guidance regarding formulation, dose, and administration, intravaginal diazepam is commonly used off-label for HTPFD management.[20,21] Adapted from oral dosing, experts felt a starting dose of 5–10 mg vaginally was appropriate (Appendix 3, available online at http://links.lww.com/AOG/D592). Vaginally-administered diazepam results in lower peak serum plasma concentrations, longer half-life, and fewer side effects, supporting the recommendation for vaginal over oral administration.[21,22] As there are no commercial vaginal diazepam formulations, and compounded medications are typically not covered by insurance, this treatment can be financially challenging. As the absorption of oral tablets placed vaginally is poor, resulting in reduced therapeutic benefit, it was not felt to be an acceptable alternative.[23] Until insurance coverage improves for compounded vaginal preparations, this therapy is not universally accessible.

Psychosocial factors play a significant role in chronic pain, dictating severity and prognosis. Comorbid depression and anxiety among women with chronic pelvic pain can reach 66%.[24] In addition, central sensitization, amplification of central nervous system responses to peripheral inputs, may also occur in patients with chronic pain. These factors highlight how CBT is an acceptable treatment option for pain due to HTPFD and pain-related depression and anxiety.

Clinically significant reductions in pain score and resting muscle tone are observed after pelvic floor BTXA injection across studies, although there is wide variability in dose, number of injection sites, and method of injection.[25] For example, experts indicated injections should be bilateral and targeted to hypertonic muscles using 10–40 units per muscle group. However, there remain unanswered questions regarding optimal injection technique, identification of injection sites, and injection amount; larger randomized



Fig. 1. Treatment algorithm for high tone pelvic floor dysfunction. The consensus statements regarding treatment approaches for high tone pelvic floor dysfunction were organized into an algorithm with levels of treatment ranging from least invasive and most evidence-based to more invasive approaches with weaker supporting evidence. Treatment approaches that did not reach expert consensus were not included in the final treatment algorithm. Behavioral interventions include timed voiding, urge suppression, and dietary modifications for bowel and bladder symptoms. GI, gastrointestinal; PMR, physical medicine and rehabilitation; PT, physical therapy; PFPT, pelvic floor physical therapy; Dx, diagnosis; HTPF, high-tone pelvic floor.

Torosis. Treatment Algorithm for High-Tone Pelvic Floor Dysfunction. Obstet Gynecol 2024.

controlled trials are needed before definitive recommendations on BTXA can be made.

As evidenced by efficacy in patients with Fowler's syndrome, SNM's therapeutic effect in HTPFD is hypothesized to be related to reviving brainstem autoregulation and resetting pelvic floor function.[26] SNM improves pain scores between 35% and 52% in patients with non-interstitial cystitis or bladder pain syndrome chronic pelvic pain, including those with HTPFD.[27] While the expert panel did not feel SNM should be used in patients without co-existing urinary or fecal urgency and frequency, data suggest there may be a benefit of SNM for HTPFD and further research is needed.

The strength of this novel consensus algorithm for the treatment of HTPFD derives from broad experiences of an expert panel with diverse medical specialties and geographic locations. However, this algorithm provides only limited guidance on the application of the therapeutics beyond PFPT due to poor quality evidence. Even retrospective studies on an HTPFD population are limited by the lack of specific ICD10 diagnostic codes. Without wider recognition of this condition, improvements in the diagnosis and treatments will continue to stagnate.

With this expert-driven treatment algorithm, patients can now progress systematically through treatment, allowing for further studies on therapeutic efficacy. In turn, this algorithm can be revised as research develops.

In summary, a diverse group of experts generated a consensus treatment pathway for HTPFD supported by available literature according to rigorous criteria. With clearer treatment recommendations, health care professionals can better guide patients improving awareness, outcomes, and satisfaction with care.

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