Clinical Case Discussion

What is the Best Treatment Option for Coexisting Pelvic Floor Dysfunctions?

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1. Background

In the presented case, a 27-yr-old woman was referred with very strong urgency and frequency (15 times/d) and imperative micturition but no incontinence. She had deep dyspareunia and pain in the lower abdomen. Micturition relieved the pain for only 5 min. Clinical examination revealed tenderness of the lower abdomen, hypertonic pelvic floor, and vaginal and rectal pain. Neurologic evaluation was normal. All laboratory and computed tomography investigations were normal. Office cystoscopy showed normal results although the introduction of the scope was painful. An urodynamic test was performed only at baseline and showed small bladder capacity and detrusor overactivity (DO). She was first treated with physiotherapy and medical therapy, namely Nitrofurantoin, Diclofenac, Oxycodone, Oxybutynin, Amitriptyline, without improvement. However, pain symptoms disappeared overtime, while urgency persisted. According to clinical characteristics and test findings, the patient was diagnosed with idiopathic overactive bladder syndrome/bladder pain syndrome (OAB/BPS). She was first treated with sacral neuromodulation (SNM) without any improvement. Therefore, she was then submitted to intravesical onabotulinumtoxinA (BoNT-A) injections. The patient had a good response after BoNT-A; however, catheterization was necessary for bladder emptying, and the patient had to repeat the injections every year. This raises the question: what is the best treatment option for coexisting pelvic floor dysfunctions?

2. Discussion

The authors present an interesting case of a young lady with a symptom complex that lies in between OAB and BPS. This is an entity that we often encounter in clinical practice and is often difficult to approach: which symptom complex shall we tackle first or shall we tackle both? Unfortunately, we lack a clear and systematic view of the therapeutic algorithm used for this patient. With a primary working diagnosis of idiopathic DO and OAB symptoms, it is remarkable that no trial of antimuscarinics was performed. Instead, antiseptics, various pain killers, including amitriptyline, and pelvic floor relaxation therapy were initiated, all of them implicating a primary working diagnosis of pelvic/BPS.

BPS is characterized by pain referred to the urinary bladder and associated with other urinary symptoms, such as pain with full bladder and urgency/frequency in the absence of proven urinary infection or other obvious pathologies. Frequency in BPS more likely results from fear of pain; however, about 54% of patients showed persistent frequency even though pelvic pain improved after conventional therapy [1]. In this particular case, the clinicians diagnosed BPS and OAB, "two sides of the same coin". However the authors lacked in providing tests, validated questionnaires, or pain scale results, at baseline and during follow-up, assessing symptoms and their severity. Most likely, the presence of suprapubic pain improving after micturition, the absence of leakage and the lower abdomi-

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nal tenderness, and rectal and vaginal pain may have led to a BPS diagnosis, but we lack the description of cystoscopic findings. Moreover, hydrodistension with bladder biopsy could have clarified the diagnosis. Of note, we also lacked an urodynamic evaluation after BoNT-A.

There is no standardized treatment regimen for BPS. The current treatments are usually performed in a stepwise approach including physiotherapy, oral medications, endourological procedures (intravesical instillations, hydrodistention, laser fulguration, and BoNT-A injections), neuromodulation, and cystectomy.

While antimuscarinic agents are the mainstay of OAB therapy, there is no evidence to support their efficacy in the treatment of BPS [1].

SNM has been approved for the treatment of OAB and idiopathic urinary retention, for decreasing incontinence episodes, pad use, and voiding frequency, and in improving bladder capacity and voided volume, with an overall success/improvement rate ranging from 61% to 90%; however, there is still limited evidence regarding its use on BPS. SNM also shows high rates of efficacy in the long term for patients with urgency incontinence, urgency/frequency syndrome, and idiopathic retention [2].

SNM can represent an alternative treatment for BPS in experienced centers after failure of medical treatment since the simplicity of the surgical technique and low patient morbidity associated make it an attractive option before more aggressive surgeries.

In a study involving 78 patients with refractory BPS symptoms, Gajewski and Al-Zahrani [3] implanted a permanent neuromodulator in 59% patients. After a mean follow-up of 61 mo, 72% of the implanted patients reported a persistent benefit (on intention-to-treat analysis: 42.3%) and the average global response assessment scale improvement was 80% [3]. Given the aforementioned results, in this clinical case, SNM could be a possible treatment, hence the grade B recommendation in the European Association of Urology (EAU) guidelines.

An alternative to SNM can be represented, as it was in the clinical case, by detrusor injection BoNT-A. At present, BoNT-A has become a well-established therapy in the management of neurogenic detrusor overactivity and idiopathic OAB. Although these are the only licensed indications within the urinary tract, there are wide ranges of off-license indications including BPS.

In a recent, randomized, double-blind, placebo-controlled trial on 60 patients suffering of BPS refractory to medical treatment, Kuo and Kuo [4] demonstrated at 8-wk follow-up that the bladder injection of 100 UI of BoNT-A + hydrodistention reduces bladder pain and augments bladder capacity compared with placebo + hydrodistention. Complications are dysuria (40%), urinary tract infection (UTI) (5%), retention (2.5%), and hematuria (2.5%) [4].

In a longer-term study of 15 patients, Giannantoni et al [5] reported a subjective improvement in 13 patients (86.6%) at 3 mo, with recurrence of pain in 11 patients at 5 mo and recurrence in all patients at 1 yr [5]. These studies have significant heterogeneity in terms of inclusion criteria, definition of BPS, efficacy outcomes, BoNT-A dose, and site of injection. The longer effect achieved over time in this case could probably be explained by the reduction of pain symptoms over time.

Although BoNT-A injections remain unlicensed for BPS, the recent American Urological Association (AUA) guidelines have recommended them (100 UI) as a fourth-line treatment. Moreover, in an AUA guidelines amendment, it was stated that the injection of 200 UI gives no better results than 100 UI [6]. Both SNM and BoNT-A would fit in the recommended phenotype-oriented approach for the treatment of BPS of the EAU guidelines.

In literature, no evidence-based hierarchy exists to guide urologists when trying to select one therapy over another, and the decision often comes down to personal preferences. The difficulty encountered when trying to decide among the currently available third-fourth line options is that high-level comparative studies do not exist.

The ROSETTA trial was hoped to provide evidences in terms of the best treatment for OAB in women. However, this trial had several limitations, including the injection dose (200 UI), which was higher than the recommended dose, and the unbalanced criteria for achieving surgical proficiency. The BoNT-A arm had a slightly better reduction in urgency incontinence episodes, but the differences were not clinically meaningful. Moreover, BoNT-A patients had higher rates of UTIs and need for transient catheterizations. Last but not least, there was no difference in patient preference [7].

3. Conclusions

According to recent guidelines and literature, there is still no clear evidence to make SNM or BoNT-A the preferred option after the failure of standard treatment. Both procedures have roughly the same success rates (40%) as well as durability drawbacks [8]. SNM is also associated with a revision rate of approximately 30–40% [9]. However, it has to be underlined that many women undergoing SNM have coexisting pelvic floor dysfunction. Given this association with other pelvic floor problems, it follows that any positive effect on quality of life following SNM may be attributed not only to this action on bladder symptoms, but also on this “holistic” effect on vaginal symptoms and on bowel and sexual function [10]. BoNT-A injections, on the contrary, represent an organ-oriented approach. A patient with isolated bladder problems (even if they include both elements of OAB and BPS, as it was in this case) is, therefore, a good candidate for botox injections.

Conflicts of interest: The authors, Manuela Tutolo and Enrico Ammirati have nothing to disclose. Frank Van der Aa has spoken on behalf and received honorarium from Astellas, Pfizer, and GlaxoSmithKline. He is a consultant for Medtronic, Allergan, and Astellas.

References


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