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## FEMALE STRESS URINARY INCONTINENCE: TREATMENT OPTIONS AND MAIN CHALLENGES

Stress urinary incontinence (SUI) is defined as an involuntary leakage of urine upon effort, physical exertion, sneezing or coughing. It affects 10-39% of the female population. This condition alters the physical, social, emotional and sexual wellbeing of affected women, thus impairing their quality of life. Therefore, an adequate assessment and tailored treatment should be offered.

Understanding the etiology and severity is a key point in order to choose a proper treatment. Appropriate knowledge of the pathophysiological mechanism of SUI is mandatory to select the correct treatment option. The predominant factor causing SUI is a reduced closure pressure of the urethra. A secondary mechanism is a failure of the urethral support; however, both mechanisms may coexist in the same woman.

International clinical guidelines recommend the assessment of the severity of SUI and the bothersome nature of related symptoms through validated questionnaires<sup>[1]</sup>, before considering treatment alternatives. SUI can be classified as mild, moderate, severe or extremely severe. Women and health care professionals should know that 27.9% of women affected with, especially in mild to moderate cases, remission can be spontaneous<sup>[2]</sup>.

Alternative available treatments have different efficacy rates related to the severity of symptoms, as well as to the cause of SUI. Thus, the management of women with SUI who does not respond to first line treatment should be offered by specialized health care professionals experienced in the urogynecology field to guarantee an adequate diagnosis before considering new therapeutic lines.

Current medicine tends to promote a patient-centered care model and to enhance the self-management of chronic pathologies that affect quality of life, such as SUI. One of the tools to implement patient-centered care consists of “shared decision-making”, which encourages patient to take part in the decision process and, together with the health team, to jointly develop a therapeutic plan<sup>[3]</sup>. To empower patients, it is crucial to provide them with high quality evidence-based data regarding the different treatment options, discuss potential benefits and harms, and consider the patients’ values and preferences, as well as the severity and etiology of the symptoms related to SUI.

According to international and national guidelines, there is level 1, grade A evidence to recommend conservative management based on lifestyle interventions and supervised pelvic floor muscle training (PFMT), as first line treatment for SUI. A recent

Cochrane review<sup>[4]</sup> highlights that there is moderate or high certainty evidence that PFMT or PFMT plus biofeedback and cones have more benefits than controls for curing or improving SUI, being continence pessary plus PFMT more beneficial than continence pessary alone; PFMT plus educational intervention was more beneficial than cones; more-intensive PFMT was more beneficial than less-intensive PFMT; and PFMT plus an adherence strategy was more beneficial than PFMT alone.

Despite high quality evidence on that field, the lack of awareness of health care professionals needs addressing on an urgent basis<sup>[5]</sup>. Knowledge of PFMT is essential to provide appropriate patient education and support. However, most midwives, nurses, physiotherapists, gynecologists or urologists are not aware on how to perform a pelvic floor muscle assessment, neither to instruct and supervise an exercise program according to the clinical guidelines. In addition, there is significant and recurrent exposure of other non-evidence based exercise programs or techniques (hypopressive exercise, yoga, pilates) that are advertised on social media, gymnastic or physiotherapist communities, that promote or offer these activities to treat SUI instead of PFMT.

Surgical treatment for SUI may include mid-urethral slings (MUS), bulking agents, and traditional surgery as autologous fascia sling or Burch colposuspension. Worldwide, MUS has been available for 20 years and is currently the preferred method for the primary surgical treatment of SUI. MUSs have shown high cure rates at mid- and long-term with low complication rates when performed by expert surgeons in the urogynecology field. However, the Food and Drug Administration (FDA) alert<sup>[6]</sup> regarding the complications following vaginal mesh to treat pelvic organ prolapse, has had an impact on all prosthetic materials, including slings for SUI repair. Due to this, this kind of surgery was restricted in some countries and most patients reject this treatment option due to the fear of risks. Consequently, other treatment options have increased in recent years. Bulking agents such as polyacrylamide hydrogel (Bulkamid®) have lower efficacy rates than MUS (two out of three women report cure or improvement). It should be noted that there are practically no complications with their use; being a good option for women who reject a sling or who are not suitable for more complex surgery or in those countries unable to offer slings. The autologous fascia sling has demonstrated a 60-90% cure rate at long term, however, it is a more complex and invasive surgery. Burch colposuspension

is a complex surgery for the management of SUI. It can be performed by open abdominal or laparoscopic approach. However, although it has a high cure rate (77%) at long-term follow-up, it has a higher risk of voiding dysfunction and *de novo* detrusor hyperactivity when compared to MUS application [7]. Commonly for all surgical alternatives, the efficacy decreases and complication rates increase when performing a recurrent surgery as compared to the primary procedure.

Energy-based devices, as laser therapy or radiofrequency to treat SUI, have emerged recently yet with controversial results. In the last issue of EGO, the paper by Novakov et al. [8], that focuses on the applications of non ablativ Erbiu laser to manage cistocele and SUI, attempts to illustrate the benefits of this treatment. The authors provide more data to the existing evidence suggesting that Erbiu laser may show potential to be an alternative therapeutic strategy for pelvic prolapse and SUI; however, it does not follow a high-quality study protocol as it has been previously suggested. In 2018, the US FDA published an alert highlighting that the safety of thermal energy devices has not been yet established and warning patients of the risk of serious adverse events. Moreover, the FDA remarked that there is insufficient evidence to support their efficacy for vaginal symptoms including SUI [9]. After that, different international associations have, in the same line, claimed against the use of energy-based devices within clinical practice that is not within a research scenario with a high-quality study protocol.

Despite this, currently the use of these therapies has exponentially increased in recent years, frequently performed by non-specialized health care professionals or experienced in the urogynecology field. It is worthy to mention the increase in patient's demand and expectations regarding these treatments.

However, to properly counsel women with SUI, we should focus on high quality evidence which is scarce in this field. Fortunately, in a recent published meta-analysis [10], based on randomized control trials (RCT), it has been summarized that the efficacy of energy-based therapy interventions is not superior to placebo. It seems that the positive results previously reported in the literature were based on poor quality studies with important bias. Hence, when high quality studies are analyzed, there is no evidence to recommend energy-based therapies to treat SUI, similar as it has occurred already with their use to manage the genitourinary syndrome of menopause. According to this, it is important to extend this message to health care professionals and women with SUI.

### **New does not mean better: evidence-based medicine**

A trend on new approaches to treat SUI, as hypopressive or energy-based devices, has been observed during recent years. However, "new" does not always mean "better". Therefore, health care professionals must be cautious with the implementation of innovative methods, taking into consideration both the

positive and negative impact on the health of women with SUI in the short and long-term, as well as the potential impact for future therapeutic strategies. New therapies should provide high quality evidence based on RCTs, compared to sham (when possible) and/or current available therapies (conservative and surgical which have already proven their efficacy and safety) in the short- and long term, including both subjective and objective outcomes to assure efficacy and safety before being implemented into clinical practice.

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