

INDIBA IN URINARY INCONTINENCE

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INTRODUCTION

More frequent than expressed among women is stress urinary incontinence (SUI) which has an enormous impact on those who suffer it, with personal and social consequences, having a strong negative impact on their psychological as well as in the relational well-being⁽¹⁾. The prevalence of SUI in adult female population varies regarding the sources from 4% up to 35%⁽²⁾ and may affect up to 50% of postmenopausal women⁽³⁾.

SUI is a multifactorial disorder in relation to aging, childbirth, menopause, and hormonal changes among other factors, female genital area loses tone which can lead to different conditions such as atrophic vaginitis, decreased sensation during coitus and stress urinary incontinence (SUI)^(4, 5). A lax vagina may be the main determinant in stress and urge female urinary incontinence⁽⁶⁾.

TREATMENT

The main traditional treatments of SUI include pelvic floor muscles training, medication and as a last step surgery is sometimes recommended. The success of these therapies varies from 25% to 90%⁽²⁾. Apart from the above mentioned possible aetiologies of SUI, histological studies report a reduction of collagen in urethra walls in case of loss of urethral support and/or sphincter dysfunction⁽⁷⁾, making the use of energy-based devices as a clear treatment option⁽²⁾.

Laser and radiofrequency (RF) are the considered technologies as energy-based devices in this scientific study. The main purpose is to heat the connective tissue of the vaginal wall from 40°C to 42°C to induce collagen contraction, neocollagenesis, vascularization, and growth factor infiltration that ultimately revitalize and restore the elasticity and moisture of the vaginal mucosa⁽⁴⁾.

Studies on the use of RF in SUI treatment

In this brief review ablative technologies have not been considered, although they have been widely used^(8, 9).

There are many studies of RF technologies for non-ablative treatment of pelvic floor disorders and vaginal rejuvenation that have shown a direct impact on SUI improvement as a “side effect”⁽¹⁰⁾. Here are some examples of how treating vagina laxity, as the main purpose, SUI condition improves:

- Magon et al.⁽⁵⁾ showed that two 30 minutes sessions for vulvovaginal rejuvenation improved SUI condition, with a reduction in overactive bladder symptoms, and reduced sexual dysfunction⁽⁵⁾.
- Vicariotto et Raichi⁽¹¹⁾ treated 25 women with 4 to 5 sessions with a quadripolar RF device for vaginal laxity and menopausal vulvo-vaginal atrophy. From those the eight patients suffering from dysuria and/or incontinence significantly improved their condition and kept improving 30 days after the end of treatment. In a second study Vicariotto et al.⁽¹²⁾ in a long term follow-up observational study, reported the efficacy and safety of their previous study up to 12 month after the end of the treatment, the study data suggested that there was no tendency to clinical deterioration even after one year since the last treatment session was applied.

The above results, altogether with the new demands by the patients: the will to reduce side effects, pain and down time, have stressed the development of non-ablative RF technology and electrodes to directly treat SUI as the main purpose:

- Lordelo et al.⁽²⁾ treated 10 patients and the Pad test at the end of five sessions to assess the results showed that 70% of the patients reduced their urinary loss 20% showed no further loss and 30% did worsen, but the Pad test at on month follow up showed that all patients (but one that did no return for follow up) did improve their results in relation to the basal state⁽²⁾.
- Leibaschoff et al treated 10 women with SUI by heating the vaginal walls to a temperature of 40-45°C, sessions lasted from 15 to 20 minutes with a total of three sessions (one per month). Scores of incontinence questionnaire decreased and 70% of the patients had a negative cough stress test after the treatment. Improvements were maintained for up to 12 weeks.
- Lalji et al. (13) reported a study on 27 women with indications of mild/moderate SUI as well as vulvo-vaginal laxity were treated with a monopolar RF device, who received three treatment sessions, one per week. On a scale of 0 to 5, the average frequency of urine leak improved from “2-3 times a week” to “once a week”, and on to “never”. The 59.3% reported decrease in the amount of leakage, 55.6% becoming

completely leak-free at the 1-month follow-up. At the 1-month follow-up visit, 88.9% expressed their condition's interference with everyday life decreased and 62.9% said the condition did not interfere with their everyday life at all as a result of the treatment. All subjects reported improvement in vaginal laxity at the 1-month follow-up visit). During the follow-up visit, 89% of the patients "agreed" or "strongly agreed" that their SUI condition improved, and 93% of the patients "agreed" or "strongly agreed" that their gratification during intercourse improved.

- Kuzlik R and Kuzlik B⁽¹⁴⁾ did a pilot study to evaluate the safety and clinical efficacy of the use of RF on vulvovaginal tissue for vaginal laxity, urinary incontinence and sexual dysfunction. The whole group (53 patients) referred improvement of the quality of life, there was a significant effect in vaginal tightening (38.1%) and urinary disorders- controlling urinary continence during coughing and urine stream increased accordingly by 32.2% and 31.9%. It turned out however, that the treatment was most effective in reducing frequency of feeling urgent.

All the above studies, whether for vaginal rejuvenation or for SUI treatment, proved to be safe and did not report any adverse effect.

There are also some examples of INDIBA's efficacy and safety in the treatment of SUI as Filoni et al. reported⁽¹⁵⁾, whose combination of traditional perineal rehabilitation therapy with INDIBA® resulted in an elimination of episodes of nocturia and enuresis. In 2018 Meeting day in Sevilla, Fulvio⁽¹⁶⁾ reported a case of a patient that after eight 30 minutes sessions (two per week) the patient referred end of effort incontinence and no more vagina heavy feeling with an objective improvement of the muscular tone of the pelvic floor. To these, can be added the testimonials on the daily use of INDIBA for pelvic floor treatment and urinary incontinence of Perrin⁽¹⁷⁾, Coudrain⁽¹⁸⁾ and Principiano⁽¹⁹⁾, three pelvic floor French specialists.

During the writing of this article, a PhD thesis in the use of INDIBA® for pelvic floor pain and associated pathologies, is in its final steps prior to its defence, will shed new light on the positive effects of INDIBA® in SUI as well as in other pelvic floor conditions.

Mechanism of action

In fact Viacriotto et al.⁽¹¹⁾ have proposed that the mechanism of action by which non-ablative RF has persistent-long term results in improving SUI is by means of an anatomical re-modelling and a real correction of the atrophy as well as the neocollagenesis triggered by the local hyperthermia. Probably this is just one of many more processes that may take part in the compromised tissues.

CONCLUSIONS

Stress urinary incontinence is a very limiting condition that has been approached by different means. Now a gentler technique, non-ablative radiofrequency, has proven to be an efficient and safe technology for this purpose.

LITERATURE

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