

Innovative Approaches to Postpartum Urogenital Health: A Pilot Study on the Therapeutic Effects of Topical Oxygen and Hyaluronic Acid

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Abstract

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BACKGROUND: The postpartum period challenges women with a variety of urogenital disorders, which significantly impact their physical and psychological well-being. Traditional treatments often fall short in addressing the complexities of these conditions, which include urinary incontinence and sexual dysfunction.

AIM: This study explores the effectiveness of a novel treatment—high-concentration oxygen combined with hyaluronic acid—aimed at improving postpartum urogenital health.

METHODS: This clinical study enrolled 41 postpartum women aged 18 to 42, undergoing a four-week treatment regimen with high-concentration oxygen combined with hyaluronic acid. This device delivers high-concentration oxygen and hyaluronic acid directly to the vaginal area. The severity of symptoms such as vulvar laxity, urogenital triangle lowering, and urethral orifice laxity was assessed at baseline and post-treatment using a four-point scale.

RESULTS: Treatment resulted in significant improvements in all targeted symptoms, with the most notable reductions observed in muco-epithelial inflammation scar (60% reduction) and vulvar laxity (54% reduction). These improvements were statistically significant ($p < 0.0001$), indicating a robust response to the therapy. The study also noted enhancements in general well-being, although these were not statistically significant.

CONCLUSIONS: The treatment with high-concentration oxygen and hyaluronic acid offers a promising new approach to postpartum rehabilitation. By significantly reducing key symptoms of urogenital dysfunction, this treatment has the potential to enhance the quality of life for postpartum women. Future studies should investigate long-term outcomes and the integration of this therapy into broader postpartum care practices.

Introduction

The postpartum period presents unique health challenges for women, prominently featuring urogenital disorders such as urinary incontinence and sexual dysfunction. These conditions not only affect physical health but also impact psychological well-being and quality of life.

Sexual health, crucial for the quality of life of women, is defined by the World Health Organization as "a state of physical, emotional, mental, and social well-being related to sexuality; it is not merely the absence of disease, dysfunction, or infirmity". Considering sexual health as an indicator of well-being, it is possible that sexual dysfunction may be a consequence of maternal morbidity.

Vaginal and perineal pain are predominantly considered nociceptive pain, but neuropathic pain due to obstetric trauma, such as pudendal neuropathy, is

also a possible contributor. Perineal and vaginal pain after vaginal delivery is associated with tissue trauma related to operative vaginal delivery, perineal laceration, and the use of episiotomy, although some studies report its occurrence even after cesarean delivery with or without labor.

Sexual activity typically resumes six to eight weeks postpartum [1]. However, the return to regular sexual activity often only begins to stabilize six months postpartum. This delayed resumption can be attributed to both physical discomforts, such as pain and fatigue, and psychological factors including anxiety and altered body image perceptions post-delivery. These challenges highlight the need for a more open discussion and proactive management of sexual health in postpartum care.

Moreover, as outlined by Fallowfield [2] the quality of life is a crucial measure that should encompass all aspects of health, including sexual health. The neglect of sexual health issues can lead to

long-term consequences, affecting a woman's quality of life and well-being. Studies, such as the systematic review by Jawed-Wessel and Sevic, have shown that pregnancy and childbirth profoundly impact sexual behaviors, yet the topic remains under-researched and under-discussed in clinical settings.

In addition to the hesitancy in discussing sexual health issues, many women experience significant psychological distress due to changes in their sexual function and body image postpartum. This distress can be compounded by the lack of information and guidance provided on navigating these changes, underscoring the necessity for healthcare providers to initiate conversations about sexual health as a routine part of postpartum care.

Other studies [3], [4] highlighted the high prevalence of urinary incontinence postpartum, affecting up to 50% of women, with significant repercussions on sexual function and overall life satisfaction. In most cases, urinary incontinence appears for the first time during pregnancy and persists into the postpartum period. Urinary incontinence during pregnancy, multiparity, and constipation are risk factors for the persistence of incontinence.

Furthermore, Diz-Teixeira et al. [5] emphasized the effectiveness of physiotherapy in managing urinary incontinence, suggesting that targeted treatments can significantly alleviate symptoms and improve recovery. Despite these advances, many women continue to experience persistent symptoms that are inadequately addressed by conventional therapies.

In response to these challenges, innovative treatments have been explored to provide more effective solutions. One such approach is the concomitant administration of hyaluronic acid and topical oxygen therapy (TOT) using a specifically designed medical device, the Vaginal Natural Oxygenation Device (VNOD). This pilot study [6] evaluated the effectiveness of VNOD in improving the symptomatology of vulvo-vaginal atrophy (VVA) in postmenopausal women—a condition that shares common pathophysiological features with postpartum urogenital disorders.

The VNOD method integrates hyaluronic acid's moisturizing and epithelial barrier enhancing properties with the regenerative capabilities of high concentration oxygen, promoting tissue repair and reducing symptoms such as vaginal dryness, burning, and itching [7], [8]. The study demonstrated significant improvements in vaginal health metrics, suggesting a promising approach for extending these benefits to postpartum women suffering from similar urogenital issues.

Given the parallels between postmenopausal VVA and postpartum urogenital disorders, our research applies the VNOD methodology to a postpartum cohort, hypothesizing that it could similarly alleviate symptoms

and improve the quality of life in this demographic. This study aims to fill the gap in effective postpartum care solutions, providing evidence for a potentially transformative approach to managing postpartum urogenital health.

The aim of the study was to observe the effects of treatment with high concentration oxygen and hyaluronic acid on patients with the following gynaecological post-partum conditions:

- Vulvar laxity;
- Urogenital triangle lowering;
- Urethral orifice laxity;
- Muco-epithelial inflammation scar;
- Mucosal redness;
- Stress urinary incontinence episodes;
- Well-being;
- Burning;
- Dyspareunia;
- Scar pain.

Materials and Methods

The clinical study was approved by the local institutional review board and conducted in accordance with the ethical standards of the Declaration of Helsinki.

Forty-one women between the ages of 18 and 42 who had given birth four to five months earlier were enrolled in the study.

Patients with vulvar dermatological changes, signs of vulvovaginal infections, or pre-neoplastic/neoplastic changes in the lower genital tract were excluded from the study.

Treatment

Treatment was performed by an appropriate device (CaressFlow Srl, Bologna, Italy) recently commercialized for the treatment of VA in postmenopausal women.

The device consists of a compressor that produces compressed air by taking in air from the outside, filtering it and compressing it. Inside the body of the machine, there are zeolite molecular sieves that use the principle of different absorption of gas molecules, allowing O₂ to pass and retaining the other gases present in the air, such as nitrogen, argon, helium and hydrogen. The body of the machine transforms the outside air into 93 ± 3% pure oxygen at a flow rate of 2 l/min.

The first part of the treatment is carried out by an airbrush connected to the machine body (Figure 1A). The airbrush is used for the treatment of external genitalia, nebulizing the combination of oxygen and hyaluronic acid (0,2% solution) for 5 minutes.

The second part of the treatment consists of the use of a vaginal cannula (Figure 1B) through which a flow of pure oxygen is delivered for 5 minutes, followed by the simultaneous delivery of oxygen and hyaluronic acid for 10 minutes.

The same 20-min session was repeated every week four times.

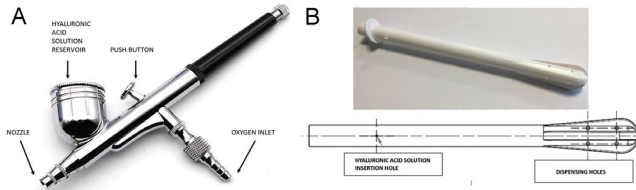


Figure 1: Airbrush (A) and vaginal cannula (B)

Evaluation

At visit 0, an accurate collection of patient history and a complete clinical examination was performed to evaluate eligibility criteria. The intensity of the following symptoms:

- Stress urinary incontinence episodes;
- Well-being;
- Burning;
- Dyspareunia;
- Scar pain;

were collected from patients with a VAS based on a four-point scale: score 1 = absence of symptom, score 2 = weak intensity, score 3 = mild intensity, score 4 = maximum intensity.

Before the treatment, the following symptoms:

- Vulvar laxity;
- Urogenital triangle lowering;
- Urethral orifice laxity;
- Muco-epithelial inflammation scar;
- Mucosal redness;

were determined by the clinician and evaluated on a four-point scale: score 1 = absence of symptoms, score 2 = weak intensity, score 3 = mild intensity, score 4 = maximum intensity.

All patients were assessed for the presence of symptoms from the second treatment session, with follow-up at 7 days after the end of treatment, for a total of 4 assessments. This study did not utilize a separate control group, but it compared the patient’s outcomes with their baseline clinical conditions.

Statistical Analysis

Statistical analysis was performed using IBM SPSS version 22.0 (IBM Corporation, Armonk, NY, USA). The significance of pairwise comparisons between treatment sessions was analyzed using the

Wilcoxon test for non-parametric data. Two-sided p-values < 0.05 were considered statistically significant.

Results

The results showed a significant improvement in all mean scores analyzed (Figure 2), except for well-being, which was not significant. The analysis of the comparisons between the different phases of therapy has shown that each subsequent treatment determined a significant improvement in all parameters.

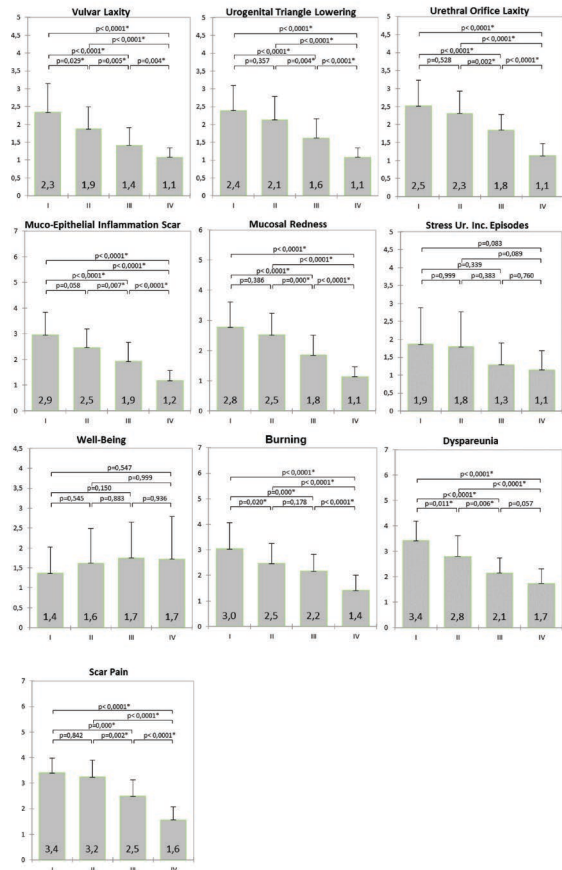


Figure 2: Analysis of Symptom Improvements in Postpartum Urogenital Health. *Significant at level alpha = 0.05

Figure 3 illustrates the percentage changes in various postpartum urogenital symptoms experienced by participants after undergoing the specified treatment. The percentages reflect the extent of symptom improvement or deterioration, with negative values indicating a reduction in symptom severity and positive values indicating an increase.

For all the parameters analysed, except for well-being, which showed a non-significant increase of 21%, the reduction in symptoms ranged from 38% for stress urinary incontinence episodes to 60% for muco-epithelial inflammatory scar.

All patients successfully completed this study. The therapy was well accepted by patients with immediate therapeutic effects and without side effects.

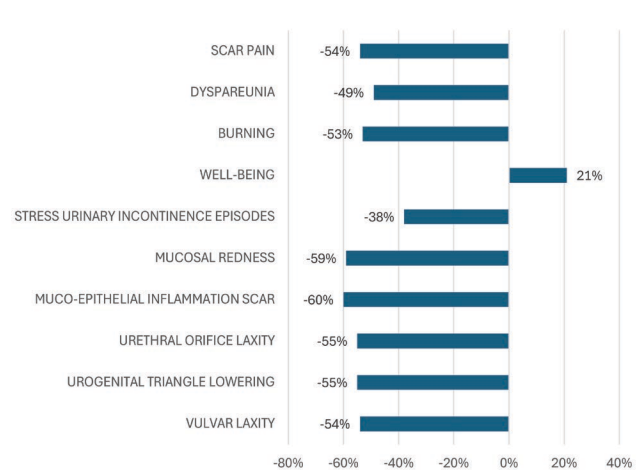


Figure 3: Mean Percentage Changes in Postpartum Urogenital Symptoms Following Treatment

Discussion

The treatment of postpartum complications holds a critical place in enhancing the quality of life and ensuring the psychological well-being of new mothers. The transitional phase postpartum presents numerous health challenges that, if inadequately addressed, can lead to significant long-term physical and psychological issues.

Rehabilitation during the postpartum period, therefore, is not merely a healthcare routine but a crucial intervention that ensures the holistic recovery of women.

Postpartum rehabilitation encompasses a diverse spectrum of practices and techniques aimed at addressing the multifaceted health issues faced by women after childbirth. These issues range from physical injuries such as perineal tears to emotional and psychological stresses that can impact a woman's return to her pre-pregnancy state. Each woman's journey through postpartum recovery is unique, influenced by the nature of the delivery, the presence of pre-existing conditions, and her overall health.

The rehabilitation process is inherently multidisciplinary, involving obstetricians, physiotherapists, psychologists, and other specialists who work together to tailor rehabilitation plans that address individual needs effectively. Techniques used in postpartum rehabilitation include but are not limited to physical therapy for strengthening pelvic floor muscles, psychological counseling to address postpartum depression and anxiety, and nutritional counseling to help women recover from dyspareunia, or painful intercourse, is a common postpartum complaint. The condition can stem from natural changes during childbirth, such as hormonal fluctuations and physical

injuries like perineal tears and episiotomies. Multidisciplinary approaches to treat dyspareunia involve physical therapies that focus on pelvic floor muscle training, psychological counseling to address anxiety associated with painful intercourse, and sometimes medical interventions such as topical estrogen therapies. These interventions aim to not only alleviate pain but also improve the quality of sexual relations, which is crucial for emotional bonding and personal well-being [9].

Intravaginal transcutaneous electrical nerve stimulation (TENS) and pelvic floor muscle training are proven to be effective in reducing symptoms of pelvic floor dysfunction, including urinary incontinence and pelvic pain. These methods enhance muscle strength and alleviate symptoms by improving neuromuscular control and reducing inflammation and pain through nerve stimulation [9]. [10].

This involves exercises aimed specifically at strengthening the pelvic floor muscles which are crucial for urinary continence and sexual function. Rehabilitation starts with simple exercises and progressively increases in intensity as the patient recovers. This method has been shown to be essential, especially in women experiencing persistent symptoms three months postpartum [11].

Against the backdrop of traditional therapies, the innovative treatment involving high-concentration oxygen and hyaluronic acid represents a significant advancement. This combination therapy leverages the healing properties of oxygen and the moisturizing effects of hyaluronic acid to promote tissue regeneration and repair. The introduction of this treatment has marked a novel approach in postpartum care, offering rapid amelioration of symptoms like vaginal dryness, inflammation, and pain, which are often significant barriers to a woman's postpartum recovery.

Recent studies have documented the effectiveness of this treatment in significantly improving the symptoms associated with postpartum urogenital disorders. For instance, clinical trials have shown marked improvements in vaginal health, with reductions in dryness, inflammation, and pain within just four weeks of treatment initiation. The implications of these findings are profound, suggesting that combining high-concentration oxygen with hyaluronic acid can expedite the healing process, thereby reducing the overall recovery time and improving the quality of life for new mothers [9], [12], [13].

Moreover, the broader implications of these improvements extend beyond physical health, influencing psychological and emotional well-being. Enhanced recovery from physical symptoms facilitates better overall mood, reduces stress, and improves the capacity for mothers to bond with their infants and resume their social and professional lives.

The rehabilitation of pelvic floor health postpartum is crucial for restoring function and enhancing quality of life, particularly in addressing conditions like vulvar laxity, urogenital triangle lowering, and urethral orifice laxity. The treatment involving high-concentration oxygen and hyaluronic acid has demonstrated significant improvements across these symptoms, which are often overlooked in typical postpartum care. As illustrated in our results, each of these conditions showed a marked improvement over the course of the treatment, which can be attributed to the regenerative properties of the therapy employed.

Vulvar laxity, which affects the structural integrity and functionality of the vulvar region, showed a progressive decrease in symptom severity across the treatment phases. This improvement is critical as it directly enhances the structural support of the pelvic floor, contributing to better overall pelvic health and functionality. Similarly, the lowering of the urogenital triangle, a common issue that can lead to discomfort and urinary incontinence, was significantly mitigated, suggesting an effective restoration of the pelvic anatomy, which is essential for maintaining urinary continence and sexual function [14].

Moreover, the urethral orifice laxity, which can significantly impact urinary control and sexual satisfaction, also saw considerable improvements. By reducing laxity in this area, the treatment helps in tightening the urethral closure mechanism, thereby enhancing urinary continence and reducing the risk of related complications. The statistical significance of these improvements ($p < 0.0001$) across the initial and final phases of treatment underscores not only the efficacy but also the potential of this therapeutic approach to serve as a cornerstone in postpartum pelvic rehabilitation [15].

These findings are pivotal as they provide empirical evidence supporting the use of high-concentration oxygen and hyaluronic acid in the targeted rehabilitation of the pelvic floor postpartum. By addressing these specific aspects of pelvic health, the treatment offers a comprehensive approach that significantly improves the structural and functional recovery of the pelvic floor, which is vital for the long-term health and well-being of postpartum women [12].

Despite the promising results, the adoption of high-concentration oxygen and hyaluronic acid treatment in routine postpartum care faces challenges. These include variability in treatment response, the need for specialized equipment, and potential accessibility issues. Future research should focus on addressing these challenges, exploring the long-term effects of the treatment, and expanding its application to a broader range of postpartum conditions.

Conclusions

In summary, the integration of high-concentration oxygen and hyaluronic acid into postpartum rehabilitation protocols offers a promising avenue for enhancing maternal health care. As evidence of its efficacy grows, it is imperative for healthcare providers to consider these innovative treatments as part of standard care practices to ensure that every woman can achieve the best possible postpartum recovery.

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