Research Square

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Fractional Carbon Dioxide Vaginal Laser for the Treatment of Urinary Symptoms: 36 Month Results

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Abstract

Purpose

Fractional carbon dioxide laser (fCO2) has been proposed to treat vulvo-vaginal symptoms of genitourinary syndrome of menopause (GSM), and urinary symptoms including urgency, urgency urinary incontinence (UUI), and stress urinary incontinence (SUI). The thermal effects of the fCO2 laser can lead to collagen remodeling, improving vaginal tissue integrity and urethral support. Our study aimed to measure the impact of vaginal fCO2 laser therapy on a general group of women with vulvo-vaginal and urinary symptoms.

Methods

Women with complaints of urogenital symptoms were enrolled in an open-label prospective trial. Participants underwent three laser treatments, each six weeks apart. Follow-up consisted of 6, 12, 24 and 36-month visits during which cough stress test was performed and questionnaires were administered. ANOVA analysis was used to compare means at each time point.

Results

100 women, 73 menopausal, with an average age of 55 were enrolled in the study. The PGI-I at 16 weeks showed 32/81 (39.5%) patients were markedly or moderately better, 20/74 (27%) at 6 months, 22/60 (36.7%) at 1 year, 17/44 (38.6%) at 24 months and 17/38 (44.7%) at 36 months. Patients reported significant improvement on the QUID-UUI at all visits out to 36 months, but no significant decrease in UUI episodes were noted. OABq symptom score and Quality-of-life significantly improved at each follow-up visit. For those reporting SUI at baseline, SUI leaks were significantly reduced at each follow-up timepoint compared to baseline ($p = 0.0066$) as were QUID-SUI scores ($p = 0.0002$). Significant reduction in the incidence of vulvar dryness ($p = 0.0005$), vulvar burning ($p = 0.0061$) and vulvar pain during intercourse ($p = 0.0258$) were seen.

Conclusion

Our results show that vaginal fCO2 laser therapy improves vulvo-vaginal symptoms and urinary symptoms. The urge / OAB patients reported significant durable improvement to 36 months. PGI-I finds 44.7% of women markedly or moderately better at 36 months. More research is needed for long-term results.

Introduction

There has been interest in the non-hormonal approach of vaginal laser therapy to alleviate distressing genitourinary symptoms of menopause (GSM) and other lower urinary tract symptoms (LUTS). A decline in estrogen and progesterone affects the hormone-sensitive vagina, vulva, pelvic floor musculature, endopelvic fascia, urethra, and bladder trigone. With menopause, the vasculature and elasticity of these regions diminish and estrogen replacement can reverse these changes.[1]

Common symptoms of low estrogen states include hot flashes, night sweats, mood swings, fatigue, weight gain, and vulvovaginal symptoms, such as dryness, burning, itching, pain during sexual intercourse (dyspareunia), and irritation.[2] Low estrogen states also increase the risk of other LUTS like OAB, urge incontinence, and stress incontinence.[3, 4]

Fractional CO_2 (fCO2) laser therapy is a minimally invasive treatment that uses micro-ablative laser energy to boost collagen production and facilitate tissue remodeling of the vaginal mucosa.[5] Pre- and post-laser treatment vaginal biopsies have significantly increased vaginal mucosal thickness without damaging surrounding tissue, as well as increase lactobacillus colonization and decrease pH.[6–8]

Most studies on fCO2 vaginal therapy involve post-menopausal women, usually with GSM. Fractional CO2 tends to improve both vulvar/vaginal symptoms and mild LUTS in these patients.[9] The improvement observed in these LUTS, when treating for GSM, has stimulated further evaluation of fCO2 for the treatment of stress urinary incontinence (SUI), urge urinary incontinence (UUI) and overactive bladder (OAB) symptoms. In addition, there is developing experience with fCO2 laser therapy for LUTS in non-menopausal women. It has been suggested that the fCO2 thermal effect can thicken and tighten vaginal walls, even in non-menopausal women, potentially enhancing support to the bladder neck and urethra to improve SUI.[10]

The objective of this study was to evaluate the role of fCO2 laser vaginal therapy to women with both vulvo-vaginal symptoms and LUTS including OAB, UUI, and SUI. We include menopausal and non-menopausal women and all treatments were free of charge. We used the PGI-I as our primary outcome measure, with subjective questionnaires and objective data.

Materials and Methods

Ethics statement

This is a prospective observational study of patients undergoing vaginal treatment with the AcuPulse® FemTouch™ (Lumenis®) fCO2 laser for urinary incontinence, vaginal itching, dryness, burning, dyspareunia, dysuria, nocturia, urinary frequency, urinary urgency, and UTI. Adult females were recruited from Corewell Health Women's Urology Clinic and surrounding private urology offices. This study was approved by Corewell Health Institutional Review Board (IRB 2018 – 142) and is a registered clinical trial (NCT03681678).

Patient population

Study participants who gave full written consent and met eligibility criteria were enrolled. Inclusion criteria included age between 18 and 90 and one or more of the following indications: SUI, recurrent UTI, or overactive bladder (OAB), symptoms of GSM, as well as vaginal symptoms (e.g. dryness, burning, itching, dyspareunia) not related to menopause. Exclusion criteria included: contraindications to fCO2 laser treatment (currently implanted synthetic pelvic mesh, sling or tape, current or previous genital cancers, radiation to the vaginal or colorectal tissue, currently pregnant or < 3 months following pregnancy, undiagnosed vaginal or cervical lesions), prior vaginal fCO2 laser treatment within the past 12 months, vaginal estrogen use within the past two months, undiagnosed vaginal bleeding, active vulvar or vaginal infections, current UTI confirmed by positive urine analysis dipstick, urine culture or patient-reported UTI symptoms, pelvic or vaginal surgery within the past nine months, and pelvic organ prolapse beyond the introitus.

Treatment Regimen

Participants underwent three treatments with the AcuPulse® FemTouch™ (Lumenis®) fCO2 laser, each six weeks apart (Fig. 1). Laser treatment was performed per routine protocol (Lumenis GmbH).[11] This included intra-vaginal treatment based on atrophy level according to the Vaginal Health Index Score (VHIS) and treatment number (Table 1). At each visit, trained providers specialized in female pelvic medicine performed a vaginal exam and assigned a score of 1–5 (abnormal to normal, respectively) on each of the following vaginal parameters: elasticity, secretion/fluid volume, vaginal pH, integrity of the epithelium, and lubrication/moisture of the vaginal wall. A VHIS less than 15 indicates vaginal atrophy. The laser is delivered in a 360-degree fashion at 6 points at each level of the vaginal wall: 12, 2, 4, 6, 8, and 10, o'clock of Hart's line. Delivery begins at the vaginal apex, and the wand is manually retracted in 1 cm increments up to the vaginal introitus. The number of levels is determined by the patient's vaginal length. Patients were given the option to receive an additional annual treatment. Annual treatments were given to 89.7%, 93.0% and 73.7% of patients at 12, 24 and 36 months respectively.

Table 1
The lumenis vaginal laser delivers low energy pulse of CO_2 (wavelength = 10.6 μm) to the vaginal mucosa in a circumferential- every 60°- and longitudinal - every 1 cm - manner. Energy levels and power density are based on VHIS scores per manufacturer's guidelines.

Atrophy level	First treatment	Second treatment	Third treatment
Severe (5 < VHIS < 15)	Energy: 7.5–10 mJ Density: 10%	Energy: 10 mJ Density: 10%	Energy: 10 mJ Density: 10%
Mild (15 < VHIS < 20)	Energy: 10 mJ Density: 10%	Energy: 10–12.5 mJ Density: 10–15%	Energy: 10–12.5 mJ Density: 10–15%
Non atrophic (VHIS > 20)	Energy: 10 mJ Density: 10%	Energy: 12.5 mJ Density: 10–15%	Energy: 12.5 mJ Density: 15%
* Table adapted from FemTouh Clinical Treatment Guide [21]			

Outcome measures

Primary outcome measure was patient-perceived symptom improvement using the Patient Global Impression of Improvement (PGI-I) 4 weeks after treatment completion and at follow-up visits. At baseline and follow-up visit, patients completed the Overactive Bladder Questionnaire short form (OABq-SF), Questionnaire for Urinary Incontinence Diagnosis (QUID), and vulvovaginal symptoms questionnaire (VSQ), and returned a 3-day voiding diary. The OABq-SF consists of two subsections that assess OAB symptom bother and quality of life. The MID of OABq-SF is 10.[12] QUID is a validated measure used to evaluate improvement in SUI or UUI incontinence in women undergoing non-surgical treatment and has no established MID. Vaginal symptoms were assessed using the VSQ, a validated 21-item questionnaire assessing patient symptoms, emotions, life impact, and sexual impact. In addition, at each visit a pelvic examination was performed, and the clinician completed a cough stress test (CST) in the lithotomy position and VHIS. For each CST, bladder volume was measured with a bladder scanner to ensure a minimum volume of 150 ml. Adverse events were documented at each follow-up visit and graded using the CTCAE scoring system. Adverse events of grade 3 or higher were considered significant (Fig. 1).

Statistical Analysis

Statistical analysis was performed using SPSS 28.0. Quantitative data, including number of stress or urge leaks and symptom or bother scores, was analyzed using mixed-effects ANOVA to account for repeated measures and missing data points (e.g. due to lost-to-follow-up). If significant, Tukey's posthoc test was applied to indicate what time points were significantly different from treatment one or baseline. Categorical data was analyzed using Chi-square test.

Results

Characteristics of Patient Population

One hundred women were enrolled in the study from July 2019 to November 2023 at a single institution. Average age at enrollment was 55 years (range 28 to 81). Most study participants were Caucasian (89%), with 9 African Americans, 1 Asian, and 1 Middle Eastern participant. Seventy-three participants reported being menopausal at study enrollment. Of these, 25 (34%) were in medically induced menopause. Most common vaginal symptom was vaginal dryness (n = 74), followed by difficult and/or painful intercourse (n = 61). Eighty-four participants reported urinary incontinence, of which 63.1% suffered from both stress and urgency incontinence. Finally, 78% of patients had OAB symptoms (urgency and/or frequency), and only 15% of study participants reported having recurrent UTI (3 or more UTIs/year) (Table 2). Eighty-four patients completed all three treatments, 60 completed 12-month follow-up, 44 completed 24-month follow-up and 38 completed 36-month follow-up (Fig. 2). The study had a high dropout/lost to follow-up rate, especially during the height of the COVID pandemic.

Table 2
Baseline characteristics

Age (years)	**N = 100**
	55.25
	(Range: 28–81y)
Race	
Caucasian	89
African American	9
Asian	1
Other	1
Ethnicity	
Hispanic or Latino	2
Menopause	73
Natural	48 (65.8%)
Medical/Surgical	25 (34.2%)
Vaginal Symptoms	
Dryness	74
Burning	37
Itching	34
Difficult/painful intercourse	61
Urinary Symptoms	
Urinary Incontinence	84
Only Stress	17 (20.2%)
Only Urge	14 (16.7%)
Both	53 (63.1%)
Urinary frequency	78
Urinary urgency	78
Recurrent UTI	15
J. Lichen Sclerosis	2

Adverse Events

No significant adverse events occurred during treatments or throughout the study. The most common adverse events included UTI (11%), vaginal burning or discomfort during treatment (11%), vaginal bleeding (8%), and bacterial vaginosis (6%). Of the 15 patients with prior history of repeat UTI, 5 patients (33%) had 1 or more UTIs during the study.

Primary objective

The PGI-I primary objective showed that 32/81 (39.5%) patients were markedly or moderately better at 16 weeks follow-up, 20/74 (27.0%) at 6 months, 22/60 (36.7%) at 12 months, 17/44 (38.6%) at 24 months and 17/38 (44.7%) at 36 months (Fig. 3). At 12 months, 21/50 (42%) menopausal women were markedly or moderately better compared to 1/10 (10%) non-menopausal women. At 24 and 36 months, 35.9% and 39.4% of menopausal women reported significant improvement in symptoms respectively. Only 5 non-menopausal women remained enrolled during the last 2 years of the study. While 60–80% reported significant symptom improvement based on the PGI-I, the n-values are too low to draw any conclusions. We could not separate the vulvo-vaginal patients from the urine incontinence patients, or the urine incontinence patients into stress and urge subgroups, because most patients had multiple symptoms resulting in too much cross over.

Impact of Laser on SUI

On baseline 3-day voiding diary, 46 patients reported an average of 7.1 (± 8.2) leaks over 3-day period (Fig. 4A). Overall, SUI leaks declined over 36 months to 2.2 (± 2.8), with significance observed at 6 months ($p = 0.0019$), 12 months ($p = 0.0209$), 24 months ($p = 0.0007$) and 36 months ($p = 0.0002$). Similarly, we observed significant improvement on the QUID-SUI sub-score at 6-month (6.2 ± 4.2; $p = 0.001$), 12-month (5.6 ± 3.8; $p < 0.0001$), 24-month (5.1 ± 3.5; $P < 0.0001$) and 36-month (4.5 ± 3.8; $p < 0.0001$) follow-up (Fig. 4B).

At baseline, 100 CST were performed, 12 (12.0%) were positive and 88 were negative. At 12-month follow-up, 54 CST were performed, 7 (13.0%) were positive and 47 were negative. The low number of positive CST in comparison to those reporting SUI leaks on 3-day voiding diary could reflect minor symptoms or that bladder volume was too low at CST given the low volume requirements of the test (> 150cc). Of the women who had a positive CST at baseline, 4 had a positive CST, 4 a negative, and three were lost-to-follow-up at 12 months follow-up. By 36 months, only 1 person had a positive CST, 3 were negative and 8 were lost-to-follow-up.

Impact of Laser on UUI

On the Baseline 3-day voiding diary, 55 (55.6%) reported UUI, with a mean of 6.5 (± 7.2) episodes. Follow-up diary showed a trending reduction in UUI episodes at 6- (4.1 ± 6.2), 12- (3.7 ± 5.6), 24- (4.1 ± 5.2), and 36-month (4.4 ± 6.6) follow-up, though no statistical significance was noted (Fig. 5A). However, patients

reported significant improvement on the QUID-UUI at all 4 follow-up visits out to 36 months (8.5 ± 3.0 to 5.9 ± 2.7; $p < 0.0001$) (Fig. 5B).

Impact of Laser on OAB symptoms

OAB symptoms were assessed based on urinary frequency (> 8 voids/day), urge intensity score, and the OAB-Short Form (OABq SF). The OABq SF evaluates OAB symptom severity and health-related quality of life. No change in the number of voids was observed from baseline at any follow-up time points (Fig. 6A). Similarly, urge intensity was not significantly different between follow-up visits (Fig. 6B). Patients reported significant improvement on the OABq symptom score (baseline = 43.8 ± 24.4, 6 months = 27.5 ± 21.5, 12 months = 29.6 ± 23.6, 24 months = 29.5 ± 23.6, 36 months = 23.3 ± 20.2, MID = 10, $p < 0.0001$). Quality-of-life was significantly improved at all follow-up visits (baseline = 69.8 ± 23.3, 6 months = 84.6 ± 16.3, 12 months = 83.7 ± 18.2, 24 months = 85.0 ± 15.4, 36 months = 86.4 ± 15.8, $p < 0.0001$) (Fig. 6C-D). For menopausal vs. non-menopausal, there was no difference noted for any questionnaire, data not shown.

Impact of Laser on Vulvar symptoms

The incidence of vulvar symptoms was assessed using the VSQ. Overall, there was no significant reduction in vulvar itching compared to baseline and follow-up time points (Fig. 7A). Women did experience improvement between baseline and follow-up time points in vulvar dryness ($p = 0.0005$), vulvar burning ($p = 0.0061$), and vulvar dyspareunia ($p = 0.0258$) (Fig. 7B-D).

Discussion

This study demonstrates that fCO2 vaginal laser therapy is safe and effective for a generalized population experiencing vaginal symptoms and/or LUTS. We observed significant improvement in vulvar/vaginal symptoms, OAB, SUI, with lesser, subjective improvements in urge incontinence. Based on PGI-I, 40% (32/81) of women reported being markedly or moderately better at 16 weeks. The heterogeneity in symptoms likely impacted the subjectivity of symptom improvement; 88% of participants reported 4 or more vaginal and/or lower urinary tract symptoms at baseline.

When assessing individual symptoms, this study showed that vulvar dryness, burning and dyspareunia were significantly improved with durability to 36-month follow-up. This is supported by other studies. A 2022 meta-analysis of 25 studies and 1,152 women reported statistically and clinically significant improvements in GSM, though the quality of the data was “low” to “very low”.[13]

In addition to vulvar symptoms, women with estrogen deficiency have increased risk of urinary symptoms like OAB, UUI, and SUI.[3, 4] The observation of LUTS improvement in the GSM population studies have stimulated more wide spread application of vaginal laser therapy to urinary symptoms. In addition, fCO2 laser therapy for LUTS is increasingly being used in non-menopausal women.

Few studies report the use of vaginal laser for OAB symptoms. In a 2020 OAB trial, fCO2 laser treatment significantly reduced ICIQ-OAB scores, and was superior to treatment with Promestriene (a vaginal estrogen) or non-hormonal lubricant.[14] In contrast, a 2021 systematic review of fCO2 studies showed minimal improvement in OAB symptoms (and only in the short term).[15] The authors concluded there wasn't enough robust data to support lasers for OAB at that time.[15] In this study we did not observe a change in frequency, though OAB symptom improvement was seen through subjective measures (OABq). This study did see an objective, though not significant, decrease in UUI episodes on voiding diary and a statistically and clinically significant decrease in UUI symptoms with QUID, but no difference was seen in urge intensity. For SUI, both subjective and objective measures demonstrated significant symptom improvement that was still observed at 36-month follow-up. In support of our study, Montera et al. demonstrated that fCO2 laser therapy significantly reduced the number of UUI/SUI episodes reported on a 3-day voiding diary at 12-month follow-up. The reduction was more pronounced in patients that had vaginal atrophy at baseline.[16]

SUI in menopausal women is typically aggravated by vaginal atrophy. However, in non-menopausal women SUI often results from childbirth-related pelvic floor changes or athletic activities. The fCO2 laser has limited tissue penetration (50–125μm) and thus the vaginal laser may not reach sufficient depth to improve anatomy/mobility related SUI. A 2023 sham-controlled trial investigated fCO2 therapy for SUI, of which 50% were menopausal. All women were advised to perform pelvic floor muscle exercises after completion of vaginal laser therapy. Though the ICIQ-UI-SF scores were improved in both sham and fCO2 groups 3 months after treatment, there were no statistically significant differences between sham and active treatment. In addition, no objective anatomic changes in bladder neck descent or levator hiatal area were observed.[17] Thus, the improvement in symptoms were likely due to pelvic floor muscle exercises and not from laser therapy. However, Gao et al. did see anatomical changes. Fractional CO_2 therapy (with valsalva maneuver) in largely non-menopausal women significantly decreased bladder neck mobility, urethrovesical angle, and length of the anterior vaginal wall.[10] In addition, bladder biopsies demonstrated thickening of stratified squamous epithelium indicating that laser therapy does impact vaginal anatomy.

This is the largest prospective, single-center trial of vaginal laser treatment for vulvar/vaginal symptoms (GSM) and LUTS including SUI, UUI, OAB. We acknowledge the limitations of our study, including a heterogeneous study population, COVID driven study dropout or loss to follow-up, lack of pad weight test, and lack of a control group. A strength is that we provide a standard laser protocol that accounts for the degree of vaginal atrophy (Table 1) and describe outcomes of vulvar/vaginal symptoms and LUTS in patients receiving vaginal fCO2 laser therapy. Another strength is our treatment of non-menopausal patients. We plan to use these data to inform future sham-controlled trials. Patients in our study had no alternative treatments for GSM during the laser study period, decreasing confounders.

Conclusion

Fractional CO_2 vaginal laser therapy has shown to improve GSM and has emerged as a novel approach for managing SUI and OAB symptoms in women, especially those associated with menopause. Evidence thus far shows promising short-term improvements: many women experience better urinary control, less urgency, and improved quality of life. Benefits are seen primarily in post-menopausal women with mild incontinence, though experience with premenopausal women for LUTS is developing. The procedure is safe and comfortable with high satisfaction rates. Vaginal laser therapy is not part of any treatment guideline and more research into LUTS in menopausal and non-menopausal women is needed.

Declarations

Data availability statement: The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interest: The authors have no direct or indirect financial interests or connections related to this study.

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Figures

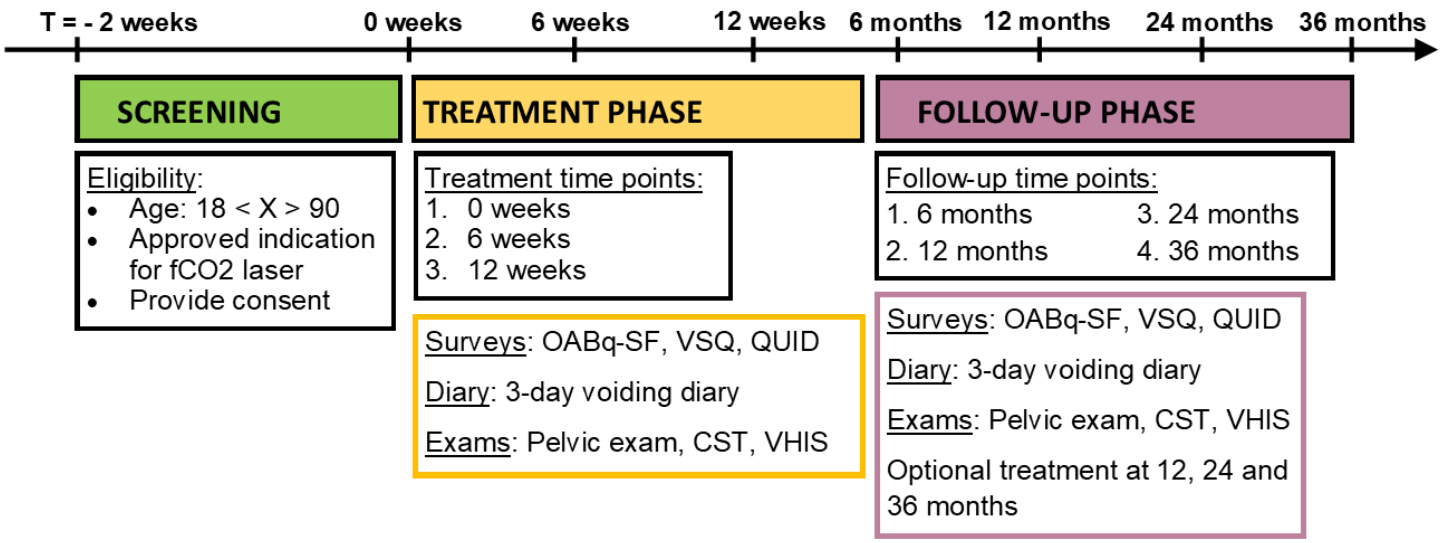


Figure 1

Scheme of study visits and activities

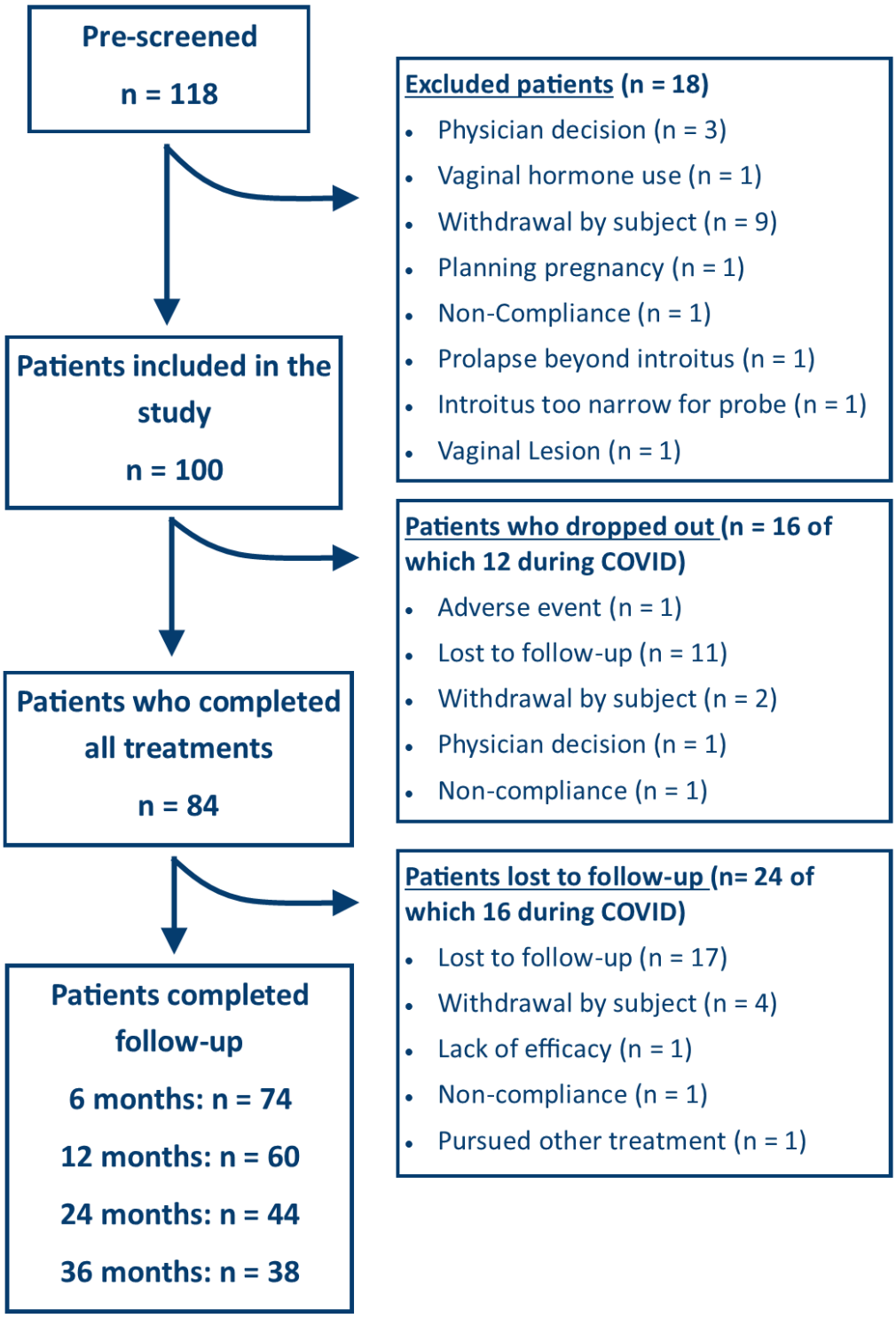


Figure 2

Study screening and enrollment log. Drop-out or lost-to-follow-up during COVID was anybody that did not complete treatment or follow-up visits between March 2020 and March 2022.

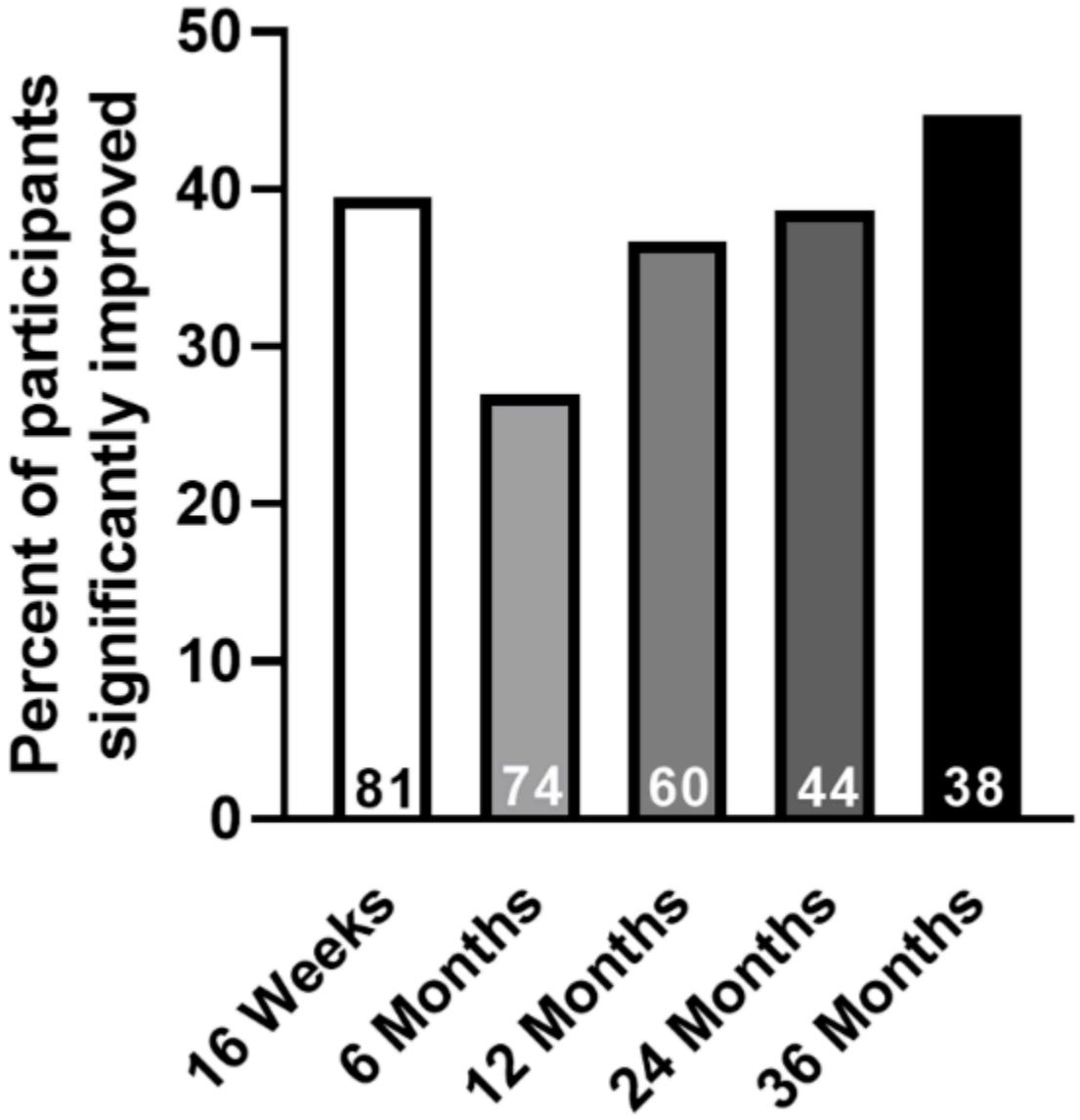


Figure 3

Overall patient-reported symptom improvement. Patients were asked to rate how their symptoms have changed since before starting laser therapy on a 7-point scale: 1. Markedly improved, 2. Moderately improved, 3. Slightly improved, 4. No change, 5. Slightly worse, 6. Moderately worse, 7. Markedly worse. This graph identifies the percentage of people stating their symptoms were significantly improved (score of 1 or 2) since starting laser therapy.

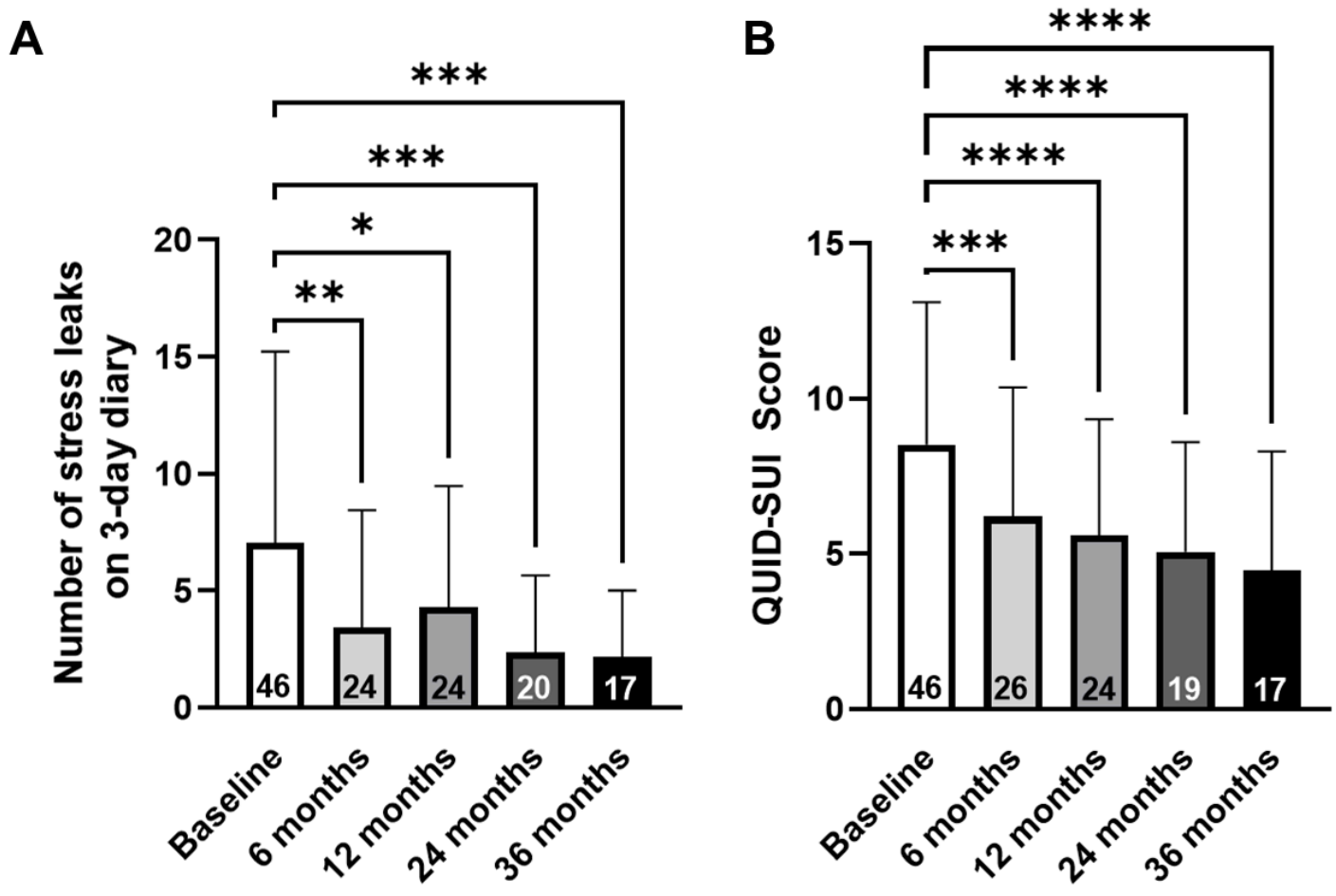


Figure 4

Laser has objective and subjective improvement on stress urinary incontinence. Only patients who reported SUI on baseline voiding diary were included in this analysis. A. Significant reduction in number of stress incontinence episodes on 3-day dairy is seen at 6, 21, 24 and 36 months (ANOVA p=0.0066). B. Patients reported significant improvement on the QUID SUI sub-section (ANOVA p=0.0002) at each follow-up time point. Tukey post-hoc test p-values: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$. Numbers in bar graph represent number of patients included in the analysis.

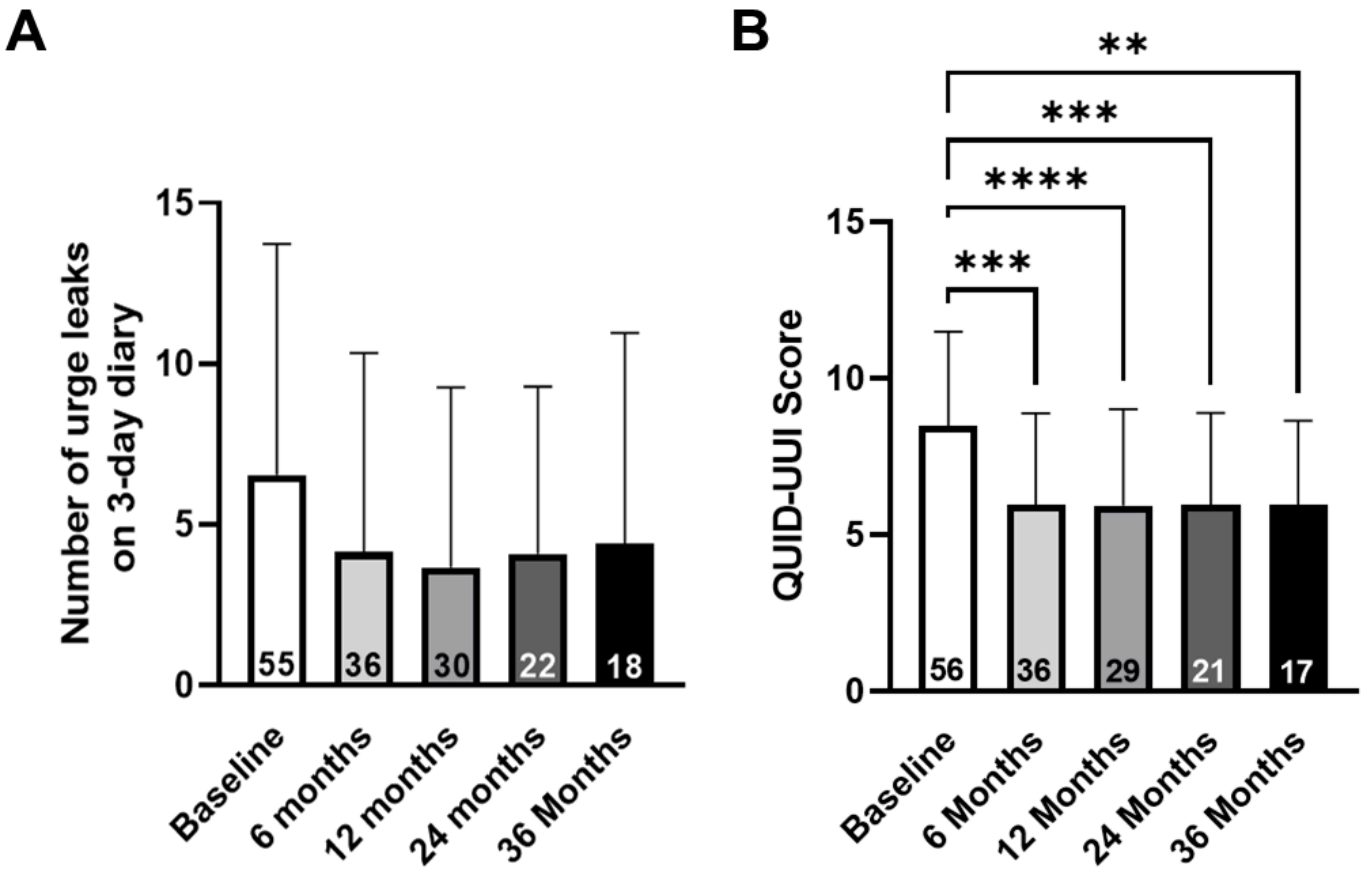


Figure 5

Significant reduction in urge incontinence episodes with Laser treatment. Only patients who reported UUI on baseline voiding diary were included in this analysis. A. Based on 3-day voiding diary, a small reduction in urge incontinence episodes was observed, though this reduction was not statistically significant (ANOVA p=0.0838). B. Patients reported significant subjective improvement in urgency symptoms on the QUID UUI sub-section (ANOVA p<0.0001) at all follow-up time points. Tukey post-hoc test p-values: ** p < 0.01, *** p < 0.001, **** P < 0.0001. Numbers in bar graph represent number of patients included in the analysis.

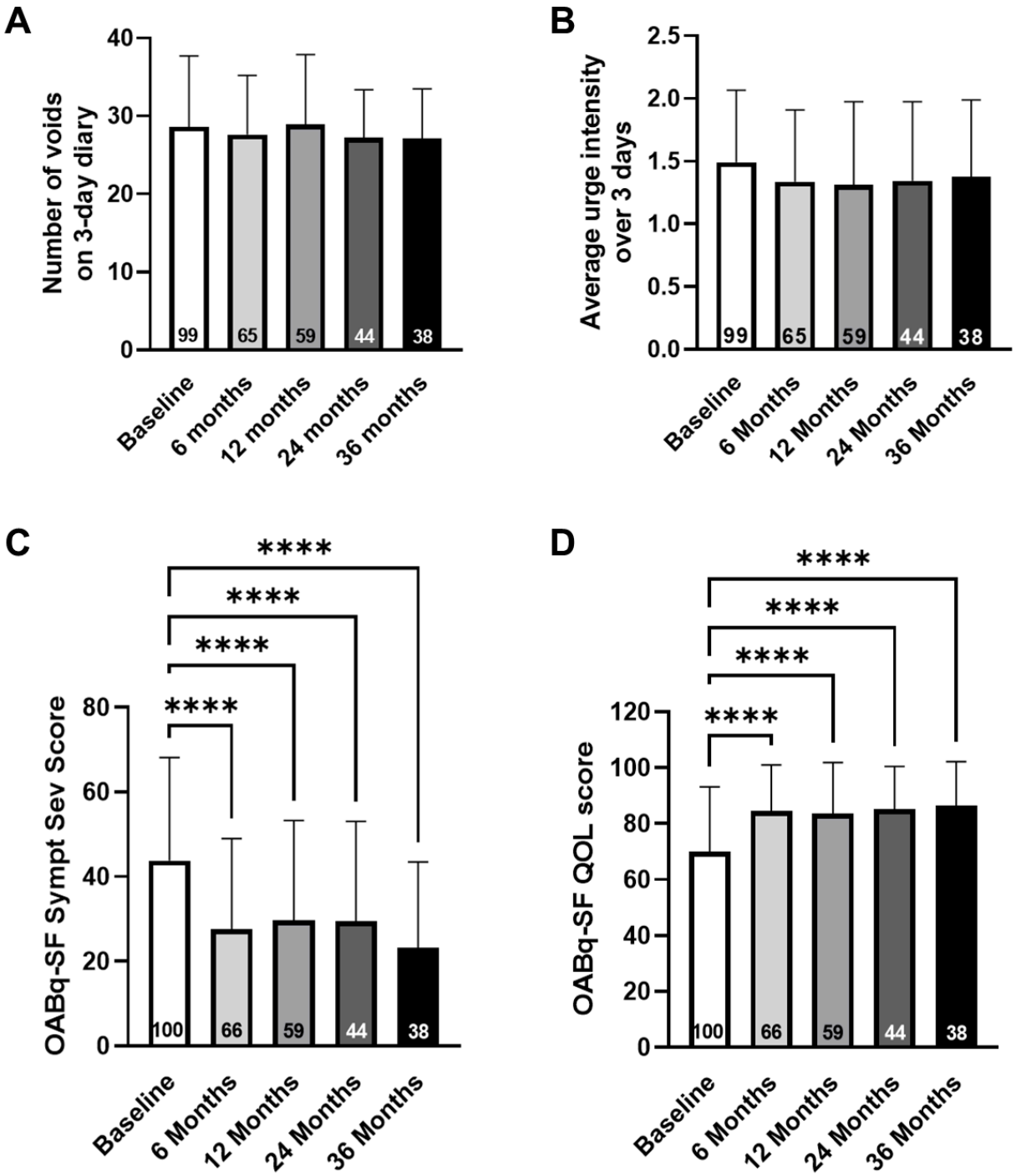


Figure 6

Laser treatment improves OAB symptoms. A. No change in the number of voids on 3-day voiding diary was noted as a result of laser treatment. B. Laser did not alter urge intensity scores. C-D. Significant subjective improvement for OAB based on patient reported questionnaires at each follow-up visit (ANOVA P<0.0001). Tukey post-hoc test p-values: **** p < 0.0001. Numbers in bar graph represent the number of patients included in the analysis.

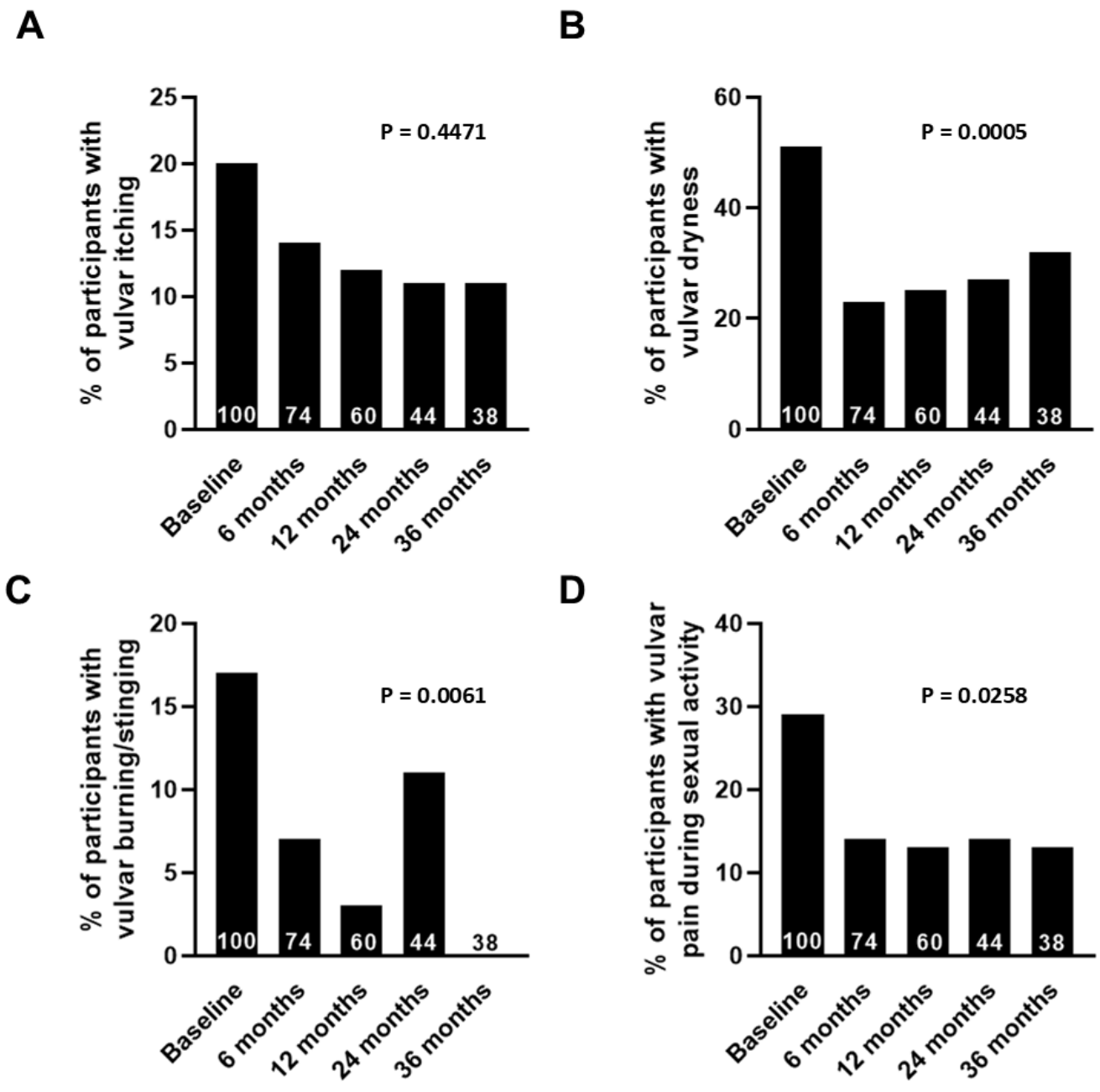


Figure 7

Laser treatment improves incidence of vaginal symptoms up to 36 months following treatment. The incidence of vulvar itching (A) was not significantly altered following laser treatment. However, patients did report improvement in vulvar dryness (B), burning (C) and pain during intercourse (D) on the VSQ in response to laser therapy. Statistical analysis performed with Chi-square test.