

Pelvic Floor Exercises Alone or in Combination with Perineal Electrical Stimulation for Uterine Prolapse: A Pilot Randomized Trial

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Abstract

Background and aims: Pelvic floor rehabilitation is a non-invasive therapy crucial element of conservative treatment for uterine prolapse. Electrical stimulation is a novel type of pelvic rehabilitation that can enhance the results of pelvic floor exercises. Researchers have well documented its effectiveness in the treatment of urinary incontinence. **Aims and objective** - The objective of the study was to see if combining perineal electrical stimulation with pelvic floor exercises provided additional advantages for uterine prolapse. **Material and Methods-** A total of twenty patients with uterine prolapse of grade one or two were randomly split into two equal groups. Group 1 received pelvic floor exercises and perineal stimulation for twelve weeks, whereas group 2 received pelvic floor exercises alone. **Result** -Perineal strength was evaluated using a perineometer, and the severity of prolapse symptoms and quality of life (QOL) using the pelvic organ prolapse symptom score questionnaire (POP-SS) on the 12th week following treatment completion. Perineal strength of group 1 was significantly higher to the group 2 [95% CI (0.04 to 12.15), $p=0.04$], indicating a relevant difference between groups, but there was no significant difference in POP-SS score at 12 weeks in group 1 relative to group 2 [mean difference <1.01 , 95% CI (-5.09 to 4.69), $p=0.93$].

Conclusion - Electrical stimulation in combination with pelvic exercises gave better results in terms of perineal strength. Moreover, both the groups improved their POP-SS scores with no significant difference between them.

Keywords

Perineal electrical stimulator, Pelvic floor exercises, Uterine prolapse, POP-SS, Perineometer

Introduction

Bulging of pelvic organs into the vaginal canal due to the frailty of structures surrounding these organs is common nowadays.

Prolapse of the anterior vaginal wall (urethrocele, Cystocele), posterior vaginal wall prolapse (enterocele, rectocele), and the apical segment of the vagina (cervix/uterus, cuff ,or vault) are all examples of pelvic organ

prolapsed. ^[1, 2]

Uterine prolapse is a frequent and painful disorder that causes the sensation that something is falling down from vagina. Constant pressure is felt on the vagina, which is usually relieved in a lying position. ^[3] Stages of uterine prolapse are classified as stage 0 (no prolapse, stage 1 (leading edge of prolapse is >1 cm above the level of the

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Manuscript Received: 01.06.2022; **Revision Accepted:** 06.08.2022;

Published Online First: 10 April, 2023

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Cite this article as: Bali S, Bagga R, Sarkar P. Pelvic Floor Exercises Alone Or In Combination With Perineal Electrical Stimulation For Uterine Prolapse: A Pilot Randomized Trial. JK Science 2023;25(2):87-92

hymen), stage 2 (leading edge of prolapse is between 1 cm above and 1 cm distal to hymen), stage 3(leading edge is 1 cm distal to hymen), stage 4(eversion of the vagina) by the Pelvic Organ Prolapse Quantification System (POP-Q) system.^[4] Around 10% of the female population opts for surgical management to overcome this problem.^[5]

The strength of pelvic floor muscles (PFM) is hugely responsible for preventing prolapse. The list of varied risk factors includes connective tissue abnormalities, genetic, pelvic floor muscle weakness, post menopausal period, vaginal delivery, multiparous women, geriatric female population, prior hysterectomy. Some of the other etiological factors include vacuum or forceps delivery, long labor time, large weight of the baby during birth [5]. Symptoms like vaginal bulging, heaviness around the pelvic area, incontinence, feeling of something coming down from the vagina, issues with defecation, low back pain, bleeding, infection are commonly reported by patients, which affect social, psychological, and sexual aspects of life.^[1,5] The incidence of uterine prolapse is directly proportional to age.^[4]

Among various treatment options conservative method is the most usually preferred one, as proved by many randomized controlled trials, but if its severe or of greater than grade 2, surgery is the only option. The effectiveness of the treatment depends on the relief of symptoms, recurrence of prolapse, and overall improvement in QOL. Pelvic floor rehabilitation constitutes an integral part of conservative treatment as it strengthens the supporting musculature of pelvic organs like the uterus, bladder, and bowel. Pelvic floor rehabilitation is non-invasive, very effective, and can be done at any place and in any position.^[6]

Electrical stimulation is a new method of rehabilitation that can add to the effects of pelvic floor exercises. Primary endings of pelvic muscles are reactive to even slight changes in their length and receptors, specially Ia and II afferent fibers, which give a good response to electrical stimulation.^[7] Its effect has been well established in the case of urinary incontinence (UI), but

no study has been done to prove its effect on uterine prolapse.^[6,8]

The study aims to use a perineometer and the POP-SS questionnaire to assess the effects of pelvic floor exercises alone and in conjunction with perineal electrical stimulation in uterine prolapse patients.

Material and Methods

This is an assessor blinded randomized pilot trial conducted at Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India from November 2020 to March 2021 to evaluate the effect of perineal electrical stimulation and pelvic floor exercises on perineal strength and QOL in uterine prolapse patients. The sample size was calculated to be 20 participants with a 5% significance level and 80% statistical power. Microsoft excel 2010 was used to calculate the same using formulae mentioned below.

$$\{Z^2 * p(1-p)/e^2\} / \{1 + [z^2 * p(1-p)/e^2N]\}$$

Ethics

The Institutional ethical committee approved the study and this trial is registered with Clinical trial registry India (CTRI) - CTRI/2020/11/028850.

Participants: All participants signed a written informed consent form before beginning the study.

Inclusion criteria

1. Women >18 years of age
2. A gynecologist graded Stage 1 and 2 uterine prolapse
3. Females with the complaint of bulge coming down from vagina were included.^[6]

Exclusion criteria

1. Patients with detrusor over activity.
2. Cistometric capacity reduction .
3. Surgical care for stress urinary incontinence in the past.
4. Cystocele or rectocele.
5. Uterine prolapse of grade 3 and higher.
6. Vulvovaginitis
7. Urinary tract infections.
8. Pregnancy.
9. Person with pacemaker.
10. Pelvic cancer.
11. Patient with psychiatrist disorders.^[6]

Table 1 (Background and Outcome Variables in Both Groups)

	GROUP 1(n=10) Mean (SD)	GROUP 2(n=10) Mean (SD)	Sig
Age(yrs)	51.5(16.1)	57.8(13.1)	0.74
Weight(Kgs)	67.4(9.2)	70.0(10.9)	0.51
Height(cms)	154.9(6.8)	157.9(3.8)	0.04*
Duration of symptoms(yrs)	6.2(4.2)	7.1(4.8)	0.72
Strength at baseline(mm of Hg)	66.1(11.7)	66.0(7.9)	0.14
Strength at completion	94.2(5.6)	88.1(7.1)	0.47
POP-SS at baseline	17.6(6.0)	18.0(7.6)	0.58
POP-SS at completion	8.1(5.1)	8.3(5.3)	0.81
Parity	2.2(0.7)	1.7(1.3)	0.32
Menopause (%)	NO 75.0%	25.0%	
	YES 43.8%	56.3%	
Grade (%)	1 60.0%	40.0%	
	2 40.0%	60.0%	

Table 2 Within Group Perineal Strength and POP-SS Scores ,pre and Post perineal Electrical sSimulation.

	Strength at baseline Mean(SD)	Strength after 12 wks Mean(SD)	P-value	POP-SS at baseline Mean(SD)	POP-SS at 12 wks Mean(SD)	P-value
Group 1(n=10)	66.1(11.7)	94.2(5.6)	0.02*	17.6(6.0)	8.1(5.1)	0.007*
Group 2(n=10)	66.0(7.9)	88.1(7.1)	0.14(NS)	18.0(7.6)	8.3(5.3)	0.001*

Paired t-test is used for within group analysis.

SD: standard deviation ;P-value: probability value;*Significance at alpha level; NS: non significant; POP-SS: Pelvic organ prolapse symptom score : p value < 0.05 is significant.

Intervention: Among the 25 participants who came for consultation, 20 fitted in the inclusion criteria. All the patients gave informed consent before starting the trial. Two groups of patients were created. One group was taught pelvic floor exercises and told to visit the department for 12-weeks (fortnightly) [9]. Women were given an individualized home exercise routine, and every day, they were told to do six sets of exercises (ten repetitions held for ten seconds in each set) [10]. Electrical stimulation of perineal muscles was provided to another group of women. Biphasic current (frequency- 50 Hz, pulse width -300 ms, intensity 0-100 mA) for 20 minutes was given to the females once a week for a period of 12 weeks [6].

Baseline data: Baseline data included sex, age, height, weight, duration of symptoms, strength of perineal muscles, POP-S score, parity, grade of uterine prolapse, and menstrual status.

Outcome measures were taken on the 12th week after completion of treatment. The outcomes were severity of prolapse symptoms and quality of life (QOL) measured by the pelvic organ prolapse symptom score questionnaire (POP-SS) and perineal strength measured by perineometer . [11-14]

Primary outcome measure:Perineometer is an effective training and measuring device that can train the perineal muscle strength as well as measure the perineal strength. It's an important tool to record perineal strength and

Table 3. Difference in Perineal Strength and POP-SS at 12 Weeks Between the Groups)

	F	t	df	P-value	95% Confidence interval	
					(lower)	(upper)
Strength at baseline	2.2	0.02	15.8	0.98(NS)	-9.38	9.58
Strength after 12 wks	0.5	2.12	17.05	0.04*	0.041	12.15
POP-SS at baseline	0.3	-0.13	17.16	0.08(NS)	-6.88	6.08
POP-SS at 12 wks	0.05	-0.08	17.97	0.93(NS)	-5.09	4.69

Unpaired t-test is used for between group analysis.

P-value: probability value; *Significance at alpha level; NS: non significant; POP-SS: Pelvic organ prolapse symptom score: p value < 0.05 is significant.

progress. To record perineal strength transducer is covered with a condom, inserted in the vaginal introitus of the patient in a gynecological position. After the transducer is inflated, the patient contracts pelvic muscles with maximum strength. Readings on the ammeter (0-100 mm of Hg) will determine the strength of perineal muscles. [13,14]

Secondary outcome measure: The Pelvic Organ Prolapse Symptom Score (POP-SS) is a seven-item questionnaire that has been scientifically established to address the frequency of symptoms, severity of prolapse, and associated discomforts and is to be filled by the patient. Each item is graded on a scale of 0 to 4, i.e., never to always, with a total range of 0-28. [15]

Recruitment: Patients were recruited from the gynecology department of the same institute after being assessed by a gynecologist.

Allocation: 25 Participants were assessed for eligibility, but only 20 were recruited for the study. Selected participants were randomly assigned by a lottery method into two groups. One group (n=10) followed the pelvic floor exercise regime, and the other (n=10) received perineal stimulation and pelvic floor exercises. No dropouts were there throughout the trial.

Blinding: An assessor who was unaware of the therapy, blinded to the treatment, recorded the outcomes. Patient blinding couldn't be maintained because of the nature of the treatment.

Data management and statistical analysis

SPSS version 26 (SPSS IBM) was used to analyze the

data. We tabulated descriptive statistics with means, SDs, and percentages to record baseline demographics and clinical characteristics. The Shapiro-Wilk test was used to analyze data normality, and parametric tests were used based on the findings. The Perineal strength (Perineometry results) and POP-SS scores data recorded in the diary were analyzed using the t-test and independent t-test for analysis within and between groups respectively. A significance level of 5% was used for all data analysis.

Results

The mean age of the participants was 54.6 years (SD 14.6), 60% of subjects in group 1 had grade 1, and 40% had grade 2 prolapse. In group 2, 40% had grade 1, and 60% had grade 2 prolapse; 56.3% of subjects in group 2 were menopausal compared to group 1, where 43.8% were menopausal. The demographics of the subjects in groups 1 and 2 are listed in Table 1.

Primary outcome measure

The strength of the pelvic floor muscles did not differ significantly between the groups at the start. Pre and post 12 weeks difference in perineal strength (p=0.02), was statistically significant (p<0.05), but the difference was insignificant for group 2 (p=0.14) (Table 2). At 12 weeks perineal strength of group 1 was significantly higher than group 2 [95% CI (0.04 to 12.15), p=0.04], indicating a significant difference between groups as shown in Table 3.

Secondary outcome measure: No relevant difference in POP-SS scores at baseline was seen between groups.

As shown in Table 2, there was a substantial statistical difference ($p < 0.05$) within each group for assessment of POP-SS scores at pre and post 12 weeks ($p = 0.007$ for group 1 and $p = 0.01$ for group 2) but no statistically significant difference in POP-SS score at 12 weeks in group 1 relative to group 2 (mean difference 1.01, 95% CI (5.09 to 4.69), ($p = 0.93$) (Table 3).

Discussion

Pelvic floor muscles are an integral part of the support system that holds the uterus and other pelvic organs in place. Strengthening or stimulation of these muscles is very important to prevent or treat uterine prolapse, and muscle tone changes can be seen as a probable cause for the same.^[6]

This study was motivated by the fact that perineal stimulation is effective for urinary incontinence may also give a good improvement in uterine prolapse [7,8].

A relevant difference was seen ($P < 0.05$) between the groups in terms of perineal strength at 12 weeks period, but the difference was not significant in terms of POP-SS score ($p = 0.93$). Intra Group analysis at baseline and 12 weeks showed a good difference in POP-SS scores in both groups, but perineal strength improved significantly only in the Ist group. The probable cause for irrelevant improvement in perineal strength at 12 weeks in group 2 can be non-compliance of females to exercises or lack of proper understanding of the procedure. We assumed that perineal electrical stimulation and pelvic exercises together would give better results in terms of strength and QOL but results only supported strength improvement, whereas QOL assessed by the POP-SS questionnaire didn't support our assumption. This can be due to small sample size or short duration of the study, so recommend further research on the same. Margaret Maxwell *et al.* [2017] did a study to investigate the effect of pelvic floor muscle training on women with pelvic organ prolapse. They found that floor exercises are an efficient and cost-effective means of rehabilitation.^[11] In another study, Liliana Stüpp *et al.* [2011] gave pelvic muscle training to uterine prolapse patients for 14 weeks, and the results showed that the muscle strength ($P < 0.001$),

endurance ($P < 0.001$), and electromyography parameters ($P = 0.008$) improved.^[10]

In a randomized, controlled trial [2014], a total of 447 patients were divided into intervention and control groups by concealed allocation; patients in the interventional group were taught pelvic floor exercises, and control group patients were given prolapse lifestyle advice leaflet. The intervention group presented significant improvement in symptoms.^[12] A study by Massimo Rivalta *et al.* [2009] stated the important role of electrical stimulation in pelvic floor rehabilitation to treat sexual functions and QOL in urinary incontinence patients.^[7] Another similar study was conducted by Giuseppe PG *et al.* [2007] to evaluate the effect of pelvic floor transvaginal electrical stimulation on Sexual function in 37 women with urinary incontinence and concluded that it's a safe therapy for patients with mild to moderate UI^[8]. The strengths of this trial were its novelty of treatment for this condition, assessor blinding, design, compliance of patients, and use of reliable and valid outcome measures.

Zhong F. *et al.* [2021]^[16] evaluated the effect of electrical stimulation biofeedback therapy along with functional pelvic floor exercises on post partum pelvic organ prolapse in 104 women with grade 0 and 1 prolapse and concluded that contraction duration and pressure was improved in study group more than control group.^[16] The method of perineal electrical stimulation used in this trial was different and the treatment was given for 12 weeks in contrary to above trial where only immediate effects of therapy were seen.

Results of the study conclude that perineal stimulation and pelvic floor exercises together give a good improvement in perineal strength than pelvic floor exercises alone but to further strengthen the conclusion larger sample size as well as longer follow up in similar research projects is needed. Both the groups improved their POP-SS scores with no major difference between them.

Study Limitation: Small sample size, shorter duration of the study, and lack of long-term follow-up were the main limitations that give room for further research.

We did not include females with greater than grade 2 prolapse because of the fact that these stages are more severe and mostly require surgery.

Conclusion

In various studies, pelvic floor exercises have been effective in treating symptoms of uterine prolapse, and perineal stimulation has proved its effectiveness in urinary incontinence. In this study, electrical stimulation in combination with pelvic exercises gave better results in terms of perineal strength. Moreover, both the groups improved their POP-SS scores with no major difference

Financial Support and Sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

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