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COMPARATIVE STUDY TO EVALUATE THE EFFECT OF CONVENTIONAL PELVIC FLOOR MUSCLE TRAINING VS PF 360 ON PAIN, PERIOD REGULARITY AMONGST FEMALES WITH MENSTRUAL DISORDERS.

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ABSTRACT Menstruation is defined as "A process in which the uterus sheds blood and tissue through the vagina."1 Every month 1.8 million people menstruate across the world.2 Average menstrual cycle is 28 days, it can be considered normal if it is regular and if it falls between 21 to 40 days. It is proven that almost 84.2% of females suffer from dysmenorrhea, and 34.2% of females suffer from severe pain.4 Dysmenorrhea and severe pain are also reported to be a symptom in many females having polycystic ovarian morphology.6 Other menstrual disorders like PCOS, Endometriosis, adenomyosis, uterine fibroids etc. are increasing due to multiple factors like lifestyle, diet, pollution, stress, anxiety, etc. Dysmenorrhea can be classified as primary dysmenorrhea with no underlying pathology. The primary reason for severe pain and other symptoms is increased prostaglandin secretion.7 In secondary dysmenorrhea, the menstrual pain is due to an underlying pathology like endometriosis, pelvic inflammatory disease, adenomyosis, uterine fibroids, etc. Dysmenorrhea, Amenorrhea, etc can be very strenuous conditions for females. Which also affects their proficiency at work and overall health. Pelvic Floor Muscles are in close vicinity of pelvic organs, whenever there is any ongoing pathology in the pelvic cavity it can directly or indirectly affect the pelvic floor muscles. The conventional pelvic floor muscle rehab done by transvaginal devices is not very comfortable especially for nulliparous or sexually inactive females and the compliance to such treatment is low. PF 360 is a unique revolutionary technology that can be better tolerated as it has mechanical stimulation rather than electrical stimulation.

KEYWORDS : Dysmenorrhea, PCOS, PCOD, Infertility, PF360

INTRODUCTION

Menstruation is defined as "A process in which the uterus sheds blood and tissue through the vagina."[1] Every month 1.8 million people menstruate across the world.[2] Average menstrual cycle is 28 days, it can be considered normal if it is regular and if it falls between 21 to 40 days. During menstruation, the endometrial layer of the uterus sheds, the uterine smooth muscle contractions, to remove the menstrual waste outside the body. The estrogen and progesterone hormones are very low during menstruation, this is the triggering factor of menstruation. The reduced level of estrogen and progesterone and increased activity of prostaglandins are known to be the cause of symptoms like pain, cramps, dizziness, fatigue, backache, headache, excessive bleeding, etc.[3]

It is proven that almost 84.2% of females suffer from dysmenorrhea, and 34.2% of females suffer from severe pain.[4] Another comprehensive review concluded that the prevalence of dysmenorrhea can vary from 16% to 91% and the prevalence of severe pain was almost 2 to 29%. The review also concluded a positive association between stress, family history of dysmenorrhea and dysmenorrhea.[5] Dysmenorrhea and severe pain are also reported to be a symptom in many females having polycystic ovarian morphology.[6]

Other menstrual disorders like PCOS, Endometriosis, adenomyosis, uterine fibroids etc. are increasing due to multiple factors like lifestyle, diet, pollution, stress, anxiety, etc.

Dysmenorrhea can be further classified as primary dysmenorrhea – no underlying pathology like endometriosis, pelvic inflammatory disease, adenomyosis, etc. The primary reason for severe pain and other symptoms is increased prostaglandin secretion.[7] In secondary dysmenorrhea, the menstrual pain is due to an underlying pathology like endometriosis, pelvic inflammatory disease, adenomyosis, uterine fibroids, etc.

Dysmenorrhea, Amenorrhea, etc can be very strenuous conditions for females. Which also affects their proficiency at work and overall health.

Pelvic Floor Muscles are in close vicinity of pelvic organs, whenever there is any ongoing pathology in the pelvic cavity it can directly or indirectly affect the pelvic floor muscles.

The conventional pelvic floor muscle rehab done by transvaginal devices is not very comfortable especially for nulliparous or sexually inactive females and the compliance to such treatment is low. PF 360 is a unique revolutionary technology that can be better tolerated as it has mechanical stimulation rather than electrical stimulation.

There is scarcity of literature to establish the relationship between pelvic floor muscle exercises with PF 360 for menstrual disorders.

METHOD

A total of 1176 patients who came to the Gynec outpatient department over 1 year, were recruited in this study. Out of 1176, 324 participants dropped the study due to various reasons. The study concluded with 852 participants. All the females from menarche to menopause who reported dysmenorrhea, irregular periods, heavy periods, PCOD, and endometriosis were included in the study.

The patients who were not willing to participate or sign the written informed consent and had any other acute or chronic infection, vaginitis, or vulvar-vestibulitis were excluded from the study.

All the participants were given an understanding related to the menstrual cycle, maintenance of menstrual hygiene, PCOS and other menstrual health-related issues.

Outcome Measures

1) NPRS (menstruation) – Numerical Pain Rating Scale was used as an outcome measure to measure the pain experienced by the participants during menstruation. They were asked to rate the overall pain experienced. The scale has a rating from 0 to 10 where 0 stands for no pain, 5 is moderate and 10 stands for worst possible pain.
2) NPRS (perineal) – The participants who had pain in their perineum or tender or trigger points on the perineum were asked to rate the intensity of pain they experienced by using NPRS.
3) Self-reported questionnaire related to the quality of periods

To check the overall improvement in overall experience with the periods, a 3-question-based Scale was designed.
I. How regular are your periods?
Very irregular – 1
Somewhat irregular - 2
Average – 3
Very regular – 4

ii. How is your blood flow during periods?
Scant – 1
Very Low – 2
Very heavy – 3
Regular – 4

iii. How satisfied are you with your overall period health?
Extremely dissatisfied – 1
Dissatisfied – 2
Satisfied – 3
Extremely satisfied – 4

To analyse the result 4 point Likert scale was used (1-4), 1 being worst and 1 being worst and 4 being best.

4) MOS – Modified Oxford MMT was used to analyse the pelvic floor muscle strength. The scale has grading from 0 to 5.

Procedure:

The participants who had spasmodic or painful perineal areas were not tested with MOS. Before carrying out the examination with MOS the perineal observation and external palpation were done. The female with painful perineum were categorized as having hypertonic pelvic floor muscles.

Study Design: Interventional Study

Sampling Design: Convenience Sampling

The participants were divided into 3 groups:

Group A (Physical Exercise + Fertility Massage + PFM Rehab) – Physical exercises and fertility massage at home and Pelvic Floor Rehab without PF 360 at the Clinic for 10 days followed by a home exercise plan which includes aerobics, fertility massage and pelvic floor exercises at home for 8 wks.

Group B (Physical Exercise + Fertility Massage + PF 360) – Physical exercises and fertility massage at home and Pelvic Floor Rehab with PF 360 at the Clinic for 10 days followed by a home exercise plan which includes aerobics, fertility massage and pelvic floor exercises at home for 8 wks.

Group C (Physical Exercise + Fertility Massage + PF 360) – Physical exercises and fertility massage at home and Pelvic Floor Rehab with PF 360 at the Clinic for 8 wks.

Physical Exercises:

All the participants were given an exercise plan, which included 30 mins of paced walking every day, 10 min of abdominal breathing exercises at least 4 times a day and 2 days a week resistance training (upper body one day and lower body another day) for 8 wks.

Fertility Massage (Abdominal Manual Therapy):

The participants were taught fertility massage, and for better understanding, the participants were given a video explaining fertility massage. Followed by fertility massage, the castor oil pack application was also explained. The fertility massage was done every day except for the days of menstruation, it was also done for 8 wks.

Pelvic Floor Rehab:

The participants were first assessed by using the MOS (Modified Oxford Scale) to find out type of the pelvic floor muscle involvement. According to the pelvic floor dysfunction, the pelvic floor rehab was planned.

Group A

The participants were advised to do pelvic floor muscle contraction if they had weakness.

The following protocol was used, 3 sets of 10 reps total 30 reps a day start with 1 sec hold time and 1 sec relax. Slowly progress to 10-sec hold and 10-sec relax 10 reps 3 sets a day.

The participants who had spasmodic pelvic floor muscles was taught pelvic floor relaxation, perineal stretching, vaginal dilators etc.

The pelvic floor rehab was asked to be continued for 8 wks.

Group B

The participants were given the treatment with PF 360 (non-invasive technology) which is designed for treating different types of pelvic floor dysfunction, the PF 360 has a target activator - Focused Tip technology which is anatomically designed. PF 360 works on the following principle,

Tonic Vibration Reflex – activates muscle spindle, which further leads to increased muscle activation

Bulbocavernosus Reflex – a gentle touch over the clitoris will activate the bulbocavernosus reflex and will lead to more muscle activation

Improves Muscle Memory – repeated activation of the pelvic floor muscles will lead to a more developed muscle activation and better recall of the movement (pelvic floor muscle activation).

Pelvic Floor Muscles activation or relaxation was done 15 mins every day at different perineal areas like perineal body, paraclitoral, paraurethral, paravaginal, para anal area and on right and left labia majora.

The Pf 360 along with pelvic floor exercises was given for 10 days and then the participants were asked to do home exercise program of fertility massage and physical exercises for 8 weeks

Group C:
The pelvic floor rehab was given with Pf 360 for 8 wks. The physical exercise and fertility massage were advised to be done at home for 8 wks.

In summary,

Groups	Treatment Provided	Duration
Group A	PFM Rehab – 3 sets of 10 reps total 30 reps a day start with 1 sec hold time and 1 sec relax. Slowly progress to 10-sec hold and 10-sec relax 10 reps 3 sets a day.	PFM Ex at clinic - 10days Home Ex plan + PFM Ex - 8 wks
Group B	PF 360 – Pelvic Floor Muscles activation or relaxation was done 15 mins every day at different perineal areas like perineal body, paraclitoral, paraurethral, paravaginal, para anal and on right and left labia majora.	PF 360 + PFM Ex – 10days, Home Ex plan + PFM Exe – 8 wks
Group C	PFM + PF 360	PF 360 + PFM Ex - 8 wks, Home Ex plan – 8 wks

* Fertility massage was not done during menstruation
* Home exercise plan include → Physical exercises, fertility massage

RESULT

There were 3 groups in this study the test used was the JONCKHEERE TREND test was used. The measurement of all 4 outcome measures, NPRS (menstrual), NPRS (perineal), and Self-reported scale for quality of menstruation and MOS were analysed for with-in group analysis and then were analysed for between-group analyses.

The participants were aged between 13 years to 45 years.

The mean Age, BMI, Parity, and pelvic floor muscle involvement of all the groups are as below:

Table 1 Demographic Details

Serial No.	Parameter	Group A (376)	Group B (391)	Group C (409)
1	Age	25 ± 4	27 ± 2	23 ± 5
2	BMI	25 ± 1.9	23 ± 3.2	26 ± 2.4
3	Parity (number of pregnancy)	2 ± 1.5	2 ± 1.8	2 ± 1.2
4	PCOS	65 ± 4	67 ± 3	73 ± 5
5	Endometriosis	10 ± 5	8 ± 4	15 ± 6
6	Chronic Pelvic Pain	4 ± 2	8 ± 3	13 ± 5
7	Dysmenorrhea	300 ± 21	337 ± 10	321 ± 12
8	UI	231 ± 10	219 ± 5	307 ± 4
9	Vaginismus	5 ±1	8 ± 4	11 ± 6
10	Dyspareunia	173 ± 12	187 ± 9	203 ± 7
11	Constipation	251 ± 10	267 ± 12	317 ± 14

Table 2 The Pre-test and Post-test measure of all the group

Groups	NPRS - Menstrual	NPRS - Perineal	MOS	Self-reported Scale
Group A Pre test	7 ± 2.16	6 ± 1.11	3 ± 0.89	1 ± 0.12
Group A Post test	6 ± 1.45	5 ± 0.98	3 ± 0.99	1 ± 0.54
Group B Pre test	8 ± 1.34	7 ± 2.12	3 ± 1.01	1 ± 0.89
Group B Post test	5 ± 2.05	6 ± 1.17	4 ± 0.87	2 ± 1.67
Group C Pre test	9 ± 1.87	8 ± 2.67	3 ± 1.46	1 ± 0.75
Group C Post test	4 ± 2.76	2 ± 1.34	5 ± 0.01	3 ± 0.45

The result for Group A within-group analysis did not show any significant improvement. (p more than 0.05)

The result for Group B within-group analysis showed significant improvement (p=0.05)

The result for Group C within-group analysis showed significant improvement (p=0.001)

The analysis when done between-groups the difference observed in group C was the highest.

DISCUSSION

This study was completed on 852 participants, who were randomly divided into 3 groups Group A 284, Group B 284, Group C 284. The total number of participants was 1176. 324 participants (116 from Group A, 108 from Group B, and 100 participants from Group C) discontinued the study due to 84 females (26%) got pregnant, 153 females (47%) could not comply with the treatment, 32 females (10 %) got transferred to another city (after marriage), 55 females (17%) were discontinued as the treatment was clashing with their job hours.

Group A, which was showed improvement in the pain parameter but the improvement was not statistically significant. Group A did not receive any intervention directly from the therapist, they were given a plan of care which was supposed to be executed every day for 6 days a week for 8 weeks at home. Telephonic consultation was given every week for all the participants, the most generally asked question was regarding the pelvic floor muscle exercises. The drop-out rate of this group was the highest given the reason being lack of motivation and no supervision of the treatment plan.

There was no change in the MOS or self-reported questionnaire which shows that pelvic floor exercises done without any supervision or guidance are not effective.

Group B, the participants were called to the clinic for 10 days, the treatment was given with PF 360 for 15 mins, according to the involvement of pelvic floor muscle, followed by the participants were asked to follow the exercises prescribed at home for 8 wks.

There was a significant difference seen in the outcome measure of pain and self-reported scale, and the pelvic floor muscle performance also improved, the reason for this change can be due to the initial neuromuscular awakening of the pelvic floor muscles by PF 360 and a better understanding of the pelvic floor exercised by the participants. The initial 10

days of treatment with PF 360 improved the quality of pelvic floor muscle activation, which increased the participant's ability to do the pelvic floor exercises properly and precisely. This protocol can be considered as the minimal effective dose.

Group C, the participants received 8 wks treatment with PF 360 and they were asked to do fertility massage and physical exercises at home on their own for 8 weeks. This group showed significant improvement in all the parameters. The pain, pelvic floor muscle strength and the self-reported scale all showed significant improvement in within-group and between-group analysis. The PF 360 when given for 8 wks significantly improved the pelvic floor muscles strength and significantly reduced the perineal pain, thus improving the overall muscle ability to function optimally. The pelvic floor muscle's ability to contract completely and strongly as well as relax completely and easily increases its function of improving lymphatic drainage thus increasing the circulation of the pelvic area.

Few participants in Group B and C who were planning for pregnancy, conceived. Out of 1176 participants evaluated 852 participants finished the study, but on initial evaluation 83% of females should pelvic floor dysfunction. The participants during the evaluation were asked about symptoms related to pelvic floor dysfunction like UI, POP, Sexual Dysfunction, Vaginismus, Dyspareunia, Constipation, and Fecal incontinence. The participants were not given any questionnaire for the specific symptoms. This can be a further topic of discussion. The prevalence of pelvic floor dysfunction in females having menstrual disorders.

CONCLUSION

This study concludes that pelvic floor rehab training with PF 360 - Focused Tip Technology can significantly reduce symptoms of menstrual disorders. PF 360 can aid in effective changes in periods quality, pain and overall periods experience for the patients suffering from menstrual disorder.

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