



Effect Of Vonfidans (Het's Device To Instantly Test And Improve Vaginal Tightness) In Females With Low Back Pain

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Abstract: Low Back Pain is a very common musculoskeletal disorder amongst postnatal females. The healthcare cost involved in managing low back pain indicates a need to have more advancements. Low Back Pain is quite common in women compared to men, and there are other pelvic floor dysfunctions like urine leakage which are associated with low back pain. This study was conducted to see the effect of Vonfidans on low back pain. There were 3 groups for all groups the conventional rehab for low back pain was same. The pelvic floor training was different in all the groups. Group C where pelvic floor rehab was given with Vonfidans showed the highest improvement. This study concludes that, Vonfidans can be an effective tool for pelvic floor muscle strengthening in patients with chronic low back pain.

Index Terms – Low Back Pain, Pelvic Floor Muscles Weakness, Vaginal looseness, Vonfidans

I. INTRODUCTION

Low Back Pain is a very common musculoskeletal disorder amongst postnatal females. The healthcare cost involved in managing low back pain indicates a need to have more advancements.

Low Back Pain is quite common in women compared to men, and there are other pelvic floor dysfunctions like urine leakage which are associated with low back pain. ^[1]

Almost 60-80% of people experience low back pain at least once in their lifetime. ^[2]

Pelvic floor muscles are the hammock-shaped muscles connecting the symphysis pubis to the coccyx and ischial tuberosities. Pelvic Floor Muscles can go for weakness due to reasons like pregnancy, childbirth, aging, obesity, hormonal imbalance etc.

Pelvic Floor Muscles along with Diaphragm, Transversus Abdominis, and Multifidus form the core. The coordinated function of all 4 muscles is required to maintain proper core stability. Any dysfunction in one or more muscles can result in compromised core stability and low back pain.

Rehab for low back pain consists of strengthening the lower back muscles and other core muscles. The details of training the pelvic floor muscles are still lacking. ^[3]

Insufficient pelvic floor muscles can affect the function of the abdominal canister. ^[4]

This study aimed to evaluate the effectiveness of Vonfidans (Het's Device test instantly and to improve vaginal tightness through instant activation and strengthening of pelvic floor muscles) on low back pain.

II. METHOD

A Double blinded, randomised controlled trial was conducted in Ahmedabad at a private hospital. Patients were recruited from a private hospital setting in Ahmedabad. The study lasted for 12 months and over 1200 females were screened. Out of which 576 females were eligible for the study. The Ethical clearance was taken from the Institutional Ethical Committee of WOW IIPRE – International Institute of Pelvic Floor Research, Rehab and Education, Certificate of Recognition from the Government of India with a legitimate DIPP Number.

Inclusion Criteria – Females above 18 years of age, having nonspecific low back pain, ODI (mild to moderate score)

Exclusion Criteria – attended specific pelvic floor rehab training, patients with pain more than 8 on NPRS, spinal or pelvic surgeries (past or current – leading to severe neurological complications), neurological deficit progressive in nature, acute infection, inflammation, structural abnormality, chronic pelvic pain, interstitial cystitis, Vaginismus, dyspareunia, or any other condition where the pelvic floor muscles

had spasm and exhibited pain, overactive pelvic floor muscles and any other cardiovascular disorder which can limit the participation in the study, etc. Also, the patient who was not willing to sign the written informed consent and was unable to speak English.

2.1 Procedure

Before the allocation in the groups, all the participants were given a detailed education related to pelvic floor muscles, their function, and their association with low back pain. Also, the correct way of performing kegel exercises (avoiding accessory muscle use and avoiding Valsalva) was taught.

The participants were randomly divided into three groups. Group A was given conventional physiotherapy for low back pain along with pelvic floor exercises administered by previous studies^{[5],[6],[7]}. Group B was given conventional physiotherapy for low back pain along with a differentiated protocol for pelvic floor exercises, described in detail in the intervention section. Group C was also given conventional physiotherapy for low back pain and instead of differentiated protocol of pelvic floor exercises alone, pelvic floor exercises with Vonfidans were taught to the patients for improving vaginal tightness. (Pelvic floor muscles strength). The participants in all the three groups were asked to use a hot pack at home for pain relief.

2.2 Intervention

Group A

Conventional physiotherapy for low back pain – in the supine position, stabilization exercise for the core started with co-contraction of abdominals and multifidus during rest and maintaining proper control during activities. The progression was from lying to kneeling, sitting, and standing. The exercises included bridging, curl-ups, abdominal training, cat-camel exercise, flexion and extension stretch of the spine, and posterior pelvic tilt. The exercises were performed for 20 repetitions with 15 seconds hold, 2 sets with 3 minutes rest period for all the exercises were performed.^[7]

Proper activation of pelvic floor muscles was taught to the participant. Care was taken to help the participant differentiate isolated and correct activation of pelvic floor muscles without using accessory muscles, breath holding, or bearing down.

Participants were instructed to squeeze their pelvic floor muscles for 6 seconds (squeeze as if you are trying to hold the urine or gas) and relax for 6 seconds, 5 contractions in 1 minute. First week they are asked to do 25 cycles which is 5 minutes a day. Second week is 50 cycles which is 10 minutes a day. The third week is 75 cycles which is 15 minutes a day, and for fourth week is 100 cycles which is 20 minutes a day.^{[5],[6],[7]}

Group B

Along with above mentioned conventional physiotherapy, participants were asked to do pelvic floor exercises in the following way, Squeeze pelvic floor muscles as if trying to hold the urine. Squeeze for 1 second and relax for 1 second do 30 repetitions, slowly progress up to 10 seconds hold 10 seconds relax for 30 repetitions.

Group C

Along with above mentioned conventional physiotherapy, participants were asked to do pelvic floor exercises with Vonfidans. The participants were given the following program.

Use 1 weight to begin. Insert 1 weight inside the Vonfidans and cover the Vonfidans with a condom. In standing position insert the Vonfidans inside the vagina like inserting a tampon or menstrual cup. Insert the head and body of Vonfidans inside the vagina, only the tail should remain outside. Stand with legs apart, such that the thighs don't touch each other. Support the tail of the Vonfidans with a finger.

Squeeze pelvic floor muscles as if trying to hold the urine. Squeeze for 1 second and relax for 1 second do 30 repetitions, slowly progress up to 10 seconds hold 10 seconds relax for 30 repetitions. Once 1 weight becomes easy, add another weight (now exercising with 2 weights) and then progress up to 3 weights.

The duration of intervention for all 3 groups was 6 weeks. The conventional physiotherapy for low back pain and pelvic floor exercises were done under the supervision of a specialist for 3 days and for the remaining days of the week, the participants were instructed to do all exercises at home. The treatment was done for 6 weeks.

2.3 Outcome Measure

Outcome measures were taken on the day of enrolment and then after 6 weeks of treatment.

NPRS

Numerical Pain Rating Scale was taken to assess the intensity of the pain during rest (NPRS R) and during activity (NPRS A). It was taken on a 0 to 10 Likert scale, where 0 being No Pain and 10 being Maximum Pain.

ODI

Oswestry Disability Index was used to score the level of disability faced due to low back pain. The score has a rating from 0 to 50, 0 to 4 being no disability, 5 to 14 being mild disability, 15 to 24 moderate disability, 25 to 34 being severe and 35 to 50 being completely disabled.

Vonfidans

Vonfidans is used to test the current status of healthy vaginal tightness (strength of pelvic floor muscle). 3 weights are used for the testing, and the patient is instructed to do 10 coughs, 10 squats, and 10 jumps while holding the Vonfidans (with 3 weights) inside the vagina using the pelvic floor muscles (No support by any other accessory muscles or even finger). If Vonfidans falls out before the completion of all the activities it shows severe vaginal laxity (extremely weak pelvic floor muscles), if it slides out before the completion of all the activities (does not fall out) it shows mild to moderate vaginal laxity (weak pelvic floor muscles) and if it stays inside the vagina even after completion of 3 activities it shows no laxity (strong pelvic floor muscles).

Grade C = Severe vaginal laxity

Grade B = Mild to Moderate vaginal laxity

Grade A = No vaginal laxity

For better analysis, the grades were designated with numbers.

Grade C = 1

Grade B = 2

Grade A = 3

III. STATISTICAL ANALYSIS

The statistical analysis for all the outcome measures was done using Microsoft Excel. JONCKHEERE TREND was used to do the statistical analysis between all the 3 groups.

The level of significance ($p < 0.05$) at a statistical significance level of 95% CIs.

IV. RESULTS

The value of Age, BMI, and parity had no difference for all three groups.

Table 1: Values of Characteristics of Participants

Characteristic	Group A	Group B	Group C
Age	35.61 ± 10.42	37.86 ± 12.01	34.87 ± 15.73
BMI	22.45 ± 1.98	22.09 ± 1.41	21.67 ± 2.06
Parity	2.16 ± 1.25	2.01 ± 1.06	2.98 ± 1.43

Descriptive statistics for all three groups for the values of NPRS, ODI, and Vonfidans are given in the below table.

Table 2: Pre-test and post-test value of Group A

Parameters	Pre Test	Post Test
NPRS – R	4.82 ± 1.54	3.41 ± 1.91
NPRS – A	6.14 ± 2.43	5.01 ± 1.56
ODI	30.97 ± 7.86	26.87 ± 8.54
Vonfidans	1.15 ± 1.05	1.89 ± 0.87

Table 3: Pre-test and post-test value of Group B

Parameters	Pre Test	Post Test
NPRS – R	5.04 ± 2.14	2.67 ± 1.43
NPRS – A	6.19 ± 2.91	3.45 ± 2.05
ODI	31.45 ± 6.51	20.65 ± 5.76
Vonfidans	1.65 ± 1.14	2.01 ± 0.78

Table 4: Pre-test and post-test value of Group C

Parameters	Pre Test	Post Test
NPRS – R	4.12 ± 1.78	2.14 ± 1.01
NPRS – A	7.14 ± 1.65	2.21 ± 1.15
ODI	29.57 ± 8.45	16.17 ± 4.54
Vonfidans	1.34 ± 1.21	2.89 ± 0.11

The within-group analysis for Group A did not show any statistically significant change in any of the outcome measures. NPRS – R ($p = 0.743$), NPRS – A ($p = 0.653$), ODI ($p = 0.598$) and Vonfidans ($P = 0.654$).

The within-group analysis for Group B showed a significant change in NPRS – R ($p = 0.057$), NPRS – A (0.065). There was no change statistically significant change in the values of ODI ($p = 0.453$) and Vonfidans (0.341).

The within-group analysis for Group C showed a statistically significant change in all the outcome measures. NPRS – R ($p = 0.013$), NPRS – A ($p = 0.024$), ODI ($p = 0.045$) and Vonfidans ($p = 0.010$)

The between Group analysis when done for all three groups using the Jonckheere Trend test, there was a statistically significant change for all the outcome measures in Group B compared to Group A and Group C compared to Group B. ($p=0.005$) for NPRS – R, NPRS – A, ODI and ($p = 0.001$) for Vonfidans.

The mean for all the outcome measures for Group C is smaller than the other groups which signifies that Group C has maximum improvement in the outcome measure.

The Jonckheere Trend test was selected, as this test enables us to find the difference between the groups and also helps to determine the group having the most significant difference compared to other groups.

V. DISCUSSION

The study was conducted to see the effectiveness of Vonfidans in patients suffering from low back pain. Outcome measures used were NPRS, Oswestry Disability Index, and Vonfidans. This was a double-blinded randomized controlled trial, where the participants were blinded to intervention given to other groups. Also, the examiner who took the pre-test and post-test assessment of NPRS, Oswestry Disability Index, and Vonfidans was blinded to the groups. The examiner who did the assessment had no contact with the patients.

Out of 1200 women screened 576 women were eligible for the study and were allocated to 3 groups. Each group had 192 participants. 27 females dropped out in Group A, 13 females dropped out in Group B and 18 females dropped out from Group C. There was a total of 58 dropouts, none of the drop outs were due to any infection, any side effect, or any other psychological or physiological reasons related to the usage of Vonfidans the intervention. 10 females from Group A dropped out due to soreness in the perineal area after the second week. (The treatment protocol, might have fatigued the already weak muscles) 7 female confirmed their pregnancy after the commencement of the study, 18 females could not adhere to the intervention due to professional and personal commitments, 7 females shifted to another city, 4 females discontinued as they met with an accident and were advised for bed rest, 12 female did not report any reason for discontinuing the intervention. The study was concluded with 518 participants.

All the groups had no significant difference in the outcome measures before the commencement of the study. Group A showed no statistically significant difference in any outcome measures. Post-Test Values of NPRS – R and NPRS – A showed a difference in Group B, but the post-test values of ODI and Vonfidans did not show any significant difference. There was a statistically significant change in Group C compared to Groups A and B in all the outcome measures, NPRS (Rest and Activity), Oswestry Disability Index, and Vonfidans.

Previous studies reflect the effectiveness of pelvic floor exercises on core stability and chronic low back pain. In the study done by Amr A. Abdel-aziem et al. concluded the importance of pelvic floor training in females suffering from chronic low back pain compared to stabilizing exercise alone. ^[5] The result of this study differs from the study of Amr A. Abdel-aziem et al, considering Group A where the exact protocol was followed.

Group A did not show any improvement in any of the outcome measures compared to Group B and Group C. The pelvic floor exercises given to all the Groups were different. In Group A the pelvic floor exercises started with a 6-sec hold and relax for 5 minutes (25 reps) for the first week, 10 minutes (50 reps) for the second week, 15 minutes (75 reps) for the third week and 20 minutes (100 reps) for the fourth week. There is only an increase in the number of reps of the contractions, there is no systemic increase in the hold time. Secondly, the participants who had severely weak pelvic floor muscle (hypotonic) (having endurance less than 6 sec) might be using the accessory muscles more than the actual pelvic floor muscles recruitment. There could be a possibility of over-training and fatigue of the pelvic floor muscles.

Group B showed an improvement in the NPRS – R and NPRS – A, as the kegel exercises taught would have increased the activation of the muscles responsible for core stabilization, but the improvement was not statistically significant.

In Group C, there was a significant improvement found in all the outcome measures. In Group C, the pelvic floor muscles activation and strengthening were done by using the Vonfidans.

There are many studies conducted to see the effectiveness of pelvic floor muscle exercises on core stabilization or low back pain. But the researches on the effectiveness of pelvic floor muscles with vaginal weights are very less. This study has shown the effect of a structured protocol designed with an intravaginal device which provides tactile, kinaesthetic, visual biofeedback as well as neuromuscular re-education and progressive resisted exercises for pelvic floor muscles. The improvement in group C can be attributed to précised pelvic floor muscles strengthening due to Vonfidans.

Improved strength of pelvic floor muscles contributes to overall improved core stability as, pelvic floor muscles form core muscles and synergistic activity of all the core muscles increases the back stability. ^[6]

The NPRS score and ODI values for Group C showed significant improvement. These findings are similar to the findings of the study by Amr A Abdel-aziem ^{[5],[7]}

A study done by Mohammad A. Mohseni-Bandpei ^[8] concluded that PFM exercise with routine treatment was not superior to routine treatment alone in patients with chronic low back pain. The result of the present study is in contrast to the findings concluded by Mohammad A. Mohseni – Bandpei. The reason for this can be 1) the small sample size of 20 candidates, compared to the large sample size taken in this study. 2) The exercise protocol for pelvic floor muscles strengthening, participants were instructed to do 5sec hold and 4sec rest. The probability of muscles getting fatigued cannot be ruled out. The participants were then asked to increase the hold time to 10 seconds and repeat it 10 times for 6 times a day. However, the progression of exercises was not described in the study. There is a possibility that participants might have started to hold directly for 10 sec without a slow progression which is needed for muscle strength building. In this study, slow, gradual progress was taught to patients in both groups. Moreover, in the study done by Mohammad A. Mohseni-Bandpei, there was no tactile and kinaesthetic feedback, proprioception, or progressive resistance exercise program given to the participants. The use of Vonfidans in the present study has provided tactile and kinaesthetic feedback, proprioception, and progressive resistance training for the pelvic floor muscles.

Many studies have shown a significant relationship between the activation of abdominal muscles and pelvic floor muscles. The study done by Kari Bo et al ^[8], Neumann and Gills ^[9] shows the relationship between abdominal muscles and pelvic floor muscle activation during different movements and positions. These findings signify the importance of training the pelvic floor muscles in patients with chronic low back pain. Progressive resistance training through Vonfidans can help to increase the strength of pelvic floor muscles. When Vonfidans is used along with stabilization exercises, can improve the lower back strength, thus giving a stronger back for women. The pelvic floor muscles out of all the core muscles form the base for the spine. Thus the role of pelvic floor muscles as the base becomes more foundational in providing the core stability and overall stability of the spine.

The pelvic floor muscle exercises suggested in this protocol were in standing, as the standing is the standard anatomical position of a human body. ^[10] Pelvic Floor muscle recruitment is required maximum during strenuous activity along with other abdominal muscles like coughing, bending, and lifting weights. All the core muscles work simultaneously to maintain core stability. ^{[9],[11]}

VI. CONCLUSION

This study concludes that progressive pelvic floor muscle strengthening when done with Vonfidans significantly helps with the reduction of pain and disability in females suffering from chronic low back pain. Along with conventional physiotherapy treatment, Vonfidans has been proven extremely effective for “women’s back pain” as it helps to strengthen the pelvic floor muscles and creates a stronger back for women (through core muscle strengthening).

Thus, it can be stated that Vonfidans can be an effective tool for pelvic floor muscle strengthening in patients with chronic low back pain.

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