

COMPARISON OF VONFIDANS (HET'S DEVICE, TO INSTANTLY TEST AND IMPROVE V TIGHTNESS) AND VAGINAL TAMPON ON VAGINAL TIGHTNESS AND WELL-BEING IN WOMEN WITH SEXUAL DYSFUNCTION – RANDOMIZED CONTROL TRIAL

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Abstract

Background: Vaginal laxity is a very common condition. Vaginal laxity means the looseness of the vaginal muscles. Women generally address it by using the term like feeling loose down there. Vaginal laxity usually occurs due to various factors like pregnancy, child birth, hormonal changes, menopause, obesity, constant straining etc. There are multiple consequences of vaginal laxity like urine leakage, pelvic organ prolapse, sexual dysfunction. **OBJECTIVE:** To compare the effect of Vonfidans and vaginal tampon on vaginal tightness that is pelvic floor muscles strength and sexual well being in women with sexual dysfunction. **Materials and Methods:** A randomized control trial involving 873 females above the age of 18 years experiencing sexual dysfunction due to vaginal laxity that is weak pelvic floor muscles was carried out for 14 months. One group did pelvic floor muscle training with Vonfidans and another group used tampons. The treatment time was 4 weeks 5 days a week at home by self-use. Outcome material taken was Vonfidans for testing the vaginal tightness, FSFI- Female sexual function index for testing the sexual well-being. **Result:** Group using Vonfidans had shown significant improvement in both the outcome measures Vonfidans(p>0.05) and FSFI(p>0.05), compared to the group using tampon. **Conclusion:** The study concludes that Vonfidans can efficiently strengthen the pelvic floor muscles, improve vaginal tightness and sexual well being of women with sexual dysfunctions.

INTRODUCTION

Pelvic floor muscles play a very important role when it comes to the sexual wellbeing of a female. These muscles are attached to the clitoris. The pelvic floor muscles pumps the blood to the clitoral glans during sexual activity, this increased blood flow towards the clitoris increases arousal and orgasm of the female.^[1] Also, the pelvic floor muscles are responsible for a tighter grip over the penis during sexual activity. The tighter the grip the better will be the sexual satisfaction for both the partners. Female sexual dysfunction is not very uncommon. The prevalence can range between 8% to 85.2 %.^[2] There are multiple factors which are responsible for affecting the pelvic floor muscles function and thereby affecting sexual well-being. These factors are pregnancy, childbirth, hormonal changes, menopause

etc. It is believed that as the age advances the sexual activity decreases this usually occurs due to multiple other changes going in the body but it can certainly be affected by the strength of the pelvic floor muscles.

Sexual cycle response is generally classified into sexual desire, sexual arousal, orgasm, resolution. Pelvic floor muscles play a vital role in all these phases. The weak pelvic floor muscles can result into insufficient blood flow to the clitoris for achieving orgasm.^[3]

Strengthening the pelvic floor muscles that are improving tightness of vagina can greatly increase the sexual wellbeing for both the partners. There are several treatment options available to increase sexual wellbeing like laser, radio frequency, G Spot amplification etc but all these are quite costly procedures, which carries the chances of infection,

adhesion, painful intercourse and also they don't have long lasting effect.

In spite of research and meta-analysis on pelvic floor muscle function and sexual well-being, there are very few articles to see the effect of pelvic floor muscles training on sexual dysfunction which can be done by self without any supervision.

This study aims to compare the effect of Vonfidans and Vaginal tampons on vaginal tightness in women with sexual dysfunction.

MATERIALS AND METHODS

Study Design: Randomized control trial was conducted where women with reported sexual dysfunctions were included. The participants were divided into 2 groups: one group did pelvic floor muscles exercise using Vonfidans and another group did pelvic floor muscles exercise using Tampon.

This was a double blinded study, where the assessor was blinded to the group allocation and other demographic, gynecological, obstetric details of the participants. And the participants were blinded for the treatment given to other groups.

Participants: The study was carried out in the OPD of a private hospital in Ahmedabad, Gujarat, India. The study duration was 14 months. The women above 18 years of age and who fulfilled the inclusion criteria were recruited for the study. The procedure for both the groups was 4 weeks 5 days a week.

Inclusion Criteria

- Female with sexual dysfunction due to weak pelvic floor muscles
- 18 to 65 years age
- Hypoactive sexual desire disorder
- Arousal disorder
- Orgasmic disorder

Exclusion Criteria

- Hypertonic pelvic floor muscles or non-relaxing pelvic floor muscles
- Chronic pelvic pain
- Having any acute infection or inflammation
- Vaginismus
- Dyspareunia
- Moderate to severe prolapse
- Not willing to sign consent form
- Unable to comprehend command
- Any other medical condition which can limit the participation of female.
- Who cannot understand English

Outcome Measures:

Vonfidans,^[4]

It is the world's first and only device which can instantly test the vaginal tightness through instant activation of pelvic floor muscles. It is a highly reliable and valid tool. It is an intravaginal device which is to be used with a condom. The test through Vonfidans was done in the following way, The participants were asked to empty their bladder before the testing. In a standing position with legs apart, the

participants were instructed to insert the Vonfidans with 3 weight balls in it and covered with condom, such that only the tail remains out. If the Vonfidans stays inside then the participants were asked to do 10 cough, 10 squat and 10 jumps. The interpretation is as follows.^[5]

Description Vonfidans Interpretation Inability to hold Vonfidans in standing position while patient is trying to hold Vonfidans by contracting PFM it falls out before beginning or before completion of all 3 functional activities C (falls out) Extremely weak pelvic floor muscles (severely reduced vaginal tightness, means severe vaginal laxity) Inability to complete all 3 functional activities while patient is trying to hold Vonfidans by contracting PFM (it may slide/displace downward or outwards) B Weak pelvic floor muscles (mild to moderate reduction of vaginal tightness, means mild to moderate vaginal laxity)

Ability to complete all functional activities without any downwards or outward displacement of Vonfidans while patient is trying to hold Vonfidans by contracting PFM A Strong pelvic floor muscles (healthy vaginal tightness, means no vaginal laxity).

For better and easier statistical analysis the grade are calculated on 3 point likert scale.

Grade A = 3

Grade B = 2

Grade C = 1 FSFI

Female Sexual Dysfunction Index is a self-reported scale for evaluation of sexual function in women. The scale has 19 questions related to different female sexual response cycles. The woman has to answer the question as per the activity done in the last 4 months like caressing, foreplay, masturbation, sexual stimulation and sexual intercourse. Each question is rated on a 5 point likert scale. The higher the score better is the sexual function.^[6]

Intervention

The women with sexual dysfunction were recruited from a private hospital. Out of 1163, 981 participants were fully filing the inclusion criteria. 981 participants were recruited into the study and the study was concluded on 873 women. Majority of dropouts (45 women) were due to pregnancy, 30 dropped out due to lack of compliance of treatment and 7 did not see it appropriate to give reason for dropping out and 26 women from the Group B training with vaginal tampon dropped out due to vaginal infection. There were no such drop out or incidence of vaginal infection in the Group A Vonfidans as the Vonfidans is to be used with a condom and proper hygienic precautions were already explained to the participants beforehand.

873 participants were randomly allotted in two groups, Group A – pelvic floor muscle training with Vonfidans and Group B – pelvic floor muscle training with Vaginal tampon.

A treatment plan for 4 weeks, 5 days a week was given to both the groups. The treatment protocol followed was: -

General Instructions: At the time of recruitment the participants were assessed by an examiner who was

blinded to the demographic, obstetric and gynecological history of participants and intervention given.

All participants were instructed properly regarding correct activation of pelvic floor muscles and avoiding breath holding, using accessory muscles and bearing down.

Vaginal tightness testing with Vonfidans was done by the participants by their own, at the hospital when they came for first evaluation. The examiner had explained the testing method and the interpretation of the test in detail to the participants before they did the testing with Vonfidans. Participants were instructed to report their grades to the examiner.^[4] The FSFI score were evaluated by the examiner.

Reassessment was done after 4 weeks, participants who were menstruating were asked to do additional 5 days training to compensate for the lack of exercise during menstruation. Also they were asked to do pelvic floor contractions without a device during the days of their menstruation as per their comfort.

Position: Standing with feet apart

Frequency: 3 sets of 10 reps a day

Intensity:

Group A (Vonfidans) – start with 1 second hold & relax for 1 second, once 1 second feels easy, progress to 2 sec hold & 2 sec relax, the goal was to progress up to 10 sec hold and 10 sec relax 10 repetitions and 3 sets, with 1 weight and then slowly with all 3 weights inside the vagina. At the end go for 5 to 10 quick contractions of your vaginal muscles.

Group B (Vaginal tampon) – start with 1 sec hold & relax for 1 second, once 1 second feels easy, progress

to 2 sec hold & 2 sec relax, the goal was to progress up to 10 sec hold and 10 sec relax, 10 repetitions and 3 sets. At the end go for 5 to 10 quick contractions of your vaginal muscles.

Method: Group A with Vonfidans – participants were asked to keep 1 weight inside Vonfidans, cover the Vonfidans with condoms and insert the Vonfidans inside the vaginal opening. Support the tail of the Vonfidans with 1 finger. The women were then given the instruction to do pelvic floor muscle contractions in the following way, “squeeze your pelvic floor muscles as if you want to stop the urine flow”. Those who could not understand this, the command was given as “try to squeeze the vaginal muscles to hold Vonfidans inside”.

Group B with Vaginal tampon - with vaginal tampon inside the same command was given – “squeeze your pelvic floor muscles as if you want to stop the urine flow”. Those who could not understand this, the command was given as “try to squeeze the vaginal muscles to hold a tampon inside”.

RESULTS

Microsoft Excel was used for statistical analysis. The data obtained were not following a normal distribution so Wilcoxon signed rank test was used for within group analysis and Mann Whitney U was used for between group analysis.

The study was concluded on 873 participants, the descriptive analysis for both the groups are as shown in [Table 1].

Table 1: The demographics and clinical data of the participants

Parameter	Group A – Vonfidans	Group B – Vaginal Tampon
Age	30.43 ± 10.98	32.67 ± 11.45
BMI	21.67 ± 2.34	22.19 ± 1.45
Parity	2 ± 1.3	2 ± 1.01

Table 2: Pretest and Posttest data for Group A

Outcome Measure	Pre Test	Post Test	Z value	P Value
Vonfidans	1 ± 1.14	2 ± 1.01	6.17	0.05
FSFI – 19	17.65 ± 4.54	27.65 ± 2.45	4.01	0.05

Table 3: Pretest and Posttest data for Group B

Outcome Measure	Pre Test	Post Test	Z value	P Value
Vonfidans	1 ± 1.11	1 ± 1.89	2.32	0.72
FSFI – 19	18.97 ± 3.41	20.21 ± 3.45	2.69	0.65

Table 4: Posttest data for Group A and Group B

Outcome Measure	Post-test Group A	Post Test Group B	Z value	P Value
Vonfidans	2 ± 1.01	1 ± 1.89	5.15	0.05
FSFI – 19	27.65 ± 2.45	20.21 ± 3.45	4.18	0.05

Above tables show the within group and between group analysis.

There is a statistically significant improvement in Group A within group analysis as well as in between Group analysis compared to Group B for the outcome measure of Vonfidans and FSFI-19.

DISCUSSION

Female sexual dysfunction is a very complex condition to address, as it involves psychological, physiological and emotional aspects. And there are various factors which affect the sexual behavior of a woman. It requires a biopsychosocial model to understand and address the female sexual behavior.^[7]

In this study, Out of 873 around 408 women complained of Hypoactive desire disorder, 317 women complained of issues with arousal and 148 women complained of orgasmic disorder. Group A had 434 participants and Group B had 439 participants.

Out of 434 participants in Group A, 397 participants reported a significant improvement in their overall sexual wellbeing. This can be attributed to improvement noticed in the vaginal tightness that is the pelvic floor muscles strength.

Improved pelvic floor muscles strength, in other words improved vaginal tightness which increases the women's ability to achieve orgasm with better intensity, frequency and quality.^[8]

Pelvic floor muscles especially the bulbocavernosus and ischiocavernosus muscles are responsible for increasing the blood flow toward the clitoris. And the pubococcygeus and pubovaginalis muscle is responsible to provide the grip to the penis during sexual activity.^[5,9]

Dr. Andrew Siegel, states that pelvic floor muscles are responsible to increase pelvic blood flow, to increase vaginal lubrication, to make the clitoris erect, and also to tighten the grip of the vagina thus contributing to better orgasm.^[10]

In Group B, the participants who did training with Tampon did not show significant improvement in terms of vaginal tightness and sexual function.

The reason can be due to a) no progressive weight training, b) as the tampon gets stuck with the wet vaginal mucosa there is no additional demand on the pelvic floor muscles to keep it inside.

26 participants in Group B the group trained with vaginal tampons dropped out due to vaginal infection.

Also, for every treatment the participants required a fresh tampon, which ended up in high cost for the study. The tampon insertion can cause irritation of the vaginal mucosa and can also cause erosion of the layer of vagina and cervix which can contribute negatively to the long term health of the user.^[11]

Tampon can cause tiny tears in the vaginal mucosa which can result into Toxic Shock Syndrome.^[12]

There are more health risks associated with tampons rather than the benefit. The idea to pull the tampon string out while squeezing the pelvic floor muscles should also be questioned. As pulling the tampon out and then resisting it can further irritate the vaginal mucosa and can cause more damage.

The participants in Group A reported improved vaginal tightness and increased pelvic floor muscles strength, along with that they also reported improved sexual desire, sexual arousal, stronger sexual sensations (stronger vaginal sensation), better vaginal lubrication, increased grip over the penis, increased ability to reach orgasm, intensified & more satisfying orgasm and improved sexual relationship for both partners.

Group A participants did the training with Vonfidans, Vonfidans is designed by keeping the anatomical shape of vagina in mind. The narrow end of the

Vonfidans coincides with the location of pelvic floor muscles at the outer one third of the vagina. The movement of tail of the Vonfidans provides the visual and manual proprioception. The resisted training with Vonfidans further increases the strength of the pelvic floor muscles, making them thicker and firmer. Thicker and firmer the vaginal muscles means pelvic floor muscles the better they stretch during sexual activity providing more pleasure.

The results of this study that strengthening the pelvic floor muscles and improving vaginal tightness improves the sexual function is similar to the finding of the study done by Golmakani N et al.^[13]

Vaginal tampons are designed as a menstrual product and not for strengthening of pelvic floor muscle or for tightening the vagina. This study don't support the use of tampon for strengthening the pelvic floor muscles. Instead, Vonfidans offers more efficient, result oriented, and lifetime solution for vaginal tightness & sexual wellness through strengthening of pelvic floor muscles. Therefore, Vonfidans should be recommended for vaginal tightness and sexual wellness of every woman.

CONCLUSION

This study concludes that, Vonfidans is a highly efficient device for improving the vaginal tightness and sexual well-being through strengthening of the pelvic floor muscles. Vonfidans should be used to improve vaginal tightness (pelvic floor muscles strength) and sexual wellbeing in women.

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