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Validity & Reliability of Vonfidans (Het's Device to Instantly Test Vaginal Tightness) to Test the Vaginal Tightness

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ABSTRACT

Vaginal laxity is a very common issue faced by many females. Looseness in the vagina is explained as laxity. Vaginal laxity can result into pelvic floor dysfunctions like urine leakage, pelvic organ prolapse, sexual dysfunction, reduced vaginal sensations, low back pain etc.
Pregnancy and childbirth can be considered as the most common cause for developing vaginal laxity. In spite being so common condition, vaginal laxity is very less discussed and reported issue. By far there is no tool to test the vaginal tightness (strength of pelvic floor muscles). This study was aimed to measure the validity and reliability of Vonfidans to test the vaginal tightness. An observational study was conducted across 1011 participants who were classified as asymptomatic, urine leakage, sexual dysfunction, fecal leakage, having more than 1 symptoms. Outcome measure of VLQ, FSFI, MOS, PFDI – 20 were analysed with the results of Vonfidans to check for the validity of Vonfidans to current level of vaginal tightness. This study concluded that Vonfidans is reliable and valid tool to measure current level of vaginal tightness.

Keywords: Vonfidans, Reduced Vaginal Laxity, Vaginal Tightness.

INTRODUCTION

Vaginal laxity can be explained as sensation of vaginal looseness or looseness in the vagina.[1] It is generally reported as reduced sexual sensation or lack of sexual satisfaction.[2] It can also be associated with other symptoms of pelvic floor dysfunctions like urinary incontinence, pelvic organ prolapse, back pain etc. [2] Vaginal laxity is reported to be a poorly examined and evaluated symptom of pelvic floor dysfunction. [3,4]

Pregnancy and childbirth results in weakness of pelvic floor muscles which can further lead to pelvic floor dysfunction and vaginal laxity. The pathophysiology of the vaginal laxity is not clearly understood, but the fact of levator ani muscle trauma and over distention during pregnancy and childbirth can be explained as an pathophysiology of vaginal laxity.[5,6]

The VLQ (vaginal laxity questionnaire) is a self- reported scale which was used to

measure the vaginal laxity, FSFI Female Sexual Functional Index was used to measure sexual function. Modified oxford scale was used to check the pelvic floor muscle strength.

As of now, there is no validated tool which can be used to measure the vaginal tightness/laxity (Strength of Pelvic Floor Muscles - V-tightness). The lack of accurate measurement interferes with early and preventive intervention, which can increase the serious complication faced by the female having significant vaginal laxity.

Vonfidans is an intra vaginal device that can be a revolutionary diagnostic tool to objectively assess the current state of vaginal tightness. Objectively diagnosing vaginal laxity (reduced vaginal tightness) through Vonfidans, can help to prevent multiple intimate health issues that generally happens due to vaginal laxity, like urine leakage, pelvic organ prolapse, sexual dysfunctions, reduced vaginal sensations, back pain etc. This study is aimed to measure the validity of Vonfidans to test the strength of pelvic floor muscles (vaginal tightness) in female above the age of 18 years.

MATERIALS & METHODS

An observational study was conducted in Ahmedabad, Gujarat India. This study was conducted at the OPD of a Private Hospital. Ethical clearance was obtained from Institutional Ethical Committee of IIPRE – International Institute of Pelvic Floor Research, Rehab and Education – Recognized by the Central Government of India, after clearing the queries raised by the ethical board related to the potential financial liability of the participants. There was no financial liability on the participants, women above 18 years of age who were sexually active and willing to participate were included in the study. The participants included the patients who came for the follow up visits, the relatives or family member of the patients and other females who were staying in the nearby area. The participants were explained about the vaginal laxity (or how tight you feel your vagina as compared to before) and the effect of pregnancy and childbirth on vaginal health in a group session before their involvement in the study. The participants were also asked whether they reported any other complaints related to pelvic floor dysfunction like urinary incontinence, feeling of something coming out, coital incontinence, reduced sexual drive, reduced vaginal sensations, inability to hold urine, urine leakage while coughing, sneezing etc, back pain or episodes of fecal incontinence etc.

Women who had symptoms of grade 2 or more prolapse, who was pregnant, had UTI, had symptoms of hypertonic pelvic floor, female had chronic pelvic pain, Vaginismus, dyspareunia, interstitial cystitis, or any other condition that causes spasm of pelvic floor muscles, not willing to sign the written informed consent, also the females who did not understand English were excluded from the study.

In total, 1300 women were approached out of which 1011 women over the period of 10 months were evaluated. The attrition was 22.2 %. Some of these women did not have any complaints of vaginal laxity. They are referred as women without symptoms. The women were given the Vaginal Laxity Questionnaire to report vaginal laxity. Female Sexual Function Index is the scale used to assess the sexual function of the female. Pelvic Floor Distress Inventory – 20 (PFDI-20) was also used as an outcome measure. Modified Oxford MMT was used to assess the pelvic floor muscle strength. And Vaginal Tightness test was done by using the Vonfidans. For modified oxford MMT and Vonfidans the participants were asked to empty their bladder and bowel. The findings of all the 5 tools were analyzed.

To check the reliability of the Vonfidans. The participants were asked to do the test and the retest on the same day with a gap of 2 hours in between the test.

Participants were divided according to symptoms

Group A: Urinary Incontinence

Group B: Sexual Dysfunction
Group C: Fecal Incontinence
Group D: More than 1 symptom present
Group E: Asymptomatic

Vaginal Laxity Questionnaire:
So far, it is the only available tool / option to measure the vaginal laxity. [1] It has 7 point likert scale (1-7) where 1 being very loose and 7 being very tight. This scale is used in studies related to the effectiveness of radiofrequency therapy for vaginal laxity (to improve vaginal tightness). [7]

Female Sexual Function Index:
The FSFI scale is a self- reported scale to assess the sexual function, the participants had to answer the questions in FSFI based on their past 4 months experience with caressing, foreplay, masturbation, sexual stimulation and vaginal intercourse. The FSFI scale has 19 questions related to sexual desire, sexual arousal, lubrication, pain and satisfaction. English version of the Scale was used. The version was obtained from Mapi Research Trust. The FSFI scale uses a 5 point likert scale (1-5) where higher number suggest better sexual functioning. The sum of every domain is first multiplied with the domain factor and then the final score is calculated by adding up the total score of the individual domain.[8] The FSFI is a valid and reliable inventory to assess sexual function. [9]

Modified Oxford MMT:
Modified Oxford MMT is a digital muscle grading scale which is used to grade the pelvic floor muscles strength. Before the examination correct pelvic floor contractions were explained to the patient. The use of accessory muscles were avoided and breathing technique was also taught to the participants. The participants were asked to empty their bladder and bowel before the vaginal examination. The participants were taken on the examination table with their hips and knees flexed and abducted. The female examiner was blinded to the demographic details and other obstetrics and gynecological history of the participants to avoid the bias. A gloved and well lubricated index finger was inserted into the vagina (the depth was such that the tip of the finger is free and the contraction of pelvic floor muscles was felt at the phalanx). The participants were asked to squeeze the pelvic floor muscles as if they are trying to stop the urine flow (pull in and lift up your vagina, rectum, and urethra). The MOS has grades from 0 to 5 where 0 = no contraction, 1 = flicker contraction, 2 = weak muscle contraction, 3 = moderate muscle contraction, 4 = good muscle contraction and 5 = strong muscle contraction. The MOS has moderate to strong correlation with perineometer and ultrasound measurement. [10]

PFDI – 20:
Pelvic Floor Distress Inventory -20, is a PROM (Patient Reported Outcome Measure). This scale is used to measure the distress faced by the patients having pelvic floor dysfunction.
The Scale in total has 20 questions which has questions related to pelvic organ prolapse, bladder health and ano-rectal health. The PFDI-20 is considered as Grade –A recommendation by ICI (International Consultation on Incontinence) for clinical practice.
Every question can be answered as No or Yes, No is given a point 0 and Yes is further specified by using 4 points 1 being not at all, 2 being somewhat, 3 being moderately, 4 being quite a bit.
The score ranges from 0 to 100. 0 being no distress and 100 being very severe distress.[11]

Vonfidans: To instantly test Vaginal Tightness:
Vonfidans is an intra-vaginal device that is used to assess current level of vaginal tightness. By far, it is the only tool which can be used to assess the vaginal tightness (through pelvic floor muscles). Vonfidans has 3 parts head, body (ridges) and tail (rod). The participants were asked to empty the bladder and bowel before testing with

Vonfidans. Vonfidans with 3 weights was used for the testing of Vaginal Tightness. Before insertion Vonfidans was covered with Condom. Participants were then asked to insert Vonfidans inside the vagina such that only the tail (rod) remains out. They were explained to insert it as if they are inserting the tampon or a menstrual cup in standing position. Participants were then asked to stand straight with legs apart so that thighs don't touch, (if the legs are near to each other or the thighs touch each other the hip adductors will hold the Vonfidans and the testing will be false positive).

If the participant can maintain this position then she was asked to do 10 coughs, 10 squats and 10 jumps, while maintaining the pelvic floor muscle contraction. The interpretation of the Vonfidans is as follows.[12]

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)

As, the test is done in standing position with all the functional activities it reflects the strength of the vaginal muscles. In other words, it reflects current state of vaginal tightness.

For better analysis the grade of Vonfidans are calculated on 3 point Likert Scale (1-3), 1 being an actual grade of C, 2 being an actual grade of B and 3 being an actual grade of A.

1 = C Grade
2 = B Grade
3 = A Grade

Figure 1: Vonfidans

As Vonfidans can be even used as a treatment device, a provision in the form of suspender is provided at the tail to which a weight bag can be attached to provide progressive resisted exercises.

RESULT

The statistical analysis was done using Microsoft excel. The data were analyzed to check the distribution. The data for VLQ and MOS had normal distribution but the data of FSFI and PFDI - 20 was skewed to the right. And as the data of Vonfidans was ordinal. So a non-parametric test of correlation coefficient Spearman's Coefficient Correlation test was used to analyze the data of measurement of VLQ with Vonfidans, FSFI with Vonfidans, MOS with Vonfidans and PFDI-20 with Vonfidans.

The data of test and retest study of Vonfidans was normally distributed.

The data of test – retest was analyzed using Intraclass correlation.

Table 1: Descriptive analysis of parameters (Mean ± SD)

Serial No	Parameters	Findings
1.	Age	40.4 ± 20
2.	BMI	23.2 ± 2.4
3.	Parity	2 ± 1.4
4.	VLQ	3.52 ± 1.2
5.	FSFI-19	18.27 ± 2.1
6.	MOS	2.52 ± 2.4
7.	PDFI-20	38.92 ± 10
8.	Vonfidans	1. C – 45% 2. B – 38.1% 3. A – 13.9 %
9.	Urinary Incontinence	20.06%
10.	Sexual Dysfunction	28.2 %
11.	Fecal Incontinence	3 %
12.	More than 1 symptom of PFD	5 %
13.	Asymptomatic	43.74%

For all the groups, the spearman's correlation coefficient test was done to analyze the measurement of VLQ with Vonfidans, FSFI with Vonfidans, MOS with Vonfidans PFDI-20 with Vonfidans.

Table 2: For Group A (Urinary Incontinence) measurement with Vonfidans

Serial No	Outcome measure	r value	p value
1	VLQ	0.75	<0.005
2	FSFI	0.86	<0.005
3	MOS	0.56	<0.05
4	PFDI – 20	0.82	<0.001

Table 3: For Group B (Sexual Dysfunction) measurement with Vonfidans

Serial No	Outcome measure	r value	p value
1	VLQ	0.91	<0.001
2	FSFI	0.94	<0.001
3	MOS	0.81	<0.005
4	PFDI – 20	0.78	<0.005

Table 4: For Group C (Fecal Incontinence) measurement with Vonfidans

Serial No	Outcome measure	r value	p value
1	VLQ	0.52	<0.05
2	FSFI	0.60	<0.05
3	MOS	0.36	<0.05
4	PFDI – 20	0.76	<0.005

Table 5: For Group D (More than 1 symptom present) measurement with Vonfidans

Serial No	Outcome measure	r value	p value
1	VLQ	0.83	<0.005
2	FSFI	0.85	<0.005
3	MOS	0.76	<0.005
4	PFDI – 20	0.84	<0.001

Table 6: For Group E (Asymptomatic) measurement with Vonfidans

Serial No	Outcome measure	r value	p value
1	VLQ	0.91	<0.001
2	FSFI	0.94	<0.001
3	MOS	0.90	<0.001
4	PFDI – 20	0.93	<0.001

Test – retest reliability when analyzed using Intraclass correlation came to be 0.93 (95% confidence interval)

There was a significant correlation between Vonfidans & VLQ, Vonfidans & FSFI, Vonfidans & MOS, and Vonfidans & PFDI-20.

Vonfidans when used to assess the vaginal tightness had shown high reliability.

DISCUSSION

Vaginal tightness (strength of pelvic floor muscles) is known to be reduced with multiple factors like age, parity, obesity, diabetes, hormonal imbalance etc. Reduced vaginal tightness (strength of pelvic floor muscles) can result into many associated pelvic floor dysfunctions like reduced vaginal sensations, urinary incontinence, pelvic organ prolapse, sexual dysfunctions, low back pain etc. There are many treatment options available for improving the vaginal tightness (pelvic floor muscles strength) ranging from simple kegel exercises / pelvic floor muscles contraction to more costly, complicated and known to have side-effects surgical approach like cosmetic gynecology and even the radiofrequency or laser therapy treatment.[14]

But there is no reported, reliable and valid tool to objectively test the vaginal laxity (reduced vaginal tightness).[1] In this study the reliability and validity of Vonfidans to test the vaginal tightness was checked for a wide range of female from different age groups, having different complaints. In all the age groups Vonfidans showed high reliability and validity to test the current status of vaginal tightness.

The tools used for the measurement of validity of Vonfidans are VLQ, PFDI-20, FSFI and MOS.

The VLQ is the scale used to measure the vaginal laxity/reduced vaginal tightness perceived by the patient. PFDI-20 is used to measure the distress experienced by the patient due to pelvic floor dysfunction. FSFI scale measures the sexual health and the MOS (Modified Oxford Scale) is used to measure the strength of the pelvic floor muscles. The measurement of the individual

tools and their correlation with the findings of Vonfidans were analyzed.

The present observational study was done on 1011 female above the age of 18 years upto 60 years. The mean age was 40.4 ± 20. Out of 1011 women 203 female had issues with mild urinary incontinence, 285 female reported reduced vaginal sensations, 30 females reported the symptoms of fecal incontinence, 51 female reported issues of urine leakage, reduced vaginal sensation and fecal incontinence, 442 females did not report any symptoms.

In the present study Reduced vaginal tightness (strength of pelvic floor muscles) is associated with other pelvic floor dysfunctions like urine incontinence, fecal incontinence, reduces vaginal sensation etc, which is similar to the finding of Patrick Campbell et al.[2]

The present study on validity of vonfidans for testing current status of vaginal tightness was done using all 3 weighted balls. As the final goal for the treatment with vonfidans is to achieve 30 reps of 10 sec hold – relax. The females who had reached the goal of 30 reps of 10 sec hold – relax with 3 weight balls, showed no symptoms of vaginal laxity.

In Groups A,B,C,D,E the Vonfidans and all the other parameters used (VLQ, FSFI, MOS, PFDI-20) showed significant strong to moderate correlation which shows that the female who reported the symptoms of laxity on VLQ and symptoms of sexual dysfunction on FSFI also had reduced Vaginal Strength when examined with Vonfidans. This can be explained by the fact that Vonfidans tests vaginal tightness (strength of pelvic floor muscles). If the strength is compromised it can lead to stress urinary incontinence as the increased intraabdominal pressure will not be with-holded or counteracted by the pelvic floor muscles. Also, the vaginal grip which plays a very essential role in sexual performance will be compromised if the vaginal tightness is compromised.

The shape of the Vonfidans is designed by keeping the functional vaginal anatomy in mind. The vaginal introitus will be surrounded by the pelvic floor muscles and the vaginal grip over penis during sexual activity is better appreciated by both partners if the pelvic floor muscle contracts strongly, leading to stronger vaginal sensations. The ridges of the Vonfidans can further guide to test level of tightness of vagina and progression.

The Vonfidans measurement and the measurement of MOS had shown low to moderate correlation the reason can be the subjective and vagueness of the MOS grading. The female examiner recruited for the study has been working in the field of women health and pelvic floor since many years, yet the manual testing by MOS itself has low reliability.[15]

The measurement of Vonfidans and PFDI – 20 had shown significant correlation in all the groups. The PFDI-20 questionnaire shows the distress caused by the pelvic floor dysfunction. The significant correlation between Vonfidans and PFDI-20 measurement shows that the female who reported distress also had symptomatically reduced vaginal tightness. The reduced vaginal tightness can lead to many pelvic floor related issues. Women who showed reduced vaginal tightness on Vonfidans also reported reduced level of confidence.

Reduced vaginal tightness (strength of pelvic floor muscles) was correlated with weak pelvic floor muscles, the female who reported low score on FSFI, VLQ and PFDI – 20 also had weak pelvic floor muscle strength on MOS and on Vonfidans also they demonstrated significant weakness.

For the reliability the test and retest were done within 2 hours. The findings for the test and retest were statistically significant having Intraclass Correlation Coefficient as 0.93 (95% confidence interval).

Also the average time taken to finish the test was measured and it came out to be around 50 ± 5 seconds. Vonfidans can be considered as a highly reliable and valid tool to test the vaginal tightness and that too in a short period of time.

CONCLUSION

In the above study there was a strong to moderate correlation between Vaginal Laxity Questionnaire and Vonfidans measurement. There was a strong to moderate correlation between FSFI and Vonfidans measurement. PFDI-20 and Vonfidans measurement also shown strong correlation and a moderate to low MOS and Vonfidans Measurement. There was a significant correlation between the VLQ, FSFI, MOS, PFDI-20 and Vonfidans measurement. The female who reported laxity on VLQ, also demonstrated low FSFI score, high score on PFDI-20, weak pelvic floor muscles and reduced Vaginal tightness. The test and retest reliability of the Vonfidans was high. It is concluded that, Vonfidans is world's first reliable and valid device to instantly test vaginal tightness (strength of pelvic floor muscles).

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REFERENCES

1. Allison Polland MD, V. D. (2021). Description of Vaginal Laxity and Prolapse and Correlation With Sexual Function (DeVeLoPS). *Sexual Medicine, Elsevier* .
2. Patrick Campbell MB, M. K. (2018). Self Reported Vaginal Laxity – Prevalence, Impact, and Associated Symptoms in Women Attending a Urogynecology Clinic. The Journal of Sexual Medicine, Elsevier (1515-1517)
3. C Manzini, T. Friedman (2020). Vaginal Laxity: Which measure of Levator Ani distensibility is most predictive? Ultrasound in Obstetrics & Gynecology, Wiley (683-687)
4. Hans Peter Dietz, M. S. (2018). Vaginal Laxity: What does this symptom mean? International Urogynecology Journal, (723-728)
5. Hans Peter Dietz, Wilson PD, Milsom I (2016). Maternal birth trauma: Why should it matter to urogynecolosists? Current Opinion in Obstetrics and Gynecology, Wolters Kluwer, (441-448)
6. Kamisan Atan, B. G. (2015). The association between vaginal parity and hiatal dimensions: a retrospective observational study in a tertiary urogynecological centre. BJOG, An International Journal of Obstetrics and Gynecology, (867-872)
7. Michael Krychman MD, C. R. (2017). Effect of Single – Treatment, Surface – Cooled Radiofrequency Therapy on Vaginal Laxity and Female Sexual Function: The VIVEVE I Randomized Control Trail. The Journal of Sexual Medicine, Elsevier (215-225).
8. Cindy M Meston, B. F. (2020). Scoring and Interpretation of the FSFI: What can be learned from 20 years of use? The Journal of Sexual Medicine, Elsevier (17-25)
9. Dennis A Revicki, M. A. (2011). Content Validity of the Female Sexual Function Index (FSFI) in pre – and postmenopausal women with hypoactive sexual desire disorder. The Journal of Sexual Medicine, Elsevier (2237-2245)
10. VollØyhaug, S. M. (2016). Assessment of pelvic floor muscle contraction with palpation, perineometery and transperineal ultrasound: a cross sectional study. Ultrasound Obstetrics and Gynecology, Wiley Online Library (768-773
11. Guilherme Tavares de Arruda, D. A. (2022). Internal structure and classification of pelvic floor dysfunction distress by PFDI -20 total score. Journal of Patient reported outcomes. Article Number 51.
12. Het Desai (2020). Het's Manual of Pelvic Floor Rehabilitation. Jaypee Publishers (45-48)
13. Sali Talab, A. B (2019). Correlates of vaginal laxity symptoms in women attending a urogynecology clinic in Saudi Arabia. International Journal of Gynecology and Obstetrics, Wiley, (278-282)
14. Leah S. Millheiser MD, R. P. (2010). Radiofrequency Treatment of Vaginal

Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening. The Journal of Sexual Medicine, Elsevier (3088-3095)

15. Cristine Homsi Jorge Ferreira, Patrícia Brentegani Barbosa, Flaviane de Oliveira Souza, Flávia Ignácio Antônio, Maíra Menezes Franco, Kari Bø, (2011) Inter-rater reliability study of the modified Oxford Grading Scale and the Peritron manometer, Physiotherapy, Volume 97, Issue 2, Pages 132-138.

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