Evaluation of Long-Term Surgical Success and Satisfaction of Patients After Vestibulectomy

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Objective: Vestibulectomy is one of the only proven therapeutic treatments for provoked vulvodynia (PVD). However, little is known about long-term surgical success.

Methods: Patients who underwent vestibulectomy between 1991 and 2003 were interviewed to assess frequency of intercourse and degree of pain during various activities, as well as satisfaction with and willingness to recommend the surgery. We also examined the outcome relation to PVD type being primary or secondary. Differences in pain over time were assessed using a paired-sample t test or a Wilcoxon signed-rank test.

Results: Of 85 eligible patients, 50 (59%) were contacted and 32 (38%) participated. All underwent vestibulectomy 12-24 years prior by the same surgeon. All experienced sexual intercourse without pain at some point after surgery (median = 4 months). Penetration pain averaged 9.13 (scale = 0-10) before surgery and dropped to 0.47 at the time of follow up (p < .001). Other activities that were reported as painful before surgery also improved significantly. No patients reported worsening of pain over time; 87.5% were able to engage in sexual intercourse immediately after the recovery period, and 97% were able to do so at the time of follow up. Ninety-four percent of respondents were highly satisfied, 97% would undergo the surgery again, and 100% would recommend it to others. The type of PVD was unrelated to treatment outcome (p = .297).

Conclusions: Vestibulectomy is an excellent treatment for PVD and has successful long-term outcomes.

Key Words: vulvodynia, provoked vulvodynia, PVD, vestibulectomy, retrospective follow-up, patient satisfaction

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P rovoked vulvodynia (PVD), defined as pain upon touch or pressure without spontaneous or ongoing pain, is the most common cause of pain during sexual intercourse.¹ At physical examination, the patient displays heightened sensitivity even to the slightest touch without the presence of infection or any other dermatological or gynecological disease.² The prevalence of PVD has been estimated at 10%–15%.^{3,4} Studies have indicated a vestibular mucusal nerve fibers hyperproliferation among women experiencing the problem.⁵ This may be affected by an increase in mast cells that may play a part in the regulation of nerve growth factors,⁶ as well as by various genetic and hormonal factors, including hormonal contraceptives.7

Surgical treatment for PVD was first suggested by Woodruff et al.8 in 1981. Since then, several variations have been carried out. A literature review by Goldstein et al.⁹ in 2006 found that 28 of 32 articles reported a surgical success rate of 80% or more.

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A review by Andrews¹⁰ in 2011 reached similar conclusions, with an average surgical success rate of 79%. However, the definition of surgical success varies from one study to another. In addition, the small number of patients in each study, the short follow-up periods, and differences between procedures and surgeons make it difficult to make definitive conclusions. Previous long-term follow-up studies have reached varying results. For instance, Foster et al. (1995)¹¹ reported a success rate (defined as significant reduction of pain) of 88% at 4-year postsurgery, whereas De Jong et al.,¹² also in 1995, reported a 43% success rate at 7-year postsurgery. We reported that surgery was significantly less successful in women with primary PVD-with onset of the symptoms occurring with first provoking physical vestibular contact, than in secondary PVD.¹³ These findings have been confirmed¹⁴ and then debated.15

The purpose of this study was to determine whether vestibulectomy is an effective long-term treatment for PVD, based on the satisfaction of patients who have undergone the surgery. We also examined whether effectiveness after more than 10 years was related to the type of PVD being primary or secondary.

METHODS

Vestibulectomy Surgical Technique

As previously described and shown by us in detail,^{16,17} an excision is carried out encompassing the vestibule and extended on the perineum to half the distance between the fourchette and the anus. The vestibular tissue is undermined under and cephalad to the hymen and surgically excised. The anterior vestibule is also removed, encircling the urethral meatus. The posterior vaginal tissue is then elevated and dissected from the underlying recto-vaginal septum to a length of approximately 2 cm. This vaginal flap is then advanced and fixed to the perineal skin. Interrupted 3-0 and 4-0 Vicryl sutures are used to obtain hemostasis and approximate the skin edges. Two months after the surgery, the patients came back to a scheduled follow up examination to check if the introital sensitivity was resolved.

Study Design and Population

This was a retrospective follow-up study of women who underwent vestibulectomy at least 10 years before follow-up by the same surgeon (J.B.). This surgery was performed for women who had a significant level of pain that was strong and intolerable during intercourse. Before surgery, all the women were examined to exclude other causes of pain, and Q-tip test was performed as previously reported.^{4,13,16,17} Eighty-five patients' records were reviewed for details needed to make contact. Afterward, an Interior Ministry population database was used to locate their addresses and contact information. Letters were sent to these 85 women, and then, if they did not respond, they were contacted by phone calls, to schedule person face-to-face interviews. In accordance with the requirements of the institutional review board (Helsinki Committee), the interviews were conducted in person, face to face, and not by phone, and only by one of the authors (A.D.). The surgeon himself did not take any part in these interviews. The English version of the questionnaire is attached (Appendix

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TABLE 1. Patients Characteristics

	No. women (%)
Characteristic	
Eligible for inclusion	85 (100)
Not located	35 (41)
Located, but refused to interview	9 (18)
Located, initially agreed but then refused to interview	7 (14)
Forgot undergoing surgery	2 (4)
Interviewed	32 (59)
Women who currently have an intimate partner (% of 32 interviewed)	27 (84)
Type of localized PVD:	
Primary	9 (28)
Secondary	15 (45.9)
Not clear	8 (26)
Date when surgery was performed to the 32 interviewed patients	1991–2003
Mean age at the time of surgery (range)	24 (20–31)
Mean age at follow up (range)	43.12 (35–54)
Mean no. years of follow-up (range)	18.75 (12–24)

1, http://links.lww.com/LGT/A171). In addition, the original records of the women who were finally interviewed were reviewed for ascertainment of the PVD diagnosis, type of PVD (primary or secondary), and complications during and after surgery.

Study Variables

The study variables were patient satisfaction, pain level, and frequency of intercourse. These were assessed via a Hebrew-translated questionnaire that was validated in previous prospective studies on vestibulodynia from our group¹⁸ and was based on the modified Brief Pain Inventory¹⁹ and the McGill Pain Questionnaire.²⁰

Statistical Methods

Data are described as mean with SD and range or as proportions. Reduction in pain levels over time was tested using a paired-sample t test as a parametric test or a Wilcoxon signed-rank test as a nonparametric test A p value less than 5% is considered statistically significant. The institutional review board (Helsinki Committee) at the Galilee Medical Center approved this study before the study began (approval number: 0131-14-NHR on February 23, 2015).

Role of the Funding Source

Funding for statistical support was provided by Galilee Medical Center's research fund. The funder had no other involvement in this work.

RESULTS

Demographic Data

Of the 85 eligible patients, only 50 (59%) were successfully located; as depicted in Table 1, 32 (64%) of these were interviewed for the study after having signed a consent form. Of the 50 patients who were contacted, 9 (18%) refused to be interviewed and 7 (14%) initially consented to interview but then changed their mind and refused. Our impression was that these 2 groups of women refused to cooperate because they chose to withhold the information from their family. Two other patients (4%)

did not remember undergoing the procedure. The 32 remaining patients underwent vestibulectomy between 1991 and 2003. The age of patients at the time of surgery ranged from 20 to 31 years (average = 24 years). The age at follow-up ranged from 35 to 54 (average = 43.12). The number of years of follow-up ranged from 12 to 24 (average = 18.75 years). At the time the interview was conducted, 27 women (84%) were in an ongoing relationship with a partner with whom they had regular sexual relations. Of those who had no partner, all responded that dyspareunia was not the reason for the lack of partner. A total of 28.1% of women undergoing surgery were diagnosed with primary PVD, and 45.9% had secondary PVD. Data were not absolutely clear as for the type of PVD in the other women.

Seeking Further Treatment After Surgery

Thirty women (94%) needed no further treatment beyond vestibulectomy. The 2 women who had undergone further treatment noted that the surgery was partially helpful. The additional treatment included intramuscular injections of interferon and unidentified topical cream. Another patient noted that she sought out a hypnotist but ultimately did not undergo hypnosis therapy. No complications were recorded during or after surgery. However, this study does not have the power to draw conclusion about the complications rate.

No women mentioned the use of hormonal therapy, systemic, or topical as treatment aimed at relieving vestibule pain.

Sexual Intercourse After Surgery

All patients reported that they had experienced sexual intercourse without pain at some point after the surgery. More than 90% noted that they had experienced pain-free sexual intercourse for the first time within 12 months of surgery (see Table 2). The mean time to painless sexual intercourse was 4 months.

Variation in Degree of Pain Relief After Surgery. Patients were presented with a list of activities known to induce pain in the vestibule and were asked to rank, on a 0-10 scale, how much that activity hurt before the surgery compared with how much it hurts today ($0 = no \ pain \ at \ all$, $10 = maximal \ pain$). As expected, 100% of patients noted that before surgery, penetration during intercourse was the most painful activity, scoring a 9.13 on this Numeric Rating Scale of pain. Nonpenetrative sexual relations, touching the vaginal opening with a finger, and insertion of a tampon were described as painful activities, and in addition, substantial pain was described after sexual relations and in postcoital urination, when such occurred. After surgery,

TABLE 2.	Time From Surgery Until First Painless Intercourse
in Months	- /

Months	No. women (%)	Cumulative %		
1.5	1 (3.1)	3.1		
2	7 (21.9)	25.0		
3	6 (18.8)	43.8		
4	6 (18.8)	62.6		
5	1 (3.1)	65.7		
6	5 (15.6)	81.3		
12	3 (9.4)	90.7		
24	1 (3.1)	93.8		
72	1 (3.1)	96.9		
216	1 (3.1)	100.0		
Total	32 (100)			

Timing	Mean	N	SD	Mean of difference	SD of difference	р
1. During penetration presurgery	9.13	32	1.264	8.656	1.382	<.001 ^a
During penetration today	0.47	32	0.950			
2. During nonpenetrative intercourse presurgery	3.88	32	3.774	3.688	3.623	<.001 ^a
During nonpenetrative intercourse today	0.19	32	0.592			
3. After intercourse presurgery	6.42	31	3.686	6.129	3.585	<.001 ^a
After intercourse today	0.29	31	0.783			
4. Touching the vaginal opening with a finger presurgery	6.74	31	3.172	6.613	3.138	<.001 ^a
Touching the vaginal opening with a finger today	0.13	31	0.562			
5. Inserting a tampon presurgery	5.00	19	4.308	4.842	4.285	<.001 ^b
Inserting a tampon today	0.16	19	0.688			
6. Wearing tight pants presurgery	2.73	26	3.779	2.346	3.555	.004 ^b
Wearing tight pants today	0.38	26	1.577			
7. Riding a bicycle or a horse presurgery	2.53	15	4.015	2.333	3.885	.063 ^b
Riding a bicycle or a horse today	0.20	15	0.561			
8. Sitting cross-legged presurgery	1.10	31	2.181	1.097	2.181	0.009^{a}
Sitting cross-legged today	0.00	31	0.000			
9. Urination without prior sexual intercourse presurgery	1.00	32	2.185	0.906	2.161	0.024^{a}
Urination without prior sexual intercourse today	0.09	32	0.530			
10. Urination after intercourse presurgery	3.59	32	3.766	3.250	3.793	<.001 ^a
Urination after intercourse today	0.34	32	1.208			
11. Other specific activity presurgery	6.75	8	3.536	5.750	4.334	.031 ^b
Other specific activity today	1.00	8	2.070			

TABLE 3. Variation in Degree of Pain Relief From Presurgery to the Long-Term Follow-up

there was a sharp and significant reduction (p < .001) in pain in all of these activities, with a particularly prominent reduction in pain during penetration from a mean of 9.13 on the pain scale to a mean of 0.47 (see Table 3). The similar evaluations of the various activities also support the consistency of the patients.

Variation in Degree of Pain Relief From Surgery to the Long-Term Follow-up. All patients reported that after the surgical recovery period of 2 months, there had been no recurrence or increase in pain over the years. Twenty-three patients (72%) noted that immediately after the recovery period, they were able to have intercourse without any pain, and this remained the situation at the time of follow-up. Five patients (16%) reported some pain after recovery that receded gradually over the years, and 4 patients (13%) reported some pain that had continued until the time of follow-up.

Frequency of Intercourse. All patients reported improved ability to have intercourse immediately after the recovery period. Twenty-eight patients (88%) reported the ability to have sex as

they pleased immediately after recovery, and the remainder reported some restrictions in having sex due to pain. When asked about their present condition, 31 patients reported the ability to have sex as they pleased, and 1 patient reported restrictions in having sex due to pain (see Table 4).

Satisfaction With the Procedure. All patients reported an alleviation of pain since the surgery. Of these, 30 patients (94%) reported a significant improvement and 2 patients (6%) reported a slight improvement (see Figure 1). Ninety-seven percent of patients reported that they would undergo the procedure again, and 100% would recommend it to a friend experiencing the same condition. Five patients (16%) noted that in light of the lengthy recovery period of 2 months, they would have preferred to exhaust nonsurgical treatment options before vestibulectomy (see Figure 2).

Association of PVD Type With the Long-Term Surgical Outcome. Among the 24 women with unambiguous data on their PVD type (see Table 1), there were no significant

TABLE 4. Frequency of Intercourse After Surgery and in the Past 2 Months

		Postsurg	ery	In the past 2 months			
Frequency of intercourse	No. women	%	Cumulative %	No. women	%	Cumulative %	
Not at all	0	0	0	0	0	0	
More than presurgery, but still with some pain	4	12.5	12.5	1	3.1	3.1	
As I please, with some inconvenience	4	12.5	25.0	2	6.3	9.4	
As I please, with no pain	24	75.0	100.0	29	90.6	100.0	
Total	32	100.0		32	100.0		

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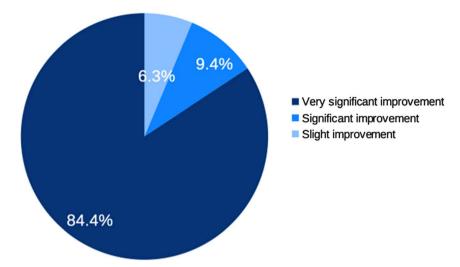


FIGURE 1. Patients' reported improvement in symptoms at long-term follow-up.

differences between the 9 women with primary and 15 with secondary PVD in all variables examined at the interview, for example, current pain with intercourse, none in 6 and 12, and slight pain, 3 and 2 in women with primary and secondary PVD, respectively (p = .297). There were also no differences in patients' satisfaction, patients' approval to undergo the treatment again, recommend treatment to a friend, and the current frequency of intercourse between women of either PVD type. Data were not tabulated.

DISCUSSION

Provoked vulvodynia has remained an enigma for years. Its cause has yet to be fully identified, and treatment remains in dispute. Although the surgical success of PVD has been reviewed several times, and it has been found to be the most effective treatment method, there is still a debate among experts as to whether all women experiencing PVD should be offered surgery or whether it should be reserved for those who have not been cured by nonsurgical treatments. The present study showed that vestibulectomy is a single procedure that can correct the local mucosal pain condition for many years.

In 2016, Goldstein et al.²¹ published a comprehensive review of the evaluation and treatment of vulvodynia. This was in keeping with the paradigm change proposed by Bogliatto and Miletta,²² which challenges the view of vulvodynia as a single ailment stemming from a single cause that has a single treatment option and replaces it with a multimodal approach that concentrates on etiological causes and appropriate treatments for each case. This approach requires cooperation between medical and paramedical specialists in the field who use the same terminology²³ to communicate with one another and offer the patient the optimal diagnostic and therapeutic plan.

Even when vestibulectomy has been found to be suitable for a patient, it is important to note that although the procedure has been proven effective, there is no standard preferred surgical technique, so there is a need to randomly compare short- and long-term outcome of various surgical techniques, such as excision of tissue confined to the areas of allodynia versus removing maximum tissue as in the present study.

In a 2012 study by Tommola et al.,²⁴ 66 women who had experienced severe PVD and were initially treated conservatively were followed. The study showed that 41% of women were content with conservative treatment, and the rest, who were deemed treatment failures, underwent surgery. Satisfaction and treatment success did not vary greatly between those who had undergone surgery and those who had not. This study leads to the conclusion that surgery should be offered after attempting noninvasive treatment options. Additional publications and guidelines suggest that surgery be a last resort, implying after all noninvasive therapies.²⁵ However, the successful outcome of the present study supports a different approach that surgery should not be withheld if a patient wishes it after a discussion of the relative rates of cure of other therapies. We note that in the part of our questionnaire where free-text comments could be added, 1 patient reported feeling that she had wasted too much time on noninvasive treatment methods

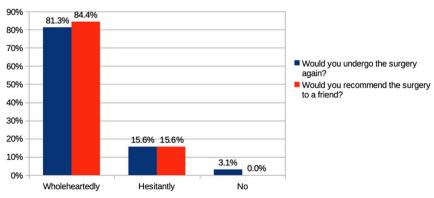


FIGURE 2. Patients' opinions regarding vestibulectomy.

that did not benefit her and that in retrospect, she would have preferred to go directly to the most effective solution for her, which was surgery. This comment is not, in our opinion, sufficient to change the entire therapeutic approach, but there is definitely a need to address patients' suffering and their emotional willingness to invest time and resources in treatment methods that, although noninvasive, have significantly lower success rates.

In this study, if we define *surgical success* as the patient's ability to have sex as she pleases, in a patient previously diagnosed with PVD, we find that 87.5% of patients experienced surgical success immediately after the recovery period, and 97% of patients currently reported surgical success a decade or more after surgery. This held although tempered by time and recall and the possibility of recurrence, thus arguing against the frequent assumption that PVD may recur. Therefore, vestibulectomy is a long-term solution for vestibule pain. Further studies should confirm these data with the other surgical variations, as possibly a less extensive surgery might also lead to favorable long-term resolution of PVD.

In an earlier publication from our group, we found that the 1-year risk of vestibulectomy to fail in resolving or even improving PVD was 4.97 (95% CI = 1.74 - 19.55) compared with secondary PVD.¹³ However, in the present evaluation, PVD type did not affect the outcome of pain, sexual function, and satisfaction with treatment. Nevertheless, only 24 women that their PVD type was certain were left for analysis of this variable.

The objective of this long-term follow-up was to determine whether surgical results are retained over time, and the answer seems to be unequivocally affirmative. No patient reported recurrence or worsening of pain, and the patients' ability to have sexual intercourse remained good, or even improved, over time. Penetration pain, which was severe before surgery, was almost completely alleviated. Regarding subjective patient satisfaction, we see that 100% of patients noted improvement after surgery, with 84.4% reporting the highest level of satisfaction. As for other treatment options, nearly all patients needed no other medical intervention after surgery.

This study's main advantage, beyond reporting outcomes more than 12 years after surgery, is the inclusion of women who underwent surgery by the same method and with the same surgeon (J.B.), which enabled us to reduce the discrepancies stemming from technical differences between surgeons and techniques and to obtain higher-quality results.

In addition, all patients of this study who underwent vestibulectomy had a presurgery severe form of PVD, defined as a significant level of pain that was strong and intolerable during intercourse. They were examined and PVD was confirmed by Q-tip swab test; otherwise, they had not been offered a vestibulectomy. This presurgery severity level was confirmed at the interview.

Another advantage is that there were no follow-up interviews or conversations of the surgeon himself with the women. The other author, who was uninvolved with the care of the women (A.D.), made all the interviews. The women were reassured that the surgeon would not be exposed to their individual responses but only to an anonymous summary of the total data. This prevented a bias that might have been introduced if women wanted not to offer disappointing answers to their surgeon.

A limitation of the study is that we managed to locate only 59% of eligible women, and of these, only 64% consented to participate. The reason for the relatively low rate of location was the long period that had passed since the surgery. Some women had moved out of the country or changed their names, and thus, they could not be located through the population registry. However, it is unlikely that the inability to contact these women was in any way related to their surgical outcome. A possible assumption for the 64% consent rate is the unwillingness of some women to reveal to their families that they had undergone the procedure; since the surgery, they may not have informed their partner about the surgery. It should be noted that some patients consented to be interviewed by phone but withdrew their consent upon learning that the interview was to be in person. It is possible that women whose surgery was ineffective would be more likely to enroll in the hope that there is a new treatment available. In this case, our results would underestimate surgical success. Given these considerations, we do not view the response rate as an impediment to drawing our conclusions.

Finally, recalling data from that long ago might have been a reason for potential recall bias. However, the interviewer was impressed that in all women the tremendous relief with the success of surgery became an unforgettable event.

CONCLUSIONS

This study demonstrates that vestibulectomy, as performed in the present study, is an effective surgical procedure with a high success rate. In addition, it results in total elimination or significant reduction in pain related to penetration or insertion of objects. Results are maintained over long periods, and improvement occurs over time in cases where surgery does not immediately eliminate all pain. Women who have undergone the surgery report high levels of satisfaction and would encourage other women who experience this condition to undergo the surgery to resolve their pain. In light of a 2-month recovery period, as well as a small but extant risk of postsurgical complications, experts advise to consider noninvasive treatment options before surgery, in concert with the patient. However, in the absence of such options with similar proven success, vestibulectomy remains the best treatment for this painful condition.

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