

# Current Practices On Diagnosis And Management Of Women With Vulvodynia

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## Research article

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# Abstract

**Introduction and hypothesis:** To describe clinical characteristics, previous medical assessment, past treatments and vulvar pain relief among women with vulvodynia.

**Methods:** Brazilian women with vulvodynia (n=144) were assessed for vaginal infection and vulvar pain intensity by means of a cotton swab test based on a numerical rate scale (NRS). All women answered the Female Sexual Function Index questionnaire and a structured instrument about present vulvar symptoms and previously experienced treatments. Vulvar pain relief achieved with previous treatments was qualified through a 4-point Likert-scale.

**Results:** Previous vulvar pain duration was 5.8 ( $\pm$ 4) years. More than 50% consulted with three or more physicians and 49% remained without a conclusive diagnosis. Diagnosis and treatment vulvovaginal infection was very common. The most commonly used treatments were lubricants (66%), topical anesthetics (36%) and vulvar care techniques (36%). All of them provided only low pain relief. Physical therapy and oral gabapentin provided strong vulvar pain relief.

**Conclusion:** Prolonged duration of vulvar pain, multiple visits to healthcare professionals and poor relief of pain are common aspects in the clinical history of women with vulvodynia. Vulvovaginal symptoms other than pain are common, highlighting the importance of the screening tests in order to avoid misdiagnosis.

**Brief summary:** Women suffering with vulvodynia symptoms are frequently misdiagnosed. This study described symptoms, diagnosis and treatment received by women with chronic vulvar pain.

## Introduction

Vulvar pain is a highly prevalent symptom among women of all ages [1]. Many causes may lead to vulvar pain or discomfort, such as vaginal or urinary infection, neurologic disorder, local trauma, hormone imbalance, immunosuppressive diseases, among others [2]. However, the diagnosis of vulvodynia is characterized by chronic vulvar pain or irritation that occurs without a clear identifiable cause [2].

The prevalence of vulvodynia is relatively high, affecting from 10 to 28% of women in the United States [1, 3, 4]. However, this number may still underestimate the real prevalence of the condition, since previous studies report vulvodynia as an underdiagnosed condition [1, 3, 5]. The possible reason why the diagnosis of vulvodynia remains a challenge for both patients and practitioners may be due to unawareness of the condition and lack of infrastructure required in the diagnosis exclusion process. Furthermore, it is important that health care professionals recognize the many subtypes of vulvodynia, in order to understand its broad manifestations. Vulvodynia can be 1) localized or generalized; 2) provoked, unprovoked or mixed; and 3) primary or secondary, depending on whether vulvar pain started at the beginning of sexual activity or sometime after painless intercourse, respectively [2]. In addition, pain can be described in a different manner by patients, who usually use words such as “burning”, “itching”,

“stinging”, “irritation”, “stabbing” and/or “rawness” [1]. Such variation when reporting symptoms to health care providers might lead to a delay in diagnosis or even misdiagnosis and thus lead to unsuitable treatment [1].

Owing to the unclear pathophysiology and multifactorial characteristic of vulvodynia, several potential treatment modalities are used to reduce pain intensity and/or improve sexual function [6, 7]. According to practice guidelines, most common available modalities are vulvar care (genital hygiene and clothing recommendations); psychotherapy; oral analgesics; topical anaesthetics; tricyclic antidepressants; anticonvulsants and physical therapy of the pelvic floor muscles [5, 6–8]. However, there is no gold standard treatment for vulvodynia, and there is a lack of knowledge of whether those modalities promote long-term relief of vulvar pain. The success of treatment in obtaining relief from symptoms in women with vulvodynia may depend on correct diagnosis and adherence to recommended treatment.

There seems to be a lack of awareness of adequate diagnosis for women with this debilitating condition during routine gynecologic consultations [4, 9] misdiagnosis of vulvodynia may lead to multiple attempts at treatment, increasing expenses both for the individual and society [5, 10]. Moreover, anxiety, psychological burden and sexual dysfunction may be consequences of a misdiagnosis or delayed diagnosis [11–13]. Despite that, no studies have investigated the course of patients seeking health care since the onset of vulvar symptoms in the Brazilian population. This type of information is essential for the development of strategies to improve accuracy of the diagnosis and treatment of vulvodynia. The knowledge seeking care process for vulvar pain diagnosis and treatment should be pursued and improved.

The aim of the present study is to explore clinical characteristics, previous diagnosis, current vulvovaginal signs and symptoms, pain intensity, sexual function, as well as self-reported vulvar pain relief, obtained by previous treatment experienced in women suffering from vulvodynia.

## Methods

This is a descriptive study, part of a larger randomized study, however, the data presented here are previous to the randomization. The aim is to describe clinical characteristics, medical assessment, treatments and vulvar pain relief among women with vulvodynia. This is a cross sectional descriptive study comprised of data derived from a larger, randomized study, can be accessed in *Clinicaltrials.gov*, registration number NCT02871661.

The study was approved by the Institutional Review Board of the University of Campinas, under number 1.588.648, CAAE: 54665316.5.0000.5404.

Women were invited to participate in the study when seeking the Family Planning (12%), Genital Infection Disease (14%) or Pelvic Rehabilitation (20%) Outpatient Clinic of the Women’s Hospital of the Campinas University, and through local radio and television calls (54%). Patients interested in volunteering were asked to contact the main researcher and set a pre-screening interview in order to verify eligibility criteria.

There were 167 premenopausal women recruited, aged 18 years of age or older who reported having vulvar pain lasting for at least three months. The diagnosis of vulvodynia was confirmed at the evaluation assessment by either, complaint of spontaneously or provoked vulvar pain (during or after intercourse) for more than three months [14] or based on Friedrich criteria modified by Bergeron et al and described elsewhere [15]. Therefore, all subtypes of vulvodynia were included.

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article. All volunteers underwent a physical examination performed by a gynecologist to exclude other possible diagnoses associated with vulvar pain, with vaginal content collection for bacterioscopy and fungal growth analysis in laboratory. Vaginal pH was also measured using an indicator paper (pH indicator strips; Merck Laboratories, Germany) placed on the right side of the vagina wall for one minute.

Exclusion criteria included history of neoplasm, cognitive alteration, pregnancy, breastfeeding, diagnosed premature ovarian insufficiency, previous oophorectomy, anterior and/or posterior surgical repair and vulvovaginal candidiasis or bacterial vaginosis, and atrophic vaginitis. Women with persistent vulvar pain after treatment were included in the study.

All volunteers signed an informed consent form.

After the eligibility criteria was confirmed, volunteers completed out a structured interview about sociodemographic, medical and gynecological history. Current vulvovaginal symptoms were assessed by physical examination, searching for vulvar fissure, oedema and erythema, vaginal discharge, and foul odor. Pain was elicited in response to light pressure using the cotton swab test (CST). Mean score of sexual pain was based on the last 30 days and pain intensity was based on a numerical rating scale (NRS). Patients were asked to choose a number from 0 (no pain) to 10 (worst pain) that best represented pain intensity. In this study, a trained physical therapist applied gentle pressure in the following regions: 3h, 4h-5h, 6h, 7h-8 and 12h positions of the vaginal clock using a sterile cotton swab, and asked the patient to immediately rate pain sensation after pressure was applied to each position. The CST reported in this study was averaged considering all positions tested. Vulvar pain on attempts of vaginal penetration, during or after sexual intercourse, was self-reported by patients, and considered the main discomfort attributed to sexual intercourse.

For assessment of sexual function, women completed a self-reported questionnaire on sexual function, the Female Sexual Function Index (FSFI) [16]. This 19-item self-report questionnaire assesses global sexual functioning, including specific evaluations of desire, arousal, lubrication, orgasm, sexual satisfaction, and pain. Scores ranged from to 2 to 36. Women with a score equal to or less than 26 were identified as having sexual dysfunction, as suggested by scientific medical literature [16].

The patients answered a questionnaire that included all the treatment options for vulvodynia in order to inform about previous treatments. They were requested to mark treatment modes used specifically to manage vulvodynia. Symptom relief of vulvar and sexual pains were reported according to a 4-point Likert-Scale, based on NRS. Regression of 0 point on the NRS was compatible to "no relief"; 1 point of

regression, “poor relief”; 2 points of regression on the NRS, “mild relief” and 3 or more points of regression on NRS “strong relief of vulvar pain”. The scale had a Cronbach's Alpha of  $\alpha = .871$ , suggesting high internal consistency.

Statistical analysis used descriptive methods. Data information presenting categorical variables are shown as frequency (n) and percentage (%). Continuous data are presented as mean and standard deviation. In order to increase accuracy when measuring sexual function of the population studied, women who reported not having current sexual intercourse were analysed as missing data for FSFI, so the total score would not underestimate the sexual function of this sample, as proposed by Jiann, 2012 [17].

## Results

To identify vulvodynia cases, 169 women were screened, 144 were eligible for the study (Fig. 1). Mean patient age was 29 ( $\pm 9.2$ ) years old. Population characteristics of participants are shown in Table 1.

Table 1  
Sociodemographic characteristics of women with vulvodynia  
enrolled in the study (n = 144)

<b>Variables</b>	<b>Frequency n (%)</b>
<b>Age (years, mean ± SD)</b>	29 (± 9.2)
<b>Caucasian ethnicity</b>	105 (73%)
<b>Education</b>	22 (15.3%)
<b>High school</b>	96 (67%)
<b>College or undergraduate degree</b>	26 (18.7%)
<b>Graduate school or professional training</b>	
<b>Religion</b>	68 (46.5%)
<b>Catholic</b>	43 (30.3%)
<b>Other</b>	33 (23.2%)
<b>None or atheist</b>	
<b>BMI (mean ± SD)</b>	22.6 (± 4.8)
<b>Relationship status</b>	13 (9.2%)
<b>No partner</b>	5 (3.3%)
<b>Sporadic partner</b>	126 (87.5%)
<b>Steady partner</b>	
<b>Parity</b>	100 (69.4%)
<b>Nulliparous</b>	14 (9.7%)
<b>1</b>	30 (20.9%)
<b>2 or more</b>	
<b>Miscarriage</b>	10 (6.9%)
<b>Yes</b>	
<b>Deliveries</b>	110 (76.4%)
<b>None</b>	22 (15.3%)
<b>Caesarian section</b>	12 (8.3%)
<b>Vaginal birth</b>	

Variables	Frequency n (%)
<b>Previous pelvic surgery (other than cesarian)</b>	21.5 (22.9%)
Yes	
<b>Sedentary lifestyle</b>	58 (40.3%)
Yes	
<b>Associated health problem</b>	55 (38.2%)
Yes	
<b>Contraception method*</b>	2 (1.4%)
None	61 (41.3%)
Hormonal	33 (23%)
Condom	60 (14.1%)
Other <sup>(a)</sup>	
<b>Tabaco use</b>	11 (7.4%)
Yes	

Comorbid conditions were common and found in 38% (n = 55) of the studied population: 19.4% had been previously diagnosed with either depression or anxiety disorder, of whom 16 patients were taking antidepressants; 9.7% had a previous diagnosis or clinical suspicion of endometriosis; 1.4% had lupus; 4.9% had bladder pain syndrome; 2% had irritable bowel syndrome and 2.8% had fibromyalgia. More than one comorbid condition was found in 19%.

History of vulvar pain lasted from five months to 19 years, with a mean of 5.8 ( $\pm$  4.1 SD) years. The mean time interval between the onset of symptoms and diagnosis of vulvodynia was 5 ( $\pm$  4.3 SD) years. Only 29.4% had a confirmed diagnosis of vulvodynia prior to participating in the present study (n = 40), and the mean time elapsed since detection of vulvodynia was 2.6 ( $\pm$  8.6 SD) years.

Vulvar signs and symptoms reported, in addition to or instead of pain, were: burning (81.2%), erythema (57.6%) and itching (36.1%), see Table 2. Most women (82.4%) had sought medical help, and 50.7% had visited three or more health care professionals with vulvar pain as the main reason for consultation. However, 49.2% of these patients remained without any diagnosis, and 21.3% received a diagnosis other than vulvodynia as the cause of vulvar pain (Table 2). One-third of the participants reported at least one treatment for vaginal infection in the last 12 months. Of those, 89% informed that the infection was candidiasis. However, only 28% were tested for vaginal infection through laboratory exams.

Table 2  
Clinical characteristics of women with vulvodynia (n = 144)

<b>Vulvovaginal signs and symptoms*</b>	<b>83 (57.6%)</b>
Vulvar erythema	80 (55.5%)
Current vaginal discharge	37 (25.7%)
Bad odor	30 (20.8%)
Fissure	27 (18.7%)
Oedema	117 (81.2%)
Current vulva/vaginal burning	52 (36.1%)
Itching	
<b>Patients seeking health care professionals (n = 136**)</b>	<b>24 (17.6%)</b>
None	21 (15.5%)
1	22 (16.2%)
2	69 (50.7%)
3 or more	
<b>Type of health professional visited* (n = 136)</b>	<b>28 (17.6%)</b>
None	104 (76.5%)
Gynecologist	32 (23.5%)
Psychiatrist	11 (8.2%)
Physical therapist	7 (5.2%)
Others <sup>(a)</sup>	
<b>Previous Diagnosis** (n = 136)</b>	<b>67 (49.2%)</b>
None	5 (3.7%)
Low estrogen	21 (15.5%)
Candidiasis	3 (2.2%)
Non-organic <sup>(b)</sup>	40 (29.4%)
Vulvodynia	

<b>Vulvodynia setting</b>	61 (42.4%)
<b>Primary</b>	83 (57.6%)
<b>Secondary</b>	
<b>Vulvodynia subtype</b>	106 (73.6%)
<b>Localized provoked</b>	8 (5.5%)
<b>Localized mixed</b>	12 (8.4%)
<b>Generalized provoked</b>	18 (12.5%)
<b>Generalized mixed</b>	
<b>CST test according to NRS (mean ± SD)</b>	5.1 (± 3.3)
<b>Sexual pain on last 30 days (mean ± SD, n = 132)</b>	7.06 (± 2.9)
<b>FSFI total score (N = 126)</b>	118 (93.6%)
<b>≤ 26.55</b>	

Secondary (57.6%) and localized provoked (73.6%) were the most prevalent subtypes of vulvodynia. Self-reported average pain score during the last sexual intercourse was high, with a mean score for FSFI of 16.8 (± 7.7 SD). No sexual intercourse in the last 30 days was reported by 18 (12.5%) women, of whom five said being due to pain reasons.

More than 20% (n = 34) did not undergo any treatment for vulvodynia. Among treated women, most had tried at least two (2 ± 1.6 SD) treatment options to deal with vulvar pain, and the majority described poor relief or no relief. The most commonly cited treatments for “strong relief of vulvar pain” (three or more decreased points in pain according to NRS) were physical therapy for the pelvic floor muscles, psychotherapy, tricyclic antidepressant, gabapentin and topical anesthetics (Table 3). Use of lubricant during intercourse (67.5%) and specific hygiene/vulvar care (34.2%) were also frequently reported as techniques adopted to reduce vulvar pain. Other treatments used were topical steroid, antifungal, low oxalate diet and other antidepressants.

Table 3  
Vulvar pain relief reported in previous treatment for vulvodynia

Treatment or method used (n = 110) (N-%)	Vulvar pain relief			
	No relief n (%)	Low n (%)	Mild n (%)	Strong n (%)
Lubricant (73-66.4%)	43 (58.9)	23 (31.5)	5 (6.8)	2 (2.8)
Topical anesthetic (40-36.4%)	4 (10)	21(52.5)	10 (25)	5 (12.5)
Specific hygiene (37-33.6%)	26 (70.3)	8 (21.6)	3 (8.1)	0
Oral Antifungal (36-32.7%)	27 (75)	8 (22.2)	1 (2.8)	-
Oral Tricyclic antidepressant (34 - 31%)	11 (32.3)	16 (47)	5 (14.7)	2 (6)
Topical antifungal (28-25.5%)	25 (89.2)	1 (3.6)	1(3.6)	1 (3.6)
Physical therapy for pelvic floor muscles (18-16.4%)	2 (11.1)	2 (11.1)	8 (44.4)	6 (33.4)
Psychotherapy approach (17-15.5%)	7 (41.2)	4 (23.5)	4 (23.5)	2 (11.8)
Other antidepressant (14 - 13%)	9 (64.3)	5 (35.7)	-	-
Topical hormone (11 - 10%)	3 (27.3)	5 (45.4)	2 (18.2)	1 (9.1)
Oral hormone therapy (8 - 7%)	6 (75)	1 (12.5)	1 (12.5)	-
Oral Gabapentin (6-5.2%)	2 (33.3)	2 (33.3)	1 (16.6)	1 (16.6)
Topical gabapentine (5-4.5%)	1 (20)	2 (40)	2 (40)	0
Low oxalate diet (5-4.3%)	3 (60)	0	1 (20)	1 (20)
Topical amitriptyline (3-2.6%)	2 (66.7)	0	1 (33.3)	0

\*More than one treatment was possible.

## Discussion

Our data showed a high number of women who had years of lasting of vulvar pain, mostly who sought three or more doctors and either remained without diagnosis or received diagnosis different to vulvodynia. As a consequence of the probable inappropriate diagnosis received for the vulvar pain complaint, these women were frequently treated with inappropriate therapies for the management of vulvodynia, such as antifungal and topical hormones.

Some of these findings are in line with the results showed by Harlow & Stewart's [3], that two-thirds of North-American women with chronic vulvar pain who sought medical care visited three or more physicians, many of whom failed to provide a diagnosis. Scientific literature suggests lack of awareness of the condition by both practitioners and patients as the main reason for the low rates of correct diagnosis and appropriate treatment [1, 15]. The present study also points to the fact that, in addition to typical vulvar pain, other vulvar signs (fissure, vaginal discharge, foul odor, erythema) and symptoms (burning, itching) were frequent. All those characteristics can make the diagnosis unclear, leading to a wrong interpretation of vaginal infection, for instance.

In fact, our data showed that many of the participants who sought medical care had been repeatedly treated for vulvovaginitis, obtaining poor or no symptom relief. This finding is consistent with Reed et al [1], who found that more than one-third of women diagnosed with vulvodynia were treated for candidiasis before receiving the final diagnosis and presented no improvement in vulvar symptoms. A possible explanation for the large number of women treated for candidiasis before reaching the final diagnosis also relies on the pathogenesis of vulvodynia that associates a high prevalence of yeast infections preceding VVD diagnosis [18]. However, it is important to consider that a large number of women might be diagnosed with candidiasis when complaining of vulvodynia symptoms. This concept has been previously suggested by Harlow et al [19], who affirmed that the diagnosis of vulvodynia and recurrent yeast infection probably have a bidirectional association. In the present study, most participants treated for candidiasis after seeking medical care for the complaint of vulvar pain, reported they had no laboratory tests to confirm the suspicion of infection, and remained with the main symptoms. This finding also suggests that patients are overdiagnosed with vaginal infections when seeking a diagnosis for vulvodynia, supporting the bidirectional association.

Indeed, the opposite might also occur. Our study found that only one-third of the volunteers diagnosed with vulvovaginal disorders at the eligibility screening process still fitted the diagnosis of vulvodynia after treatment. This reinforces the need to follow recommendations for the exclusion of different diagnoses in order to increase accuracy in the diagnosis of vulvodynia [14]. Laboratory tests confirming the hypothesized diagnosis of vaginal infection, for instance, should be encouraged as an objective measure to avoid misdiagnosis.

Furthermore, our data showed that the self-reported average pain score during the last sexual intercourse according to NRS was two points higher than the mean obtained in the CST. Although our sample was made up of both provoked and unprovoked vulvodynia, the first subtype was highly predominant. Diagnosis criteria for vulvodynia usually follows the ones proposed by Friedrich [20] that include 1)

severe pain on vestibular touch or attempted vaginal entry, 2) tenderness to pressure localized within the vulvar vestibule, and 3) physical findings confined to vestibular erythema of various degrees. However, it is important to highlight that although the CST has been broadly used as a reliable tool to confirm the 2nd criteria, it only predicts provoked vulvodynia subtype. Therefore, self-reported complaints of high intensity of vulvar and/or sexual pain, should enrich clinical guidance for vulvodynia diagnosis as much as CST. Furthermore, Bergeron et al increased generality of vulvodynia diagnosis by showing the reliability of these criteria, modifying Friedrich criteria by limiting it to the 1st and 2nd criteria only, excluding the need to confirm erythema findings on the vulva vestibule [15]. However, more than half of the present studied population was evaluated with vulvar erythema. These findings suggest that although, as proposed by Bergeron et al [15], not all women with vulvodynia may present this clinical sign, it is indeed important that practitioners pay attention to the fact that the presence of vulvar erythema is an expected finding in women with this condition.

In addition to diagnostic issues, a consensus also exists over the difficulty in treating vulvodynia [21]. The most commonly prescribed medication for the treatment of vulvodynia is tricyclic antidepressants, selective norepinephrine reuptake inhibitors and anticonvulsants. Nevertheless, there is no general agreement that any of these drugs is highly effective in relieving vulvar symptoms [8]. While some studies suggest that the use of these medications can only benefit women with generalized, unprovoked vulvodynia subtype [22, 23], others have shown similar effects of oral medication comparing the different subtypes of vulvodynia [7, 8, 24, 25]. Our data showed that the tricyclic antidepressant was the most widely prescribed drug, but only a small portion of women reported having strong vulvar pain relief. However, further studies are needed to suggest this finding as related to the predominant characteristic of the sample that had the provoked vulvodynia subtype.

A recent meta-analysis comparing medication *versus* placebo for treatment of vulvodynia showed that both improve sexual function, although medication has a minimally superior effect [26]. The same study highlights the importance of adding a more efficacious treatment for female sexual dysfunction. Our data showed that, unfortunately, only a minimum amount of the women assessed received appropriate treatment for the management of vulvodynia. Nevertheless, the most commonly reported measures were either oral or topical medication (antifungal, hormone, gabapentin, steroids, amitriptyline), followed by lubricants, topical anesthetics and specific hygiene or vulvar care techniques, described as resulting only in a low symptom relief. Very few women reported having tried other efficacious treatment modes, such as physical therapy, even though it has been recommended by many guidelines as a first-line treatment for vulvodynia [7, 14, 27]. Although only a few women underwent physical therapy to treat vulvodynia in this study, the high percentage of those that reported achieving a high relief of vulvar pain with this approach supports its effectiveness.

Due to the study design, it was not possible to assess whether previous treatment improved sexual function. It is assumed, however, that they would also be characterized as having sexual dysfunction at that time, as this is an expected aspect of women with vulvodynia [4, 9]. Only 10% of our volunteers scored above the cut-off point, which is indicative of normal sexual function. It is clear that sexual

dysfunction in this population is a consequence of vulvar pain, especially during intercourse [11, 28]. Nevertheless, whether the volunteers assessed in this study maintained or worsened their sexual function index over time remains unclear. The fact that this study depicts white, highly educated women, which may not be highly representative of our country, is also a limitation of our study. It is possible that increasing the number of women with vulvodynia, the numbers of delays in achieving a correct diagnosis and appropriate treatment would have increased even more in a population with lower levels of education. In addition, the self-reported characteristic of the study was the basis for the main variables assessed including: number of physicians sought, previous diagnosis and prescribed treatment, level of vulvar discomfort relief, among others. However, previous research has demonstrated a broad agreement between self-reported and medical record data among highly educated women [29]. All women were clinically examined to confirm the diagnosis of vulvodynia, which also provides support to the goals analyzed.

Our findings highlight the importance of developing strategies to increase awareness about the diagnosis of vulvodynia and develop suitable treatment for the condition. These data emphasize the lack of a clear diagnosis of vulvodynia, confirmed by few appropriate treatment modes and a wide use of inefficient methods to deal with persistent vulvar pain.

In summary, a prolonged duration of vulvar pain, multiple visits to healthcare professionals and poor relief of pain with previously undergone treatments are common aspects in the clinical history of women with vulvodynia. Vulvovaginal signs and symptoms other than pain are common, and highlight the importance of having a better clinical and/or laboratorial tests supporting its diagnosis.

## Declarations

**Ethics approval and consent to participate:** This study has been approved by the Institutional Review Board of the University of Campinas (CAAE: 54665316.5.0000.5404), and written informed consent was obtained from all individual participants included in the study and confidentiality and anonymity were ensured. All procedures performed in studies were in accordance with the ethical standards of the institutional and/or national research committee and with the Helsinki declaration.

**Consent for publication:** Not applicable.

**Availability of data and materials:** The dataset used and analyzed during the current study are available from the corresponding authors upon making official request.

**Competing interests:** The authors declare that they have no conflict of interest.

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**Authors' contributions:** MG Bardin: Project development, Data collection, Data analysis, Manuscript writing and editing. PC Giraldo: Project development, Data analysis, Manuscript writing and editing. JF Fante: Data collection. CC Araujo: Data analysis, Manuscript editing and editing. MP Cyr: Data analysis, Manuscript editing and editing. AA Marques: Data analysis, Manuscript editing and editing.

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# Figures

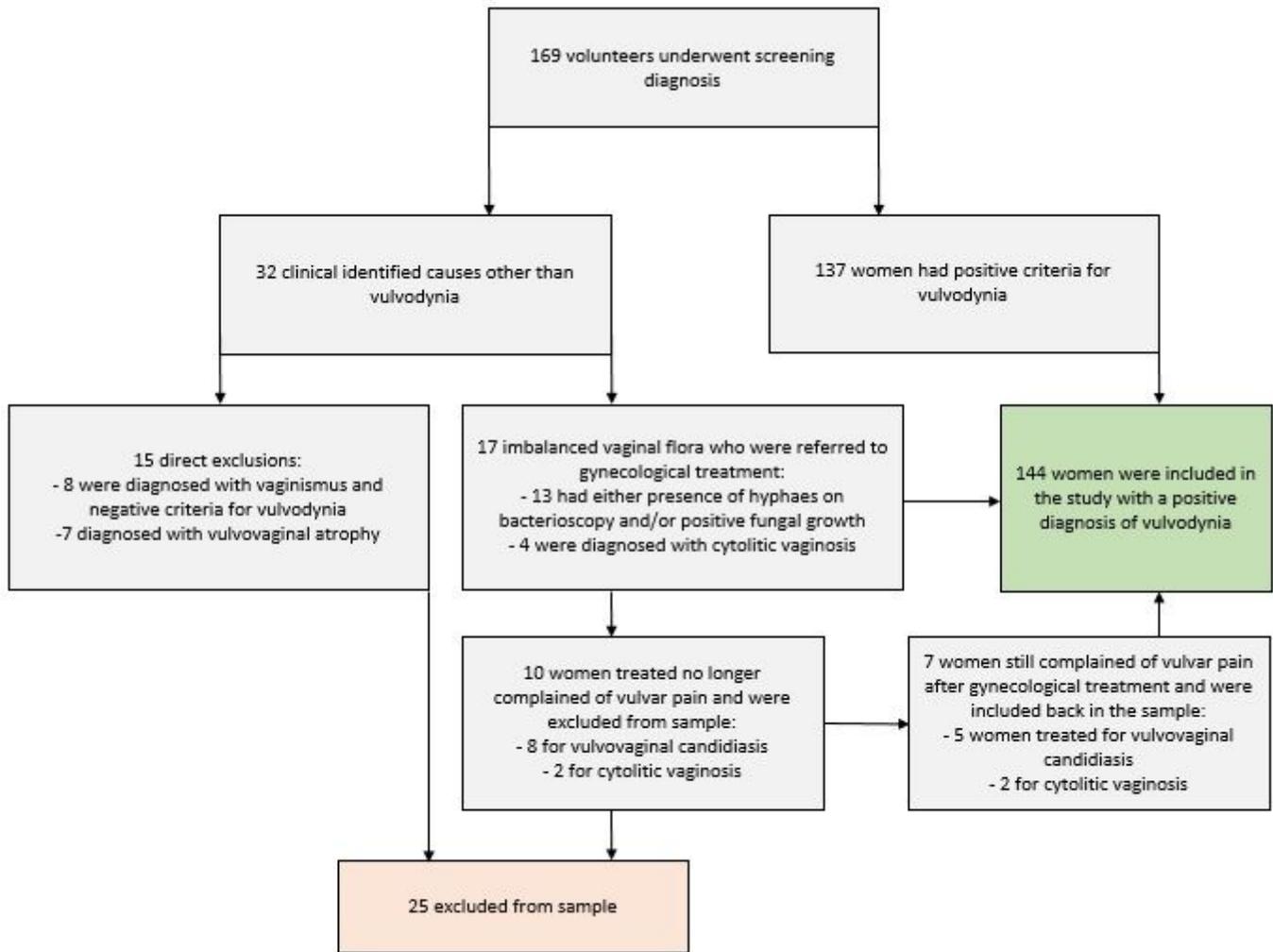


Figure 1

Flow chart of recruitment study.