



Sexual well-being in patients with vulvar disease: results from a preliminary prospective matched case–control study



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ARTICLE INFO

Article history:

Received 9 June 2015

Received in revised form 16 July 2015

Accepted 6 August 2015

Keywords:

Sexual well-being

Vulvar diseases

FSFI

ABSTRACT

Introduction: Only a few studies have focused on the description of sexual well-being in patients with vulvar disease (VD). The aim of this study was to test the hypothesis that VD patients have an overall impaired sexual well-being that varies depending on the type of VD.

Study design: An observational, prospective, single center and 1:1 matched case–control study was conducted in Nantes University Hospital (France). All new patients attending the specific consultation for VD between June 2011 and January 2013 were included. A control group was randomly selected from women who had a scheduled consultation for gynecologic follow-up. A validated French version of the Female Sexual Function Index (FSFI) was used. This self-administered questionnaire was distributed to all case and control women. VD was classified into 4 groups: inflammatory, (pre)malignant, infectious, and other VD. Descriptive statistics and multivariate mixed analyses were performed.

Results: Seventy-two VD patients and seventy-two control women completed the FSFI questionnaire. The median FSFI score was 21.1 in the VD patients versus 28.1 in the control patients. In the multivariate analysis, the FSFI score was significantly decreased by an average of 4.5 points ($p = 0.003$) in the VD patients. On the FSFI subscores, VD had significant impacts on items related to “arousal”, “pain”, “lubrication”, “satisfaction”, and “desire”. When comparing the VD groups, the total FSFI score seemed lower for (pre)malignant VD.

Conclusion: This preliminary study showed that VD patients had an impaired sexual well-being.

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Introduction

Female urogenital problems are one of the top ten reasons for consultation with a gynecologist or a general practitioner [1]. Despite their relatively high frequency, many physicians have difficulties in establishing a clear diagnosis as well as in managing these patients, particularly those with a chronic or recurrent form of vulvar disease (VD).

The management of VD is complex and is a diagnostic and therapeutic challenge for clinicians. VD is indeed at the junction of

several medical specialties, including gynecology, dermatology, urology and endocrinology. Because of varying vulva anatomical features, lack of clinical studies focused on these disorders, confusion between VD and sexual disorders, and the inherent difficulty in classifying VD [2], appropriate management remains relatively unclear in the medical community. Groups of specialized health professionals have nevertheless recently organized themselves to promote better communication between gynecologists, dermatologists and pathologists, to develop a standardized VD classification and to conduct more clinical and epidemiological research in the field [3,4]. Despite this recent structuring of health professionals involved in VD management, major gaps still exist in the associated medical research.

Indeed, accurate epidemiological data on VD and the associated consequences are scarce [5,6]. This is particularly true in the field of sexual well-being. To our knowledge, only a few studies have

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focused on the description of sexual well-being in patients with VD as well as the patient or VD characteristics that modulate the disease. In particular, the impact of VD on sexual well-being according to the VD type (inflammatory, malignant, etc.) is unknown. Furthermore, no clear evidence of an impaired sexual well-being in VD patients compared to the general female population has been truly demonstrated.

As a consequence, no specific questionnaires for patients with VD are currently available. Several questionnaires assessing sexual well-being can nevertheless be found in the literature; however, only a few of these questionnaires meet the required scientific quality criteria [7,8]. One of these questionnaires is the Female Sexual Function Index (FSFI) [9,10].

The aim of this study was thus to describe the population of patients attending a specific consultation for patients with VD at the Nantes University Hospital and test the following hypotheses: (1) patients with VD have an overall impaired sexual well-being and (2) sexual impairment varies depending on the type of VD and patient characteristics.

Material and methods

An observational, prospective, single center and 1:1 matched case–control preliminary study was conducted in Nantes University Hospital between June 2011 and January 2013. The study was approved by the ethics committee (Institutional Review Board: 2012-12 0000 1072).

Assessment of sexual well-being

The French version of the Female Sexual Function Index (FSFI), a self-administered questionnaire meeting the required scientific quality criteria, was used: The FSFI, developed in 2000 by Raymond Rosen, assesses female sexual dysfunction (FSD) [9]. A French version has been recently validated [11]. The FSFI is adapted for both sexually active and non-active women. Compared to other validated questionnaires, the FSFI questions have an advantage in that they do not ask overly invasive questions regarding sexual practices. A 6-item questionnaire allows the assessment of female sexual function (desire, arousal, lubrication, orgasm, satisfaction and pain) over the past four weeks. The total score ranges between 2 and 36; higher scores are associated with a lower degree of FSD. The choice of a pertinent threshold to define FSD is discussed in the literature, but a consensus seems to be found for values of less than 23 [12–14].

Patients

All new patients attending the VD consultation between June 2011 and January 2013 were included. Women who were <18 years old, pregnant, not able to read or write French or had a psychiatric or neurological disease were excluded. Recruitment was performed by the physicians. After explaining that participation was voluntary and anonymous, all patients who provided a signed informed consent were asked to freely complete the French version of the FSFI and a questionnaire on sociodemographic data (age, marital status, and occupation) in the waiting room. The physicians involved in the study asked all participants whether they had properly understood the questionnaire. In addition, medical data were collected by the physicians (gravidity, parity, menopausal status).

Control group

The results were compared to those of a control group of randomly selected women without VD or any others chronic or

acute diseases (chronic pelvic pain, endometriosis, cancer, bleeding, depression, etc.) who were not pregnant and had a scheduled consultation for their annual gynecologic follow-up between June 2011 and January 2013 at the Obstetrics and Gynecology Department of Nantes University Hospital. Similarly to the VD patients, the recruitment and the collection of medical data was made by the physicians. One control woman was selected for each VD patient in the two weeks following the VD patient inclusion. The patients were matched according to their menopausal status.

Statistical methods

Patient sociodemographic and medical characteristics were described using medians and interquartile ranges (IQR). Due to the small sample size, quantitative variables were compared using the paired Wilcoxon test and qualitative variables were compared using Fisher exact test. VD was classified into 4 homogeneous groups as follows: inflammatory, malignant and premalignant, infectious, and other VD based on clinical and histological criteria. A multivariate mixed linear model was used to compare the case and control patients with different sociodemographic characteristics known to influence female sexual function (e.g., age, marital status and occupation). Due to the matching based on menopausal status, a random effect was defined to take into account the impact of this matching. FSFI scores were compared between the VD groups using medians. The accepted level of significance was defined at 0.05. Statistical analyses were conducted using R.14.1 software (R Development Core team, Austria, Vienna) [15].

Results

Between June 2011 and January 2013, 72 of the 73 eligible patients attending the VD consultation were included in the study. The median age of the study population was 48 years (IQR: 34–64). Seventeen (23.6%) women were widowed or single, 16 (22.2%) women were nulliparous, 33 (45.8%) women were postmenopausal, and 40 (55.6%) women had a regular job. In the control group ($n = 72$), the median age was also 48 years (IQR: 37–56). Six women (8.3%) were widowed or single, 11 (15.3%) women were nulliparous, 33 (45.8%) women were postmenopausal, 53 (73.6%) women had a regular job. The descriptive data are shown in Table 1.

In the VD population, the primary reason for consultation was inflammatory VD ($n = 33$, 46%), followed by other VD ($n = 20$, 28%), malignant and premalignant VD ($n = 11$, 15%), and infectious VD ($n = 8$, 11%) (Table 2). The three most commonly encountered diseases were vulvar lichen sclerosus ($n = 18$, 25%), vulvar psoriasis ($n = 8$, 11%), and vulvar itching ($n = 7$, 10%).

The median FSFI summary score was 21.1 (IQR: 13.4–26.5) in patients with VD and 28.1 (IQR: 22.5–30.3) in the control patients (Table 3). Eleven VD patients (15%) were not sexually active during the 4 weeks preceding the interview, versus 4 (6%) women in the control population. Each FSFI subscore was lower in the VD patients than in the control patients. For each score, a multivariate mixed model adjusted for age, marital status, and occupation type was performed to test the significance of the negative impact of VD on sexual well-being (Table 4). The presence of VD significantly decreased the FSFI summary score ($p = 0.003$). An average score reduction of 4.5 (S.D. = 1.5) was observed in the patients with VD compared to the control patients. When considering subscores, a negative impact of VD was also significantly found for desire (VD impact = -0.7 , S.D. = 0.2, $p = 0.002$), arousal (VD impact = -0.9 , S.D. = 0.3, $p = 0.003$), lubrication (VD impact = -0.8 , S.D. = 0.3, $p = 0.017$), satisfaction (VD impact = -0.6 , S.D. = 0.3, $p = 0.028$), pain (VD impact = -1.5 , S.D. = 0.4, $p = 0.001$) and, to a lesser extent, orgasm (VD impact = -0.6 , S.D. = 0.3, $p = 0.076$).

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