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ORIGINAL ARTICLE

Gender differences in genital lichen sclerosus: data from a multicenter Italian study on 729 consecutive cases

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ABSTRACT

BACKGROUND: Studies specifically conducted to assess gender differences in genital lichen sclerosus (GLS) are not available. This multicenter study aimed to identify possible gender-related differences on GLS clinical features, history and course, through collecting data from a large mixed-sex sample of patients.

METHODS: This was a cross-sectional study on 729 subjects (53.8% females, 46.2% males) affected with GLS, consecutively observed within a network of 15 Italian dermatology units. The following information was specifically collected: clinical features and severity of symptoms related to GLS, extragenital involvement, previous therapies, diagnostic suspicion at referral, type of referring physicians, development of genital squamous-cell carcinoma (SCC).

RESULTS: Females complained of symptoms more frequent and severe than men; pallor and scarring-sclerosis-atrophy were the most frequent features without gender differences; itching-related signs were more frequent in females than in males as well as extragenital involvement; prior to receiving a definitive diagnosis, females received treatment more frequently than males; 40% of patients were referred with a misdiagnosis; the highest rate of correct suspected diagnosis at referral came from dermatologists than from other physicians; duration of the disease was found to predispose to SCC development.

CONCLUSIONS: Our findings highlighted several gender differences on clinical presentation and symptom profile of GLS. In spite of some characteristic features, misdiagnosis at referrals was frequent.

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KEY WORDS: Vulvar lichen sclerosus; Sex characteristics; Therapeutics; Squamous cell carcinoma.

Genital lichen sclerosus (GLS) is a chronic-relapsing inflammatory disease of the genital area with a huge impact on quality of life.[1, 2] In fact patients complain of distressing symptoms and sexual dysfunction.[3, 4] An increased risk of genital cancer is also recognized.[5, 6]

The GLS Italian Study Group, in the framework of the Italian Group for Epidemiological Research in Dermatology (GISED) and the Italian Society of Dermatology (SIDeMaST), collected clinical and history data from a mixed-sex, large sample of Italian patients in order to explore the main gender-related differences.

Materials and methods

Study patients

This was a multicenter, cross-sectional study on a group of consecutive patients affected with GLS, observed in an outpatient setting within a network of 15 Italian Dermatology Units between January 2013 and December 2014. The data elaborated in the present study come from the same data set from which a previous assay analyzed other parameters with different aims.[7] Patients of both gender and any age, with a clinical and/or histological diagnosis of GLS made after the 1st January 2008, regardless of the disease onset, were considered eligible for the study. The majority of patients received their first definite diagnosis at the Dermatology Units participating in the study, which are referral centers for GLS. In the case of lack of histological confirmation, the diagnosis of GLS, performed by experienced dermatologists, was clinically evident beyond any doubt. Exclusion criteria were: clinical or histological features showing possible resemblance with other diseases, such as lichen planus or plasma cell vulvitis/balanitis; lack of agreement between clinical and histological features; any active genital infection. Presence of LS in other skin or mucosal sites was not an exclusion criterion.

Data collection

Information was collected by using a standardized data collection form and included, for the purpose of this analysis: clinical features and severity of symptoms related to GLS, genital sites involved, extragenital involvement, previous therapy (defined as every pharmacological or non-pharmacological treatment utilized by the patients for treating GLS prior to being included in the study), diagnostic suspicion at referral, the physician who sent the patient to the study dermatology units for investigation and management (general practitioner, specialist in dermatology, gynecology, pediatrics, surgery, other specialist), previous development of a histologically confirmed genital squamous cell carcinoma (SCC) on pre-existing LS. The following objective features were recorded: pallor (leukoderma), hyperkeratosis, ecchymosis and itching-related excoriations, fissures, erosion/ulceration, sclerosis-scarring; loss/agglutination of the labia minora and burying of the clitoris were adjunctive features for the female patients; adhesions of the foreskin to the glans and phimosis were assessed in the males. These objective parameters were recorded as present or absent. Severity of GLS-associated symptoms were based on patient's self-assessment by using three separate visual analogue scales (VAS, which included a numeric rating scale 0-10) evaluating itching, burning, and dyspareunia. Each assessed symptom was arbitrarily subdivided according to its severity into three main groups: 1) absent, when the VAS was 0; 2) mild to moderate, when the VAS was 1-5; 3) severe, when the VAS was ≥6. These cut offs were defined in accordance with our clinical experience on patient discomfort and quality of life impairment.

Written informed consent was obtained from patients or from their parents for patients younger than 18 years, before inclusion in the study. Data were first collected by the treating dermatologist at the participating center by using a paper questionnaire and then inserted by a technician into a centralized database.

The study was approved by the Ethics Committee of the University Hospital of Ferrara, Italy, which was the coordinating center, and by the Ethics Committee of the individual centers participating into the study.

Statistical analysis

Data were presented as means with standard deviations or numbers with percentages for continuous and categorical variables respectively. For the purpose of the analysis continuous variables were categorized by using clinically relevant values as cutoff points. Gender differences for variables under study were assessed after controlling for age by using logistic regression models with gender entered as dichotomous outcome. All tests were considered as significant at $P<0.05$. The analysis was carried out using SPSS software v. 20.0 (IBM Corp.).

Results

Clinical symptoms and signs

Demographics of the 729 patients (392 females [53.8%] and 337 males [46.2%], mean age 57.3±17.4 years [range

TABLE I.—*Anatomical sites involved by the disease.*

Sex	Site	N. (%)
Females	Labia minora	328 (85.6%)
	Clitoris/clitoral hood	257 (67.1%)
	Fourchette	219 (57.2%)
	Labia majora (inner face)	211 (55.1%)
	Vestibule	154 (40.2%)
	Perianal region	134 (35.0%)
	Perineum	130 (33.9%)
	Extralabia and inguinal folds	30 (7.8%)
	Other	13 (3.4%)
Males	Internal sheet of the foreskin	233 (70.4%)
	Glans	230 (69.5%)
	External sheet of the foreskin	203 (61.3%)
	Coronal sulcus	177 (53.5%)
	Urethral meatus	42 (12.7%)
	Body of the penis	22 (6.6%)
	Perineum	1 (0.3%)
	Perianal region	3 (0.9%)
	Scrotum	3 (0.9%)
	Other	31 (9.4%)

Each patient may have more than one involved site.

6-97]) included in the study are reported in detail elsewhere.[7] Listed in Table I are the sites involved by the disease among the study population.

Table II shows clinical signs and severity of symptoms related to the disease. Overall, the most common signs were pallor (86.3%), sclerosis-scarring (58.3%), and hyperkeratosis (29.6%). Agglutination and/or loss of the labia minora (61.7%) and sealing of the clitoral hood with possible partial to complete burying of the clitoris (41.6%) were common features in females, while phimosis (25.5%) was also quite frequent in males. Hyperkeratosis, purpuric lesions with itching-related excoriations, and fissures were significantly more frequent in females than in males. Extragenital involvement was found in 5.8% of the entire population, and was more frequent in females (9.7%) than in males (1.2%). The trunk was the most frequent extragenital localization of the disease in comparison with other body sites (P<0.001).

Regarding GLS symptoms, 454 patients (62.3%) com-

TABLE II.—*Clinical signs and symptoms of GLS, overall and by gender.*

Parameter	Total	Female	Male	P value*
Clinical signs				
Pallor (leukoderma)	629 (86.3%)	346 (88.3%)	283 (84.0%)	0.11
Sclerosis-scarring	425 (58.3%)	236 (60.2%)	189 (56.1%)	0.98
Hyperkeratosis	216 (29.6%)	133 (33.9%)	83 (24.6%)	0.02 #
Fissures	149 (20.4%)	92 (23.5%)	57 (16.9%)	0.04 #
Erosion/ulceration	123 (16.9%)	74 (18.9%)	49 (14.5%)	0.41
Ecchymosis and itching-related excoriations	106 (14.5%)	76 (19.4%)	30 (8.9%)	<0.001 #
Loss/agglutination of the labia minora	–	242 (61.7%)	–	–
Partial to complete burying of the clitoris	–	163 (41.6%)	–	–
Phimosis	–	–	86 (25.5%)	–
Adhesions of the foreskin to the glans	–	–	73 (21.7%)	–
Extragenital involvement	42 (5.8%)	38 (9.7%)	4 (1.2%)	<0.001
Symptoms				
Itching (VAS)				
Mean±SD	3.2±3.4	4.4±3.6	1.9±2.4	<0.001
0	259 (36.3%)	94 (24.3%)	165 (50.6%)	<0.001
1-5	267 (37.4%)	142 (36.7%)	125 (38.3%)	0.48
≥6	187 (26.2%)	151 (39.0%)	36 (11.0%)	<0.001
Burning (VAS)				
Mean±SD	2.8±3.2	3.6±3.5	1.7±2.5	<0.001
0	295 (41.8%)	120 (31.3%)	175 (54.3%)	<0.001
1-5	257 (36.5%)	142 (37.1%)	115 (35.7%)	0.69
≥6	153 (21.7%)	121 (31.6%)	32 (9.9%)	<0.001
Dyspareunia (VAS)				
Mean±SD	2.8±3.8	3.7±4.2	1.9±3.0	<0.001
0	355 (54.5%)	158 (47.9%)	197 (61.4%)	<0.001
1-5	128 (19.7%)	54 (16.4%)	74 (23.1%)	0.06
≥6	168 (25.8%)	118 (35.8%)	50 (15.6%)	<0.001

Numbers may not add up to the total due to missing data.
VAS: visual analogue scale.
*Significance after controlling for age by using logistic regression models with gender as dichotomous outcome; # statistically significant difference.

plained of itching, 410 (56.2%) complained of burning, and 296 (40.6%) reported dyspareunia. When comparing genders, all three symptoms were highly significantly more frequent among females than among males (P<0.001). Moreover, for all assessed symptoms, females were more likely to give a higher VAS score than males (P<0.001). Consistently, symptoms were scored as severe more frequently by female subjects than by males (P<0.001).

Previous therapies

About 69% of patients had undergone previous treatments for their condition (Table III). The rate of female patients who had received treatments prior to being included was higher than that of males (P<0.001). Topical corticosteroids were the most frequently used therapy, without differences between genders. Moisturizers and emollients were also frequently used by patients, mainly by females (P=0.003). Both topical calcineurin inhibitors (2.5%) and topical retinoids (0.4%) were used in a small percentage of our population. Topical sex hormones, mostly testosterone and estrogens in females, were rarely used as well. On the contrary, about 10% of the study patients had been treated with topical antimycotics and about 3% with systemic antimycotics.

Referring physicians and diagnosis at referral

Overall, the request for a visit in the participating referral centers was made mainly by dermatologists (40.6%) in comparison with other specialists (Table IV). However, when considering genders separately, the gynecologist was the main referring physician for female subjects (44%) while the general practitioners for males (42.4%). In 59% of cases, the patients were referred with a correct suspicion of lichen sclerosus. A correct referring diagnosis was more frequent among females than among males (P=0.003, C square test). In 16% of cases, the referring diagnosis wa generically genital itching; 6% of patients were referre with a suspicion of mycosis. The rate of referrals with correct diagnosis from dermatologists resulted significan ly higher (P<0.001, Chi square test) when compared wi referrals from other physicians.

Cancer development

Ten patients (six females and four males) had develope a SCC, corresponding to 1.4% of the enrolled popul tion. Incidence of SCC was not different between ge ders (P=0.76, Fisher' test). Previous corticosteroid trea ment was not associated with SCC development (P=0.5 Fisher' test). Duration of GLS was the sole factor assoc ated with an increased risk of developing a SCC (P=0.0 Mann-Whitney U-test).

Discussion

Several reviews concerning GLS have pointed out di ferences between genders without providing prima data.[3, 8-10] To date no studies have directly compared ma and female patients affected with GLS in order to ide tify possible differences on clinical features, history a course of the disease.

Based on data from 729 GLS consecutive patients dia nosed at a network of 15 Italian dermatological units, w assessed possible gender-related differences on GLS clin cal features, history and course. The sites most frequent involved in females were the labia minora, clitoris, clit ral hood, and fourchette, while in the enrolled males GL

TABLE III.—*Therapies received prior to being included in the study*

Therapy	Patients			P value*	Adjusted P value**
	Females	Males	Total		
Previous therapies for GLS	296 (75.5%)	209 (62.0%)	505 (69.3%)	<0.001	<0.001
Topical corticosteroids	193 (49.2%)	148 (43.9%)	341 (46.8%)	0.15	0.18
Emollients/moisturizers	168 (42.9%)	108 (32.0%)	276 (37.9%)	0.003	0.003
Topical vitamin E	55 (14.0%)	40 (11.9%)	95 (13.0%)	0.39	0.25
Topical antifungals	47 (12.0%)	29 (8.6%)	76 (10.4%)	0.14	0.21
Systemic antifungals	12 (3.1%)	9 (2.7%)	21 (2.9%)	0.75	0.80
Topical calcineurin inhibitors	10 (2.6%)	8 (2.4%)	18 (2.5%)	0.88	0.59
Topical estrogens/phytoestrogens	8 (2.0%)	1 (0.3%)	9 (1.2%)	0.04	–
Topical testosterone	5 (1.3%)	2 (0.6%)	7 (1.0%)	0.46	–
Topical vitamin A	4 (1.0%)	1 (0.3%)	5 (0.7%)	0.38	–
Topical retinoids	3 (0.8%)	0 (0.0%)	3 (0.4%)	0.25	–
Other	42 (10.7%)	40 (11.9%)	82 (11.2%)	0.62	0.96

TABLE IV.—*Diagnosis at referral and referring physicians, overall and by gender.*

Parameter	Females	Males	Total	P value*
Diagnosis at referral				0.003 †
Lichen sclerosus	243 (62.8%)	183 (54.8%)	426 (59.1%)	
Pruritus	58 (15.0%)	58 (17.4%)	116 (16.1%)	
Mycosis	14 (3.6%)	29 (8.7%)	43 (6.0%)	
Lichen planus	8 (2.1%)	3 (0.9%)	11 (1.5%)	
Lichen simplex chronicus	5 (1.3%)	3 (0.9%)	8 (1.1%)	
Sexual transmitted disease	2 (0.5%)	6 (1.8%)	8 (1.1%)	
Vulvodynia	6 (1.6%)	0 (0.0%)	6 (0.8%)	
Contact dermatitis	2 (0.5%)	3 (0.9%)	5 (0.7%)	
Leucorrhoea	2 (0.5%)	0 (0.0%)	2 (0.3%)	
Phimosis	0 (0.0%)	1 (0.3%)	1 (0.1%)	
Ulcer	1 (0.3%)	0 (0.0%)	1 (0.1%)	
Viral infection	1 (0.3%)	0 (0.0%)	1 (0.1%)	
Plasmacellular vulvitis	1 (0.3%)	0 (0.0%)	1 (0.1%)	
Other	44 (11.4%)	48 (14.4%)	92 (12.8%)	
Referring physician ^				<0.001
Dermatologist	154 (40.1%)	136 (41.2%)	290 (40.6%)	
Gynecologist/urologist	169 (44.0%)	54 (16.4%)	223 (31.2%)	
General practitioner/pediatrician	61 (15.9%)	140 (42.4%)	201 (28.2%)	

*Significance after controlling for age by using logistic regression analysis with gender as dichotomous outcome; † the proper diagnosis (lichen sclerosus) was tested against all other; ^ the rate of proper diagnosis was significantly higher (P<0.001) when the referring physician was a dermatologist (57.6%) compared to gynecologist/urologist (31.2%) or general practitioner/pediatrician (11.2%).

mostly affected the inner surface of the prepuce and the glans, whereas urethral involvement was rare. Perineum and perianal area were involved in more than one third of female patients, whereas only less than 1% of male subjects had perineum or perianal involvement. In agreement with the literature, extragenital lesions were more frequently observed in females than males,[1, 9, 11, 12] and trunk was the extragenital site most commonly affected.

Pallor was the most typical objective feature of GLS in both genders, occurring in about 86% of cases without differences between female and male subjects. Sclerosis and/or scarring processes with fusions of tissue and loss of normal architecture and function were present in almost 60% of patients, without gender differences too. Hyperkeratosis was more frequent in females than in males as well as scratching-related signs, such as ecchymosis and excoriations. This latter finding was likely the consequence of scratching due to a significantly more severe itching in females compared with males. In general, GLS was found to be more frequently and more severely accompanied by subjective symptoms in females than in males. In line with this observation, the rate of patients reporting a detrimental effect of the disease on sexual life was significantly higher among females than males. Females especially reported dyspareunia and apareunia. In this study, the true frequency of dyspareunia was probably underestimated as it was assessed considering the entire population without excluding those patients denying sexual activity for reasons other than disease-related pain.

Most patients had received pharmacological and/or non-pharmacological treatments before being visited at the study centers and before receiving a definitive diagnosis of GLS. Females were treated more frequently than males, possibly in relation with the higher frequency and severity of symptoms in females compared with males. Topical corticosteroids were the most frequently prescribed therapy in males and females. Moisturizers and emollients had been used by 40% of patients, mainly females. Moreover, 13% had used topical vitamin E. It is noteworthy that other recommended treatment for GLS, such as topical calcineurin inhibitors and topical retinoids, had been prescribed to a very small proportion of patients. Concerns about the long-term safety profile of topical calcineurin inhibitors in a disease with a premalignant potential may account for this finding. On the other hand, a relevant rate of patients had been treated with topical or systemic antifungals. This is not a surprise as multiple conditions may mimic GLS. In line with this, about 40% of enrolled patients had not received a correct diagnosis before being seen at the referral centers participating to the study. On this regard, it is interesting that females were referred with a correct suspected diagnosis more often than males. Furthermore, in our population the highest percentage of requests fitting with a final diagnosis of GLS came from dermatologists when compared with both general practitioners and other specialists. This suggests that clinical competence is crucial in making a correct diagnosis.

Genital SCC was a concomitant observation in 1.4% of

the enrolled population. The reported rate of occurrence of SCC in GLS patients show large variations from less than 1% to 5%.[5, 13-16] These variations may depend on several factors, including the selection of the population and the length of the follow-up. Although SCC development has been described predominantly in association with female genital GLS, in our population no gender differences were found. As previously reported, the duration of symptoms was the main indicator of cancer risk.[17]

Limitations of the study

The results reported herein should be viewed in light of the limitations of the study. Firstly, all of the included patients were identified from tertiary referral clinics; as such, the results of this study may not be fully representative of the overall GLS population. Furthermore, univocal methods for the assessment of GLS severity are not available and severity grades and cut-offs in the present study have been arbitrarily defined. A clear distinction between vulvar atrophy related to patients' age rather than to their lichen sclerosus is difficult to establish. Thus, the role of the former on symptoms' occurrence and severity cannot be ascertained. Finally, our cohort exclusively comprised Caucasian patients and therefore, our data might not be generalizable to other ethnic groups.

In spite of these limitations, up to date this is the largest study including GLS patients of both sexes; the large sample size allowed the authors to reliably assess features and gender differences concerning this disease.

Conclusions

The main findings of the present study could be summarized as follows: females usually complain of more frequent and severe subjective symptoms compared with males; pallor and scarring-sclerosis-atrophy are clinical features found in most patients, representing an important clue to the clinical diagnosis; misdiagnosis is common, especially among physicians unfamiliar with the condition; the duration of the disease is a risk factor for the association of GLS with SCC development.

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