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ORIGINAL RESEARCH

Why do some patients with vulval lichen sclerosus on long-term topical corticosteroid treatment experience ongoing poor quality of life?

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Abstract

Objective: To identify reasons for ongoing poor quality of life (pQOL) in a subset of long-term topical corticosteroid-treated vulval lichen sclerosus (VLS) patients.

Methods: A prospective cross-sectional study of patients attending a dermato-gynaecology practice in Sydney, Australia, comparing VLS patients with good quality of life (gQOL) and pQOL, in pre-treatment and long-term treatment groups, using the Vulval Quality of Life Index (VQLI). Demographics, VQLI scores and treatment characteristics were compared between gQOL and pQOL patients.

Results: A total of 255 biopsy-proven VLS patients, 67 in pre-treatment and 188 in long-term treated groups were considered. There were 33 (49.3%) pQOL patients in pre-treatment and 13 (6.9%) in treatment groups ($p < 0.001$). The highest-scoring domain in treated pQOL patients was sexuality (1.7 [interquartile range (IQR) 1.0–2.0]), followed by anxiety [1.3 (IQR 1.0–1.5]), symptoms (1.0 [IQR 0.5–1.5]) and activities of daily living (0.7 [IQR 0.3–1.0]). Compared to treated gQOL, treated pQOL had significantly higher proportions of patients with partial treatment adherence (8 [61.5%] vs 42 [24.0%], $p = 0.006$), suboptimal disease control (7 [53.8%] vs 20 [11.4%], $p < 0.001$), scarring progression (3 [23.1%] vs 7 [4.0%], $p = 0.024$) and urinary incontinence (5 [38.5%] vs 27 [15.4%], $p = 0.049$).

Conclusions: Only a minority of long-term treated VLS patients reported ongoing pQOL. Of those who did, sexuality and anxiety domains were found to be the main sources of distress. Three major areas distinguishing gQOL from pQOL patients were (1) treatment adherence and disease control, (2) psychological factors and (3) urinary incontinence.

Abbreviations: ADLs, activities of daily living; ERT, oestrogen replacement therapy; gQOL, good quality of life; IQR, interquartile range; pQOL, poor quality of life; QOL, quality of life; SD, standard deviation; TCS, topical corticosteroids; VIN, vulval intraepithelial neoplasia; VLS, vulval lichen sclerosus; vSCC, vulval squamous cell carcinoma; VQLI, Vulval Quality of Life Index.

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KEYWORDS
long-term care, quality of life, topical corticosteroids, VQLI, vulval diseases, Vulval lichen sclerosus

INTRODUCTION

Vulval lichen sclerosus (VLS) is a chronic inflammatory dermatosis of the vulva, most commonly affecting peri- and post-menopausal women. VLS can be highly debilitating if left untreated, as it predominantly manifests with intense vulval pruritus, pain from excoriations and fissuring, as well as dyspareunia, thereby interfering with day-to-day activities and negatively impacting on quality of life (QOL).[1,2] Inadequate treatment also increases the risks of vulval scarring, destruction of vulval architecture and vulval squamous cell carcinoma (vSCC).[3–8]

Topical corticosteroids (TCS) are the first-line treatment in VLS. Traditionally, they were administered for a short duration and only continued 'as needed' due to fear of side effects. However, recent evidence has challenged this notion, leading to a paradigm shift in TCS administration from short-term to long-term, individualised TCS regimens. Long-term TCS therapy was not only demonstrated to be safe but also crucial to lower the risks of scarring progression, vSCC, disease recurrence and maximise QOL in women with VLS.[4,6,7,9–11] Those who were fully adherent to prescribed regimens were shown to have significantly better disease outcomes and QOL than non-adherent patients.[4,6,7]

Nevertheless, one question still remains – it has been observed across a number of studies, including those involving long-term TCS therapy, that there is a proportion of women with VLS who continues to feel dissatisfied and reported poor QOL despite treatment.[6,12–14] As no previous studies have investigated potential explanations for this occurrence, it is the objective of this study to fill the gap in knowledge.

Recently, a validated instrument, the Vulval Quality of Life Index (VQLI), has been developed.[15] It is a time-efficient yet comprehensive QOL instrument with proven high reliability and validity, exploring physical, psychosocial and sexual aspects of vulval diseases. By conducting a QOL study on long-term treated VLS patients using the VQLI, and focusing on patients still reporting poor QOL, we aim to (1) identify life domains still perceived unsatisfactory by this group of patients and (2) investigate factors distinguishing them from those reporting good QOL. The results of this study will assist clinicians in developing further management strategies to maximise QOL in women with VLS.

METHODS

Study design

A prospective cross-sectional study of women with VLS presented to a subspecialty dermato-gynaecology practice in Sydney, New South Wales, Australia from March 2018 to November 2019. Ethics approval was obtained from the Northern Sydney Local Health District Human Research Ethics Committee. A randomised controlled trial was not conducted, as there is robust evidence indicating that insufficient treatment with TCS can lead to scarring and neoplasia.[4,6,7] Therefore, the authors believe it would be unethical to conduct such a study.

Inclusion criteria were age 18 years or older and a biopsy-proven diagnosis of VLS. 'Pre-treatment' group included new VLS patients who have not been commenced on TCS. 'Treatment' group included VLS patients who have been treated with TCS in the clinic for 2 years or longer.

Data collection

Following written consent, participants were invited to complete the VQLI (Appendix S1). Additional information was obtained, including age, ethnicity, menopausal status, use of oestrogen replacement therapy (ERT), symptom duration prior to diagnosis, presence of vulval intraepithelial neoplasia (VIN) or vSCC at diagnosis, presence of scarring at diagnosis, anxiety/depression, urinary incontinence, relationship status and whether a participant is sexually active. For the treatment group, the following information was also obtained: treatment duration, TCS potency according to Australian TCS classification (Class I = mild, Class II = moderate, Class III = potent, Class IV = superpotent), treatment adherence assessed using Likert scale (partial adherence – 'not at all' [0] / 'some days' [1] / 'most days' [2] vs full adherence – 'always' [3]), disease control (suboptimal [new/enlarging white patches or new/progression of scarring, or development of VIN / vSCC] vs optimal – [no new/enlarging white patches and no new/progression of scarring and no development of VIN / vSCC]), scarring progression and side effects. All patients were monitored using detailed clinical photography.

Outcome variables

The VQLI consists of 15 questions divided into four domains, namely symptoms (questions 1–2), anxiety (questions 3–5,14), activities of daily living (ADLs) (questions 6–10,15) and sexuality (questions 11–13). Each question was graded as 0 ('not at all'), 1 ('a little'), 2 ('a lot') or 3 ('very much').[15] The minimum total score is 0/45 and the maximum is 45/45, interpreted as follows: 0–5 = VLS has nil to minimal impact on QOL, 6–13 = mild impact on QOL, 14–23 = moderate impact on QOL, 24–37 = severe impact on QOL and 38–45 = very severe impact on QOL. Median and interquartile range (IQR) of total and domain scores are presented. The mean score of individual item was also calculated to enable accurate item ranking within each domain.

Pre-treatment and treatment participants were classified as (a) good QOL (gQOL) patients if they achieved total scores of 0–13, i.e. VLS had nil/minimal/mild impact on their QOL, or (b) poor QOL (pQOL) patients if they achieved total scores of 14–45, i.e. VLS had moderate/severe/very severe impact on their QOL.

The primary outcomes of interest in this study were differences in characteristics between gQOL and pQOL patients, including demographics, VQLI scores, treatment adherence and outcomes. The secondary outcomes of interest were interactions between scores and other variables in each group.

Statistical analysis

Statistical analyses were conducted using SPSS version 27.0 (IBM Corp.). Continuous and ordinal variables were reported as medians with IQR. Categorical variables were reported using frequencies and percentages. Associations between two continuous or ordinal variables were assessed using Spearman's rank-order correlation. Comparisons between two groups measured on an ordinal or a continuous scale were performed using Mann–Whitney U test. Proportions of categorical variables were compared using Chi-square or Fisher's exact test. Statistical significance was defined as two-sided $p < 0.05$.

RESULTS

Demographic data

The study population consisted of 255 participants, 67 in pre-treatment and 188 in treatment groups. In pre-treatment group, 34 (50.7%) were classified as gQOL and 33 (49.3%) as pQOL patients. In treatment group, 175 (93.1%) were classified as gQOL and 13 (6.9%) as pQOL patients.

Table 1 shows comparisons of baseline characteristics between gQOL and pQOL patients. There were no significant demographic differences pre-treatment. In the treatment group, pQOL had more than double the proportion of urinary incontinence compared to gQOL (5 [38.5%] vs 27 [15.4%], $p = 0.049$). Further, treated pQOL had higher proportions of patients who were in ≥60 age group, menopausal, sexually abstinent due to dyspareunia and had VIN / vSCC at diagnosis, but not at levels that were statistically significant.

VQLI scores

Pre-treatment

Median total scores were 7.5 (IQR 6.0–10.0) in gQOL and 22.0 (IQR 16.0–29.0) in pQOL ($p < 0.001$). Pre-treatment domain scores are shown in Figure 1a, displaying a similar trend in domain ranking between untreated gQOL and pQOL.

Treatment

Median total scores were 2.0 (IQR 0.0–5.0) in gQOL and 15.0 (IQR 14.0–17.0) in pQOL ($p < 0.001$). Domain scores in treatment group are shown in Figure 1b. 'Symptoms' (0.5 [IQR 0.0–0.5]) was the highest-scoring domain in gQOL; however, 172 (98.3%) reported 'not at all' or only 'a little' symptomatic. The rest of VQLI domains in gQOL had median scores of zero. In pQOL, the highest-scoring domain was sexuality (1.7 [IQR 1.0–2.0]), followed by anxiety [1.3 (IQR 1.0–1.5]), symptoms (1.0 [IQR 0.5–1.5]) and ADLs (0.7 [IQR 0.3–1.0]). Significant score reductions following treatment were observed across all domains in gQOL (Figure S1A) but only in symptoms and anxiety in pQOL (Figure S1B).

Individual item scores are shown in Figures 2 and S2. In domain sexuality, question-12 regarding interference with sex life was the highest-scoring item in treated gQOL (mean 0.4 [SD 0.7]), and question-13 regarding distress, guilt or worries about sex was the highest-scoring item in treated pQOL (mean 1.7 [SD 1.1]) (Figure 2b). The largest item score difference between treated gQOL and pQOL, representing the sexuality item where the two groups differed the most, was found in question-13 (mean difference = 1.4).

In domain anxiety, question-14 regarding concerns about long-term health implications was the highest-scoring item in gQOL (mean 0.5 [SD 0.5]) and pQOL

TABLE 1 Demographics and clinical characteristics between good quality of life (gQOL) and poor quality of life (pQOL) patients

	Pre-treatment			Treatment		
	Good quality of life (*N* = 34)	**Poor quality of life (*N* = 33)**	***p*-Value**	**Good quality of life (*N* = 175)**	**Poor quality of life (*N* = 13)**	***p*-Value**
Age, median (IQR), years	57.0 (48.5–69.0)	56.0 (48.0–66.0)	NS	63.0 (56.0–70.0)	65.0 (61.0–67.0)	NS
18–39, *n* (%)	4 (11.8)	6 (18.2)	NS	7 (4.0)	0 (0.0)	NS
40–49, *n* (%)	4 (11.8)	7 (21.2)		19 (10.9)	1 (7.7)	
50–59, *n* (%)	8 (23.5)	6 (18.2)		38 (21.7)	2 (15.4)	
≥60, *n* (%)	18 (52.9)	14 (42.4)		111 (63.4)	10 (76.9)	
Race/Ethnicity, *n* (%)[a]						
White, non-Hispanic	33 (97.1)	27 (81.8)	NS	170 (97.1)	13 (100.0)	NS
Asian	1 (2.9)	3 (9.1)		3 (1.7)	0 (0.0)	
Others	0 (0.0)	3 (9.1)		2 (1.1)	0 (0.0)	
Relationship status, *n* (%)[a]						
Single	13 (38.2)	7 (21.2)	NS	45 (25.7)	3 (23.1)	NS
In a relationship	21 (61.8)	26 (78.8)		130 (74.3)	10 (76.9)	
Sexually active, *n* (%)[a]						
Yes	18 (52.9)	22 (66.7)	NS	115 (65.7)	7 (53.8)	NS
No	16 (47.1)	11 (33.3)		60 (34.3)	6 (46.2)	
Due to pain	0 (0.0)	5 (15.2)		1 (0.6)	1 (7.7)	
Due to other reasons	16 (47.1)	6 (18.2)		59 (33.7)	5 (38.5)	
Menopause, *n* (%)[a]						
Yes	26 (76.5)	23 (69.7)	NS	151 (86.3)	12 (92.3)	NS
No	8 (23.5)	10 (30.3)		24 (13.7)	1 (7.7)	
Oestrogen replacement therapy, *n* (%)[a]						
Yes	5 (14.7)	9 (27.3)	NS	82 (46.9)	7 (53.8)	NS
Topical	5 (14.7)	8 (24.2)		76 (43.4)	7 (53.8)	
Systemic	0 (0.0)	1 (3.0)		5 (2.9)	0 (0.0)	
Combination	0 (0.0)	0 (0.0)		1 (0.6)	0 (0.0)	
No	29 (85.3)	24 (72.7)		93 (53.1)	6 (46.2)	
Urinary incontinence, *n* (%)	3 (8.8)	3 (9.1)	NS	27 (15.4)	5 (38.5)	*
Anxiety/Depression, *n* (%)	6 (17.6)	7 (21.2)	NS	27 (15.4)	3 (23.1)	NS
Symptom duration prior to diagnosis, median (IQR), months	15.0 (8.5–42.0)	24.0 (12.0–78.0)	NS	24.0 (12.0–60.0)	24.0 (12.0–102.0)	NS
Scarring at diagnosis, *n* (%)	15 (44.1)	21 (63.6)	NS	120 (68.6)	8 (61.5)	NS
VIN/vSCC at diagnosis, *n* (%)	0 (0.0)	1 (3.0)	NS	1 (0.6)	1 (7.7)	NS

Abbreviations: IQR, interquartile range; NS, not significant; VIN, vulval intraepithelial neoplasia; vSCC, vulval squamous cell carcinoma.

p-values: * $p < 0.05$.

[a]Percentages may not add up to 100% or total percentages in the preceding subheading due to rounding.

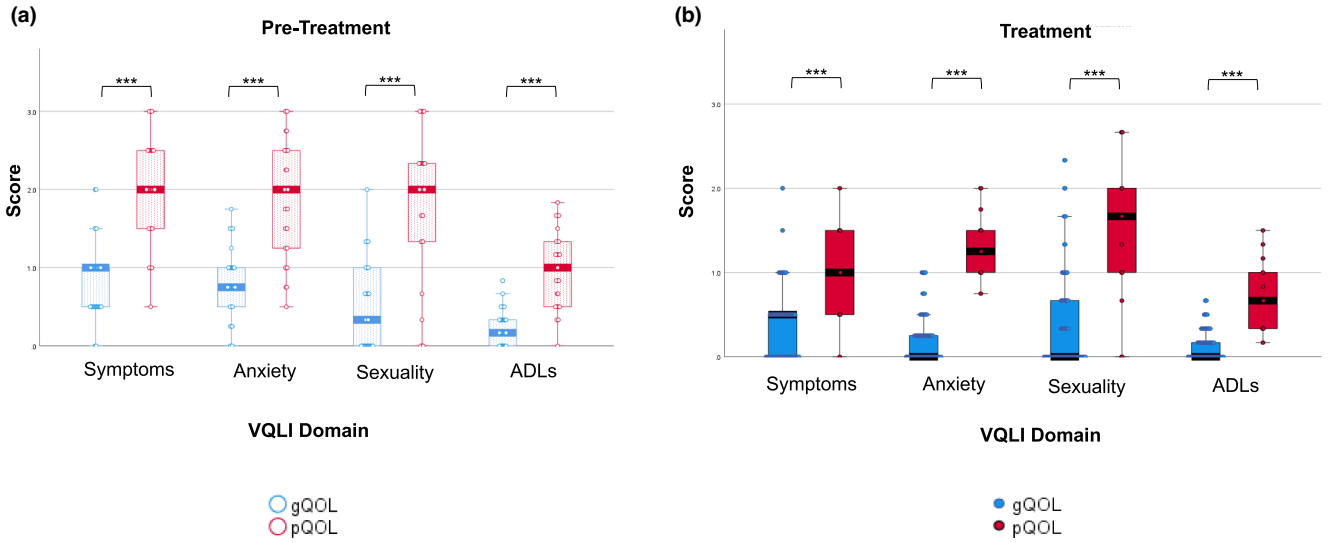

FIGURE 1 VQLI domain scores of (a) Pre-Treatment gQOL ($N = 34$) vs pQOL ($N = 33$), (b)Treatment gQOL ($N = 175$) vs pQOL ($N = 13$). p-values: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, NS = not significant

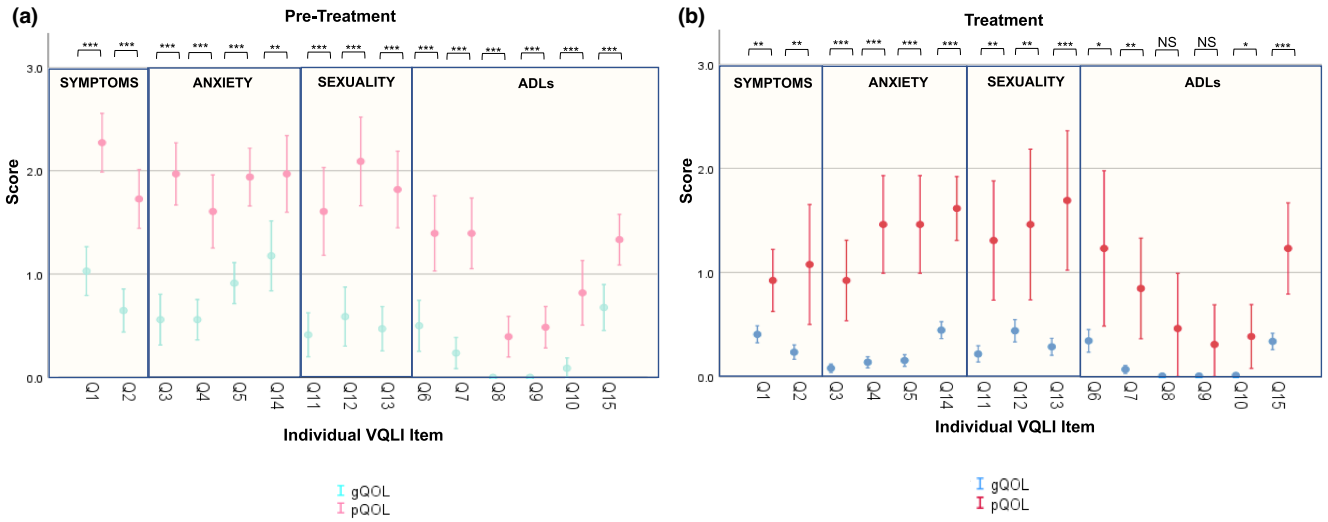

FIGURE 2 Individual VQLI item scores of (a) Pre-treatment gQOL ($N = 34$) vs pQOL ($N = 33$), (b) Treatment gQOL ($N = 175$) vs pQOL ($N = 13$). p-values: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, NS = not significant

(mean 1.6 [SD 0.5]) (Figure 2b). However, the largest score difference between gQOL and pQOL was found in question-4 regarding body image and sense of self (mean difference = 1.3). In pQOL, question-4 was strongly positively correlated with question-5 regarding distress and anxiety felt due to VLS ($r_s = 0.61$, $p = 0.027$) and no other VQLI items.

In domain ADLs, question-6 regarding impact on clothing choice and question-15 regarding treatment inconvenience were the highest-scoring items in both gQOL (question-6: mean 0.3 [SD 0.7], question-15: mean 0.3 [SD 0.5]) and pQOL (question-6: mean 1.2 [SD 1.2], question-15: mean 1.2 [SD 0.7]) (Figure 2b). The largest score difference between gQOL and pQOL was also found in these two items (mean difference = 0.9). Question-6 was most strongly correlated with question-1 regarding itch, pain, stinging and burning ($r_s = 0.43$, $p < 0.001$). Score of question-15 was higher in partially adherent than fully adherent patients (mean rank 111.1 vs 88.5; $p = 0.003$).

In domain symptoms, question-1 was the highest-scoring item in gQOL (mean 0.4 [SD 0.5]), and question-2 regarding dysuria, heat intolerance, discharge or wetness was the highest-scoring item in pQOL (mean 1.1 [SD 1.0]) (Figure 2b). The largest score difference between gQOL and pQOL was found in question-2 (mean difference = 0.9). Score of question-2, but not question-1, was higher in treated patients with urinary incontinence (mean rank 112.8 vs 90.8; $p = 0.006$). All patients with

urinary incontinence were menopausal. There was no difference in proportions of urinary incontinence between ERT and non-ERT menopausal women (19 [21.3%] vs 13 [17.6%]; $p = 0.55$).

All domain scores were higher in patients with partial adherence and suboptimal disease control (Table 2).

Treatment outcomes

Partially adherent patients had significantly higher proportions of suboptimal disease control (22 [44.0%] vs 5 [3.6%], $p < 0.001$) and scarring progression (8 [16.0%] vs 2 [1.4%], $p < 0.001$) compared to fully adherent patients.

As shown in Table 3, pQOL had significantly higher proportions of partially adherent patients ($p = 0.006$), suboptimal disease control ($p < 0.001$) and scarring progression ($p = 0.024$) compared to gQOL. There were no significant differences in treatment duration, TCS potency or proportions of side effects. Out of 188 long-term treated patients, side effects were only reported in 15 (8.0%) – 13 (6.9%) were erythema and 2 (1.1%) were dryness and irritability. All side effects resolved following reduction in TCS potency.

DISCUSSION

More than 90% of women with VLS treated with long-term, individualised TCS treatment reported no to mild ongoing impact on their QOL. In a minority of patients who reported ongoing poor QOL, the two most distressing areas were sexuality and anxiety; ADLs and symptoms were of less concerns. Three major factors distinguishing gQOL from pQOL patients were identified in the current study, namely (1) treatment adherence and disease control, (2) psychological factors and (3) urinary incontinence.

Treatment adherence and disease control

There was a notable difference in the degree of treatment adherence and disease control between pQOL and gQOL groups. The former demonstrated 2.6, 4.7 and 5.8 times as many non-adherent patients, poorer disease control and scarring progression, respectively, as the latter. Additionally, treatment adherence and disease control were observed to be common denominators across all VQLI domains – those with higher adherence and disease control achieved significantly lower scores indicating higher satisfaction in every domain.

The difference in adherence rates was congruent with the survey results in the ADLs domain. One of the major

TABLE 2 Interactions between domain scores and other variables in all treated patients ($N = 188$)

	Treatment						Others		
	Treatment adherence			Disease control			Urinary incontinence		
	Partial ($N = 50$)	Full ($N = 138$)	*p*-value	Suboptimal ($N = 27$)	Optimal ($N = 161$)	*p*-Value	Yes ($N = 32$)	No ($N = 156$)	*p*-value
Symptoms, median (IQR)	0.5 (0.0–0.5)	0.0 (0.0–0.5)	*	0.5 (0.5–1.0)	0.0 (0.0–0.5)	***	0.5 (0.5–0.8)	0.0 (0.0–0.5)	**
Anxiety, median (IQR)	0.3 (0.0–0.8)	0.0 (0.0–0.3)	*	0.5 (0.3–1.0)	0.0 (0.0–0.3)	***	0.3 (0.0–0.8)	0.0 (0.0–0.3)	NS
Sexuality, median (IQR)	0.3 (0.0–1.0)	0.0 (0.0–0.7)	**	1.0 (0.0–1.3)	0.0 (0.0–0.7)	***	0.2 (0.0–1.0)	0.0 (0.0–0.7)	NS
ADLs, median (IQR)	0.2 (0.0–0.3)	0.0 (0.0–0.2)	**	0.3 (0.0–0.6)	0.0 (0.0–0.2)	***	0.2 (0.0–0.3)	0.0 (0.0–0.2)	**

Abbreviations: ADLs, activities of daily living; IQR, interquartile range; NS, not significant.

p-values: $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$.

TABLE 3 Treatment characteristics and outcomes of good quality of life (gQOL) vs poor quality of life (pQOL) patients

Treatment characteristics/Outcomes	Good quality of life, *n* (%) (*N* = 175)	Poor quality of life, *n* (%) (*N* = 13)	*p*-value
Treatment duration, median (IQR), months	58.0 (36.0–84.0)	72.0 (40.0–84.0)	NS
TCS potency[a,b]			
Class I	8 (4.6)	2 (15.4)	NS
Class II	123 (70.3)	6 (46.2)	
Class III	15 (8.6)	1 (7.7)	
Class IV	29 (16.6)	4 (30.8)	
Treatment adherence			
Partial adherence	42 (24.0)	8 (61.5)	**
Full adherence	133 (76.0)	5 (38.5)	
Disease control			
Suboptimal	20 (11.4)	7 (53.8)	***
Optimal	155 (88.6)	6 (46.2)	
Scarring progression	7 (4.0)	3 (23.1)	*
Developed VIN / vSCC during treatment	0 (0.0)	0 (0.0)	NA
Side effects[a]	13 (7.4)	2 (15.4)	NS
Erythema	12 (6.9)	1 (7.7)	
Dryness and irritability	1 (0.6)	1 (7.7)	

Abbreviations: IQR, interquartile range; NS, not significant; NA, not computed due to constant value; TCS, topical corticosteroids; VIN, vulval intraepithelial neoplasia; VLS, vulval lichen sclerosus; vSCC, vulval squamous cell carcinoma.

p-values: *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

[a]Percentages may not add up to 100% or total percentages in the preceding subheading due to rounding.

[b]Recorded data on TCS potency are only representative of the TCS strength at the time of survey and not of the whole treatment duration, as treatment regimens in the clinic are to titrate TCS potency according to individual clinical progression and disease response to treatment.

ADLs issues expressed by pQOL patients, the score of which was significantly higher than gQOL patients, was regarding treatment inconvenience. Non-adherence to topical agents is a well-known challenge in dermatology.[16] In a recent study by Nic Dhonncha et al., the most common reasons for non-adherence to TCS reported by women with VLS were forgetting (43%), concerns about using too much TCS (39%), concerns due to label instruction to 'apply thinly' (34%) and concerns about using TCS on broken skin (33%). Similar to other studies,[17–19] Nic Dhonncha and colleagues found the sources of contradictory advice generating corticosteroid phobia frequently came from patients' general practitioners and pharmacists. This highlights the need for increased collaboration and re-education of healthcare professionals on the importance and safety profile of long-term TCS therapy in women with VLS.

Interestingly, symptom duration and proportions of scarring at diagnosis did not significantly differ between gQOL and pQOL patients. This suggests that patients with delayed diagnosis could have an equal chance to achieve QOL as high as those who received prompt diagnosis, provided full adherence to prescribed treatment regimens. This is an important finding given delayed diagnosis is still exceptionally common in VLS.[1,2,6]

In addition to their perception of treatment, in the ADLs domain pQOL patients also differed greatly from gQOL patients in how much they felt VLS has influenced their clothing choice. As the item regarding clothing choice was most strongly associated with question-1 regarding itch, pain, stinging and burning, it is likely that pQOL patients continued to be limited in their ability to wear a variety of clothing fits and materials due to suboptimal symptom control, resulted from poor treatment adherence. The role of clothing as an important means to express one's individuality has been frequently discussed in social sciences.[20] For women with VLS, who often feel as if their female identity has been stolen from them,[21] being restricted in their ability to choose their outfits could further jeopardise their confidence and sense of self.

Psychological factors

Anxiety as an issue was strongly observed in two of the highest-scoring domains in treated pQOL patients, i.e. sexuality and anxiety. In the sexuality domain, pQOL patients rated question-13, regarding distress, guilt or worries about sex, as the most important issue, rather than

question-12 which asks about dyspareunia. This may suggest that psychological factors, rather than physical factors, are the more substantial contributors to sexual dysfunction in pQOL patients.

It has previously been shown in a number of studies that women with VLS tend to have higher sexual distress, more negative genital self-image and lower engagement in sexual intercourse despite viewing it as important as controls.[22–24] The emotional impact caused by the disease seems to have the potential to last long-term, as some patients continued to experience sexual dysfunction and low frequency of sexual activities despite significant symptom improvement post-treatment,[13,14] a finding similarly demonstrated by pQOL patients in our study. The higher their level of anxiety, the worse their sexual functioning was observed to be.[6,25]

Of note, some non-sexually active pQOL patients responded to items in the sexuality domain with answers other than 'not at all'. The definition of sexuality by the World Health Organisation is '*...encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction ... experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationships ... not all of them are always experienced or expressed ... influenced by the interaction of biological, psychological, social, economic, political, cultural, legal, historical, religious and spiritual factors*',[26] underpinning (1) the complexity of sexuality issues in VLS beyond the management of dyspareunia alone and (2) that sexuality is also impacted and should be addressed in women with VLS who are not sexually active.

In the anxiety domain, both gQOL and pQOL patients were most concerned about long-term health implications of the disease; however, the level of concern expressed by pQOL patients was significantly higher than gQOL. The area where the two groups differed the most was their perception on body image and sense of self. The pQOL group demonstrated a much more negative body image and sense of self, with worse perception associated with higher level of distress and anxiety. As previously mentioned, women with VLS have been shown to have more negative genital self-image than healthy controls.[24] Many women have revealed feeling embarrassed, dirty, and as though their female identity has been taken away from them, particularly when there has been a change in vulval architecture.[21] This is an important issue to address, as without sufficient management, it could perpetuate aforementioned issue regarding sexual dysfunction and vice versa. Psychological interventions to foster healthy body image as well as sex and relationship counselling where appropriate may be of great values.

Urinary incontinence

There was a significantly higher proportion of patients with urinary incontinence in treated pQOL than gQOL groups. In the symptom domain, pQOL patients were much more troubled by question-2 regarding dysuria, heat intolerance, discharge or wetness than gQOL patients. Given that treated patients with urinary incontinence scored higher in question-2, but not question-1, compared to those without urinary incontinence, it is likely that the issues with dysuria, heat intolerance, discharge or wetness reported by pQOL patients were mostly contributed by urinary incontinence.

There was no difference in proportions of urinary incontinence between ERT and non-ERT users. This does not necessarily negate the utility of ERT in the management of urinary incontinence. Rather, these patients may have severe urinary incontinence which requires more complex management beyond conservative and ERT therapies alone.[27]

Limitations

Data were obtained from a single-centre dermatogynaecology practice, hence the potential for selection bias. Adherence rates were self-reported. The VQLI originally consists of five QOL groups, which were transformed into two variables in this study, gQOL and pQOL; however, we believe that this approach was justifiable and appropriate to this study. The study was not randomised; however, in a pre-malignant condition we believe this to be unethical. The long-term treated pQOL group has a small sample size, as only a minority of long-term treated patients achieved scores high enough to be categorised as pQOL patients. Nevertheless, this in fact emphasises the effectiveness of maintenance TCS therapy in maximising QOL in women with VLS. The results of this study have provided important insights into areas requiring further improvement in VLS management, not previously investigated elsewhere.

CONCLUSIONS

Only a minority of long-term treated VLS patients reported ongoing poor QOL. Of those who did, sexuality and anxiety domains were found to be the main sources of distress. Three major areas distinguishing gQOL from pQOL patients were identified: (1) treatment adherence and disease control, (2) psychological factors and (3) urinary incontinence. The findings of this study emphasise the importance of holistic management in VLS and act as a reminder

for clinicians to not overlook other comorbidities which may contribute to patient ongoing symptoms or poor QOL. The direction for future research is to investigate effective strategies to address issues identified in the current study.

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[Correction added on 26 November 2022, after first online publication: CAUL funding statement has been added.]

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

ETHICS STATEMENT

Ethics approval was obtained from the Northern Sydney Local Health District Human Research Ethics Committee.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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