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ORIGINAL RESEARCH

# Quality of life impact and treatment response in vulval disease: Comparison of 3 common conditions using the Vulval Quality of Life Index

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## Abstract

**Background/Objectives:** To compare the quality of life in patients with vulval lichen sclerosus (VLS), vulval lichen planus (VLP) and chronic vulvovaginal candidiasis (CVVC), as measured by the Vulval Quality of Life Index (VQLI).

**Methods:** A retrospective, single-centre cohort study was conducted at a combined dermatology and gynaecology practice from March 2018 to November 2021. VQLI scores and patient data were systematically collected and recorded in an online patient database. Treatment regimens were individualised and titrated to clinical response.

**Results:** Over 3 years, a total of 200 women were recruited: 59 with CVVC, 79 with VLP and 62 with VLS. The median duration of follow-up for all patients was 45.43 (16.25–80.89) weeks. At baseline, the median (interquartile range [IQR]) VQLI score was 24.00 (19.00–31.00), 21.00 (12.00–26.00) and 14.00 (7.00–26.00) for CVVC, VLP and VLS, respectively. At follow-up, the median (IQR) VQLI score for CVVC, VLP and VLS was 9.00 (3.00–15.00), 9.00 (3.00–16.00) and 5.00 (2.00–10.00), respectively. All three groups showed a significant improvement in VQLI score ($p < 0.0001$). At baseline, the highest scoring domains were 'Sexual Function' for CVVC and 'Future Health Concerns' for VLP and VLS. At follow-up, the highest scoring domains were 'Sexual Function' for CVVC and VLP, and 'Future Health Concerns' for VLS.

**Conclusions and Relevance:** Vulval disease has an immense impact on QOL, especially in patients with CVVC. The VQLI is useful to clinicians in identifying the unique impact of each vulval condition on a patient's QOL in order to provide better patient-focussed care.

KEYWORDS

candidiasis, chronic, lichen planus, quality of life, vulval lichen sclerosus, vulvovaginal

Ashod Kherlopian, Marlene Wijaya and Gayle Fischer are co-authors and contributed equally to this work.

## INTRODUCTION

Vulval skin disease often leads to significant disease burden due to debilitating symptoms and anatomical changes. These conditions are chronic, and for many women, the disease symptoms and treatment have an immense impact on their physical, psychological and sexual health. Moreover, for vulval lichen sclerosus (VLS) and to a lesser extent vulval lichen planus (VLP), there is also known risk of malignant transformation if left untreated.[1,2] Existing literature has been mostly limited to the quality-of-life (QOL) studies in VLS[3–10] whilst VLP[5,10,11] and chronic vulvovaginal candidiasis (CVVC)[12] have been less thoroughly researched. Given this paucity of literature, it is prudent to investigate the ways in which each condition can uniquely impact a patient's QOL so that clinicians can better provide individualised care.

### Vulval lichen sclerosus

Vulval lichen sclerosus is a chronic, progressive inflammatory dermatosis which is one of the most common conditions treated in vulval clinics. Its true prevalence is uncertain and may be under-reported, with estimates ranging from 0.1% in children and 0.1%–0.3% in women.[13,14] The majority of patients present after the age of 50; however, it is seen in all age groups including children. It typically presents with pruritis; however, pain and dyspareunia can also occur. Importantly, up to one-third of patients may be asymptomatic, leading to delayed diagnosis.[15] Its complications may include loss of vulval architecture and 5% risk of developing squamous cell carcinoma of the vulva.[15]

### Vulval lichen planus

Vulval lichen planus is a chronic inflammatory condition charactered by erosive, papulosquamous or hypertrophic lesions on the vulva with possible vaginal involvement. It is exceptionally rare in children with most patients presenting in the 6th decade of life and beyond. It presents with debilitating pain and pruritis, apareunia and discharge.[16,17] Diagnosis and appropriate management are often delayed as there is a broad range in morphology and histopathology is often not conclusive.[18] Like VLS, complications include post-inflammatory scarring and malignancy risk of approximately 2.8%.[1,2]

### Chronic vulvovaginal candidiasis

Chronic vulvovaginal candidiasis is an unremitting condition of menstrual women casually associated with species of *Candida* and usually presents in the second decade of life after onset of menses.[19,20] It should be distinguished from recurrent vulvovaginal candidiasis (RVVC), which is described as four or more discrete episodes of vulvovaginal candidiasis per year.[19,21] Notably, CVVC classically presents as continuous pruritis, pain and dyspareunia with exacerbations prior to menses. The incidence of CVVC is uncertain, but it is thought to occur on a spectrum with RVVC, which has an incidence of 5%–8% per year.[21] Current recommendations for treatment include prolonged oral antifungal treatment.[20,22,23]

Outcome measure tools commonly utilised to assess the QOL of patients with vulval disease are often inadequate and inconsistent between studies. A 2013 systematic review reported that whilst outcome measures such as the Dermatology Life Quality Index (DLQI) and Hospital Anxiety and Depression Score (HADS) assessed sexual function and pain, there were no vulval-specific outcome measures.[24] However, the Vulval Quality of Life Index (VQLI) is a recently developed questionnaire designed to assess the severity of vulval disease and can be used to monitor response to treatment in a clinical setting[6,25] (Appendix S3). It covers the seven domains of daily life, namely Symptoms (Questions 1–2), Feelings and Emotions (Questions 3–5), Activities of Daily Living (Questions 6–10), Relationships (Question 11), Sexual Function (Questions 12–13), Future Health Concerns (Question 14) and Treatment (Question 15). Patients indicate on a 4-point Likert scale from 0 ('Not at all') to 3 ('Very much') for each of the 15 items. The total score ranges from 0 to 45: the higher the score, the greater the disability.

### Aim

This study aims to compare the QOL in patients with VLS, VLP and CVVC, as measured by the VQLI, to determine how the overall and different vulval specific QOL domains are impacted by each disease and the extent to which treatment alleviates this impact.

## METHODS

A retrospective, single-centre cohort study of women was undertaken at a large, combined dermatology and gynaecology practice from March 2018 to November 2021. The inclusion criteria were patients aged at least 18 years who had biopsy-proven VLS or satisfied the diagnostic criteria for VLP or CVVC (Appendix S1,S2), as detailed in previous studies,[16,19] and the completion of at least two VQLIs before initial treatment and during maintenance treatment. The exclusion criteria included women with concomitant vulval conditions (for example, VLS/VLP overlap).

This study was approved by the Human Research and Ethics Committee of Northern Sydney Local Health District (RESP/18/070). Written or oral consent was obtained from all patients.

## Study protocol

Data were collected and recorded in an online patient database at time of consult. Patient demographics, medical history and prescribed treatment regimen were recorded. Patients were invited to complete a VQLI at each visit. The date of VQLI completion and their results were recorded. Clinically significant treatment response was defined as at least a 50% reduction in baseline VQLI score. Adherence data were patient-reported as either 'All of the time', 'Most of the time', 'Some of the time' and 'None of the time'.

## Treatment regimens

Patients with VLS and VLP received individualised treatment regimens according to disease severity with the target of normal skin appearance and subjective symptom control. For more severe VLP disease, systemic immunosuppressive therapy was added to achieve symptom control. Once disease and symptom suppression had been achieved, long-term maintenance therapy was initiated with the aim to gradually reduce topical corticosteroid (TCS) potency to identify the lowest, most effective dose and in the cases of systemic immunosuppression to establish a stable effective regime.

Patients with CVVC were treated with an induction course of daily oral 50–100 mg fluconazole until the patient was asymptomatic, reducing to 2–3 times a week for maintenance. Boric acid suppositories (600 mg daily) were considered for *C. glabrata*–positive swabs. Maintenance therapy was individualised as required, for example, if patients were required to be on a course of antibiotics, their fluconazole dosing frequency would be increased for that same period of time.

For all conditions, maintenance treatment was continued preventatively, even when asymptomatic.

## Statistical analyses

At completion of the 3-year observational period, all data were entered into an Excel spreadsheet (Microsoft Office, 2016). Statistical analyses were conducted using GraphPad Prism Version 9 (GraphPad Software, 2019). Descriptive statistics are presented, and VQLI scores for each domain and total VQLI scores were calculated for each of the three conditions for baseline and follow-up. The significance of the difference between scores at baseline and follow up was compared using the Mann–Whitney U-test or two-way analysis of variance, as appropriate. Significant results were expressed using asterisks: $*p<0.05$, $**p<0.01$, $***p<0.001$ and $****p<0.0001$. This convention was used throughout.

# RESULTS

## Demographic data

A total of 200 women were recruited: 59 with CVVC, 79 with VLP and 62 with VLS. All patients either showed histopathological evidence of VLS or VLP or met the clinical diagnostic criteria for VLP or CVVC.[12,16]

The median (interquartile range (IQR)) age of presentation was 37.00 (26.00–45.00) years for CVVC, 60.00 (47.00–70.00) years for VLP and 60.50 (49.75–68.00) years for VLS (Table 1). The median (IQR) age at symptom onset was 23.00 (20.00–36.00) years for CVVC, 56.00 (47.00–67.00) years for VLP and 56.50 (46.00–64.00) years for VLS. At both time of disease onset and time of presentation, patients with CVVC were significantly younger than patients with VLP ($p<0.0001$) and VLS ($p<0.0001$). Additionally, CVVC patients were also more likely to be sexually active (49/59, 83.05%) compared to VLP (47/77, 59.49%) and VLS patients (39/62, 62.9%).

The median duration of follow-up for all patients was 45.43 (16.25–80.89) weeks. CVVC patients had significantly shorter duration of follow-up compared to VLS ($p<0.0001$) and VLP patients ($p<0.007$). Twenty-three (29.87%) VLP patients required systemic immunosuppressive therapy.

## VQLI scores

At baseline, the median (interquartile range (IQR)) VQLI score was highest for CVVC patients at 24.00 (19.00–31.00), followed by VLP patients at 21.00 (12.00–26.00) and VLS patients at 14.00 (7.00–26.00). At the end of the follow-up period, the mean (IQR) VQLI score for CVVC, VLP and VLS was 9.00 (3.00–15.00), 9.00 (3.00–16.00) and 5.00 (2.00–10.00), respectively. All three groups showed a highly statistically significant improvement in VQLI scores at baseline and at end of follow-up ($p<0.0001$) (Figure 1).

# ANALYSES OF VQLI DOMAINS

At baseline, the highest scoring domains were 'Sexual Function' for CVVC and 'Future Concerns' for VLP

**TABLE 1** Demographics

| | CVVC ($n = 59$) | VLS ($n = 62$) | VLP ($n = 79$) | Total ($n = 200$) |
|---|---|---|---|---|
| Age at presentation, median (IQR), years | 37.00 (26.00–45.00) | 60.50 (49.75–68.00) | 60.00 (47.00–70.00) | 55.50 (37.00–66.00) |
| Age at onset, median (IQR), years | 23.00 (20.00–36.00) | 56.50 (46.00–64.00) | 56.00 (47.00–67.00) | 50.00 (30.00–61.00) |
| Duration of follow-up, median (IQR), weeks | 27.00 (14.00–54.00) | 77.00 (17.00–124.30) | 46.29 (20.29–77.86) | 45.43 (16.25–80.89) |
| Diagnosis of anxiety/depression, n (%) | 11.00 (18.64%) | 6.00 (9.68%) | 15.00 (18.99%) | 32.00 (16.00%) |
| Pharmacological therapy | | | | |
| Topical therapy only | – | 62.00 (100%) | 56.00 (70.88%) | – |
| Topical and systemic Immunosuppressive therapy | – | 0 | 23.00 (29.11%) | – |
| Sexually active, *n* (%) | | | | |
| Yes | 49 (83.05%) | 39.00 (62.90%) | 47.00 (59.49%) | 135.00 (37.50%) |
| No | 10.00 (16.95%) | 23.00 (37.10%) | 32.00 (40.51%) | 65.00 (32.50%) |

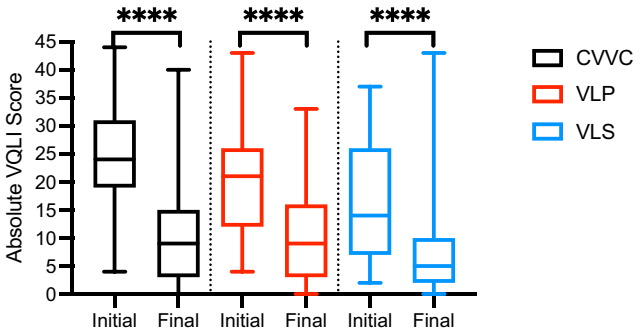


**FIGURE 1** Box plot showing of absolute initial and final Vulval Quality of Life Index (VQLI) scores of patients with chronic vulvovaginal candidiasis (CVVC; $n = 59$), vulval lichen planus (VLP; $n = 79$) and vulval lichen sclerosus (VLS; $n = 62$). Median, interquartile range, min and max are outlined. Ns = not significant, $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$, $^{****}p < 0.0001$.

and VLS. At follow-up, the highest scoring domains were 'Sexual Function' for CVVC and VLP and 'Future Concerns' for VLS (Appendix S4).

## Symptoms (questions 1–2)

This domain was scored out of 6 points. At baseline, CVVC patients reported the highest mean score at 3.712 [95% CI (3.340, 4.084)], followed by VLP at 3.204 [95% CI (2.929, 3.478)] and VLS at 2.887 [95% CI (2.463, 3.311)] (Figure 2).

At end of follow-up, CVVC patients continued to score significantly higher at a mean of 2.085 [95% CI (1.745, 2.424)], followed by VLP at 1.512 [95% CI (1.252, 1.770), $p = 0.218$] and VLS at 1.242 [95% CI (0.9380, 1.546), $p = 0.0021$].

## Feelings and emotions (questions 3–5)

This domain was scored out of 9 points. At baseline, CVVC patients scored the highest with a mean of 5.322 [95% CI (4.651, 5.993)]. Both VLP and VLS patients scored significantly lower than CVVC with a mean of 3.200 [95% CI (2.835, 3.565), $p < 0.0001$] and 3.903 [95% CI (3.194, 4.612), $p = 0.0028$], respectively.

At end of follow-up, CVVC, VLP and VLS patients scored similarly with means of 2.085 [95% CI (1.501, 2668)], 2.093 [95% (1.590, 2.597)] and 1.306 [95% CI (0.8786, 1.734)], respectively.

## Activities of daily living (questions 6–10)

This domain was scored out of 15 points. At baseline, CVVC patients scored the highest with a mean of 5.814 [95% CI (4.910, 6.717)]. Both VLP and VLS patients scored significantly lower with a mean of 4.041 [95% CI (3.145, 4.937), $p = 0.0100$] and 2.935 [95% CI (2.213, 3.658), $p < 0.0001$], respectively.

At end of follow-up, CVVC, VLP and VLS patients scored similarly with means of 2.102 [95% CI (1.496, 2.707)], 1.904 [95% (1.304, 2.504)] and 1.290 [95% CI (0.7008, 1.880)], respectively.

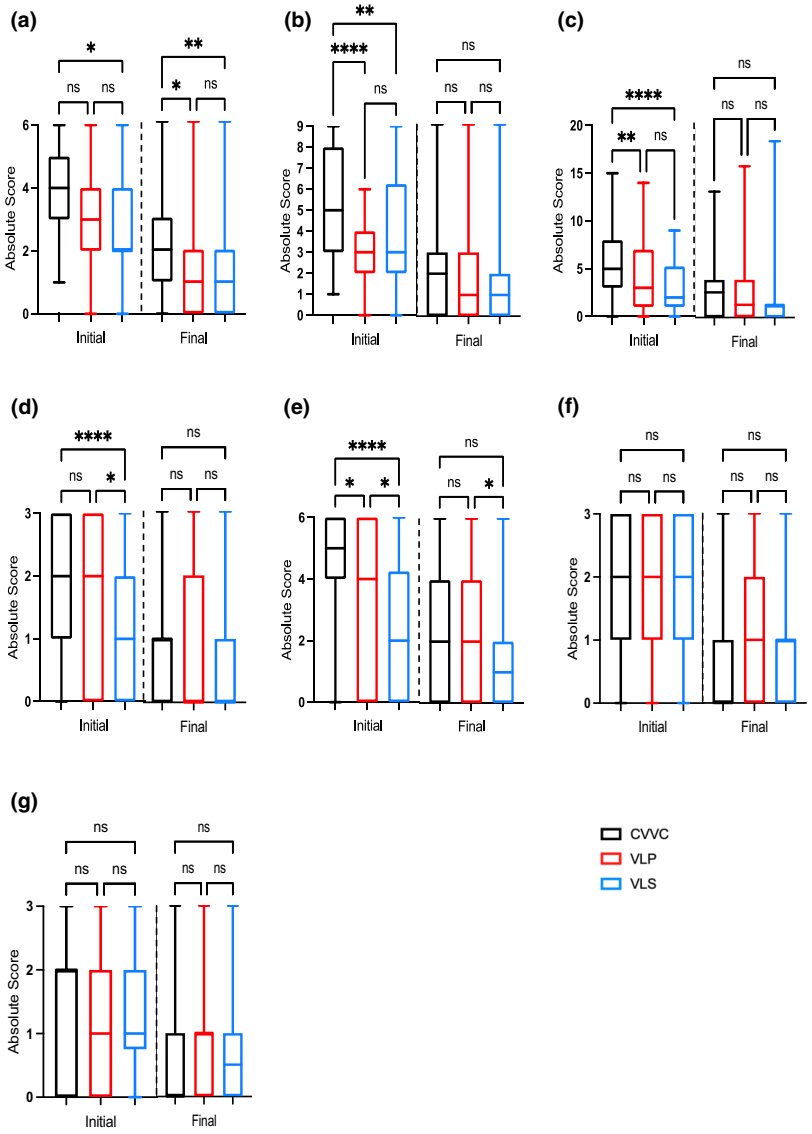


**FIGURE 2** Box plot showing absolute initial and final Vulval Quality of Life Index (VQLI) scores per domain in patients with chronic vulvovaginal candidiasis (CVVC, $n = 59$), vulval lichen planus (VLP, $n = 79$) and vulval lichen sclerosus (VLS, $n = 62$). (a) Comparison of absolute VQLI scores in the 'Symptoms' domain consisting of questions 1–2. (b) Comparisons of absolute VQLI scores in the 'Feelings and Emotions' domain consisting of questions 3–5. (c) Comparisons of absolute VQLI scores in the 'Activities of Daily Living (ADLs)' domain consisting of questions 6–10. (d) Comparisons of absolute VQLI scores in the 'Relationships' domain consisting of question 11. (e) Comparisons of absolute VQLI scores in the 'Sexual Function' domain consisting of questions 12–13. (f) Comparisons of absolute VQLI scores in the 'Future Health Concerns' domain consisting of question 14. (g) Comparisons of the absolute VQLI scores in the 'Treatment' domain consisting of question 15. Median, interquartile range, min and max are outlined. Ns = not significant, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

## Relationships (question 11)

This domain was scored out of 3 points. At baseline, VLS patients scored the lowest with a mean of 1.129 [95% CI (0.8365, 1.422)]]. Both VLP and CVVC patients scored significantly higher than VLS with a mean of 1.630 [95% CI (1.346, 1.915), $p = 0.0338$] and 2.034 [95% CI (1.756, 2.312), $p < 0.0001$], respectively.

At end of follow-up, CVVC, VLP and VLS patients scored similarly with means of 0.8983 [95% CI (0.6436, 1.153)], 0.9726 [95% (0.7061, 1.239)] and 0.5806 [95% CI (0.3623, 0.7990)], respectively.

## Sexual function (questions 12–13)

This domain was scored out of 6 points. At baseline, CVVC patients scored the highest with a mean of 4.525 [95% CI (4.019, 5.031)], followed by VLP at 3.458 [95% CI (2.864, 4.052)] and VLS at 2.435 [95% CI (1.860, 3.011)].

At end of follow-up, VLS patients continued to score the lowest at a mean of 1.403 [95% CI (0.9587, 1.848)], followed by CVVC at 2.153 [95% CI (1.630, 2.676)] and VLP at 2.236 [95% CI (1.733, 2.739)].

### Future health concerns (question 14) and treatment (question 15)

At both baseline and end of follow-up, there were no statistical differences between the three groups.

## RATE OF VQLI CHANGE

The rate of QOL improvement, measured by percentage change in VQLI score over weeks, significantly differed between the 3 cohorts ($p = 0.006$) (Figure 3). Patients with CVVC had the greatest rate of improvement (slope = 1.050), followed by patients with VLP (slope = 0.7971) and VLS (slope = 0.3312).

## FACTORS INFLUENCING VQLI CHANGE

Patients who were sexually active reported a median (IQR) initial VQLI score of 23.00 (14.00–29.00), which was significantly higher than patients who were not sexually active who reported a median VQLI score of 15.00 (9.00–21.50, $p = 0.0004$). At the end of the follow-up period, patients who were sexually active reported a median VQLI score of 8.00 (3.00–15.00). This was similar to patients who were not sexually active who reported a median VQLI score of 5.00 (2.00–11.00).

Treatment adherence data were collected for all VLS patients and only a small proportion of CVVC and VLP patients. 'Good adherence' was defined as following treatment regimens 'All of the time' or 'Most of the time'. 67.74% (42/62) of VLS patients, 87.5% (14/16) of CVVC patients and 93.75% (15/16) of VLP patients self-reported good adherence with treatment. VLS patients who reported good adherence scored significantly higher on their initial VQLI with a median (IQR) of 16.50 (8.75–28.00), compared to patients who were not adherent who scored 9.50 (6.25–13.75). At end of follow-up, there was no significant difference in VQLI score between the two groups.

There was no significant difference in both baseline and follow-up VQLI scores between patients who had a diagnosis of anxiety and/or depression compared to patients who did not.

## DISCUSSION

This study monitors the changes in the QOL and treatment response in patients with CVVC, VLP and VLS using the VQLI. Previous studies often examined QOL of patients

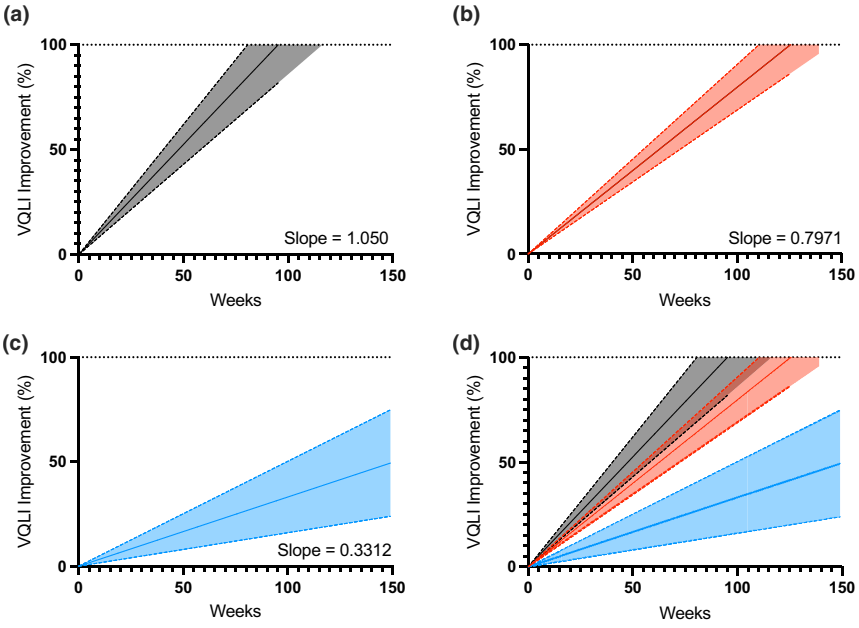


**FIGURE 3** Lines of best fit of percentage improvement in Vulval Quality of Life Index (VQLI) scores since treatment. Mean, 95% confidence bands and slope are shown. (a) Chronic vulvovaginal candidiasis ($n = 59$, slope = 1.050) (b) Vulval lichen planus ($n = 79$, slope = 0.7971). (c) Vulval lichen sclerosus ($n = 62$, slope = 0.3312). (d) Superimposed lines of best fit from patients with chronic vulvovaginal candidiasis (grey), vulval lichen planus (red) and vulval lichen sclerosus (blue).

with vulval disease from a single time point,[6] and the extent of patient suffering and improvement after treatment have rarely been the focus of investigation.[26] For this purpose, our study examined the sequential changes in VQLI in three common vulval conditions and found that patients in all three groups ultimately improved to similar levels of QOL with treatment, despite initial differences in QOL.

Vulval disease has an immense impact on QOL across the three conditions, with CVVC patients rating their QOL impact the highest as captured by the VQLI. In all domain areas, CVVC patients had scores significantly higher than or equivalent to VLP and VLS at baseline. Their highest scoring domain was 'Sexual Function', which may be attributed to its younger patient demographic who are usually of reproductive age, sexually active, and either seeking relationships or caring for young children.[12] Even though VLP and VLS are more concerning to clinicians due to their potential for scarring and malignancy, the patients' experience of CVVC via the VQLI indicates a significant level of distress that should not be dismissed. Fortunately, patients with CVVC also demonstrated the greatest rate of improvement (Figure 3). This suggests that the specific burden of disease in CVVC cohort may be more readily treated than VLS and VLP as treatment is simple, involving an oral antifungal rather than the need for topical therapy which patients often see as burdensome and messy. These findings highlight the significant impact of treatment on the lives of CVVC patients and should encourage clinicians to proactively enquire about sexual health given its propensity to affect the patient's QOL.

At baseline, the highest scoring domains for VLP and VLS were 'Future Health Concerns', which may reflect the patient's response to learning about the potential for malignancy when first diagnosed. At follow-up, the highest scoring domain remained the same for VLS, whilst VLP patients scored the highest in 'Sexual Function'. This change in VLP may reflect the erosive nature of the condition that often involves the vagina, leading to pain and discharge, in addition to itch and scarring that is common to both conditions.

The identification and management of vulval disease continues to be delayed. The average length of symptoms prior to presentation was the longest for CVVC patients at 9.54 years, followed by VLS patients at 4.59 years and VLP patients at 2.96 years. This is similar to previous studies that reported a mean delay of 4.6–7.9 years for VLS patients.[6,27] The barriers to obtaining a diagnosis are often multifactorial and complex, involving misdiagnosis, stigma and embarrassment.[27,28] This is especially significant for patients with VLS and VLP as untreated disease has been associated to a higher rate of malignant transformation.[1,2]

Clinically significant treatment response, defined as at least a 50% reduction in baseline VQLI score, was observed in all three groups. Complete response was possible; however, only about one-third of patients across all three groups scored in the 'minimal severity' (comprising scores 0–5) in their final VQLI with only 20 patients, 10% of total, achieving 0 points even with maximal therapy. This is likely since the burden of disease is not only influenced by disease symptoms, but other ongoing issues such as the need for maintenance treatment, the difficulty of spontaneous sexual activity and concerns about the future intimate relationships.[27–29] This is reflected in our study where sexual activity was associated with greater QOL impact at both baseline and end of follow-up.

Another possibility for low levels of complete response is the lack of compliance with maintenance treatment. A previous study with 507 women with VLS with the same treatment regime found that the objective suppression of symptoms occurred in 93.3% of compliant patients, but in only 58% of partially compliant patients[15] however, this was not reflected in our study. Interestingly and perhaps unsurprisingly, we found that patients who reported a higher VQLI score at presentation were more likely to be compliant with treatment. Therefore, clinicians should emphasise the need for maintenance treatment, especially to those who may be less symptomatic. Further studies using non-patient reported measures of compliance are needed.

Overall, the VQLI proved to be a useful and quick assessment tool that is easy to incorporate into standard assessment in clinical practice. VQLI completion at baseline and at each review appointment provides valuable information on treatment response, and each domain is affected by the burden of disease. A previous study by Felmingham et al. (2020) has found that the VQLI demonstrates good correlation with the clinician-rated severity score as well as patient symptom score. The monitoring of sequential VQLI scores allows for a clear demonstration of the waxing and waning nature of these diseases, which is most prominently observed in CVVC and VLP patients (Figure 3). These spikes in VQLI may represent flares in disease due to stress, lapses in compliance to treatment or attempts to down-titrate treatment to the lowest, most effective dose.

The limitations of our study include its retrospective nature; however, all data were collected and documented at time of consultation, thus reducing the risk of information error and bias. Given that this study was conducted in a specialist clinic where patients may have already been partially treated with TCS prior to referral, it likely underestimates the true burden of disease. Another limitation is the lack of structured time frames for VQLI completion by the patients as patients were invited to complete a repeat VQLI in person during their review appointments or digitally. However, the number of weeks since initial

appointment was reported and taken into account when representing the rate of VQLI improvement (Figure 3). Additionally, patient-reported adherence data were recorded for approximately a quarter of patients with CVVC and VLP. Future studies using objective measures of adherence are needed.

## CONCLUSION

This study compares the sequential changes in the QOL of patients with three different vulval diseases through the VQLI. Our study also identifies the domains that most impact QOL in these women with CVVC, VLP and VLS. We found that patients with CVVC rated their QOL impact the highest, followed by VLP and then VLS. 'Sexual Function' and 'Future Health Concerns' were the two highest scoring domains across all three conditions at both baseline and follow-up. Ultimately, the VQLI offers a comprehensive and structured approach to evaluating the patient's symptoms, allowing clinicians to provide individualised treatment according to the patient's needs.

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### CONFLICT OF INTEREST

All authors of this study declare of no conflicts of interest and have consented for publication.

### ETHICAL APPROVAL

The study has been approved by the Human Research and Ethics Committee of the Northern Sydney Local Health District (RESP/18/070).

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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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