Outcome Measures in Adult Vulvar Lichen Sclerosus: A Systematic Review

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Objectives: Core outcome domains (CODs) for treatment of adult vulvar lichen sclerosus (VLS) have recently been established through a Delphi study. A number of measuring tools are available for evaluating VLS. The aim of this study is to identify available standardized measurement tools for the major CODs for VLS that have recently been defined, namely, physical findings and quality of life (QoL) specific to VLS.

Materials and Methods: A systematic search through September 8, 2023, for measuring tools applicable to VLS regarding physical findings and QoL including sexual function or sexual well-being and self-image was performed.

Results: Thirty-five studies were included in the systematic review describing 26 tools covering the following 6 outcome domains: QoL-general health, QoL-lichen sclerosus specific, symptoms, clinical signs, emotional impact, and sexual functioning.

Conclusions: In current research, there is no uniformity in use of measurement tools for evaluating VLS. The established CODs to evaluate treatment of VLS are applicable for evaluating disease course as well. A comprehensive study to reach consensus regarding measurement of physical findings, QoL-lichen sclerosus specific, sexuality, and self-image taking the predetermined CODs and other factors such as age into account is needed.

Key Words: core outcome domains, lichen sclerosus, quality of life, self-image, sexual health, vulva

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Vulvar lichen sclerosus (VLS) is a chronic skin disease primarily affecting the anogenital region.[1] Clinical manifestations at any age may include itching, pain, bleeding due to fissures, and permanent loss of vulvar architecture.[1] The disease is most often diagnosed in postmenopausal women, but up to 15% of cases are prepubertal females.[2,3]

Studies about how VLS in adults affects sexual well-being, self-image, and other aspects of quality of life (QoL) have been performed.[4–10] Difficulties in sexual functioning leading to significant sexual distress,[7] sexual dysfunction,[4] and diminished genital self-image[8] have been demonstrated. Remarkable in this field of research is the use of a variety of scales. A recent systematic review and meta-analysis on sexual dysfunction in LS patients found a lack of consensus on a uniform measure of sexual dysfunction and distress.[11] This lack of consensus is common in other areas of vulva-specific research as well.[12,13]

To provide the best care, high-quality research with uniform outcome measures is desirable. Simpson et al.[12] in a systematic review focused on the outcome domains (ODs) showed that multiple different scales are used to measure the same outcome. In 2023, a Delphi study was published, which identified 3 core outcome domains (CODs): clinical (visible) signs, symptoms, and quality of life–lichen sclerosus specific (QoL-LS specific).[14] The aims of the current study are to investigate what instruments are already available for evaluation of VLS and to analyze to what extent these tools cover the CODs delineated by the recent Delphi study,[14] including physical findings, symptoms, and VLS-specific QoL.

MATERIALS AND METHODS

Shortly after data collection was completed for a case series on juvenile VLS (JVLS) performed at our institution, the Delphi study was published with CODs for VLS.[*,14] To reflect upon our choice of questionnaires in that case series, we proceeded to perform a systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[15] The search strategy, designed and conducted together with an information specialist (WMB), combined a broad search of terms for VLS with vulvar disease, the concept of self or self-image, questionnaires or surveys, and sexuality. The databases Medline (via Ovid), Embase (via Embase.com), Web of Science Core Collection, and Cochrane central Register of Controlled Trials (via Wiley) were searched for English language publications from inception and last updated September 8, 2023 (Supplement A, http://links.lww.com/LGT/A349).

Screening based on title and abstract was performed by two independent reviewers (BM, CvD). Discrepancies were discussed with a third reviewer (MJtK-B). Studies that developed or introduced a questionnaire using a standardized measuring tool potentially applicable to VLS-patients were included. Studies that focused

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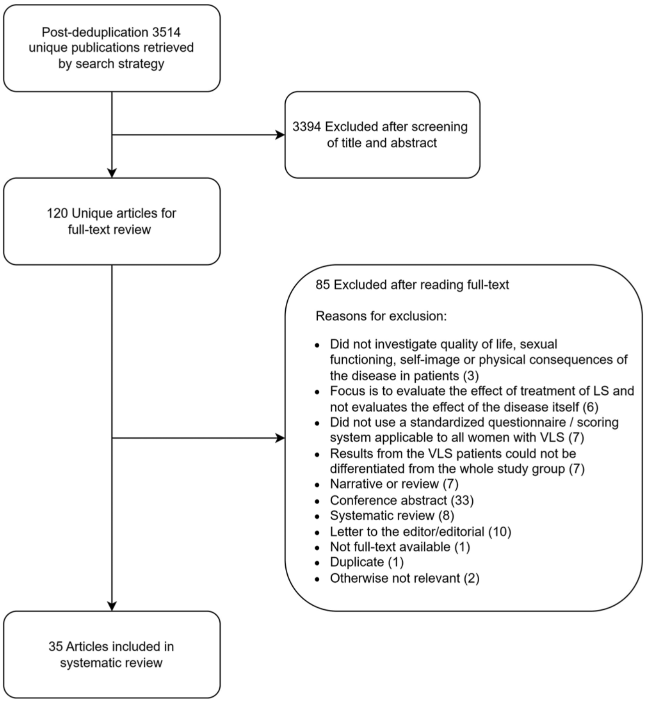

FIGURE 1. PRISMA flowchart of the systematic review on measurement instruments used in research on vulvar lichen sclerosus.

on the effects of a specific treatment and did not investigate the sequelae of the disease itself were excluded. Full texts of included articles were then reviewed for final inclusion. Predefined exclusion criteria (listed in Supplement A, http://links.lww.com/LGT/A349) were, for example, the publication was not applicable to all adult women with VLS (e.g., exclusion if only postmenopausal women or only cancer survivors were studied) or the focus was on evaluation of a treatment and not the effect of the disease itself. Articles that reported on the development and validation of a questionnaire applicable to VLS patients were included. A cross-reference of included articles was carried out.

For each publication, we investigated study parameters, questionnaires and scorings systems used, number of patients, age range, and main findings as well as main outcome measure(s) and which (C)ODs as delineated by the Delphi study, namely physical findings, symptoms, and VLS-specific QoL, were addressed.[14] Finally, the questionnaires and scoring systems found were categorized by scale type in the following 4 OD categories: disease severity, QoL, sexual well-being, and genital self-image. Quality of life may be subdivided into QoL-generic, QoL-dermatological, and QoL-vulvar. The Endnote Citation and Reference Management Tool version 20 was used for identification, screening, and categorizing eligible publications. Data was analyzed using Microsoft Excel 365 version 16.0.16212.42301.

RESULTS

The literature search identified 3514 unique publications through September 8, 2023. Based on title or abstract, 120 remained for full text analysis. Thirty-five articles were included. A cross-reference check found no additional publications (see Figure 1). Table 1 shows the included publications listed chronologically, describing the study, the questionnaires applied and outcome measures with the corresponding (C)OD.[14] Of the 35 studies included,[5–10,16–44] 14[16–21,25–28,33–36] developed a new scoring system or questionnaire. Twenty-six different tools were found, and 4 different ODs identified: QoL, symptoms, clinical (visible) signs, emotional impact, and sexual functioning. The OD QoL includes the subtypes QoL-general health, QoL-dermatological specific and QoL-LS specific. Nineteen publications, more than half, date from 2020 or later (see Table 2).

Scale Type: Symptoms and Physical Findings

The scale type physical findings and symptoms covers the CODs clinical (visible) signs and symptoms, depending on the tool. Within this scale type, 6 tools were found. Gunthert's clinical score for VLS,[20,22] the Adult Vulvar Lichen Sclerosus Severity Scale (AVLSSS),[27,32,34] and the Clinical Lichen Sclerosus Score (CLISSCO)[36] cover the CODs clinical (visible) signs and symptoms. The Vulvar Architecture Severity Scale (VASS)[28] and the "Clitoral phimosis, Interlabial sulci involvement, Vulvar introitus narrowing-classification" (CIV-classification)[35] cover the COD clinical (visible) signs, and the Electronic Personal Health Questionnaire-vulva (ePAQ-vulva)[26] covers the COD symptoms but has not yet been applied in VLS research. The AVLSSS has been applied 3 times,[27,32,34] Gunthert's clinical score for VLS twice,[20,22] and the CLISSCO,[36] VASS,[28] and CIV-classification,[35] each only once. Beyond validation studies, only the AVLSSS[27,32,34] and Gunthert's clinical scores for VLS[20,22] have been applied in VLS research.

Scale Type: QoL

The QoL scales are of 3 subtypes. The QoL-generic subtype covers the QoL-general health COD. Six questionnaires that had been applied just once in VLS research were found, the EQ-5D VAS[†,5] Short Form-12 (SF-12),[5] Short-Form-36 (SF-36),[24] WHO-5[d,9] WPAI:GH,[d] and PHQ-9[d,42] The subtypes QoL-dermatologic and QoL-vulvar cover the QoL-LS specific COD. Within this domain 4 questionnaires, the Skindex-29,[5,6,43] DLQI,[7,9,30,41,43] DSQL-V[d],[16] and Vulvar Quality of Life Index (VQLI)[10,31,33,37,38,44] have been

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[†] EQ-5D VAS: EuroQoL Group Visual Analogue Scale; WHO-5: World Health Organization-5 questionnaire; WPAI:GH: Work Productivity and Activity Impairment-General Health; PHQ-9: Patient Health Questionnaire-9; DSQL-V: Dermatology-Specific Quality of Life-Vulvar.

TABLE 1. Literature on Measurement Instruments Used and Their Relation to Defined Core Outcome Domains for Vulvar Lichen Sclerosus

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Rajagopalan et al. (1999)[16]	Cross-sectional study. Adapts and tests the DSQL evaluation tool to measure QoL in LS-patients.	Quality of life: *Quality of life–LS specific*	DSQL-V	**DSQL-V:** First publication to develop a dermatology specific QoL measure for vulvar disease, tested for VLS. The severity of the disease as measured by the physician is correlated with the patient reported QoL scores. All major QoL domains except for work/school functioning were affected.
Bramwell and Morland (2009)[17]	Cross-sectional study. Develops a measure of genital appearance satisfaction for women.	Genital appearance satisfaction: *Sexual functioning, emotional impact*	GAS-scale	**GAS scale**: An 11-item scale for measuring genital appearance satisfaction for the general population (women>16 y old). GAS scores correlated for self-esteem.
Herbenick and Reece (2010)[18]	Cross-sectional study. Develops and validates a measure for female genital self-image. Assesses the relationship between female genital self-image and sexual function.	Female genital self-image: *Sexual functioning, emotional impact* Sexual function: *Sexual functioning*	FGSIS-7, FSFI	**FGSIS-7 and FSFI**: FGSIS-7 was the first genital self-image scale. Phases of development into a 7-item score for measuring female genital self-image described. Scores on the FGSIS correlated positively and significantly with the FSFI except for FSFI Desire domain.
Van de Nieuwenhof et al. (2010)[7]	Case-control study. Evaluates QoL and sexual functioning in female patients with LS as compared with healthy controls.	Quality of life: *Quality of life–lichen sclerosus specific* Sexual functioning: *Sexual functioning* Sexual distress: *Sexual functioning*	DLQI, FSFI, FSDS	**DLQI, FSFI, FSDS:** 215 VLS patients and 61 aged-matched controls. Mean total DLQI score of patients with LS was comparable to other dermatological conditions, minor impact on QoL regarding working or studying. Patients with LS had FSFI and FSDS scores significantly poorer than controls.
Herbenick et al. (2011)[19]	Case-control study. Tests the FGSIS-7 in a nationally representative sample of women in the United States.	Female genital self-image: *Sexual functioning, emotional impact* Sexual function: *Sexual functioning*	FGSIS-7, FGSIS-4, FSFI	**FGSIS-7, FGSIS-4, FSFI**: 4-item version, the FGSIS-4, tested on large sample of women in United States. Better fit to the data than the FGSIS-7. Reliable and valid in representative sample. Scores on the FGSIS-4 were positively related to the scores on the FSFI. Subsequently FGSIS (7 item questionnaire) has been applied by other researchers, not the FGSIS-4.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Gunthert et al. (2012)[20]	Cross-sectional study. Develops and validates a patient-administered symptom score and a physician-administered clinical score for the diagnosis and evaluation of VLS.	Disease severity: *Clinical (visible) signs, symptoms*	Gunthert's clinical scores for vulvar lichen sclerosus	**Gunthert's clinical score for VLS:** First clinical scoring system for VLS: 6 clinical features (scored by clinician) and a symptom-based 4-item composite score (scored by patient). Tested on VLS and non-VLS vulvar disease patients. Lack of redundancy and internal consistency shown.
Zielinski et al. (2012)[21]	Cross-sectional study. Started with expert consensus; develops and tests measure of genital self-image.	Genital self-image: *Sexual functioning, emotional impact*	GSIS-20	**GSIS-20:** Five experts determined the content validity of the scale. A sample of 277 participants, divided into 4 groups, was used for factor analysis of the initial scale (GSIS). The remaining 20 items (GSIS-20) were tested again. Internal consistency reliability.
Lansdorp et al. (2013)[5]	Cross-sectional study. Measures the effect of VLS on HRQoL in VLS patients compared to other skin disease patients and the general population.	Quality of life: *Quality of life-LS specific, Quality of life-general health*	Skindex-29, SF-12, and the EQ-5D VAS	**Skindex-29, SF-12 and the EQ-5D VAS**: VLS patients show moderately impaired HRQoL with Skindex-29, some burden of disease on SF-12 in both physical and mental domains, as compared to general population. Mean EQ-5D VAS associated with severity of burden of disease.
Naswa and Marfatia (2015)[22]	Cross-sectional study. Assesses the usefulness for diagnosis of Gunthert's clinical scores for vulvar lichen sclerosus for the clinical diagnosis and evaluation of VLS.	Disease severity: *Clinical (visible) signs, symptoms.*	Gunthert's clinical scores for vulvar lichen sclerosus	**Gunthert's clinical score for vulvar lichen sclerosus**: applied to 36 patients at an out-patient clinic, shows usefulness of this tool, and use in validating the clinical diagnosis.
Weinfurt et al. (2015)[23]	Cross-sectional study. Adjusts the Patient-Reported Outcomes Measurement Information System (PROMIS)(R) Sexual Function and Satisfaction measure (SexFS) v1.0 for diverse groups including men and women to a version 2.0.	Sexual functioning: *Sexual functioning*	PROMIS SexFS v2.0	**PROMIS SexFS v2**: Builds on the SexFS version 1 (oncology specific) and a review of possible other items regarding sexuality used in literature to expand for nononcology cases. V2.0 has 11 scored scales and 6 non scored item pool. Can be customized choosing relevant domains for specific studies.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Iannaccone et al. (2016)[24]	Case-control study. Investigating and scoring the following domains in VLS patients: discomfort, personality traits and couple relationship and adjustment through coping and resilience.	Discomfort: *Quality of life–general health* Couple relationships: *Impact on important relationships* Personality, Coping, Resilience: *n.a.*	MMPI-2, SF-36, ISS, COPE, CR-RISC	**MMPI-2, SF-36, ISS, COPE, CR-RISC**: scales measuring respectively personality factors, health status, couple relationship, coping and resilience. 53 VLS patients and 55 controls analyzed. VLS patients score significantly higher in MMPI-2, ISS, and CR-RISC scales and significantly lower in SF-36 and COPE scale. In VLS patients an impact on relationships, health status and coping and an increase in resilience is seen.
Flynn et al. (2017)[25]	Cross-sectional study. Assesses vulvar discomfort with sexual activity among women in the United States.	Sexual functioning: *Sexual functioning*	PROMIS SexFS v2 vulvar discomfort scales: PROMIS Vulvar Discomfort with Sexual Activity-Labial and Vulvar Discomfort with Sexual Activity-Clitoral scales	**PROMIS SexFS v2 vulvar discomfort scales:** PROMIS Vulvar Discomfort with Sexual Activity-Labial and Vulvar Discomfort with Sexual Activity-Clitoral scales. Development of two separate 4-item scales, one to measure labial discomfort and pain and one to measure clitoral discomfort and pain. Tested on 1046 women, psychometric evaluation of the new measures indicated acceptable reliability and model fit.
Gray et al. (2017)[26]	Cross-sectional study. Develops an electronic patient-reported outcome measure (PROM) specifically designed for vulvar disorder.	Symptoms: *symptoms* Sexual function: *Sexual functioning* Quality of Life*: Quality of life–LS specific*	ePAQ-Vulva	**ePAQ-Vulva:** 6 clinical domains and 28 questions. Tested in 98 patients. Internal and interrater reliable.
Van Cranenburgh et al. (2017)[6]	Cross-sectional study. Evaluates satisfaction with treatment and QoL in LS patients.	Quality of life: *Quality of life–LS specific* *Satisfaction with treatment:* n.a.	Skindex-29, study specific-questionnaire	**Skindex-29:** 294 VLS patients, 1/3 had severe impairment of HRQoL. Mean HRQoL scores were in the 'moderate' range for the overall score and for the symptoms domain and were in the 'mild' range for the emotional and functioning domains. Higher HRQoL emotions score, and higher disease severity were significantly associated with lower treatment satisfaction.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Sheinis and Selk (2018)[27]	Consensus study. Delphi consensus exercise for a disease severity scale in LS patients.	Disease severity: *Clinical (visible) signs, symptoms*	Adult Vulvar Lichen Sclerosus Severity Scale	**Adult Vulvar Lichen Sclerosus Severity Scale:** Members of the International Society for the Study of Vulvovaginal Disease participated in Delphi consensus exercise: consensus on inclusion of 7 symptoms and 11 signs and 6 architectural changes. No consensus was reached regarding method of measurement for any of the symptoms and signs that reached consensus for inclusion.
Hodges et al. (2019)[8]	Prospective case-control study. Tests the FGSIS in women with VLS compared to controls.	Female genital self-image: *Sexual functioning, emotional impact*	FGSIS-7	**FGSIS**: applied to 16 VLS patients and compared to 16 healthy controls. Decreased level of female genital self-image in women with VLS.
Almadori et al. (2020)[28]	Cross-sectional study. Develops and validates a grading scale based on the aesthetic unit principle to evaluate the extent of VLS.	Disease severity: *Clinical (visible) signs*	VASS	**VASS**: 6-region, 4-point grading system to evaluate the extent of the LS. Based on scoring by 14 professionals of 25 photographs: Intraobserver reliability consistent over time, high reliability level among different observers.
Corazza et al. (2020)[29]	Cohort study. Addresses the prevalence and severity of dyspareunia in VLS patients and defines a profile of VLS patients suffering from dyspareunia.	Dyspareunia: *Sexual functioning* Itch: *Symptoms* Burning: *Symptoms*	0–10 VAS scale for dyspareunia, itch, burning	**VAS-scores dyspareunia**: 90 women evaluated for itching, burning and dyspareunia, 56.7% reported dyspareunia. Itching and burning is more common among patients with dyspareunia in comparison to those without dyspareunia.
Corazza et al. (2020)[30]	Cross-sectional study. Assesses the burden of suffering with PRISM and DLQI in patients with chronic inflammatory vulvar diseases.	Quality of life: *Quality of life-lichen sclerosus specific* Perceived suffering: *Emotional impact*	PRISM, DLQI	**PRISM:** visual nonverbal instrument for self-assessing burden of suffering **DLQI:** dermatology specific QoL-questionnaire. 107 women with inflammatory vulvar disease (LS, LP and LSC), of which 87 women with LS. No significant difference in DLQI or PRISM scores between the 3 groups was found.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Felmingham et al. (2020)[31]	Cross-sectional study. Assess the correlation between the VQLI score and disease severity in VLS patients.	Quality of life: *Quality of life-lichen sclerosus specific* Disease severity: *Clinical (visible) signs, symptoms*	VQLI, *combined with a self-designed global clinician severity score and patient-rated symptom score based on itch only*	**VQLI:** compared to a global clinician-rated severity score (architectural and cutaneous changes) and patient-rated score (itch/discomfort): Architectural and cutaneous changes each rated on 4-point Likert-scale. 109 VLS subjects scored. No correlation of VQLI to age, duration, complaints or if subject was sexually active. Positive correlation VQLI with both clinician-rated score and overall itch/discomfort score.
Green et al. (2020)[32]	Original online survey. Determines most important outcome measures for women with VLS to assess disease severity.	Disease severity: *Clinical (visible) signs, symptoms.*	Adult Vulvar Lichen Sclerosus Severity Scale	**Adult Vulvar Lichen Sclerosus Severity Scale:** rated by 958 patient-respondents. Most important items to assess disease severity were irritation, fusion of the labia, soreness, change in vulvar skin, and decrease in QoL. Shows need for assessment with combination of patient-rated (symptoms) clinical-rated (signs and anatomical changes) and QoL- measures.
Saunderson et al. (2020)[33]	Cross-sectional study. Develops and validates a vulvar-specific instrument that assesses aspects of vulvar disease.	Quality of life: *Quality of life–Lichen sclerosus specific*	VQLI	**VQLI:** Development in 4 phases of a vulvar QoL index. The 7-domain 15-item questionnaire was validated. Most common diagnosis in the field test cohort was LS (39.1%).
Sheinis et al. (2020)[34]	Cross-sectional study. Tests items from previous study[21] by directing world experts to rate the severity of the disease using photographs of LS.	Disease severity: *Clinical (visible) signs, symptoms*	Adult Vulvar Lichen Sclerosus Severity Scale	**Adult Vulvar Lichen Sclerosus Severity Scale:** 13 signs (petechiae and overall score added to previous list of 11[21]) and 6 architectural changes associated with LS judged by 6 experts for 50 photographs. Complete lack of consensus regarding perception of severity for individual signs and architectural changes as well as for overall disease severity.
Boero et al. (2021)[35]	Cross-sectional study. Develops an architectural classification for VLS to measure disease severity.	Disease severity: *Clinical (visible) signs*	CIV-classification	**CIV-classification**: 7 experts defined a grading system with 5 ascending grades and 3 anatomical criteria (phimosis of the clitoris, involvement of the interlabial sulci, narrowing of the vulvar introitus) for measuring and grading severity of VLS. 13 experts evaluated pictures from 137 patients. High level intraobserver and interobserver reliability.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Erni et al. (2021)[36]	Cross-sectional study. Assesses the prevalence and severity of 23 items proposed by Sheinis et al. (2018) and develops a clinical severity scale.	Disease severity: *Clinical (visible) signs, symptoms*	CLISSCO	**CLISSCO:** Assessment of the prevalence and severity of 23 items. Scale validated by 16 raters, scale consisting of 3 symptoms, 3 signs and 6 architectural changes rated on a 0–4-point Likert-scale. CLISSCO proved to be reliable.
Wijaya et al. (2021)[10]	Cross-sectional study. Evaluates QoL in untreated VLS.	Quality of life: *Quality of life–LS specific*	VQLI	**VQLI**: applied to VLS patients. In 68 patients, median age 58, scores indicate moderate to severe impairment due to the disease.
Vittrup et al. (2022)[9]	Cross-sectional study. Evaluates effect of VLS on QoL, sexuality, and signs of depression.	Sexual functioning: *Sexual functioning* Quality of life: *Quality of life–LS specific, quality of life–general health*	FSFI, DLQI, WHO-5	**FSFI, DLQI, WHO-5:** 158 VLS patients. Reduced sexual functioning, moderate effect on everyday life, 40% of the women had signs of depression.
Wijaya et al. (2022)[37]	Cross-sectional study. Identifies reasons for ongoing poor quality of life (pQOL) in a subset of long-term topical corticosteroid treated VLS patients.	Quality of life*: Quality of life – LS specific*	VQLI	**VQLI:** 255 participants, 67 untreated and 188 under treatment. Groups were divided into pQoL (VQLI score between 14–45) and good QoL (gQoL) (VQLI score between 0–13). Significantly more subjects with pQoL in pretreatment group. Three major areas distinguishing gQoL from pQoL patients were (1) treatment adherence and disease control, (2) psychological factors, and (3) urinary incontinence.
Wu et al. (2022)[38]	Case-control study. Compares QoL in VLS, VLP, CVVC.	Quality of life: *Quality of life–LS specific*	VQLI	**VQLI**: used to compare QoL in 3 vulvar conditions, VLS, VLP and CVVC. At baseline (pretreatment), CVVC patients' QoL was most affected by the disease followed by VLP and then VLS patients. All 3 groups showed significant improvement in VQLI scores at end of follow-up (posttreatment).
Yildiz et al. (2022)[39]	Case-control study. Evaluates sexual function, anxiety levels and genital self-image in VLP, VLS patients compared with fungal vulvitis controls and healthy control patients.	Sexual functioning: *Sexual functioning* Anxiety: *Emotional impact* Genital self-image: *sexual functioning, emotional impact*	FSFI, Beck anxiety index, FGSIS	**FSFI, Beck anxiety index, FGSIS:** 4 groups of patients. Lower sexual function in VLP and VLS groups compared to fungal vulvitis controls and healthy controls. VLP and VLS patients with poorer self-image have more sexual problems and anxiety.

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TABLE 1. *(Continued)*

Authors	Study description	Outcome measure: *Which core outcome domain*	Outcome measure: Which instrument	Description instrument and findings
Caspersen et al. (2023)[40]	Mixed methods approach, a cross-sectional online survey of women with VLS on sexual function and sexual distress, combined with qualitative study	Sexual functioning: *Sexual functioning* Sexual distress: *Sexual functioning*	FSFI, FSDS	**FSFI** and **FSDS:** 172 participants in an online cross-sectional survey showing that VLS has considerable influence on sexual functioning and sexual distress. This was a mixed methods study where qualitative analysis of 5 women who were interviewed.
Geisler et al. (2023)[41]	Cohort study on dermatological QoL as related to treatment adherence	Quality of life: *Quality of life–lichen sclerosus specific*	DLQI	**DLQI** scores of 25 VLS patients as related to treatment adherence showing that there is a relatively small effect of VLS on DLQI scores in both groups but score worse in nonadherent group
Jablonowska et al. (2023)[42]	Online survey case controlled regarding risk factors for diminished work productivity, depression and diminished sexual quality of life	Quality of life: Q*uality of life–general health and* Sexual functioning: *sexual functioning*	WPAI:GH, PHQ-9, SQOL-F	**WPAI:GH:** Work Productivity and Activity Impairment: General Health, scores loss of work productivity **PHQ-9:** patient health questionnaire scoring for depression and **SQOL-F:** sexual quality of life-female. 51 women with LS and 47 controls filled out questionnaires. Authors conclude that women with VLS are at risk for diminished work productivity, depression and diminished sexual quality of life.
Morrel et al. (2023)[43]	Online survey of adult women who had histologically confirmed VLS as juveniles (up to age 18)	Quality of life: Q*uality of life–lichen specific and* Sexual functioning: *sexual functioning*	DLQI, Skindex-29, FSFI, FSDS-R	**DLQI, Skindex-29, FSFI, FSDS-R:** survey of 81 adult women mean age 29 diagnosed as juveniles. Revision of histology. Answers to questionnaires compared to histological findings. Women scored better than previously reported for VLS-patients in studies of older women. Score FSFI poorer that epidemiological information for this age group.
Pyle et al. (2023)[44]	Case series regarding correlation of histopathology with clinical findings in untreated VLS	Quality of life: *Quality of life–LS specific,* Disease severity: *Clinical (visible) signs, symptoms*	VQLI, CLISSCO	**VQLI:** severe score associated with higher dermal thickness and epidermal sclerosus **CLISSCO:** Assessment of the prevalence and severity of 23 items, severe pruritus associated with greater lymphocytic inflammatory densities. A total of 6 cases were analyzed.

n.a. indicates not applicable.

applied to VLS. Of these questionnaires the DLQI, which is a QoL-dermatological specific questionnaire, and the VQLI, a QoL-vulvar specific questionnaire, were used most often respectively 5 and 6 times. The DSQL-V just once,[16] in its own validation study.

Scale Type: Sexual Well-being

The scale type sexual well-being covers the sexual functioning OD. Within this scale type, 5 questionnaires, the Female Sexual

TABLE 2. Scale Type, Core Outcome Domains and Questionnaires for Measuring Quality of Life, Sexual Well-being, Self-image, and Physical Findings in VLS

Scales type	Core outcome domain[a]	Tools	Studies that used the tool	Validation study	Applied to LS	Times used in a study on VLS (n)
Physical finding (symptoms and signs)	Clinical (visible) signs, symptoms	Gunthert's clinical scores for VLS	Gunthert et al. (2012)[20]	Yes	Yes	2
		Gunthert's clinical scores for VLS	Naswa and Marfatia (2015)[22]	-	Yes	
	Symptoms	ePAQ-vulva	Gray et al. (2017)[26]	Yes	-	-
	Clinical (visible) signs, symptoms	AVLSSC	Sheinis and Selk (2018)[27]	Yes	Yes	3
		AVLSSS	Green et al. (2020)[32]	-	Yes	
		AVLSSC	Sheinis et al. (2020)[34]	Yes	Yes	
	Clinical (visible) signs, symptoms	CLISSCO	Erni et al. (2021)[36]	Yes	Yes	1
	Clinical (visible) signs	VASS	Almadori et al. (2020)[28]	Yes	Yes	1
	Clinical (visible) signs	CIV-classification	Boero et al. (2021)[35]	Yes	Yes	1
QoL-generic	Quality of life–general health	EQ-5D VAS	Lansdorp et al. (2013)[5]	-	Yes	1
	Quality of life–general health	SF-12	Lansdorp et al. (2013)[5]	-	Yes	1
	Quality of life–general health	SF-36	Iannaccone et al. (2016)[24]	-	Yes	1
	Quality of life–general health	WHO-5	Vittrup et al. (2022)[9]	-	Yes	1
	Quality of life–general health	WPAI:GH,	Jablonowska et al. (2023)[42]	-	Yes	1
	Quality of life – general health	PHQ-9	Jablonowska et al. (2023)[42]	-	Yes	1
QoL-dermatological	Quality of life-lichen sclerosus specific	Skindex-29	Lansdorp et al. (2013)[5]	-	Yes	3
		Skindex-29	van Cranenburgh et al. (2017)[6]	-	Yes	
		Skindex-29	Morrel et al. (2023)[43]	-	Yes	
	Quality of life-lichen sclerosus specific	DLQI	Van de Nieuwenhof et al. (2010)[7]	-	Yes	5
		DLQI	Corazza et al. (2020)[30]	-	Yes	
		DLQI	Vittrup et al. (2022)[9]	-	Yes	
		DLQI	Geisler et al.(2023)[41]	-	Yes	
		DLQI	Morrel et al. (2023)[43]	-	Yes	
QoL-vulvar	Quality of life-lichen sclerosus specific	DSQL-V	Rajagopalan et al. (1999)[16]	Yes	Yes	1
	Quality of life-lichen sclerosus specific	VQLI	Saunderson et al. (2020)[33]	Yes	Yes	6
		VQLI	Felmingham et al. (2020)[31]	-	Yes	
		VQLI	Wijaya et al. (2021)[10]	-	Yes	
		VQLI	Wijaya et al. (2022)[37]	-	Yes	
		VQLI	Wu et al. (2022)[38]	-	Yes	
		VQLI	Pyle et al. (2023)[44]	-	Yes	
Sexual well-being	Sexual functioning	FSFI	Herbenick and Reece (2010)[18]	Yes	-	7
		FSFI	Van de Nieuwenhof et al. (2010)[7]	-	Yes	
		FSFI	Herbenick et al. (2011)[19]	-	Yes	
		FSFI	Vittrup et al. (2022)[9]	-	Yes	
		FSFI	Yildiz et al. (2022)[39]	-	Yes	
		FSFI	Caspersen et al. (2023)[40]	-	Yes	
		FSFI	Morrel et al. (2023)[43]	-	Yes	
	Sexual functioning	FSDS	Van de Nieuwenhof et al. (2010)[7]	-	Yes	3
		FSDS	Caspersen et al. (2023)[40]	-	Yes	
		FSDS-R	Morrel et al. (2023)[43]	-	Yes	
	Sexual functioning	PROMIS SexFS v2.0	Weinfurt et al. (2015)[23]	-	Yes	1

Continued next page

TABLE 2. *(Continued)*

Scales type	Core outcome domain[a]	Tools	Studies that used the tool	Validation study	Applied to LS	Times used in a study on VLS (*n*)
	Sexual functioning	PROMIS SexFS v2 vulvar discomfort scales	Flynn et al. (2017)[25]	Yes	-	-
	Sexual functioning	SQOL-F	Jablonowska et al. (2023)[42]	-	Yes	1
Self-image	Sexual functioning, emotional impact	GAS-scale	Bramwell and Morland (2009)[17]	Yes	-	-
	Sexual functioning, emotional impact	FGSIS-7	Herbenick and Reece (2010)[18]	Yes	-	2
		FGSIS-7	Hodges et al. (2019)[8]	-	Yes	
		FGSIS-7	Yildiz et al. (2022)[39]	-	Yes	
	Sexual functioning, emotional impact	FGSIS-4	Herbenick et al. (2011)[19]	Yes	-	-
	Sexual functioning, emotional impact	GSIS-20	Zielinski et al. (2012)[21]	Yes	-	-

Function Index (FSFI), Female Sexual Distress Scale (FSDS), Patient Reported Outcomes Measurement Information System Sexual Function (PROMIS) SexFs-v2.0, PROMIS SexFS v2-Vulvar discomfort scales, and Sexual Quality of Life-Female (SQOL-F)[42] were found in the literature. The FSFI[7,9,19,39,40,43] was used most frequently in studies on VLS ($n = 6$). The FSDS,[7,40,43] was used 3 times and PROMIS SexFSv2.0[g23] just once. The PROMIS-SexFS-v2-vulvar discomfort scale, developed for the potential application to various specific vulvar conditions, has not yet been applied in VLS research.

Scale Type: Self-image

Self-image, though not identified as an OD,[14] is related to the ODs sexual functioning and emotional impact. Within this scale type, 4 questionnaires, the Genital Appearance Satisfaction scale (GAS-scale),[17] Female Genital Self-Image Scale 7 (FGSIS-7),[18] FGSIS-4,[19] and the Genital self-image scale (GSIS-20)[21] were found. Only the FGSIS-7 has been applied to LS, being used 3 times in VLS research.[8,18,39]

DISCUSSION

We report on the results of a systematic review of instruments available for the study of adult VLS. The present systematic review includes 35 publications encompassing 26 different measurement tools, of which only 8 have been applied more than once. The available tools cover the CODs as established by Simpson et al.,[14] namely, disease severity and QoL-LS specific.

Regarding physical findings and symptoms, the aim of the AVLSSS and CLISSCO is making scoring of disease severity reproducible. In the CLISSCO Erni et al.[36] reduced the items of the AVLSSS to those items with “excellent” interrater reliability. “Excellent” interrater reliability of an item was defined as an interclass correlation coefficient of greater than 0.9, when the item was judged by 16 experienced clinicians who scored 5 cases of VLS of varying severity. In addition, the items “hyperkeratosis,” “lichenification,” and “sclerosus” were considered not specific enough and were excluded from the scoring system.[36] Sheinis et al.[34] discuss the lack of interrater reliability of these 3 items even based on photographic analysis, which concurs with our experience in daily clinical practice and our recently performed case series.[‡] Nonetheless, though still difficult to score, the concepts “hyperkeratosis,” “lichenification,” and “sclerosus” are frequently used in clinical practice, and we believe that they should not be discarded until consensus on a comprehensive scoring system is reached.

Although the OD QoL-generic was not identified as a COD by Simpson,[14] using a generic questionnaire may facilitates comparison of QoL in different diseases and should be considered in future research. A study, using the SF-36, a questionnaire similar to the RAND-36.v2, found worse Health Related Quality of Life (HRQoL) in adult VLS-patients when compared to healthy controls.[24] In our series of young women with VLS since childhood scored by the RAND-36.v2, 4 domains tested showed some impact of the disease on HRQoL while there was no impact in the domain social functioning, possibly because these young women with VLS since childhood have developed adequate coping mechanism.[§,45]

Sexual functioning is not one of the established CODs[14] and was deemed not relevant to children nor adults who are not sexually active and thought likely to be captured by the OD QoL-vulvar. The effects of the disease on sexual functioning may be underestimated using generic or nonvulvar-specific dermatological QoL assessment in women in good general health. Regarding QoL and sexual wellness, there is a significant impairment of sexual function in subjects with VLS based on the FSFI and FSDS compared to healthy controls of similar age,[7,43] even despite adequate treatment.[4]

Genital self-image is an important aspect of sexual well-being and should be evaluated. However, no cutoff value for the FGSIS has as yet been established. Positive genital self-image in general positively correlates with sexual functioning and inversely correlates with sexual distress.[18] In addition, VLS patients with poorer genital self-image have more sexual problems and anxiety.[39] The needs of VLS patients may be different from the needs of patients with other dermatological conditions,[46] due to the sensitive and intimate nature of the disease, and needs of VLS patients may also be related to factors, such as age at onset.

No questionnaire or set of questionnaires has been delineated to comprehensively evaluate the effect of VLS. We agree with Sheinis et al. that LS severity cannot be assessed by visual inspection alone and needs to include symptoms and QoL assessment as well.[34] A lack of consensus is also common in other areas of vulva-specific research. A systematic review of randomized controlled trials on vulvar skin conditions showed little consistency in outcome assessment.[12] Scales and categories of assessment varied widely. This systematic review highlights the need for consensus on measurement tools to evaluate the CODs that have been delineated for VLS not only with regard to evaluation of treatment but also regarding the effects of disease.

[‡] Reference companion manuscript.

[§] Reference companion manuscript.

Limitations and Strengths

A limitation is that the analysis of the literature was based on the CODs identified for clinical trials on VLS rather than observational studies.[14] Nevertheless, we believe that these CODs as developed by a broad group of stakeholders are applicable to observational studies, which may also be considered a strength of our systematic review.

CONCLUSIONS

This systematic review on measurement tools for the study of vulvar lichen sclerosus found that the CODs as defined by stakeholders are covered in current literature.[14] This, however, does not imply that these tools sufficiently cover all aspects of the patient's experience with VLS.

High-quality studies are needed to improve knowledge of diagnostic criteria and validated measurement tools in vulvar research.[47] To meet the needs of women with VLS the CODs with associated tools may be adapted and validated for different age groups. A consensus on which tools to apply to observational studies is needed. With these tools, including analysis of QoL, sexual well-being, self-image and measurement of physical consequences, high-quality research can be performed geared to various age groups. This will help professionals together with patients in better understanding the course of VLS and addressing the specific needs of patients.

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