

Round 2 - Vulvar Lichen Sclerosus Severity Scale

Welcome to the Adult Vulvar Lichen Sclerosus Severity Scale Survey

Thank you so much for continuing to participate in this survey. By this point, you should have received an email with both your individual responses, as well as a summary of the responses provided by your colleagues so far. Please take a look at this data before you proceed in this survey.

As already mentioned in the email you were sent, we have made some changes in this survey.

The things we have changed are as follows:

1. The scale we have provided you to rate signs and symptoms is now a 4-point scale rather than a 5-point scale.

Some items have been added based on your comments as follows:

1. A few items to assess in the symptoms category (bleeding and pain with intercourse, skin bleeding with scratching, peri-anal involvement, and I don't have any symptoms for those patients who are asymptomatic)

2. Further explanation as to what is meant by the term "anterior changes"

3. Methods of measuring symptoms and signs (see survey)

Due to comments and confusion we have removed:

1. The two questions to rate signs as mild, moderate, or severe (as we recognized and were provided feedback to indicate that this question did not make sense.)

2. We also removed the sign "posterior changes" as we found that according to its definition, it overlaps with narrowing of the introitus for which consensus has already been reached.

The items that have reached consensus and will be included in the final scale have been removed for the next 2 rounds.

Items for which >75% consensus was reached (>75% assessed the item as being very important or essential towards determining disease severity):

- a. Symptoms
 - i. Itch
 - ii. Quality of Life

b. Signs

i. Fissures

ii. Whitening

iii. Crinkly/fine wrinkling of skin/parchment-like skin

iv. Extent of disease (figure of eight. Vs. localized to labia, localized to clitoris, localized to the perineum or combined.)

v. Architectural changes/anatomical distortion

1. Clitoral hood fusion

2. Labial fusion/resorption

3. Narrowing of the introitus

As before, if you have any questions, please feel free to address them to the principal investigator:

Dr. Amanda Selk: amanda.selk@utoronto.ca.

Please read the consent letter which was emailed to you in your invitation to participate in this survey. By choosing to move forward with the survey, it will be understood that you consent to participate in this research.

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* 1. When you are assessing the severity of adult vulvar lichen sclerosus, please rate the importance of each of the following PATIENT REPORTED symptoms on a scale of 1-4 (1 - not important at all, 2 - not very important, 3 - very important, 4 - essential)

	Not important at all	Not very important	Very important	Essential
Irritation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dryness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain unrelated to intercourse (burning, soreness, discomfort, etc.) at rest or during activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain with intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bleeding and pain with intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Skin tearing with intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty urinating (dribbling, having to stand up to void)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty with bowel movements (constipation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bleeding with scratching	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I don't have any symptoms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (please specify)

* 2. How should these symptoms be measured?

- Presence or absence of symptoms (e.g. Yes/No)
- If screen positive then... 5 point severity scale (e.g. 1 absent/never, 2 sometimes/occasionally, 3 often, 4 most of the time, 5 all the time)
- If screen positive then... 10 point Visual Analogue Scale (e.g. 1 no itch at all, 10 being the worst itch imaginable) note: this option requires descriptors for every symptom so if you choose this option, please suggest descriptors in the "other" section below.
- If screen positive then... Scale for severity (5 point as above) + Scale for frequency (e.g. every day, \geq once per week, \geq once every 2 weeks, \geq once per month, $<$ once per month)
- If screen positive then... Scale for severity (10 point as above) + Scale for frequency (e.g. every day, $>$ once per week, $>$ once every 2 weeks, $>$ once per month, $<$ once per month)
- Other (please specify)

* 3. When you are assessing the severity of adult vulvar lichen sclerosus, please rate the importance of these other PATIENT REPORTED symptoms on a scale of 1-4 (1 - not important at all, 2 - not very important, 3 - very important, 4 - essential)

	Not important at all	Not very important	Very important	Essential
Changes/decrease in sexual function	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mood changes (depression/anxiety)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 4. How should these other symptoms (sexual function and mood) be measured?

- Presence or absence of symptoms (e.g. Yes/No)
- If patient screens positive then... 5 point severity scale (e.g. 1 no impact, 2 barely affected, 3 slightly affected, 4 moderately affected, 5 strongly affected)
- If patient screens positive then... 10 point Visual Analogue Scale (e.g. 1 no decrease in sexual function, 10 being complete inability to have sex)
- If patient screens positive then... Use previously validated scale for severity (e.g. female sexual dysfunction index)
- If patient screens positive then... Scale for severity (5 point as above) + Scale for frequency (e.g. every day, \geq once per week, \geq once every 2 weeks, \geq once per month, $<$ once per month)
- If patient screens positive then... Scale for severity (10 point as above) + Scale for frequency (e.g. every day, \geq once per week, \geq once every 2 weeks, \geq once per month, \leq once per month)
- If patient screens positive then... Use previously validated scale for severity (e.g. female sexual dysfunction index) + Scale for frequency (e.g. every day, \geq once per week, \geq once every 2 weeks, \geq once per month, $<$ once per month)
- Other (please specify)

* 5. Patients should be asked about their symptoms over what time period i.e. over the past week/month/year? An example would be: "Over the past month, please rate how often you feel the following: itch"

Please note: specifying a time period is necessary in order to use the scale being developed for research now or in the future. Testing this scale for validity will require a standardized time period.

- Week
- Month
- 3 months
- 6 months
- 1 year
- Other (please specify)

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* 6. When determining the severity of adult vulvar lichen sclerosis, consider the following signs on physical exam, and please rate each sign's importance on a scale of 1-4 (1 - not important at all, 2 - not very important, 3 - very important, 4 - essential)

(Note: if you are unclear as to the meaning of a specific term - please take this into consideration when rating it's importance in determining disease severity.

Also note: this list was generated based on our comprehensive review of the literature, all items included are due to our desire to be as all-inclusive as possible to get a consensus on which of these items are important, not due to our own opinion that these items are important.)

	Not important at all	Not very important	Very important	Essential
Erosions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ulcerations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hyperkeratosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Telangiectasia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Petechiae	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ecchymosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Colour (normal vs abnormal)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pallor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypopigmentation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Erythema	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Excoriations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lichenification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Induration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Elasticity (or loss of elasticity)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sclerosus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Edema	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Atrophy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Whether the disease is symmetrical vs. asymmetrical	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (please specify)

* 7. How should these clinical signs be measured?

- Presence or absence of signs (e.g. Yes/No)
- If patient screens positive then... Classify sign subjectively as mild, moderate, or severe.
- If patient screens positive then... Classify sign as focal (less severe) or extensive (more severe)
- If patient screens positive then... Classify sign as mild, moderate, or severe depending on percentage of vulva affected (mild - <30%, moderate - 30-50%, severe - >50%)
- If patient screens positive then... Classify sign as mild, moderate, or severe based on definitions provided with the scale (e.g. 3 photos or descriptions showing what mild erythema, moderate erythema, and severe erythema look like) (please note: all descriptions/classifications would require consensus and this option would be technically quite difficult to obtain)
- Other (please specify)

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* 8. When architectural changes/anatomical distortion are present on physical exam, please rate each particular change's importance on a scale of 1-4 (1 - not important at all, 2 - not very important, 3 - very important, 4 - essential)

	Not important at all	Not very important	Very important	Essential
Anterior changes (fusion anteriorly below the clitoris, causing urethral occlusion at its extreme)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perianal involvement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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* 9. How should architectural changes/anatomical distortion be measured?

- Presence or absence of that change (e.g. Yes/No)
- If patient screens positive then... Classify subjectively as Mild, Moderate, or Severe
- If patient screens positive then... Classify extent of change as slight, partial, or complete (e.g. slight, partial, or complete labial fusion)
- If patient screens positive then... Classify according to percentage of architecture impacted (e.g. <30% labial fusion, 30-50% labial fusion, >50% labial fusion)
- Other (please specify)

* 10. When recording architectural changes/anatomical distortion in a patient's chart, how do you prefer to describe that change?

- A) Taking a photo
- B) Colouring in a diagram of the vulva (to indicate where the changes are)
- C) Either A or B is acceptable
- Neither is necessary (a photo or diagram is not required)
- Other (please specify)

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11. Thank you so much for participating! Please remember that we will be emailing you with the 3rd survey of 3 in 2 weeks time.

Please feel free to suggest other items you'd like us to incorporate into our last survey.

Please feel free to provide us comments.