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## **Is urinary incontinence associated with vulval lichen sclerosus in females? A cross-sectional study**

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Dear Editor,

Increasing evidence suggests the pathogenesis of male genital lichen sclerosus (LS) is driven by chronic, occluded exposure of susceptible epithelium to the irritant effect of urine (1, 2). It is not clear how this can be extrapolated to females, however, the typical 'figure of eight' distribution seen in female genital LS suggests that urine could be implicated. This has not yet been robustly investigated (3).

This study utilised data prospectively entered into the East Lancashire Hospitals NHS Trust vulval dermatology database between 2017-2020. Cross-sectional analysis was performed to determine the odds of urinary incontinence (UI) in LS, compared with other genital conditions in adult females. The LS group were women with genital LS, diagnosed clinically and/or histologically. The non-LS group were women with genital conditions other than LS, identified from the same clinic. UI was screened for using the validated International Consultation on Incontinence Questionnaire Urinary Incontinence (ICIQ) Short Form (4). Power calculation demonstrated for 90% power and 5% error to detect a 20% difference, 110 patients were needed per group. Ethical approval was not required as data were unlinked and anonymous.

All patients were assessed by a Consultant Dermatologist with a specialist interest in vulval disease. Clinical diagnosis (plus histological if available), demographics, body mass index (BMI), parity and ICIQ score were recorded.

Age was identified as an a priori confounder; BMI and parity were potential confounders(5). The association between potential confounders and LS and UI status were analysed using the two-sample t-test for normally distributed data or Mann-Whitney U-test for non-normally distributed data. Univariate logistic regression was conducted to determine the association between LS and UI. Multivariable logistic

regression using the 10% change in the adjusted odds ratio (OR) was used to assess for confounding and to obtain a final model, which included all confounders. Sensitivity analyses were conducted excluding patients with LS/LP overlap and irritant contact dermatitis (ICD) secondary to UI.

The most common diagnoses in the non-LS group were eczema, candidiasis, vulvodynia and irritant contact dermatitis. Baseline characteristics for all participants (n=384) are presented in table 1. The prevalence of UI was 63% in the LS group and 34% in the non-LS group,  $P < 0.001$ . Women with LS were significantly older (median 62 versus 50,  $P < 0.001$ ). The LS group had higher BMI (median 29 versus 26 ( $P < 0.001$ )) and parity (median 2, IQR 2-3 versus 0-2,  $P < 0.001$ ). The LS group reported lower washing frequency than the non-LS group (median 1, IQR 1-1 versus 1-2,  $P = 0.047$ .)

Parity and BMI were significantly associated with both LS and UI status. Participants with missing data for these variables or UI status were excluded from the final analysis (n=31); 353 participants were included in the multivariable analysis (LS n=112, non-LS n=241). BMI and parity were not found to be confounders using the 10% rule. The unadjusted OR for UI was 3.85 (95%CI 2.40-6.18),  $P < 0.001$ . The final age-adjusted OR was 2.56 (95%CI 1.55-4.24),  $P < 0.001$ .

Sensitivity analysis excluding LS/LP overlap (n=8) from the LS group increased the age-adjusted OR to 2.80 (95%CI 1.67-4.70)  $P < 0.001$ . When ICD secondary to UI (n=21) was excluded from the non-LS group, OR was 3.15 (95%CI 1.87-5.30). Excluding both these groups, the age-adjusted OR was 3.55 (95%CI 2.10- 6.04)  $P < 0.001$ .

To our knowledge, this is the first study using a validated screening tool for UI and prospectively collected data, which is powered to determine the odds of UI in vulval LS. The prevalence of UI was 63% and the odds were increased 2.5-fold.

Few studies report the prevalence of UI in women with LS. A recent meta-analysis found pooled prevalence was 0.35 (95%CI 0.13-0.58), comparable with that of the general population(3). Our LS population were similar to those in two previous cross-sectional studies; older with higher parity (5) and BMI than those without LS (6). In women of comparable age and BMI to our LS population, 46% of women aged 60-64 (7) and 50% of those with BMI 25-29 had UI(8). Less frequent washing

in women with LS is an interesting finding, however discussion is beyond the scope of this letter.

The strengths of this study were the use of a validated screening tool for UI, and diagnosis by an expert clinician, with histological confirmation when required. The entire database was utilised to minimise selection bias. Data were collected from a single centre; therefore, study population and secondary care setting may limit generalisability. A key limitation associated with the cross-sectional design is that the direction of association between UI and LS cannot be determined.

This study provides evidence of a link between UI and vulval LS. Large population-based cohort studies are now needed to determine the nature of this association.

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Table 1. Baseline characteristics of study participants

Variable	LS group (n=126)	Missing data (LS)	Non-LS group (n=258)	Missing data (non-LS)	Statistical significance (P-value)
Age (median, IQ range)	62 (55-71)	0	50 (34-64)	0	<0.001
BMI (median, IQ range)	29 (25.5-33)	10	26 (23-32)	12	<0.001
Parity (median, IQ range)	2 (2-3)	2	2 (0-2)	2	<0.001
Self-reported UI (number, percentage)	n=79 (63%)	2	n=87 (34%)	3	<0.001
ICIQ score (median, IQ range)	5 (0-11)	4	0 (0-5)	5	<0.001
Washing frequency (median, IQ range)	1(1-1)	0	1(1-2)	6	0.047