Vulval dermatology database: descriptive analysis

Date: July 2021, amended September 2022
Funder: N/A

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Study Synopsis

Title of Study:	Vulval dermatology database: descriptive analysis
Study Centre:	East Lancashire Hospitals NHS Trust
Duration of Study:	6 months
Primary Objective:	This study will describe the patient population attending a specialist vulval dermatology clinic between 2017 and 2020.
Secondary Objective:	Not applicable
Rationale:	A cross-sectional study will be undertaken using anonymised data collected prospectively from patients attending a vulval clinic over a 2.5 year period, as part of routine clinical practice.
Methodology:	Cross-sectional study
Sample Size:	Approximately 500
Screening:	All cases entered prospectively at routine clinic attendance.
Registration /Randomisation:	Not applicable
Main Inclusion Criteria:	All patients entered in vulval dermatology database
Main Exclusion Criteria:	None
Duration of Treatment:	Not applicable
Statistical Analysis:	Descriptive statistics will be reported to describe the study population.

Introduction

Vulval clinics have developed to provide specialist care for women with vulval disease. The vulval skin can be affected by specific conditions such as lichen sclerosus and lichen planus, but may also be involved in more widespread dermatoses. Common dermatoses may present very differently in the vulval skin and diagnosis may be challenging. Management of vulval conditions may present a unique set of challenges. The vulval skin is a combination of keratinised epithelium and non-keratinsed mucosa. It is sensitive and at risk of irritation from local friction, heat, lack of moisture and changes in normal flora. Exposure to urine and faeces can also cause irritation and trigger flares of vulval skin conditions, with delayed response to treatment. Vulval skin conditions can be perceived as embarrassing and can interfere with sexual functioning, self-image and interpersonal relationships.

Vulval disease is common but an area of medicine that is historically under-researched. The James Lind Alliance Priority Setting Partnership has identified that we still know very little about the epidemiology and aetiology of lichen sclerosus and this is also true of many other vulval conditions. Optimising patient care, patient outcomes and service design depend upon robust data which is currently lacking. This study looks at data which could be collected routinely during the course of standard clinical practice. Disease incidence, patient pathways, outcome measures and potential associated factors are reported. This data is not generalisable but could inform future projects such as a national vulval disease database to improve patient care and support ongoing research into this neglected area.

Aim/Primary and Secondary Objectives

The primary aim of this study is to describe the patient population attending a specialist vulval dermatology clinic between 2017 and 2020.

Study Design

This cross-sectional study will analyse data entered into the database at the time of clinical contact including:

- Demographic details
- Body mass index (BMI) – excluding patients aged <20 years old
- Parity – excluding patients aged <16

- Ethnicity
- Referral source
- Duration of symptoms
- Diagnosis
- Patient reported incontinence (faecal, urinary)
- Vulval hygiene practices
- Outcome measures at presentation: Dermatology Life Quality Index (DLQI), Visual Analogue Score (VAS), International Consultation of Incontinence Questionnaire (ICIQ) score
- Sexual function
- Biopsy and patch testing

We anticipate that some data may be missing. The number of patients with missing data for each variable will be clearly reported.

Study Population

Female patients (adults and children) referred to the vulval dermatology clinic at East Lancashire Hospitals Trust.

Inclusion criteria

All cases in the database will be included.

Exclusion criteria

There will be no exclusions

Identification of participants and consent

Patient details were entered in the secure database as part of routine clinical practice.

Withdrawal of subjects

Not applicable.

Study Outcome Measures

This study will describe the patient population by clinical diagnosis, in terms of demographics, outcome scores, hygiene practices and investigations.

Assessment of Safety

Not applicable.

Statistics and Data Analysis

Descriptive statistics (percentages and means (standard deviations)) will be used to describe the study population. Statistical analysis where required will be performed using STATA SE statistical software by Dr de Brito.

Study closure

Patient details entered in database prior to data extraction.

Ethical Consideration

Advice has been sought from the University of Nottingham (base of Dr Simpson, Academic supervisor for this project) regarding Ethical Approval. Research governance coordinator and ethical approval is not required as data will be anonymised and unlinked during data analysis. The data custodian at the collection site has been contacted and has given the necessary permission to use these data in the way described.

Finance and Indemnity

Not applicable

Publications

The results of this work will be disseminated to healthcare professionals through publication of the systematic review and cross-sectional study separately in peer reviewed journals. The findings will also be submitted for presentation at clinical conferences.