

# **Genital Psoriasis**

Clinical Features, Management, and Impact on Quality of Life

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A thesis submitted in fulfilment of the requirements for the degree of Master of Philosophy

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## **Statement of originality**

This thesis is submitted to the University of Sydney in fulfilment of the requirements for the degree of  
Master of Philosophy.

This is to certify that to the best of my knowledge, this thesis is my own work, and that all sources of  
assistance have been acknowledged. This thesis has not been submitted for any degree of diploma at  
this or any other institution.

Michelle Wu

## Table of Contents

Acknowledgements.....	v
Publications and Presentations .....	vi
Authorship Attribution Statement.....	vii
Artificial Intelligence.....	viii
Australian Government Support.....	viii
Glossary .....	ix
Thesis Abstract .....	1
Chapter 1: Introduction.....	2
1.1 Overview of Genital Psoriasis .....	2
1.2 Literature Review .....	3
1.2.1 Clinical Presentation .....	3
1.2.2 Management Overview .....	5
1.2.3 Topical Treatments .....	12
1.2.4 Systemic Treatments.....	13
1.2.5 Environmental Measures.....	15
1.2.6 Quality of Life.....	15
1.3 Discussion .....	17
1.4 References .....	18
Chapter 2: Understanding and Managing Adult Vulval Psoriasis.....	24
2.1 Abstract .....	24
2.2 Introduction .....	25
2.3 Methods.....	26
2.3.1 Study Population and Inclusion Criteria .....	26
2.3.2 Vulval Quality of Life Index.....	26
2.3.3 Statistical Analysis.....	27
2.4 Results .....	28
2.4.1 Patient Demographics .....	28
2.4.2 Clinical Symptoms and Features.....	32
2.4.3 Management.....	32
2.4.4 Treatment Response and Adverse Effects .....	34
2.4.5 Vulval Quality of Life.....	35
2.5 Discussion .....	38
2.6 Conclusion.....	43
2.7 References .....	44
Chapter 3: Understanding and Managing Paediatric Vulval Psoriasis .....	47
3.1 Abstract .....	47
3.2 Introduction .....	48
3.3 Method and Methods.....	49
3.3.1 Study Population and Inclusion Criteria .....	49
3.3.2 Statistical Analysis.....	49
3.4 Results .....	51

3.4.1 Patient Demographics .....	51
3.4.2 Clinical Symptoms and Features.....	54
3.4.3 Management.....	54
3.5 Discussion .....	56
3.6 Conclusion.....	59
3.6 References .....	60
Chapter 4: Summary and Future Directions .....	62
4.1 Summary of Findings .....	62
4.2 Strengths and Limitations.....	63
4.3 Future Directions.....	65
4.4 Conclusions .....	65
Appendix.....	66
1. Vulval Quality of Life Survey.....	66

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## **Publications and Presentations**

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## Authorship Attribution Statement

Chapter 1 of this thesis is published in the Australasian Journal of Dermatology as: ‘Wu M, Fischer G. Adult genital psoriasis: An updated review for clinicians. Australas J Dermatol. 2024;65(3):e1-e12. doi:10.1111/ajd.14227’. Michelle Wu (MW) designed this study with the assistance of Gayle Fischer (GF). MW performed the critical appraisal of literature and drafted the manuscript. MW and GF contributed intellectually to the manuscript.

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The text from the published papers have been minimally reformatted to ensure consistency in this thesis. I am the corresponding author for all included published items.

Michelle Wu

04/05/2025

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Gayle Fischer

14/06/2025

## **Artificial Intelligence**

No content produced by generative Artificial Intelligence tools has been used in the preparation of this thesis.

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## **Glossary**

ADLs – Activities of Daily Living

BSA – Body surface area

DLQI – Dermatology Life Quality Index

FSDS – Female Sexual Distress Scale

GENPs-SFA – Genital Psoriasis Sexual Frequency Questionnaire

LPC – Liquor picis carbonis

MMF – Mycophenolate mofetil

N/A – Not available

PASI – Psoriasis Area Severity Index

PBS – Pharmaceutical Benefits Schedule

PGA – Physician’s Global Assessment

RCT – Randomised controlled trial

TCS – Topical corticosteroid

URTI – Upper respiratory tract infection.

VQLI – Vulval Quality of Life Index

QoL – Quality of Life

## **Thesis Abstract**

Genital psoriasis is a chronic inflammatory skin condition that has been reported in up to 63% of patients with psoriasis on other parts of their skin. It has a profound impact on quality of life and sexual function which is overlooked by current severity scores. Despite its prevalence and disease burden, genital psoriasis remains largely under-reported and under-treated. Historically, this has been due to the impracticality and limited efficacy data of standard psoriasis treatments when applied to genital skin. However, there have been recent advancements with several new agents currently being developed and evaluated for genital psoriasis. This thesis aims to provide an overview of the current evidence regarding the clinical features of genital psoriasis, available management options and tools for assessing patients' quality of life. This thesis also investigates the patterns of care of vulval psoriasis in paediatric and adult population in Australia through a retrospective chart review of a single dermatology referral centre. Lastly, this thesis also examines the quality-of-life impact of adult vulval psoriasis to highlight areas of focus and improvement for clinicians.

Chapter one of this thesis highlights this often-neglected genital involvement of psoriasis and its quality-of-life impact. Additionally, it discusses the current management options for genital psoriasis in adults available in Australia. Chapter two investigates the presentation of vulval psoriasis in adults, looking at their clinical features, topicals and systemic treatments, commenting on the current landscape of Pharmaceutical Benefits Schedule. Chapter three explores the presentation of paediatric vulval psoriasis, exploring its clinical features and management strategies used in Australia. Finally, Chapter four presents a summary of the thesis findings, commenting on directions for future research.

# Chapter 1: Introduction

## 1.1 Overview of Genital Psoriasis

Psoriasis is a chronic inflammatory skin condition characterised by erythematous, well-demarcated ‘salmon pink’ scaly plaques. It is estimated to affect at least 2% of the general population worldwide (Parisi et al., 2020). It is a T-cell mediated disease and can be triggered by psychological stress, genetic and environmental factors such as infections and medications (Rook et al., 2016). Genital involvement is quite common, affecting up to 63% of adults with psoriasis at some point during their lives (Ryan et al., 2015). Furthermore, in 2-5% of individuals, the disease may be confined only to the genital area (Beck et al., 2018).

Genital psoriasis poses a significant burden of disease. It is well known that patients with psoriasis have increased cardiovascular risk and mortality (Rook et al., 2016; Yang et al., 2018). Moreover, those with genital involvement experience significantly worse quality of life (QoL) than patients with psoriasis in other areas due to debilitating pruritus, sexual impairment and distress, avoidance of intimate relationships and shame (Meeuwis et al., 2011; Wiking et al., 2018). Current severity scoring systems based on body surface area affected do not accurately reflect the psychosocial and sexual impairment often experienced by these individuals. Whilst there have been newer systemic agents trialled and published; treatment options are still limited by the current Australian Pharmaceuticals Benefits Scheme (PBS) restrictions. Many of these agents are only available for those with Psoriasis Area and Severity Index (PASI) >15 and do not consider include special sites (such as genitals, scalp, or fingernails) or QoL impact. There needs to be further studies on the use of these newer therapies on genital skin to support their inclusion in the PBS restrictions.

The aim of this review is to highlight this often-neglected diagnosis and QoL impact of genital psoriasis and to discuss its current management options.

## **1.2 Literature Review**

The MEDLINE and Embase were searched through October 2022 for English-language articles relating to genital psoriasis. The Mesh search terms were: ‘genital psoriasis’, ‘anogenital psoriasis’, ‘inverse psoriasis’, ‘flexural psoriasis’, and ‘intertrigo psoriasis’. A total of 632 articles concerning genital psoriasis in adults were found from 1946 to 2022. 25 articles were original research studies investigated various treatments for genital psoriasis consisting of 877 patients. Another 6 qualitative studies explored the QoL in 2546 patients. Males comprised 61% of these studies.

### **1.2.1 Clinical Presentation**

There is considerable variation in the reported prevalence of genital psoriasis, ranging from 17-64% of people with psoriasis (da Silva et al., 2020). It tends to occur 6-10 years after the onset of psoriasis (Meeuwis et al., 2010; Mahajan et al., 2015). Although it is usually a part of generalised chronic plaque psoriasis, it may be present exclusively in the genital area in 2-5% of patients (Meeuwis et al., 2011). Genital involvement is more common in men (Meeuwis et al., 2010, 2011; Schielein et al., 2020), and in patients with increased psoriasis severity, inverse psoriasis, and scalp, nail or external auditory canal involvement (Ryan et al., 2015). No association has been found between genital psoriasis and BMI, psoriatic arthritis, active sex life or circumcision (Meeuwis et al., 2010; Ryan et al., 2015; Larsabal et al., 2019).

Psoriasis of the vulva may appear as a symmetrical, erythematous, pruritic, non-scaly or slightly scaly well-defined thin plaque that commonly affects the labia majora, mons pubis, perineum, perianal skin and natal cleft (Kapila, Bradford and Fischer, 2012; Ryan et al., 2015; Rook et al., 2016). The mucosal non-keratinised skin inside the vulva is not involved. Scale may be seen on more keratinised surfaces of genital skin (Omland and Gniadecki, 2015). The appearance is highly variable, particularly if topical corticosteroid treatment has been used. Superimposed infection with *Candida* or *Staphylococcal aureus* is common, occurring in around 20% of patients (Kapila, Bradford and Fischer, 2012). Differential diagnoses including atopic or contact dermatitis, tinea, erythrasma, lichen planus and vulval premalignant lesions should be considered.

In males, psoriatic plaques are most common on the proximal glans penis and under the prepuce for uncircumcised men, and on the glans penis and corona for circumcised men (Lowe, Suárez-Fariñas and Krueger, 2014). There is usually involvement of the glans penis in isolation or in combination with the shaft, however there has been one case report of genital psoriasis affecting the penile shaft without involvement of the glans (Zubrzycki and Leow, 2022). Common mimics include irritant balanitis, Zoon's balanitis, penile intraepithelial neoplasia or Extramammary Paget's disease (Kapila, Bradford and Fischer, 2012).

Classical plaque-type psoriasis typically shows regular acanthosis, parakeratosis, and neutrophilic collections in the stratum corneum (Rook et al., 2016). Spongiosis may be more prominent in genital psoriasis, a feature that can also be seen in candidiasis (Rook et al., 2016). These histopathological features may therefore overlap with candidiasis, and the distinction must be made based on history and microbiological testing.

Increasing evidence suggests that microbial factors contribute to the pathogenesis and clinical expression of psoriasis. Localized bacterial or candidal infections can trigger lesions in these areas (Rook et al., 2016). Infantile diaper psoriasis has been linked to *Candida albicans* infection (Bonifaz et al., 2016). The immunological role of IL-17 in antifungal defence provides a mechanistic explanation: IL-17 promotes neutrophil recruitment, antimicrobial peptide release, and clearance of *Candida* species, and blockade of this pathway with monoclonal antibodies such as bimekizumab has been associated with higher rates of vulvovaginal candidiasis (Zhou & Yao, 2022; Warren et al., 2025).

Pruritus is the most frequently reported symptom by patients and has been consistently reported as the most debilitating symptom of genital psoriasis (Meeuwis et al., 2010; Ryan et al., 2015; Larsabal et al., 2019). This is followed by burning and dyspareunia (Larsabal et al., 2019). The disease process is non-scarring and the Koebner phenomenon may be observed, with 34% of patients reporting worsening of their disease post-coitus (Meeuwis and van Rossum, 2012; Ryan et al., 2015).

### 1.2.2 Management Overview

Although there are many effective treatments for psoriasis, treatment of genital lesions remains under-researched. Genital skin is thinner and often occluded, allowing topical treatments to have increased penetration and therefore higher potency and side effects of atrophy, telangiectasia and striae (Farage and Maibach, 2004). Given the available data, topical corticosteroids continue to be the primary reported treatment approach although it is not known whether they are the most ideal, given the many options that are now available and reported (Tables 1 and 2) as there have been no head-to-head studies. The typical treatment regimen involves initiation with moderate to high potency corticosteroids such as Betamethasone dipropionate 0.05% (Diprosone 0.05% ointment) for short intervals followed by weaker topical corticosteroids such as Methylprednisolone aceponate 0.1% (Advantan 0.1% Fatty Ointment) or Hydrocortisone acetate 1% (Sigmacort 1% ointment) for maintenance therapy with return to more potent topical steroids for flares (Menter et al., 2011).

**Table 1. Evidence on topical treatment for genital psoriasis by treatment**

<b>Treatment</b>	<b>Study, Year</b>	<b>Study Type</b>	<b>Number of patients</b>	<b>Location of disease*</b>	<b>Outcomes</b>	<b>Adverse Effects</b>
<b>Topical antifungals</b>	Fourer et al., 2006	Case series	1 M, 3 F	Genital	After 1 month of topical bifonazole, 2 patients showed some improvement, 1 had worsened clinical outcome and 1 was unchanged	N/A
	Yao et al., 2018	Case report	1 M	Glans penis	Topical ketoconazole cream for 2 weeks showed no improvement	N/A
<b>Tacrolimus 0.1% ointment</b>	Bissonnette, Nige & Bolduc, 2008	Case series	12 M	Penis, shaft and/or scrotum	Tacrolimus 0.1% ointment applied twice daily for 8 weeks showed significant statistical and clinical improvement in severity	5 patients reported burning sensation and 2 patients reported pruritus
	Rallis et al., 2005	Case series	7 M	Scrotum and glans penis	Tacrolimus 0.1% ointment applied twice-daily for 10 +- 7 days showed marked improvement by week 1 and complete clearance by week 3 in all patients	Nil
	Zampetti et al., 2010	Case report	45 M	Glans	Tacrolimus 0.1% ointment applied daily for 3 weeks resulted in complete resolution of lesions in the patient	Nil
	Yao et al., 2018	Case report	1 M	Glans penis	Tacrolimus 0.1% ointment applied twice-daily resulted in complete clearance of lesions after 3 weeks in the patient	N/A
	Albert et al., 2004	Case report	1 F	Anogenital	Tacrolimus 0.1% in white soft paraffin had to be ceased due to adverse effects	Extreme irritation and worsening of pruritus
	Jese et al., 2014	Case report	1 M	Intergluteal and genitalia	Topical pimecrolimus 1% cream used with corticosteroid failed to achieve long-term clinical improvement after 18 months of regular use	N/A

<b>Vitamin D analogues</b>	Albert et al., 2004	Case report	1 F	Anogenital	Topical tacalcitol led to little clinical improvement	N/A
<b>Coal tar (LPC)</b>	Quan et al., 1996	Case report	1 M	Glans penis and distal penile shaft	LPC 2% resulted in little improvement	N/A
<b>Topical cyclosporine solution</b>	Jemec & Baadsgaard, 1993	Case study	3 M	Glans penis and inner fold of prepuce	Cyclosporin solution (100ng/ml) to lesions as wet dressing thrice daily was effective and reduced severity by 83% on average by 8 weeks.	Nil
<b>Topical crisaborole ointment</b>	Hashim et al., 2020	RCT	10 M, 4 F	Anogenital	Topical crisaborole 2% ointment twice daily was superior to placebo with 66% improvement by week 4, compared to 9% in the placebo group. 71% of patients treated with topical crisaborole ointment achieved complete clearance by 8 weeks.	Nil
	Liu & Li, 2021	Case report	3 M	Glans penis	Topical crisaborole 2% ointment twice-daily resulted in complete clearance of lesions in 2-4 weeks in all patients	N/A

\*Location of disease as described in the respective articles.

**Table 2. Evidence on systemic treatments for genital psoriasis by treatment**

<b>Treatment</b>	<b>Study, year</b>	<b>Study type</b>	<b>Number of patients</b>	<b>Location of disease*</b>	<b>Outcomes</b>	<b>Adverse effects</b>
<b>Methotrexate</b>	Albert et al., 2004	Case report	1 F	Anogenital	Oral methotrexate 7.5-10mg per week had partial response but was ceased due to gastrointestinal	Gastrointestinal disturbances
	Guglielmetti et al., 2012	Case report	1 F	Vulva, groin, and perianal region	Oral methotrexate 20mg weekly had partial response	Recurrent urinary tract infections
	Zubrzycki & Leow, 2022	Case report	1 M	Ventral penile shaft	Methotrexate (dose not reported) had partial response	N/A
<b>Apremilast</b>	Merola, Parish & Guenther et al. 2022	RCT (Unpublished, abstract only)	160 M, 70 F	Genital	Oral apremilast 30mg twice daily resulted in clear or near clearance of lesions in 35-46% of patients compared to 19-21% of patients in the placebo group.	N/A
<b>Mycophenolate mofetil</b>	Guglielmetti et al., 2012	Case report	1 F	Vulva, groin, and perianal region	Oral MMF 500mg twice daily resulted in partial response at 2 months for 2 patients	N/A
<b>Dapsone</b>	Guglielmetti et al., 2012	Case report	1 F	Vulva, groin and perianal region	Oral dapsone 100mg daily resulted in complete clearance of lesions by 4 weeks	Nil
	Singh et al., 2008	Case report	1 M	Glans penis	Oral 100mg dapsone daily resulted in complete resolution of lesions by 4 weeks.	N/A
<b>Oral antifungals</b>	Foureur et al., 2006	Case series	1 F	Diaper area	Oral fluconazole 100mg daily for 1 month led to complete clearance of lesions	N/A
	Quan et al., 1996	Case report	1 M	Glans penis and distal penile shaft	Oral itraconazole 200mg twice daily for 6 weeks resulted in partial response	N/A
<b>PUVA therapy</b>	Albert et al., 2004	Case report	1 F	Anogenital	PUVA twice weekly showed no improvement at 2 months	N/A

<b>Biologics</b>						
<b>Adalimumab</b>	Jese et al., 2014	Case report	1 M	Intergluteal and genitalia	Adalimumab (40mg subcutaneous injection fortnightly) showed almost complete clearance of lesions after 3 months	N/A
	Lanna et al., 2020	Case series	6 (N/A)	Genital	Adalimumab (40mg subcutaneously injection fortnightly) led to almost 75% improvement in symptoms.	1 patient reported urticaria, 1 patient reported injection site reaction
	Burlando et al., 2020	Prospective cohort study	8 F	Genital	40% of patients treated with adalimumab (dose not reported) achieved PASI 90 at 6 months.	N/A
<b>Etanercept</b>	Burlando et al., 2020	Prospective cohort study	1 F	Genital	Etanercept (dose not reported) did not have any change in lesions at 6 months	N/A
<b>Ustekinumab</b>	Campos et al., 2016	Case report	1 M	Groin, gluteal cleft and penis	Ustekinumab (45mg at Week 0 and Week 4, then every 12 weeks ongoing) led to almost complete clearance of genital skin.	N/A
	Burlando et al., 2020	Prospective cohort study	7 F	Genital	14% of patients with ustekinumab (dose not reported) achieved PASI 90 at 6 months	N/A
<b>Tildrakizumab</b>	Galluzzo et al., 2022	Case series	4 M, 3 F	Genital	Tildrakizumab 100mcg at week 0 and week 4, and every 12 weeks ongoing led to complete clearance of lesions at 52 weeks.	N/A
	Zubrzycki & Leow, 2022	Case report	1 M	Ventral penile shaft	Tildrakizumab (dose not reported) led to near complete clearance after 3 months	N/A
<b>Risankizumab</b>	Sotiriou et al., 2021	Prospective cohort study	12 M, 8 F	Genital	Risankizumab (dose not reported) led to clear or almost clear genital skin in 70% of patients at 16 weeks, and in 90% of patients at 24 weeks.	2 patients reported minor headache

<b>Ixekizumab</b>	Guenther et al., 2020	RCT	114 M, 25 F	Genital	Ixekizumab (160mg loading dose and 80mg fortnightly) led to clear or almost clear genital skin in 73% of patients at week 12	3 patients reported serious infections (bacteraemia and cellulitis) 14 patients had non-severe hypersensitivity reactions. 23 patients reported injection site reactions.
	Sotiriou et al., 2021	Prospective cohort study	10 M, 6 F	Genital	Ixekizumab (dose not reported) led to clear or almost clear genital skin in 69% of patients at 16 weeks, and 94% of patients at 24 weeks.	1 patient reported a headache.
	Garcia-Legaz Martinez et al., 2019	Case series	3 M, 3 F	Genital	Ixekizumab (dose not reported) led to clear or almost clear genital skin by week 16	3 patients reported injection site pain.
	AlMutairi & Ibrahim Eassa, 2021	RCT	21 M, 7 F	Genital	Ixekizumab (160mg loading dose and 80mg fortnightly) led to complete clearance of genital skin in 68% of patients	7 patients reported minor infections, 5 patients reported injection site reactions, 4 patients reported headache, and 1 patient reported an URTI.
	Callianno et al., 2021	Case series	10 M, 4 F	Genital	Ixekizumab (160mg loading dose and 80mg fortnightly) led to 90% improvement in symptoms.	1 patient reported community acquired pneumonia.
	Burlando et al., 2020	Prospective cohort study	6 F	Genital	75% of patients receiving ixekizumab (dose not reported) achieved PASI90 at 6 months.	N/A
	Ryan et al., 2018	RCT	56 M, 19 F	Genital	Ixekizumab (160mg loading dose and 80mg fortnightly) led to clear or almost clear genital skin in 73% of patients.	11 patients reported URTI, 8 patients reported injection site reactions, 3 patients reported oropharyngeal pain.

<b>Secukinumab</b>	AlMutairi & Ibrahim Eassa, 2021	RCT	18 M, 8 F	Genital	Secukinumab (300mg at weekly for 4 weeks, then every 4 weeks ongoing) led to complete clearance of genital skin in 65% of patients.	2 patients reported headache, 4 patients reported injection site reactions, and 2 patients reported URTI.
	Burlando et al., 2020	Prospective cohort study	2 F	Genital	Secukinumab (dose not reported) achieved partial improvement in lesions at 6 months.	N/A

\*Location of disease as described in the respective articles.

### 1.2.3 Topical Treatments

Other first line topical therapies include nonsteroidal options such as mild topical tar preparations, calcineurin inhibitors and topical vitamin D analogues (Table 1). Topical tar preparations (for example, 1-5% liquor picis carbonis (LPC) and calcipotriol) were most successful when used in combination with topical corticosteroids as they may cause irritation of the sensitive genital skin when used alone (Meeuwis et al., 2015). However, the use of coal tar is heavily limited by its messy application and unpleasant odour. Calcineurin inhibitors are an off-label steroid-sparing option for patients with genital psoriasis who require maintenance therapy. It is well tolerated but use may be limited by side effects such as stinging and burning however some studies have shown that they are only marginally effective (Rallis et al., 2005; Bissonnette, Nigen and Bolduc, 2008). Topical vitamin D analogues are considered even less effective than topical calcineurin inhibitors and are associated with greater adverse effects (Liao et al., 2007). Topical antifungals are unlikely to be effective in improving lesions unless there is a concurrent infection where treating this may help prevent the Koebner effect (Foureur et al., 2006; Meeuwis et al., 2011). Anthralin (dithranol), topical retinoids such as tazarotene, ultraviolet light and laser therapy are not recommended for the genital area due to potential irritancy (Meeuwis et al., 2011).

Topical phosphodiesterase-4 inhibitors (e.g. crisaborole, roflumilast) have been shown to be effective and well tolerated in genital psoriasis. In a small study involving 21 patients, crisaborole 2% ointment has been shown effective against placebo (66% versus 9%) when applied twice daily to anogenital region for 4 weeks (Hashim et al., 2020). There were no adverse events reported in this study.

Recently, the FDA has approved roflumilast 0.3% cream (Zoryve, Arcutis Biotherapeutics) for the treatment of plaque psoriasis including sensitive areas such as the face and intertriginous areas. In a post-hoc analysis of phase III trials (DERMIS-1 and DERMIS-2), 73% of patients treated with once daily roflumilast 0.3% cream showed improvements in face and intertriginous areas within 6 weeks and had lower rates of adverse effects when compared to low-to mid-potency steroids and Vitamin D analogues (Lebwohl et al., 2022; Draelos et al., 2023).

Other new topical agents with FDA-approval include the tapinarof 1% cream (Vtama, Dermavant Sciences). It is a topical aryl hydrocarbon receptor agonist which has been found to be effective for chronic plaque psoriasis and safe in intertriginous areas in two 12-week phase 3 trials (PSOARING 1 and 2, ClinicalTrials.gov numbers NCT03956355 and NCT03983980, respectively) (Lebwohl et al., 2021). However, it was associated with folliculitis, contact dermatitis and headache. It has not yet been compared against pre-existing psoriasis treatments.

Currently, there is a phase II trial evaluating the efficacy and safety of delgocitinib 0.25% ointment (Leo Pharmaceuticals) in patients with mild-to-moderate inverse psoriasis. This is a Janus kinase inhibitor that has been recently approved in Japan for treatment of atopic dermatitis.

#### 1.2.4 Systemic Treatments

In addition to topical treatments, several oral medications have been reported to successfully clear genital lesions of psoriasis (Table 2). Methotrexate is a traditional oral systemic therapy that has been widely used in clinical practice despite limited documentation in controlled trials. It has been shown to improve genital symptoms in some patients (Albert et al., 2004; Guglielmetti et al., 2012; Kapila, Bradford and Fischer, 2012) and in an unusual case of psoriasis affecting the penile shaft (Zubrzycki and Leow, 2022). However, its use can be limited by adverse effects such as severe nausea with vomiting, headache and insomnia (Ješe et al., 2014). Oral dapsone (100mg daily) has shown to be successful in clearing psoriasis lesions within 4 weeks in one patient, without any reported adverse events (Singh and Thappa, 2008; Guglielmetti et al., 2012). Mycophenolate mofetil have been shown to be successful in one case (Guglielmetti et al., 2012). The recently completed 16 week, multicentre, double-blind, phase 3 DISCREET study has showed that 30mg oral apremilast daily leads to improvement in patients with moderate to severe genital psoriasis (Merola, Parish and Guenther, 2022). Other systematic agents, such as oral cyclosporin or acitretin are used for psoriasis, there were no published studies on their use on the genital area.

For recalcitrant or severe cases of genital psoriasis, biologic agents can be used, however ixekizumab is the only biologic to have a published randomised clinical trial result (IXORA-Q) for patients with moderate-to-severe genital disease (Yosipovitch et al., 2018). Ixekizumab is a high-affinity monoclonal IgG IL-17 inhibitor which has been shown to rapidly improve genital psoriasis symptoms, QoL and sexual wellbeing of patients with genital psoriasis with results persisting up to 1 year (Guenther et al., 2020). Since then, smaller real-life case studies have shown similar results and good safety profile for Ixekizumab, with the most common adverse events including diarrhoea, injection site reactions, nasopharyngitis, upper respiratory tract infections and headaches (García-Legaz Martínez et al., 2019; Burlando et al., 2020; AlMutairi and Eassa, 2021; Calianno et al., 2021; Sotiriou et al., 2022). One small head-to-head comparison study found the greatest clinical benefit in genital psoriasis symptoms with anti-IL17 (ixekizumab, secukinumab) and anti-IL12/23 (ustekinumab) when compared with TNF-a (adalimumab, etanercept, certolizumab) (Burlando et al., 2020). Ongoing trials include a cohort study evaluating the efficacy and impact on QoL of guselkumab in study for patients with moderate facial and/pr genital psoriasis (GULLIVER; NCT04439526).

Currently in Australia, the biologic agents available for psoriasis are the TNF-a inhibitors (adalimumab, infliximab and etanercept), the IL12/23 inhibitor (ustekinumab), IL-17 inhibitors (secukinumab, ixekizumab and bimekizumab) and IL-23 inhibitors (guselkumab, risankizumab and tildrakizumab). However, these biologics are not available on the PBS for psoriasis solely in the genital area and are therefore only useful for patient where genital involvement is part of a generalised severe picture. Whilst there is PBS coverage for patients with psoriasis limited to specific sites such as the face, hands and feet, genital psoriasis is not included under the special site prescribing. To advocate for the inclusion of genital involvement in PBS criteria, further studies specifically examining the impact of these therapies on genital skin are necessary.

### 1.2.5 Environmental Measures

Supportive measures are an important adjunct in management of these patients. The priority is to minimise the potential for Koebnerisation with environmental modifications such as regular emollients, relatively loose cotton underwear, replacement of sanitary pads with tampons and adequate lubricants during sexual activity (Kelly and Ryan, 2019). Patients must be educated that this is a lifelong condition that is not curable and requires long-term maintenance.

### 1.2.6 Quality of Life

The burden of genital psoriasis on an individual's QoL remains largely underappreciated. This is partly because genital involvement is often underdiagnosed, with literature reporting a delay of over two years from symptom onset to diagnosis (Moumen et al., 2023). This delay is thought to result from patient embarrassment and clinicians not routinely inquiring about genital symptoms (Moumen et al. 2023). Consequently, limited patient and clinician awareness may lead to misdiagnosis, particularly in patients with genital only disease where it may be mistaken for a sexually transmitted infection, resulting in unnecessary anxiety (Cather et al. 2025). Additionally, vulval psoriasis in pre-pubertal females are often misdiagnosed as 'non-specific vulvovaginitis' (Fischer, 2010), delaying appropriate management.

A recent German study found that whilst 80% of patients mentioned their genital psoriasis with their dermatologist (notably, the majority of these discussions were initiated by the patient), only 1 in 4 patients discussed its impact on their sex life (Klein et al., 2022). In this study, genital psoriasis is associated with sex avoidance in 1 in 8 patients, citing pain during sexual stimulation, movement restrictions and loss of libido as the major contributing factors. This impact appears to be more pronounced in women, not due to reduced sexual function, but rather subjective sexual distress such as feelings of reduced physical attractiveness (Meeuwis et al., 2011; Larsabal et al., 2019). Given that the peak onset of psoriasis lies between 15-30 years of age where individuals are creating and maintaining sexual relationships, it is pertinent for clinicians to elicit and address sexual concerns (Ryan et al., 2015).

Another challenge lies with current severity scoring systems, such as the Psoriasis Area Severity Index (PASI) and the Physician's Global Assessment (PGA), which do not fully capture the impact of genital psoriasis. Moreover, it is well known that the severity of psoriasis does not correlate well with the disease impact on QoL (Meeuwis et al., 2011, 2015; Mrowietz et al., 2011). Numerous patients with psoriasis experience sexual dysfunction disproportionately greater than indicated by PASI (Duarte et al., 2018). However, recent guidelines have reflected a shift towards supporting the use of systematic therapies even in patients who do not meet the cut-offs for body surface area (BSA) involvement (BSA <10%) provided that other treatments have been trialled without success (Menter et al., 2011; Mrowietz et al., 2011).

In recent years, several studies have begun to characterise the quality-of-life impact of genital psoriasis; however, they are heterogenous in their choice of instruments to capture this impact. The commonly used tools include the Dermatology Life Quality Index (DLQI), Female Sexual Distress Scale (FSDS) and International Index of Erectile Function however these instruments were not specifically developed for genital psoriasis. The recently validated Genital Psoriasis Sexual Frequency Questionnaire (GENPs-SFQ) specifically assesses the impact of genital psoriasis on sexual health, however the two-question survey may not provide enough information for clinicians to provide patient-focussed care (Gottlieb et al., 2018; Yosipovitch et al., 2018). On the other hand, whilst the Vulval Quality of Life Index (VQLI) was not designed specifically for genital psoriasis, it comprehensively captures a patient's level of morbidity and is validated for patients with any type of vulval disease (Felmingham et al., 2020; Saunderson et al., 2020).

### **1.3 Discussion**

This review has covered in-depth the current landscape of treatment modalities for genital psoriasis in Australia and internationally. There have been substantial advances in psoriasis treatments however there remains limited outcome data on efficacy and safety on genital skin. It is likely that genital psoriasis would benefit from the same range of therapies available for psoriasis on the rest of the skin. The large IXORA-Q trial is encouraging as it is the first clinical trial to specifically evaluate the efficacy of ixekizumab in patients with genital psoriasis. Notably, this trial included patients with BSA>1% which is helpful when choosing treatments for patients with severe yet localised disease. In Australia, availability of such treatments continues to be restricted to those that satisfy a narrow eligibility criterion involving BSA-based severity scores. Further large-scale studies comparing the promising agents using a standardised clinical outcome measure and QoL instrument is needed.

Future studies should also take into consideration the under-representation of females in current literature exploring QoL and treatment options for genital psoriasis. Given that women have been shown to experience more sexual dysfunction compared to their male counterparts, there needs to be further investigation into appropriate treatment options for vulval psoriasis.

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## Chapter 2: Understanding and Managing Adult Vulval Psoriasis

### 2.1 Abstract

This study aims to explore the clinical presentation, management and impact on quality of life in women with vulval psoriasis. A retrospective, single-centre cohort study of women was conducted at a large, dermatology practice from January 2016 to January 2024. Sequential Vulval Quality of Life Index (VLQI) scores and patient data were systematically collected and recorded in an online patient database. Treatment regimens were individualised and titrated to clinical response.

The study included a total of 350 patients with vulval psoriasis over an eight-year period. 13.1% of patients required systemic treatment solely for vulval disease. The median VLQI score improved from  $18.0 \pm 9.4$  at baseline, to  $9.7 \pm 7.6$  at end of follow-up ( $p < 0.0001$ ). All domains showed statistically significant improvements, except for 'Sexual Function'. The domains with the greatest improvement were 'Future Health Concerns' (69.2%,  $p < 0.001$ ), 'Feelings and Emotions' (63.4%,  $p < 0.001$ ) 'Symptoms' (58.6%,  $p < 0.001$ ) and 'Activities of Daily Living' (56.8%,  $p < 0.001$ ).

Vulval psoriasis has a substantial impact on quality of life but remains under-diagnosed and undertreated. While treatment can significantly improve outcomes, issues related to sexual function and relationships often persist. Systemic therapy may be required for a subset of patients with vulval-only disease. Routine assessment and targeted management of vulval involvement are crucial to optimising patient wellbeing.

## 2.2 Introduction

Psoriasis is a common chronic inflammatory condition that affects up to 2% of the global population (Parisi et al., 2020). Genital involvement is reported in 46-63% of cases (Ryan et al., 2015), with 2-5% of individuals experiencing psoriatic disease confined exclusively to the genital area (Beck et al., 2018). Diagnosing genital psoriasis can be challenging due to the absence of classic features like scaling and plaques, and the lack of established treatment guidelines for genital skin.

Patients with genital psoriasis experience significantly diminished quality of life compared to those with psoriasis in other regions. This is attributed to severe pruritus, sexual dysfunction, emotional distress, avoidance of intimate relationships, and feelings of shame (Meeuwis et al., 2011; Wiking et al., 2018). Existing severity scoring systems, which are based on affected body surface area, often fail to capture the profound psychosocial and sexual impairment commonly among these individuals.

Although recent years have seen an increase in literature on genital psoriasis, discussions on gender-specific challenges remain limited. Women with vulval psoriasis have been shown to experience more pronounced sexual impairment (Meeuwis et al., 2011) and heightened feelings of stigmatisation due to their disease (Hawro et al., 2017; Schmid-Ott, Hans-Werner Kuensebeck, 1999). Additionally, there are many practical challenges of applying topical treatments to the vulval area, such as difficulty of visualising or accessing the affected area, discomfort from greasy ointments and staining clothing, and cultural or personal sensitivities about touching the genital area in women. This often led to the need for systemic therapy for optimal disease control. Given the scarcity of literature on vulval psoriasis, this study aims to elucidate its clinical characteristics, management strategies and their challenges and how treatment may improve its impact on quality of life.

## **2.3 Methods**

This study was a retrospective chart review conducted at a large dermatology practice. All patients provided informed consent. Patient examinations were conducted by two dermatologists, who documented findings in the electronic medical record. Data extraction was performed by an independent clinician. Treatment escalation was determined based on a combination of clinical examination findings and Vulval Quality of Life Index (VQLI) scores.

### **2.3.1 Study Population and Inclusion Criteria**

The patient database was searched for cases of "vulval psoriasis" between January 2016 and January 2024 to identify patients with a clinical diagnosis of vulval psoriasis. Eligible participants were women over 18 years of age at diagnosis who had clinical photographs and/or documented clinical signs and reviewed in clinic at least on two occasions (initial and follow-up).

Data from medical records and clinical photographs were reviewed, including age of onset, reported symptoms, age at diagnosis, features visible in clinical photographs and their anatomical locations, microbiology results, and treatments initiated, their response and adverse effects.

### **2.3.2 Vulval Quality of Life Index**

The VQLI is a validated tool designed to assess the severity of vulval disease and monitor response to treatment in clinical settings (Saunderson et al. 2020, Supplementary Material 1). It encompasses seven domains: 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 rate each item on a 4-point Likert scale from 0 ("Not at all") to 3 ("Very much"). Total scores range from 0 to 45, with higher scores indicating greater disability. Patients complete the VQLI at each visit.

### 2.3.3 Statistical Analysis

Data were recorded in an Excel spreadsheet (Microsoft Office, 2016) and results are presented as sums or means  $\pm$  standard deviation. Statistical analysis was conducted using GraphPad Prism, applying Wilcoxon signed-rank test or one-way ANOVA as appropriate, with a significance level of  $P < 0.05$ .

## 2.4 Results

### 2.4.1 Patient Demographics

Table 3 summarises patient demographics. A total of 350 women aged 18 and older were included, with a mean age of onset at  $39.8 \pm 18.0$  years and a mean age of presentation at  $50.1 \pm 17.1$  years. The median follow-up time was 93.8 weeks. Evidence of extragenital psoriasis was found in 72.0% of patients; however, only 20.3% of these patients had a prior diagnosis of psoriasis. Thirty percent of women reported a first-degree family member with psoriasis. Microbiological swabs were performed in women with clinical suspicion of infection and positive results were found in 23.42% of women, with common pathogens including *Candida* species (57.3%), *Gardnerella vaginalis* (25.6%), and *Staphylococcus aureus* (17.1%).

**Table 3. Demographics of 350 cases of vulval psoriasis referred to a single dermatology referral practice.**

<b>Demographics</b>	<b>Number (Mean <math>\pm</math> SD)</b>
Age of onset (years)	39.83 $\pm$ 18.04
Age of presentation (years)	50.11 $\pm$ 17.12
Duration of symptoms prior to diagnosis (years)	10.64 $\pm$ 10.22
Positive family history	59/197 (29.95%)
Secondary infection*	82/350 (23.42%)
Staphylococcal aureus	14/82 (17.07%)
Gardnerella vaginalis	21/82 (25.61%)
Candida species	47/82 (57.32%)
Streptococcus pyogenes	2/82 (2.44%)
Psoriasis present at distant sites	242/336 (72.02%)
Diagnosed prior to appointment	49 (20.25%)
Symptoms	
Pruritus	312/350 (89.14%)
Pain or fissuring	128/350 (36.57%)
Discharge	39/350 (11.14%)
Dyspareunia	104/350 (29.71%)
Dysuria	12/350 (3.43%)
Features	
Non-specific erythema	334/350 (95.40%)
Well demarcated edge	203/350 (58.00%)
Raised plaque	135/350 (38.57%)
Lichenification	117/350 (22.43%)
Scale	121/350 (34.57%)
Location of disease	

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Labia majora	244 (69.71%)
Sulcus	197 (56.29%)
Labia minora	160 (45.71%)
Perineum	152 (43.43%)
Perianal	138 (39.43%)
Natal Cleft	65 (19.11%)
Inner thighs	50 (14.71%)
Mons	45 (12.86%)
Buttocks	16 (4.57%)
Treatments	
Topicals	
Hydrocortisone acetate 1%	29
Desonide 0.05%	14
Methylprednisone aceponate 0.1%	262
Betamethasone dipropionate 0.05%	64
Betamethasone dipropionate OV 0.05%	15
Clobetasol propionate 0.02%	4
Tacrolimus 0.1%	3
Systemic treatments	51/350 (14.57%)
Phototherapy	8 (15.7%)
Acitretin	9 (17.6%)
Ciclosporin	2 (3.9%)
Apremilast	1 (2.0%)
Methotrexate	15 (29.4%)
Sulfasalazine	1 (2.0%)
Azathioprine	1 (2.0%)
Secukinumab	8 (15.7%)

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Adalimumab	1 (2.0%)
Certolizumab	1 (2.0%)
Golimumab	1 (2.0%)
Bimekizumab	2 (3.9%)
Tildrakizumab	1 (2.0%)
Treatment response <sup>^</sup>	
Phototherapy	6/8 (75.0%)
Acitretin	3/9 (33.3%)
Ciclosporin	2/2 (100%)
Apremilast	1/1 (100%)
Methotrexate	2/15 (13.3%)
Secukinumab	5/8 (62.5%)
Bimekizumab	1/2 (50%)
Tildrakizumab	1/1 (100%)

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Legend:

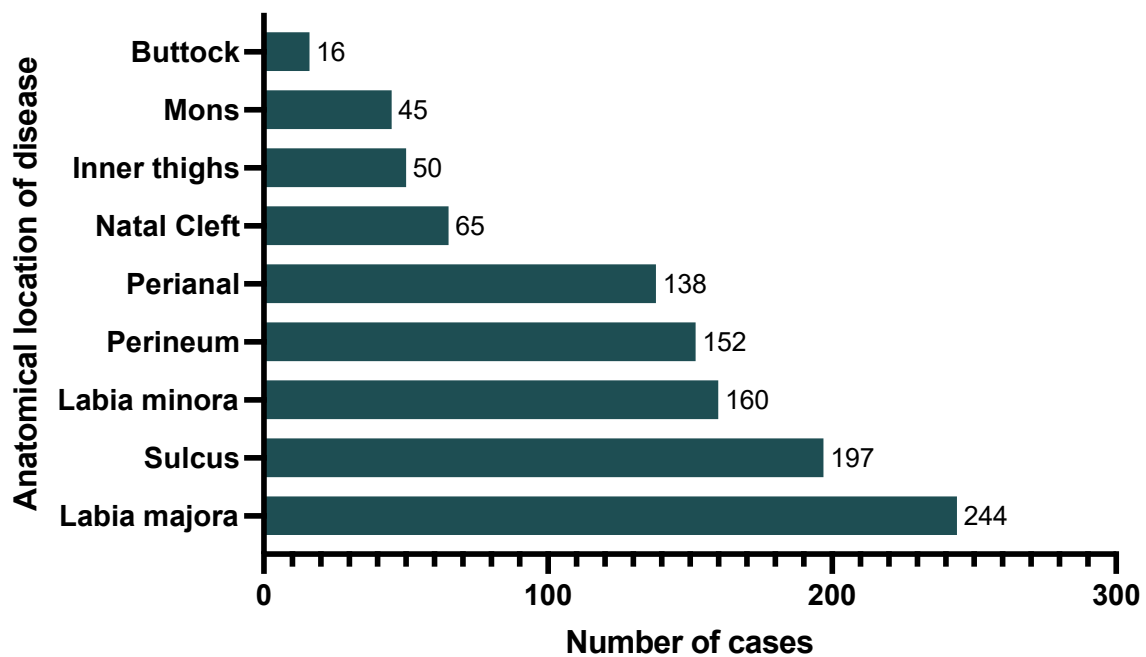
SD = standard deviation

<sup>^</sup>Patients started on systemic therapy for purely vulval disease. Treatment response was defined as clear or almost clear on clinical examination including vulval skin.

\*238/350 patients had clinical suspicion of infection on review and received a vulvovaginal microbiological swab

### 3.4.2 Clinical Symptoms and Features

The predominant symptom was pruritus (89.1%), followed by pain or fissuring (36.6%), with less frequent reports of dyspareunia (29.7%), discharge (11.1%), and dysuria (3.4%). Common clinical features were erythema (95.4%) and well-demarcated edges (58.0%). White scale (34.6%) and lichenification (22.4%) were less prevalent. Affected areas primarily included the labia majora (69.7%), sulcus (56.3%), labia minora (45.7%), and perianal area (43.4%) (Figure 1).



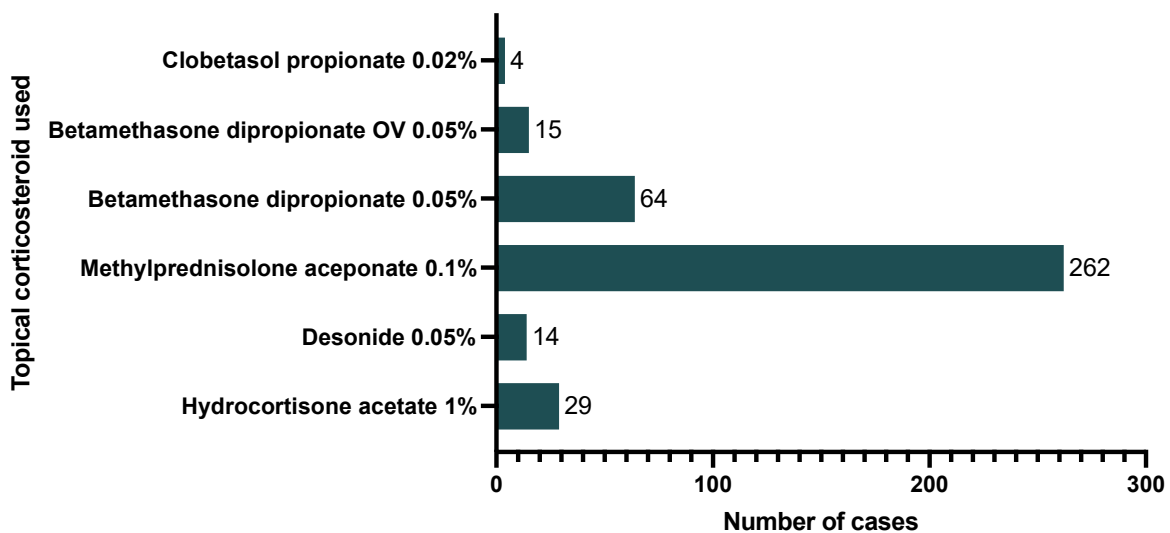
**Figure 1.** Bar graph showing the anatomical distribution of genital psoriasis in women.

### 2.4.3 Management

General skin care and management of irritant contact factors and potential allergens were discussed with all patients. This included identifying common irritants such as soaps, lubricants, fragrances, tight clothing, and exposure to urine or faeces. Practical strategies, including the use of soap-free washes, loose clothing and avoidance of irritants, were recommended; however, in some cases, such as with incontinence, complete avoidance was not possible.

All patients were initially trialled on topical treatments. Most patients (80%) were treated with a combination of 2–4% coal tar solution (liquor picis carbonis; LPC) and a moderate-potency topical corticosteroid (TCS). The most common TCS used was methylprednisolone aceponate 0.1% (74.9%), followed by betamethasone dipropionate 0.05% (18.3%) (Figure 2). Systemic treatment was used in 51 patients (14.6%), with 46 patients (13.1%) requiring addition of systemic treatments specifically for vulval disease. Five patients were switched to a biologic agent after inadequate response to methotrexate or acitretin, while six patients received a biologic as their initial systemic therapy (five on secukinumab and one on tildrakizumab) via compassionate supply.

Systemic therapies included phototherapy (n = 8), oral methotrexate (n = 15), and acitretin (n = 9). Secukinumab was the most used biologic agent (n = 8), followed by bimekizumab (n = 2) and tildrakizumab (n = 1). Patients on sulfasalazine (n = 1), azathioprine (n = 1), adalimumab (n = 1), golimumab (n = 1), and certolizumab (n = 1) had been prescribed these therapies by their rheumatologist.



**Figure 2.** Bar graph showing topical corticosteroids used for treatment of genital psoriasis in our cohort.

#### 2.4.4 Treatment Response and Adverse Effects

Among the 46 patients in our cohort treated with systemic agents specifically for vulval disease, complete clearance was achieved in 7 out of 11 patients (63.6%) receiving biologic agents and 14 out of 35 patients (40%) on other systemic therapies (Table 3). The remaining patients demonstrated significant improvement without full resolution.

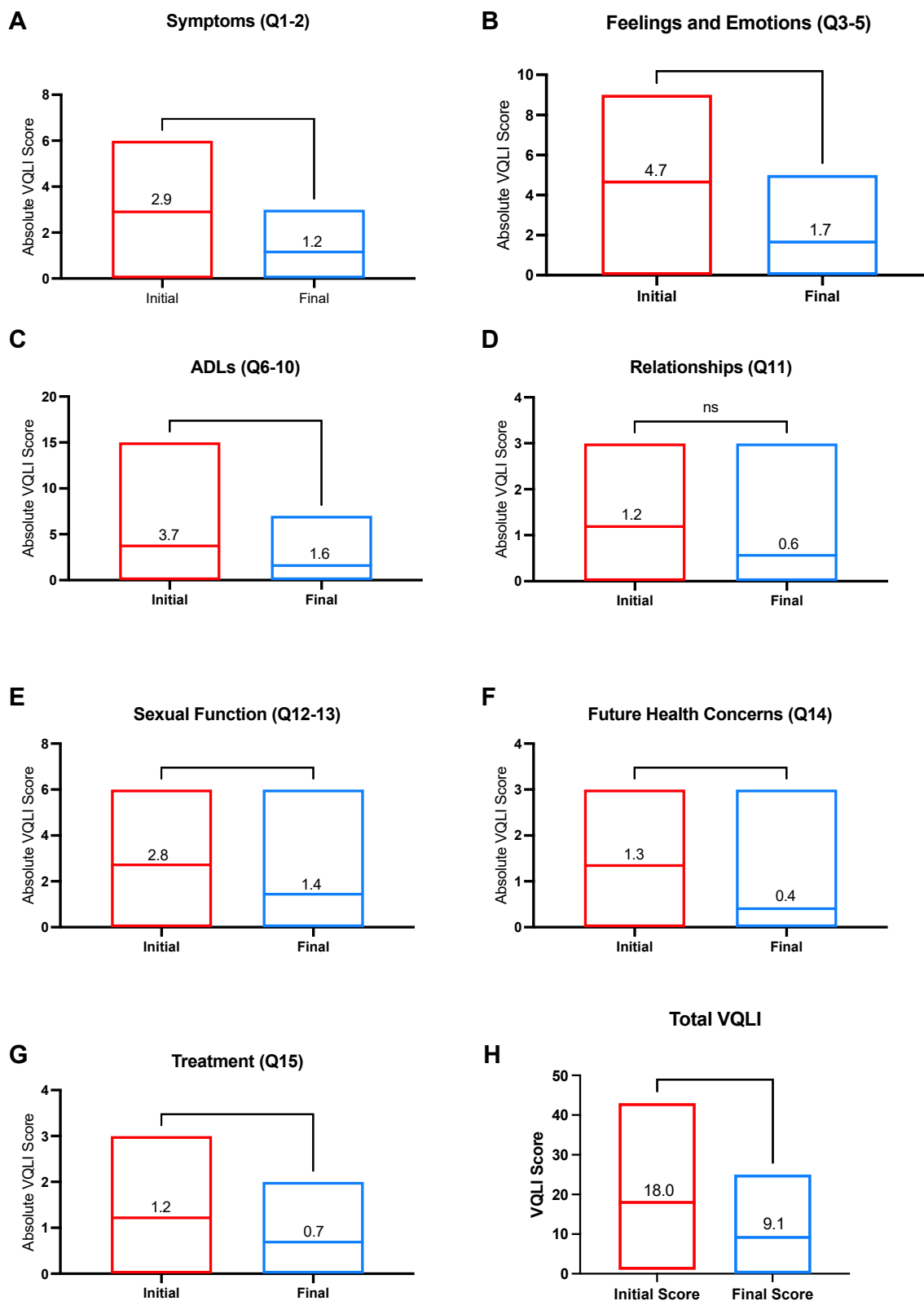
Methotrexate (10-15mg weekly) is the first line systemic agent in our study, followed by acitretin (10-20mg daily). Acitretin demonstrated greater efficacy in achieving complete clearance compared to methotrexate (33.3% versus 13.3%).

Among biologic agents, secukinumab (administered 300mg monthly (n = 7) or fortnightly (n = 1) was most frequently used, only because it was available on compassionate grounds at the time. This support has now been withdrawn, and patients are required to fund the medication themselves. Biologic agents demonstrated variable response times, with secukinumab achieving complete clearance in 5 patients over an average of 3.8 months. One patient failed to achieve complete clearance with methotrexate and secukinumab, however was able to achieve clearance with bimekizumab in 3 months. Tildrakizumab achieved complete clearance in a single case in 5 months. Phototherapy was successful in select cases, achieving complete clearance in an average of 8.6 weeks, while acitretin required 5.3 months for resolution.

Potent (class III) and very potent (class IV) corticosteroids were used safely in our cohort with no adverse effects observed under supervision. 2 patients stopped acitretin due to side-effects of hair loss whilst 2 patients stopped methotrexate due to nausea and fatigue. There were no adverse effects noted in patients treated with biologic agents.

#### 2.4.5 Vulval Quality of Life

The median VQLI score significantly improved from  $18.0 \pm 9.4$  at baseline ( $n = 124$ ) to  $9.2 \pm 7.6$  at the end of follow-up ( $n = 48$ ) ( $p < 0.0001$ ) (Figure 3). Significant improvements were observed across all quality-of-life domains except for 'Relationships'. The largest percentage improvements were noted in 'Future Health Concerns' (69.2%,  $p < 0.001$ ), 'Feelings and Emotions' (63.4%,  $p < 0.001$ ), 'Symptoms' (58.6%,  $p < 0.001$ ), and 'Activities of Daily Living' (56.8%,  $p < 0.001$ ). Less marked improvements were seen in 'Sexual Function' (50.0%,  $p = 0.008$ ) and 'Treatment' (41.7%,  $p = 0.0181$ ). While there was a 50.0% improvement in 'Relationships', it was not statistically significant.



**Figure 3.** Box plot showing absolute Vulval Quality of Life Index (VQLI) at initial visit (n = 125) and follow-up (n = 48). (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. (h) Comparisons of absolute total VQLI score. Median, minimum and maximum values are outlined.  $p < 0.05$ ,  $**p < 0.01$ ,  $***p < 0.001$ ,  $****p < 0.0001$ .

## 2.5 Discussion

This study is the largest single-cohort investigation to date examining the clinical symptoms and management of vulval psoriasis. It is the first to assess the proportion of patients requiring systemic treatment, with 13.1% needing systemic agents specifically for vulval disease. Our findings highlight a diagnostic delay of 10 years, highlighting that genital psoriasis remains under-recognised and underscoring the importance of proactive screening, personalised treatment strategies, and a re-evaluation of criteria for prescribing biologic agents.

Vulval psoriasis presents as an erythematous patch or thin plaque with the classic well-demarcated edges present in just over half of our cohort. Our study highlights an important diagnostic feature—scale buildup in the sulcus, complementing previous findings on common involvement of the labia majora, perineum, and labia minora (Ryan et al., 2015) (Figure 1). It is important however to appreciate that the well-demarcated edge expected presents in half of patients with vulval psoriasis. This may be due to prior treatment. It is also important to understand that although the vulval vestibule may be involved, the vagina is not, differentiating psoriasis from conditions such as chronic vulvovaginal candidiasis, lichen planus and vulval fixed drug eruption.

A thorough understanding of its key features is crucial for clinicians to effectively distinguish vulval psoriasis from other erythematous vulval dermatoses (Table 4). Pruritus was a common symptom, followed by pain and fissuring, consistent with existing literature (Cather et al., 2017; Meeuwis & van Rossum, 2012; Yang et al., 2018). There was a significant diagnostic delay of 11 years in our cohort, which may stem from inadequate clinician-patient discussions and examinations (Cather et al., 2017; Meeuwis et al., 2011). Proactive screening for genital involvement should be routine in clinical history and examination.

**Table 4. Summary of Differential Diagnoses for Vulval Psoriasis**

Condition	Key features	Typical distribution	Distinguishing points
Vulval psoriasis	Well-demarcated erythematous patches or thin plaques may involve modified mucous membrane but not vagina	Labia majora, interlabial sulcus, labia minora, perineum and perianal area. Vagina not involved	Extension into natal cleft Accumulation of macerated scale in the interlabial sulcus
Chronic vulvovaginal candidiasis	Erythematous patches with satellite pustules or papules on adjacent skin Associated vaginitis and scanty white discharge	Vagina, labia minora, interlabial sulcus, perineum, intertriginous areas	Continuous pruritus pain and dyspareunia with premenstrual exacerbation Worsening with antibiotics
Atopic dermatitis	Poorly demarcated erythematous plaques with scaling, excoriation and lichenification	Labia majora, perineum and perianal areas Vagina not involved	Personal or family history of atopy
Allergic contact dermatitis	Erythematous patches with vesicles or erosions Intense itching, burning and stinging	Depends on exposure, can involve the mons pubis to thighs May involve vagina if substance was inserted	History of allergen exposure Usually acute onset (within minutes to 24 hours)
Vulval fixed drug eruption	Erythematous symmetrical patch with an erosive vulvitis	Vulva, vagina, perineum, may extend to upper thighs	Drug exposure, most often NSAIDs, paracetamol and statins
Vulvovaginal lichen planus	Erythematous patches with erosions and fissuring. Scarring and vaginal involvement common	Vulva, perineum, perianal areas. Vagina often involved Oral involvement may occur	Erosions, severe pain and dyspareunia, scarring

Topical corticosteroids (TCS) remain the first-line treatment for vulval psoriasis and the only treatment that has received approval in the medical literature (Hong et al., 2021). Higher-potency TCS in short intervals may often be required for resistant cases. However, there are many more effective treatments for genital psoriasis than simply using TCS and indeed the entire spectrum of medications that are available to treat psoriasis on other parts of the skin can and should be used. The fact that, as a specific entity, this has received scant attention in the literature limits our ability to treat effectively.

Systemic therapies are required in a small subset of patients with treatment-resistant vulval psoriasis. Although acitretin was more effective in achieving complete clearance compared to methotrexate, its use was limited to post-menopausal women due to its teratogenic potential and extremely long half-life. Biologics were more successful in achieving complete clearance, often doing so within 3-6 months.

The evidence for the use of systemic agents in vulval psoriasis is limited to small case reports or series. For instance, oral dapsone (100mg daily) cleared genital psoriatic lesions within 4 weeks in one reported patient (Guglielmetti et al., 2012), while mycophenolate mofetil (500mg twice daily) resulted in partial response at 2 months in another (Guglielmetti et al., 2012). A recent phase 3 study (DISCREET) showed that 39.6% of patients treated with apremilast (30mg daily) achieved a modified genital Physician's Global Assessment (PGA) response of 'clear' or 'almost clear' at week 16, compared to 19.5% in the placebo group.

It is logical to assume that treatments that are effective on the rest of the skin will also treat vulval psoriasis. Recent literature has seen a growing focus on the use of biologics for the treatment of genital psoriasis. The first randomised controlled trial on this condition (IXORA-Q) demonstrated that ixekizumab provided rapid and sustained improvements in symptoms, quality of life, and sexual well-being for up to one year (Ryan et al., 2018). Interim results from the ongoing GULLIVER study looking at guselkumab which includes 200 patients, reported that 76.5% of participants achieved a

genital PGA score of 'clear' or 'almost clear' at 12 weeks (Bonifati et al., 2025). Comparative studies suggest that anti-IL-17 agents (e.g., ixekizumab, secukinumab) and anti-IL-12/23 agents (e.g., ustekinumab) demonstrate superior efficacy in genital psoriasis compared to TNF- $\alpha$  inhibitors (e.g., adalimumab, etanercept, certolizumab) (Burlando et al., 2020). However, a recent retrospective study found no significant difference in the achievement of PGA 0/1 between IL-23 and IL-17 inhibitors in genital psoriasis among 136 patients (Mastorino et al., 2023). Additionally, bimekizumab, a novel IL-17F inhibitor, demonstrated high efficacy, with 98.4% of patients achieving a genital PGA score of 'clear' at 16 weeks in a retrospective case series of 56 patients (Orsini et al., 2024). With the increasing availability of biologics for psoriasis, further comparative studies are essential to evaluate their specific efficacy in treating genital psoriasis.

Although the availability of biologic agents for psoriasis has significantly grown over the recent years, the lack of Pharmaceutical Benefits Scheme (PBS) coverage in Australia limits access for patients with purely genital disease, leaving availability reliant on limited compassionate supply from pharmaceutical companies. The Pharmaceutical Benefit Scheme (PBS) supports approval for special site psoriasis (face, palms and soles) but not genital disease. In the authors' opinion, this policy should be revised to include genital disease, as it would provide patients with a dramatic improved quality of life and mental wellbeing. Although all patients in our study requiring biologics were able to obtain compassionate supply, this process posed challenges. Treating dermatologists faced administrative burdens, pharmacist misunderstandings regarding compassionate use, and delays in medication access while awaiting pharmaceutical company approvals. For patients, there was the constant uncertainty of potential withdrawal of support, further complicating long-term management. Given the distinct psychosocial and functional effects of genital psoriasis, the authors propose that disease severity be measured similar to the PASI calculation used for face, hand and foot.

Additionally, despite treatment, significant burdens on sexual function and relationships persist. Compared to previous studies looking at female vulval conditions using the VQLI, the quality-of-life impact of vulval psoriasis lies between that of erosive conditions like vulval lichen planus and

sometimes asymptomatic but scarring conditions like vulval lichen sclerosus (Wu et al., 2022). Vulval psoriasis can cause notable sexual distress and stigmatisation (Cather et al., 2017; Meeuwis et al., 2011; Ryan et al., 2015), particularly among women (Alpsoy et al., 2020; Hawro et al., 2017). Although a prior study noted improvement in sexual distress with treatment of genital lesions (Meeuwis et al., 2015), however this study was limited to only 17 women, highlighting the need for more research in this area.

This retrospective study is limited by the potential for observer bias, as reviewing clinical photographs of patients with established diagnoses may lead to an overestimation of clinical features. Additionally, limitations stemming from the single-referral centre study design include variations in individual practice patterns and a potential bias toward encountering diagnostically or management-challenging cases.

## **2.6 Conclusion**

Our study underscores that vulval psoriasis is under-recognised and undertreated, with substantial impacts on quality of life. The considerable need for systemic therapy emphasises the importance of proactive screening, tailored management approaches and the need to review criteria for prescribing biologic agents. Clinicians should prioritise early detection and thorough assessments to effectively alleviate the disease burden on patients' quality of life.

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## **Chapter 3: Understanding and Managing Paediatric Vulval Psoriasis**

### **3.1 Abstract**

Paediatric vulval psoriasis in females is under-recognised and under-treated due to its nonspecific clinical appearance. This paper aims to describe the signs and symptoms of paediatric vulval psoriasis and treatment strategies used by our group. A retrospective cohort study was undertaken at a private paediatric dermatology referral practice from January 2016 to December 2022. Clinical data were prospectively collected and recorded in an online patient database. Treatment regimens were individualised and titrated to clinical response.

In 100 paediatric females with vulval psoriasis, the most common presentation was an erythematous vulval eruption (97%) which was well-demarcated in 52% of children and appeared as a plaque in one-fourth. The perianal skin was involved in 48% of cases. Extragenital psoriasis was present in 69% of patients. Most children responded to initial induction treatment with moderate-potency topical corticosteroid ointment followed by a maintenance with topical tar solution. Systemic treatment was not required for purely vulval psoriasis compared to 3% of children with extragenital psoriasis. Vulval psoriasis in paediatric females present as a chronic erythematous vulvitis, with perianal involvement in half the cases, but without vaginitis. It is a remitting and relapsing skin condition that requires long-term topical management.

### **3.2 Introduction**

Psoriasis is a common, chronic inflammatory condition that affects approximately 2% of the global population, with approximately one-third of cases starting in childhood (Kim et al., 2021). Some forms of paediatric psoriasis are well-recognised, for example napkin psoriasis and guttate psoriasis (Eichenfield et al., 2018). However psoriasis can also involve the genital area, where diagnosis is more challenging due to the absence of the characteristic scale and red plaques (Fischer, 2010; Kapila, Bradford and Fischer, 2012). Particularly in pre-pubertal females, psoriasis affecting the vulva often presents as persistent or episodic vulval erythema and is often labelled as ‘non-specific vulvovaginitis’ (Fischer, 2010). This study aims to perform a clinical audit of vulval psoriasis in children focusing on its clinical presentation, bacteriology, and treatment strategies.

### **3.3 Method and Methods**

This study is a retrospective chart review of prospectively collected data from a single private paediatric dermatology referral practice. All patients and their parents gave their informed consent. The study has been approved by the Northern Sydney Local Health District Human Research Ethics Committee (2023/ETH01106).

#### **3.3.1 Study Population and Inclusion Criteria**

All children were reviewed in person by a consultant dermatologist with significant experience in vulval dermatology. The diagnosis was made based on clinical appearance (erythematous patch or plaque, and scale in the interlabial sulcus), family history and signs of psoriasis on other parts of the skin. Children diagnosed with vulval psoriasis were prospectively tagged at time of diagnosis. The patient database was searched between January 2016 and December 2022. All children who were females under 18 years of age at diagnosis, had clinical photographs and/or clinical signs documented and reviewed in clinic at least on two occasions (initial and follow-up) were included in the study. Individuals with overlapping diagnosis such as vulval lichen sclerosus or with incomplete data were excluded.

Medical records and clinical photographs were reviewed to collect the following data: age of onset, symptoms reported, age of diagnosis, features present on clinical photographs and their anatomical location, any microbiology results and treatment(s) initiated.

#### **3.3.2 Statistical Analysis**

Study data were collected and managed using a Microsoft Excel 2023 database (Microsoft Corporation, Redmond, Western Australia). Data were analysed using descriptive statistics of variables studied and expressed as a sum or mean  $\pm$  standard deviation. Statistical analysis was performed in GraphPad Prism Version 8.3 (GraphPad Software, 2019). Statistical significances were calculated using either the one-way ANOVA or student's t- test where appropriate. Significant results

were expressed using asterisks: \*P < 0.05, \*\*P < 0.01, \*\*\*P < 0.001. This convention was used throughout.

### **3.4 Results**

#### **3.4.1 Patient Demographics**

One-hundred females aged 18 and younger were diagnosed with vulval psoriasis based on history and clinical examination (Table 5). The mean age of onset was 4.5 years (range 0-18 years), with 87% (87/100) being prepubertal at time of symptom onset. The mean time to diagnosis was 1.9 years (range 0.5 months to 8 years). A first-degree family member with psoriasis was documented in 42.9% (42/98) of children. Sixty-nine percent (69/100) of patients had evidence of psoriasis at distant sites, such as nail pitting, post-auricular or hairline scaling, and lichenification of dorsum of knees or elbows. However, only 12% (8/69) of these children were suspected to have psoriasis prior to referral to our centre. Information on the presence of possible irritant triggers resulting in Koebnerisation was collected in 64% of patients; the most common factor was night nappies (23%, 15/64), followed by ballet lessons with occlusive leotards (11%, 7/64) and swimming lessons in chlorinated pools (11%, 7/64).

Seventy percent (70/100) of children were started on treatment either by their general physician or self-initiated by parents. The most common initial treatment was intermittent courses of low-to-moderate potency TCS (57%, 40/70) such as hydrocortisone acetate 1% ointment or methylprednisone aceponate 0.1% ointment. This was followed by an antifungal cream in 36% (25/70) of children in the form of either clotrimazole 2% cream alone or in combination with hydrocortisone 1% cream. Ten percent (7/70) of children previously had a form of deworming treatment. Antibiotics were less common, with 7.1% (5/70) of children having had oral antibiotics and 4.3% (3/70) having had topical antibiotic ointment such as mupirocin 2% ointment. In terms of over-the-counter treatment, 20% (14/70) were already using a barrier cream and 15.7% (11/70) were using emollients regularly.

**Table 5. Characteristics of 100 paediatric cases of vulval psoriasis referred to a single dermatology referral practice.**

<b>Demographics</b>	<b>Number (%)</b>
Age of onset (years)	4.6 (range 0-18)
Prepubertal	87/100 (87%)
Post pubertal	13/100 (13%)
Duration of symptoms prior to diagnosis (months)	22.2 (range 0.5-96)
Positive family history	42/98 (42.9%)
Secondary infection*	13/100 (13.0%)
Staphylococcus aureus	8/13 (61.5%)
Candida albicans	3/13 (2.3%)
Streptococcus pyogenes	2/13 (1.5%)
Psoriasis present at distant sites	69/100 (69%)
Diagnosed prior to appointment	8/69 (12%)
Previous treatment	70/100 (70%)
Low potency steroid cream	40/70 (57.15)
Antifungal cream	25/70 (35.7%)
Deworming treatment	7/70 (10%)
Oral antibiotics	5/70 (7.1%)
Topical antibiotics	3/70 (4.35)
Barrier cream	14/70 (20%)
Emollients	11/70 (15.7%)
Tar	1/70 (1.4%)
Symptoms	
Pruritus	58/100 (58%)
Pain or fissuring	50/96 (52.1%)
Discharge	7/97 (7.2%)
Dysuria	14/97 (14.4%)
Features	
Non-specific erythema	97/100 (97%)
Well demarcated edge	52/100 (52%)
Raised plaque	25/100 (25%)
Lichenification	11/100 (11%)
Scale	50/100 (50%)

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Topical treatment

Hydrocortisone acetate 1% ointment	32/100 (32%)
Desonide 0.05% lotion	2/100 (2%)
Methylprednisolone aceponate 0.1% ointment	74/100 (74%)
Coal tar 2% solution	95/100 (95%)

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Legend:

\* 62/100 patients had clinical suspicion of infection on review and received a vulvovaginal microbiological swab

### 3.4.2 Clinical Symptoms and Features

The most common symptoms reported were pruritus (58%, 58/100) or pain due to fissuring (52%, 50/96). A minority of patients reported discharge (7%, 7/97) and dysuria (14%, 14/97). The varying sample size across different symptoms reflects incomplete data reporting, as not all patients consistently provided responses to each symptom-related question.

Erythema was the most common clinical feature, present in 97% (97/100) of patients. This was followed by an erythematous well-demarcated bilaterally symmetric patch (52%, 52/100) and scale (50%, 50/100) which was most obvious in the interlabial sulcus between minora and majora. Less commonly noted were a raised plaque (25%, 25/100) and lichenification (11%, 11/100). The labia majora (55%, 55/100) and interlabial sulcus (55%, 55/100) were more commonly involved, followed by the perianal skin (48%, 48/100) and perineum (39%, 39/100).

Vaginal or vulval swab for microbiological culture were performed in 62 patients with clinical suspicion of infection and positive results were found in thirteen patients. The most common pathogens were *Staphylococcus aureus* (n = 8), *Candida albicans* (n = 3; only isolated in post pubertal children) and *Streptococcus pyogenes* (n = 2). These patients were treated appropriately with oral antifungal or antibiotics.

### 3.4.3 Management

Almost all patients (95%, 95/100) were treated with a combination of 2% coal tar solution (LPC) and a moderate-potency TCS. The most common TCS used was methylprednisone aceponate 0.1% ointment (73%, 73/100), followed by hydrocortisone acetate 1% ointment (32%, 32/100).

Three percent (3/100) of patients required systemic therapy; however, all were started on treatment for their extragenital psoriatic disease. The therapies included phototherapy (n = 2) and oral methotrexate (n = 1). In addition to this, one patient with vulval and extragenital psoriasis had already been

commenced on adalimumab by a paediatric rheumatologist for juvenile idiopathic arthritis prior to review. Notably, no children required systemic therapy for purely vulval disease.

Forty-six percent (46/100) of all patients returned for follow-up with duration of follow up ranging from 2 weeks to 6 years. Of this group, 91.3% (42/46) of the patients responded to topical treatment with resolution of symptoms and objective normalisation of the skin exam.

### 3.5 Discussion

Psoriasis typically manifests in adults with characteristic well-demarcated erythematous plaques with overlying silver scale (Kim et al., 2021). However, vulval psoriasis in children lacks these typical features, making diagnosis particularly challenging (Morris et al., 2001; Beck et al., 2018; Eichenfield et al., 2018; Forward, Lee and Fischer, 2021). This is evident in our study where there was an average delay to diagnosis of nearly two years. Therefore, there is a clear need to better characterise the distinctive features of vulval psoriasis to facilitate quicker and more accurate diagnosis.

Our study describes the key clinical features of paediatric vulval psoriasis, highlight clues to help distinguish it from other common conditions. In our cohort, paediatric vulval psoriasis frequently involves the labia majora and interlabial sulcus, consistent with a previous clinical audit (Kapila, Bradford and Fischer, 2012). This distribution is distinct from the well-recognised psoriatic napkin eruption of infants which affects the mons and inguinal folds (Beck et al., 2018). The presence of presence of macerated scale on underwear or accumulation in the interlabial sulcus may be mistaken for discharge. The child may report stinging on urination due to fissuring secondary to psoriasis, rather than dysuria from a urinary tract infection. Careful history taking, thorough examination and investigations is required to establish an accurate diagnosis.

The diagnosis of vulval psoriasis in children without psoriasis elsewhere or a family history can be challenging and may seem like a diagnosis of exclusion. In many cases, as seen in our cohort, the current diagnosis is often delayed due to failed treatments with low-potency TCS, antifungal creams and oral antibiotics. However, the symptoms of vulval psoriasis often recur without long-term maintenance treatment. Diagnosis relies on careful examination and recognising subtle signs like distal disease, along with taking a detailed history. Paediatric psoriasis has been noted to present more subtly than in adults, with thinner, less scaly and poorly-defined patches (Cordoro, 2008; Forward, Lee and Fischer, 2021). In such cases, a history of cradle cap, diaper dermatitis, and positive first-degree family history with psoriasis have been found to serve as valuable diagnostic clues (Forward, Lee and Fischer, 2021). Although the high incidence of these conditions means that their presence

alone cannot reliably diagnose paediatric psoriasis, they can raise suspicion, particularly when accompanied by other suggestive clinical features. The importance of family history is reinforced by our finding that 42.9% of children in our cohort had an affected first-degree relative, consistent with previous studies showing that 30-71% of children with psoriasis have an affected first-degree relative (Morris et al., 2001; Griffiths and Barker, 2007; Kapila, Bradford and Fischer, 2012; Eichenfield et al., 2018).

There is a paucity of literature on the management of vulval psoriasis in children (Hong et al., 2021). Our treatment approach focused on symptom relief, minimising the risk of Koebnerisation, and environmental modification. A combination of methylprednisolone aceponate 0.1% ointment (a moderate potency TCS) and 2% LPC solution proved successful for most children in our cohort. For symptomatic children, initial treatment with a moderate-potency TCS aims to settle the acute episode. Once when the flare subsides, coal tar solution is used for maintenance, with the re-introduction of TCS for any subsequent flares.

Whilst methylprednisolone aceponate may not be universally available, any TCS of similar potency can be substituted. It is important to note that 1% hydrocortisone, although more readily accessible, is often insufficient to manage psoriasis flares, even in small children. Coal tar is only introduced in the maintenance period as it may sting when applied to inflamed skin during the acute flare, potentially resulting in treatment refusal in the authors' experience. In long term, management coal tar is usually well tolerated and safe (Kalb et al., 2009; Hong et al., 2021). Calcineurin inhibitors such as tacrolimus and pimecrolimus are alternative steroid-sparing options that have been shown to be effective in case reports and small case series of patients with paediatric genital psoriasis (Mansouri and Farshi, 2006; Brune et al., 2007; Hong et al., 2021). However, the burning sensation and irritation often limit their use in paediatric patients (Mansouri and Farshi, 2006; Altobelli et al., 2007; Menter et al., 2011).

Educating parents about misconceptions surrounding their child's condition is essential (Menter et al., 2011). Patient education should include guidance on irritant minimisation and acknowledging the

chronic nature of the condition (Fischer, 2010). Frequently asked questions about the likelihood of children outgrowing the condition remains uncertain. While the prognosis of childhood-onset psoriasis is generally unknown, considering the genetic nature of the condition, complete remission is unlikely. It is also known early onset of psoriasis is associated with a higher severity of disease and an increased risk of co-morbidities (Altobelli et al., 2007; Griffiths and Barker, 2007), although further research is needed to see if this holds true for individuals with exclusive genital disease.

The limitations of this study are its single centre design and a low-follow-up rate which may result in attribution bias. Approximately half of children returned for review and patients not requiring further specialist advice were returned to the care of their family physician. This practice may encounter a higher proportion of diagnostically challenging cases as it is a specialist referral centre. Furthermore, there were no patients in our cohort with darker skin tones, which limits the applicability of our findings to skin of colour patients.

### **3.6 Conclusion**

The diagnosis of vulval psoriasis in children is often difficult as its presentation often lacks the characteristic features of psoriasis. In any child with persistent erythematous vulvitis and a personal or family history of psoriasis, it is important to consider this as a differential diagnosis and to perform a full skin examination to look for other signs of the disease. In our cohort, vulval psoriasis presents as well-demarcated red patches or thin plaques. Scale is not uncommon but is macerated and found in the interlabial sulcus. The labia majora and interlabial sulcus were most involved and in half the cases the perianal skin was involved. The rest of the skin may be subtly affected with nail pitting, hairline and post-auricular erythema, and scaling and lichenification of the dorsal surfaces of elbows and knees. Most cases can be treated with a moderate-potency TCS for treatment induction and flares and topical tar solution for maintenance.

### 3.6 References

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## **Chapter 4: Summary and Future Directions**

### **4.1 Summary of Findings**

This thesis aimed to evaluate the presentation and management of vulval psoriasis in the Australian context, addressing a field that remains under-researched. The appropriate use of topical corticosteroids, systemic therapies, and newer biological agents remains under-researched.

Firstly, we critically appraised current evidence on the use of topical and systemic therapies for treating genital psoriasis. Our research provided a real-world overview on the management of genital psoriasis in Australian women. Our studies identified that approximately 10% of adult women with purely vulval disease require systemic therapies. However, these treatments are difficult to access under the PBS, highlighting the need to expand the PBS eligibility criteria to include genitals as a special site.

Secondly, our studies underscored the significant impact of genital psoriasis on QoL. While treatment improves symptoms, the condition leaves lasting effects on sexual function, relationships and treatment-related experiences. Its impact is comparable to other vulval dermatoses such as vulval lichen planus and vulval lichen sclerosus. Clinicians should proactively address these domains with patients.

Lastly, we identified the clinical signs and symptoms of vulval psoriasis in the paediatric cohort. Diagnosis is challenging however a key diagnostic clue is a persistent erythematous vulvitis with the presence of macerated scale in the interlabial sulcus. We also described the current management of vulval psoriasis in Australian children, finding that systemic treatment is not required for purely vulval presentations in this group.

## 4.2 Strengths and Limitations

This thesis represents the largest single-cohort observational study in Australia focussing on the clinical presentation and management with genital psoriasis. It offers a unique perspective, given that many advanced therapies discussed in international literature are not yet available or not accessible in Australia. Additionally, we employed a validated QoL tool specifically designed for female genital disease that allowed us to pinpoint specific domains that require improvement.

However, this retrospective study has its limitations. The study's cohort is drawn from a sub-specialist vulval dermatology practice which may see higher rates of severe, refractory or challenging disease that would be otherwise seen in general dermatology or primary care population. In a UK study based on data from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR), 6.5% of patients with chronic plaque psoriasis were treated with biologics. We would expect a similar proportion of patients with genital only disease to require biologics. However, the proportion in our cohort is higher at 13%, as it reflects a specialist dermatology practice led by a clinician with expertise in vulval disease, where many patients are referred for second- or third-opinion consultations for persistent or refractory symptoms. Consequently, our cohort represents a selected referral population rather than the broader psoriasis population seen in general practice or general dermatology clinics. Additionally, systemic treatment is likely higher in this specialist population with familiarity and access to biologics.

Additionally, the VQLI data in Chapter 2 are subject to selection and attrition bias, which limits the validity of the quality-of-life findings. Of the 350 adult patients in the cohort, only 125 (35%) completed a VQLI at baseline, and 48 (13.7%) completed two assessments. This represents a limited sample, with those who completed the surveys potentially differing systematically from those who did not, such as being more motivated, more engaged with care, or having more severe disease.

Incomplete follow-up introduces attrition bias, which can influence longitudinal outcomes. Patients with well-controlled disease may have skipped follow-ups, while those with ongoing symptoms may be overrepresented. These findings highlight the need for strategies to improve data capture, such as

reminders, electronic surveys, or the establishment of a registry for more complete longitudinal QoL assessment.

Additionally, only a few patients with skin of colour were included in our adult cohort, and none in the paediatric cohort. Specific data was not collected on the presentation of genital psoriasis in skin of colour patients, limiting the external validity of our findings. Furthermore, as this is a sub-specialist vulval dermatology clinic, the cohort is likely to have lower rates of socioeconomic disadvantage and obesity, which may limit the generalisability of our results to broader populations.

There is also potential observer bias from reviewing clinical photographs of patients with established diagnoses. The impact of this bias was minimised by using digital consultation notes alongside photographic evidence to confirm clinical features.

### **4.3 Future Directions**

Future large-scale studies should compare systemic agents using standardised clinical outcome measures and QoL instruments. Establishing a national registry would enable systematic, standardised data collection on genital psoriasis and its treatments, improving understanding and management of the condition. These studies must address the under-representation of females, particularly those of skin of colour and the unique challenges posed by female anatomy when using topical therapies. Our findings also indicate a higher rate of pruritus in genital psoriasis compared with classic extra-genital sites. Given that pruritus is a particularly debilitating symptom, further research into its mechanisms and optimal management is warranted. Such findings could support the revision of PBS criteria to include the genitals as a special site, enabling patients with genital psoriasis to access treatments that significantly improve their QoL and mental health.

### **4.4 Conclusions**

Genital psoriasis remains under-recognised and under-treated, with profound impacts on QoL that are not fully alleviated by current treatments. Despite significant advances in psoriasis therapies, limited data exist on the efficacy and safety of treatments for genital skin. The high need for systemic therapies underscores the importance of proactive screening, individualised management approaches, and revisiting prescribing criteria for biologic agents.

## Appendix

### 1. Vulval Quality of Life Survey

#### THE VQLI QUESTIONNAIRE

1. Over the past month how itchy and/or painful and/or stinging and/or burning has your vulvar skin felt?

- Very much
- A lot
- A Little
- Not at all

2. Over the past month, how often have you experienced any of the following: pain when urinating, heat intolerance, vaginal discharge, wetness?

- Very much
- A lot
- A Little
- Not at all

3. Over the last month how embarrassed or self-conscious have you been because of your vulvar skin symptoms?

- Very much
- A lot
- A Little
- Not at all

4. Over the past month how much has your vulvar skin impacted your body image or sense of self? (For instance, sense of femininity, feeling isolated, feeling different)?

- Very much
- A lot
- A Little
- Not at all

5. Over the last month how distressed or anxious have you felt because of your vulvar skin problem ?

- Very much
- A lot
- A Little
- Not at all

6. Over the last month how much has your vulvar skin problem influenced your choice of clothing (For instance underwear, jeans, gym clothes)?

- Very much
- A lot
- A Little
- Not at all

7. Over the last month how much has your vulvar skin problem disturbed your sleep?

- Very much
- A lot

- A Little
- Not at all

8. Over the last month how much has your vulvar skin problem made it difficult for you to go shopping, look after yourself or your family, home and garden?

- Very much
- A lot
- A Little
- Not at all

9. Over the last month how much has your vulvar skin problem made it difficult for you to attend social or leisure engagements? (For instance, going out for dinner or bars, dating, sport, exercise class, gym)

- Very much
- A lot
- A Little
- Not at all

10. Over the last month how much has your vulvar skin problem interfered with your ability to concentrate on work or study?

- Very much
- A lot
- A Little
- Not at all / Not applicable

11. Over the last month how much has your vulvar skin problem created problems with a partner or precluded you from pursuing a romantic relationship? (For instance, maintaining a relationship or finding a partner)

- Very much
- A lot
- A Little
- Not at all / Not applicable

12. Over the last month how much has your vulvar skin problem interfered with your sex life? (For instance, decreased libido, decreased frequency of sex, pain with sex and/or enjoyment of sex)

- Very much
- A lot
- A Little
- Not at all /Not applicable

13. Over the last month how often have you felt distressed or worried about sex because of your vulvar skin?

- Very much
- A lot
- A Little
- Not at all / Not applicable

14. How often in the last month have you been worried about long-term health implications of your vulvar skin condition? (For instance, concern about developing cancer or difficulties with fertility)

- Very much
- A lot
- A Little
- Not at all

15. Over the past month, how much of a problem has the treatment of your vulvar symptoms been (For instance messy, time consuming, expensive, inconvenient)?

- Very much
- A lot
- A Little
- Not at all / Not applicable

Overall VQLI Score Range	Impact on Quality of Life
0 to 5	minimal
6 to 13	mild
14 to 23	moderate
24 to 37	severe
38 to 45	very severe

Vulvar Quality of Life Index. Previously published in Saunderson RB, Harris V, Yeh R, Mallitt KA, Fischer G. Vulvar quality of life index (VQLI) – A simple tool to measure quality of life in patients with vulvar disease. Australasian Journal of Dermatology. 2020;61(2):152-7.