

Quality of life in Patients with Seborrhoeic Dermatitis in KwaZulu-Natal, South Africa

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(Please refer to Appendix L and Appendix M)

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LIST OF ABBREVIATIONS

QOL	Quality of Life
DLQI	Dermatology Life Quality Index
KZN	KwaZulu Natal
SD	Seborrhoeic Dermatitis
SA	South Africa
HIV	Human Immunodeficiency Virus
ARVs	Antiretrovirals
VS	Versus

ABSTRACT

Background: In developing countries, the quality of life (QOL) of skin diseases has rarely been investigated. This is the first study in South Africa (SA) that assesses the quality of life of patients presenting with seborrhoeic dermatitis, correlating clinical severity and demographic parameters.

Methods: Consenting participants over the age of 18 years, with a clinical diagnosis of seborrhoeic dermatitis, were invited to take part in the study. QOL was assessed using the Dermatology Life Quality Index (DLQI). The severity of the condition was assessed by a clinician.

Results: A total of 45 patients were included in the study. The median Severity Score was 24 and the median DLQI score was 17, which equates to a “very large effect on the quality of life”. Demographic parameters do play a significant role when comparing QOL between patients. The QOL varied depending on gender, educational level, ethnic origin, home language, marital status, residence, HIV status and site of involvement.

Limitations: Small number of patients included in the study. Data collected at a single public hospital, thus may not be fully representative of our population. The protocol did not allow for capturing drug related and, in the management, the discontinuation of possibly offending drugs was not included.

Conclusion: This study highlights that QOL tools are valuable in providing a patient’s own perspective of their debilitating skin condition.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Seborrhoeic dermatitis is a chronic superficial inflammatory skin disease characterised by scaly patches of skin that may present with varying degrees of erythema and pruritus ^[1].

The definitive aetiology of seborrhoeic dermatitis is unknown; however proliferation of the yeast *Pityrosporum ovale* now known as *Malassezia furfur* is believed to play an important role in the pathogenesis of the disease ^[2,25].

In adults the course of seborrhoeic dermatitis is characterised by remissions and exacerbations, which are independent, of the administered treatments ^[1]. Outbreaks are common under conditions of stress, fatigue, and depression ^[3].

While the disease rarely causes serious complications (erythroderma, secondary herpetic infections and secondary bacterial infections) it usually leads to a marked aesthetic deterioration that leads to emotional and social difficulties for the affected individual ^[1].

Affected patients suffer from poor self-esteem, difficulties in social interactions and significant psychological distress ^[4]. It is therefore, critically important that a clinician evaluate the extent to which the disease impacts a patient's quality of life. Measurement of this impact may be valuable in clinical practice, in the evaluation of new drug therapy and clinical and health service research. Methods of measuring QOL in dermatology can be done at the bedside and include dermatology specific measures such as the Dermatology Life Quality Index (DLQI), the Dermatology Specific Quality of Life (DSQL), the Dermatology Quality of Life Scales (DQOLS) and Skindex questionnaires. Disease specific measures include the Acne Disability Index (ADI), Psoriasis Disability Index (PDI) and the Psoriasis Life Stress Inventory (PLSI).

This is the first study in South Africa (SA), performed in the ILembe District, KwaZulu Natal (KZN) that assesses the QOL of patients with seborrhoeic dermatitis correlating with clinical severity and demographic parameters.

1.2 Epidemiology

The reported prevalence of seborrhoeic dermatitis in adults in the general population ranges from 1-3% [5]. Two local studies in South Africa, one conducted in Durban KwaZulu-Natal and another in Johannesburg reported an incidence of 2.4% and 32.7% respectively [6,7]. An increase in seborrhoeic dermatitis is thought to be due to the HIV endemic [5,7]. It often has a seasonal influence, being more common and, in chronic cases, often more severe in the winter months [5] and more commonly observed in American black patients [5].

There are two forms of seborrhoeic dermatitis. Infantile seborrhoeic dermatitis presents between the ages of 3 weeks and 12 months with a peak prevalence at 3 months [8]. The adult form of seborrhoeic dermatitis is far more common than infantile seborrhoeic dermatitis and affects men more than women [9]. However a population based study in the United States and a cross sectional study in Thailand showed a higher prevalence in females than males [10,11]. Seborrhoeic dermatitis may present initially around puberty correlating with the increase in cutaneous lipids resulting from androgen driven sebaceous gland development and sebum secretion [9]. Seborrhoeic dermatitis reaches its peak incidence at 40 to 60 years [9].

In addition, seborrhoeic dermatitis has a higher incidence in patients with Parkinson's disease [12], mood disorders [13] and those infected with HIV/AIDS [14,15] than in the general population. The reported prevalence of seborrhoeic dermatitis in HIV/AIDS is between 34%-83% [5]. While these co-occurring disorders have been the emphasis of the most research, studies have also shown that seborrhoeic dermatitis is associated with hepatitis C virus [16], chronic alcoholic pancreatitis [17], ischaemic heart disease [18] and various cancers [19]. It is also common in patients with genetic disorders, such as Hailey-Hailey disease [20], cardio-facio cutaneous syndrome [21] and Down's syndrome [22].

1.3 Aetiology and Pathogenesis

The exact cause of seborrhoeic dermatitis is unknown; however 3 factors are implicated in the disease: sebaceous gland secretion, colonization of *Malassezia* species and host response [5]. There appears to be a correlation between sebum levels and seborrhoeic dermatitis, as the disease is rarely seen before puberty and peaks in young adulthood and adolescence [5]. Furthermore the commonly affected areas of seborrhoeic dermatitis, correlate with the distribution of sebaceous glands [5]. In infantile seborrhoeic dermatitis, transplacental transfer of maternal androgens stimulates the growth of the infant's sebaceous glands [8]. The amount of sebum produced per se may not be a risk factor for the development of seborrhoeic dermatitis [26]. It has been proposed that the composition of skin surface lipids is the relevant factor in the development of seborrhoeic dermatitis [26]. Patients with seborrhoeic dermatitis have elevated triglycerides and cholesterol but decreased squalene and free fatty acids compared to normal controls [26]. Free fatty acids (which have an antimicrobial effect) are formed from triglycerides by bacterial lipases produced by *Propionibacterium* (*Corynebacterium*) *acnes* [26]. A resident of skin flora, *P. acnes* is markedly reduced in seborrhoeic dermatitis [26]. Seborrhoeic dermatitis may thus be related to an imbalance of microbial flora and alterations in skin lipids [26].

There is a strong association between the colonisation of *Malassezia* spp and seborrhoeic dermatitis. *Malassezia* yeasts a genus of 7 species are normal residents of the skin flora and are lipid-dependent organisms which proliferate in sebum [23]. *Malassezia furfur*, *Malassezia sympodialis*, *Malassezia obtuse*, *Malassezia sooffiae*, *Malassezia globose* and *Malassezia restricta* are common organism associated with seborrhoeic dermatitis [25]. They or their by-products cause inflammation by inducing a cytokine production by keratinocytes [24]. Furthermore, the lipase activity of *Malassezia* produces an inflammatory response by releasing fatty acids from skin lipids (sebaceous triglycerides) [24-26]. Flares of seborrhoeic dermatitis are associated with an increase in organism load of *Malassezia* spp. and an improvement in the disease after therapy is correlated with a reduction in the yeast count [25,26]. However the number of *Malassezia* organisms present on the skin does not always correlate with the presence or severity of the disorder [23]. Although a number of studies have shown a clinical response to seborrhoeic dermatitis with the use of antifungals [27-32] a recent study by Zani MB et al, shows that ketoconazole does not reduce the fungal amount in seborrhoeic dermatitis [33].

Seborrhoeic dermatitis has an increased prevalence in patients that are immunocompromised e.g. HIV/AIDS [14,15]. There is an increased humoral and cellular response noted, with an increase in the production of inflammatory interleukins, activation of the complement system and an increase in NK1+ and CD 16 + cells [5]. In addition, studies have shown that patients with seborrhoeic dermatitis have an increased irritation to sodium lauryl sulphate [5].

Certain drugs also induce a seborrhoeic like dermatitis however the mechanism is unknown. These include buspirone, auranofin, chlorpromazine, auranofin, gold, ethionamide, cimetidine, haloperidol, griseofulvin, lithium, interferon alpha, methyldopa, psoralens, methoxsalen, thiothixene, stanozolol and trioxsalen [24].

1.4 Clinical Features

Seborrhoeic dermatitis is characterised by the development of pruritic, erythematous patches with easily detachable yellow greasy scales [23]. In photosensitive skin types V-VII erythema may not be easily discernible. It tends to occur in areas that contain numerous sebaceous glands with a predilection for the scalp, eyebrows, eyelids, nasolabial creases, lips, ears, sternal area, axillae, submammary folds, umbilicus, groin and gluteal crease [34].

The milder form of the disease on the scalp manifests as dandruff (*Pityriasis sicca*). The scales are small, dry, and whitish, and they detach easily and spontaneously in steady amounts. In the more severe form of the disease, plaques are thick dry scales and range in size from a few centimeters to areas covering a large part of the scalp [1]. Other types of seborrhoeic dermatitis on the scalp include arcuate, polycyclic or petaloid patches, and psoriasiform, exudative or crusted plaques [34].



Figure 1.1: Seborrhoeic dermatitis of the forehead and scalp



Figure 1.2: Seborrhoeic dermatitis of the scalp: Pityriasis sicca



Figure 1.3: Seborrhoeic dermatitis of the scalp and retroauricular: Thick yellow greasy plaques: Pityriasis steatoides - erythema camouflaged by melanin in photo skin type V

On the face they are found on the eyebrows, around the nose, at the edge of the scalp, and on the inner surface of the auricle [1]. There is often erythema and scaling seen on the eyebrows. The lids may show yellowish-white, fine scales and faint erythema [34]. The edges of the lids may be erythematous and granular (marginal blepharitis) and the conjunctivae may be infected. In the nasolabial creases and on the alaenasi, there may be yellowish or reddish-yellow scaling macules, sometimes with fissures [34]. Folliculitis of the beard is common in men. Seborrhoeic dermatitis, in the ears may be mistaken for an infectious otitis externa. There is scaling in the aural canals, around the auditory meatus, usually with marked pruritus [34].



Figure 1.4: Seborrhoeic dermatitis of the face: Fine scaling and erythema of the eyebrows

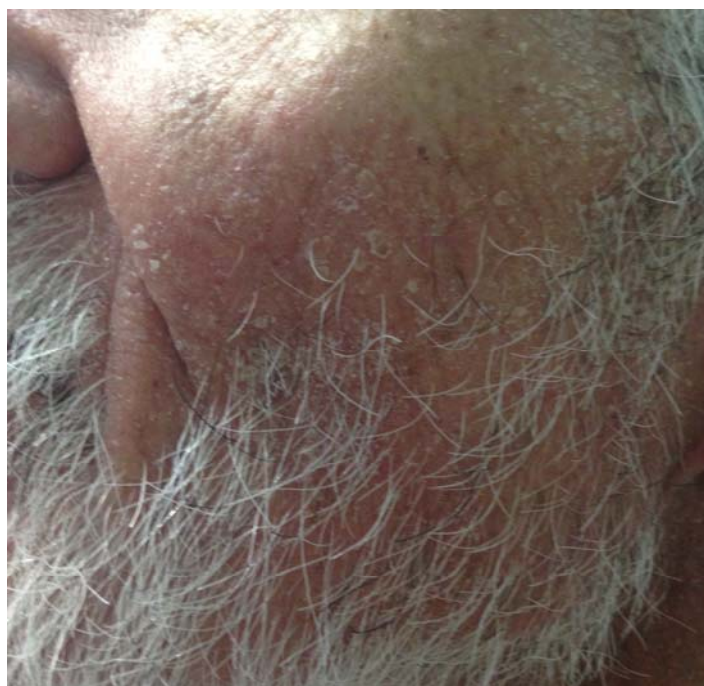


Figure 1.5: Seborrhoeic dermatitis of the beard: Fine scaling and erythema



Figure 1.6: Seborrhoeic dermatitis of the ears

They occur bilaterally in the axillae and the eruption begins in the apices and later progresses to neighbouring skin. An allergic contact dermatitis to deodorant may resemble seborrhoeic dermatitis, but differs from that of clothing dermatitis (which involves the periphery of the axillae, but spares the vault) [34].



Figure 1.7: Crusted seborrhoeic dermatitis: Intertriginous Areas

Lesions on the chest are rounded, well delineated, and reddish brown; they are located on the medial part of the chest and on the back, between the shoulder blades [34]. All of these forms are associated with varying degrees of itching [1].

Five patterns of truncal involvement have been described: [35]

- Moist, erythematous intertrigo of the infra-mammary folds, axillae, genitocrural area and umbilicus.
- The "petaloid pattern," which consists of fine scaly, polycyclic, thin plaques over interscapular area or sternum.
- 'Seborrhoeic eczematids': Annular or arcuate, round to oval, slightly scaly plaques on the trunk, sometimes with central hypopigmented clearing.
- The pityriasiform pattern imitating pityriasis rosea, comprised of 5 to 15 mm scaly lesions, oval-shape, distributed along the skin tension lines.

- The psoriasiform pattern with larger red, rounded plaques, covered with thicker scales.

Seborrhoeic dermatitis in HIV/AIDS patients may involve uncommon sites such as the extremities, involve a larger body surface area, and is more severe in patients with a CD₄ counts <200cells/microL [35].

Infantile seborrhoeic dermatitis, usually presents as yellow, greasy scales on the scalp (cradle cap) and commonly involves the vertex and frontal area [8]. The rash may also begin on the face (forehead, retroauricular areas, eyebrows, eyelids, nasolabial folds and the cheeks), and can occur in the groin, neck, umbilicus and intertriginous areas. Multiple sites may be involved and pruritus is minimum [35]. Lesions may be erythematous, scaly, hypopigmented and sometimes the infant presents with erythroderma [35].



Figure 1.8: Infantile seborrhoeic dermatitis: Scalp (Cradle Cap)



Figure 1.9: Infantile seborrhoeic dermatitis: Buttocks



Figure 1.10: Infantile seborrheic dermatitis: Groin



Figure 1.11: Infantile seborrheic dermatitis: Intertriginous Areas (Neck) – Erythema clearly seen in photo skin type V and below



Figure 1.12: Infantile seborrheic dermatitis: Intertriginous Areas (Axillae)

1.5 Differential Diagnosis

The differential diagnosis of adult seborrhoeic dermatitis includes dermatophytosis, rosacea, psoriasis, systemic lupus erythematosus, tinea capitis, tinea corporis, pityriasis rosea, secondary syphilis, pemphigus foliaceus and infective dermatitis associated with Human T-Cell Lymphotropic virus type 1 HTLV-1 (IDH). The diagnosis is usually clinical [34].

1.5.1 Psoriasis

May resemble seborrhoeic dermatitis however the distribution and type of the lesions are different [35]. Psoriatic lesions are silvery white scales which are sharply demarcated and erythematous (only in skin types I-IV) with a predilection for the extensor areas such as the elbows and knees [9]. Distinctive nail changes and a family history of psoriasis may also assist with the diagnosis [35].



Figure 1.13: Plaque type Psoriasis: Silvery well demarcated plaques



Figure 1.14: Psoriasis of the scalp



Figure 1.15: Psoriasis of the nails: Distal onycholysis and pitting

1.5.2 Rosacea

May also mimic seborrhoeic dermatitis on the face. Frequently involved areas are the nose, malar and perioral. Lesions are papulopustules and telangiectasia may be present [35].



Figure 1.16: Inflammatory papules and pustules on the nose and cheeks^[32]

1.5.3 Secondary Syphilis

Can also be misdiagnosed as seborrhoeic dermatitis as it may present with pityriasiform or psoriasiform eruptions, Palmoplantar involvement, mucosal involvement, peripheral adenopathy and positive serology may differentiate the skin conditions [35].



Figure 1.17: Secondary syphilis: Truncal lesions



Figure 1.18: Secondary syphilis: Scalp

1.5.4 Systemic lupus erythematosus (SLE)

An acute flare of SLE can present on the face as a malar eruption, however SLE rarely involves the nasolabial folds or crosses the bridge. Positive serology (antinuclear factor antibodies (ANF) and histology can confirm the diagnosis of SLE ^[35].



Figure 1.19: Systemic lupus erythematosus: Malar erythematous lesions not involving the nasiolabial folds^[35]

1.5.5 Tinea Corporis

Tinea corporis is a superficial dermatophyte infection characterized by either inflammatory or noninflammatory lesions on the glabrous skin. Typically, the lesion begins as an erythematous, scaly plaque and following central resolution, the lesion may become annular in shape. Tinea corporis may be mistaken for annular or arciform seborrhoeic dermatitis. Positive potassium hydroxide (KOH) microscopic examination and fungal culture can confirm a diagnosis of tinea corporis ^[35].



Figure 1.20: Tinea corporis

The differential diagnosis of infantile seborrhoeic dermatitis includes: ^[8]

- Atopic dermatitis
- Napkin dermatitis
- Psoriasis vulgaris
- Tinea amiantacea
- Langerhans cell histiocytosis
- Tinea capitis



Figure 1.21: Tinea capitis

1.5.6. Infective dermatitis associated with HTLV-1 (IDH)

The HTLV-1 virus is a retrovirus and has infected 10 to 20 million people worldwide with clinical manifestations in only 5 % of infected individuals ^[36].

Disease manifestations of the HTLV type 1 virus include: Adult T Cell leukaemia-lymphoma (ATL), HTLV-1 associated myelopathy (HAM) also known as tropical spastic paraparesis (TSP) and IDH ^[37].

IDH is a chronic exudative eczematous eruption ^[37], which usually presents in children older than 2 years of age ^[36,38] with resolution in adulthood. A study however conducted in KwaZulu Natal, South Africa found the mean age of onset to be 8 years old ^[38]. The virus was first described in the Caribbean ^[38] and is endemic in Japan and South America ^[36]. In KwaZulu Natal the prevalence of HTLV-1 has been reported as 2.6 % in the Ngwelezana district and 3.35 % in Ubombo district ^[38].

Clinically lesions are crusted and involve the scalp, eyelid margins, paranasal regions, neck, axillae, retroauricular areas and the groin ^[37]. In children a chronic watery nasal discharge may be present with superinfection of *Staphylococcus aureus* and beta-haemolytic streptococci ^[37]. The established criteria for the diagnosis of IDH is represented in Table 1.1.

Table 1.1 Clinical Criteria for infected dermatitis associated with HTLV-1^[38]

<i>Major</i>	<i>Minor</i>
1. Eczema of scalp, axillae and groin external ear and retro-auricular areas, eyelid margins, paranasal skin and/or neck	1. Positive cultures for <i>Staphylococcus aureus</i> and/or <i>Beta-haemolytic streptococcus</i> from the skin or anterior nares
2. Chronic watery nasal discharge without other signs of rhinitis and/or crusting of the anterior nares	2. Generalized fine papular rash (in most severe cases)
3. Chronic relapsing dermatitis with prompt response to appropriate therapy but prompt recurrence on withdrawal of use of antibiotic	3. Generalized lymphadenopathy with dermatopathic lymphadenitis
4. Usual onset in early childhood	4. Anaemia
5. Human T cell lymphotropic virus type 1 antibody seropositivity	5. Elevated erythrocyte sedimentation rate
	6. Hyperimmunoglobulinaemia (IgD and IgE)
	7. Elevated CD4 count, CD8 count, and CD4/CD8 ratio

Four of the criteria required for diagnosis, with mandatory inclusion of 1,2 and 5; to meet criterion 1, at least two of the sites must be affected.

The main route of transmission is vertical from mother to child via breastmilk ^[37]. This is supported by the study conducted in KwaZulu Natal as HTLV-1 infective dermatitis was observed in 4 of the 9 families ^[38]. The main differential diagnosis is atopic dermatitis and seborrhoeic dermatitis ^[37] and prolonged antibiotic therapy is the treatment of choice ^[37]. HTLV-1 infective dermatitis is also seen in adults co infected with HIV ^[38].



Figure 1.22: A typical patient with IDH showing exudative dermatitis with crusting on the face, scalp, external ear, and retro-auricular areas. Crusted lesions are also demonstrated on face together with blepharitis that characterises IDH in most patients ^[38]



Figure 1.23: Shows an exudative dermatitis with crusting on the face, scalp, external ear, and retro-auricular areas ^[38]

1.6 Histology

The epidermis demonstrates regular acanthosis with some thinning of the suprapapillary plates. Varying degrees of spongiosis and lymphocyte exocytosis are noted. A characteristic finding is the presence of a focal scale crust adjacent to the follicular ostia [31]. In HIV/AIDS patients, the histology differs. Widespread parakeratosis, leukoexocytosis, and necrotic keratinocytes are seen [9]. Spongiosis is less evident and a superficial perivascular infiltrate of plasma cells are seen [35].

1.7 Treatment

Several modalities may be effective in the treatment of seborrhoeic dermatitis. The mechanism of action of most common treatments includes reduction of pruritus and erythema, inhibition of skin yeast colonisation, loosening of the crusts and scales and reduction of inflammation [23]. These therapies consist of corticosteroids, antifungals and keratolytics and immunomodulators [23]. With the success of antifungals in the treatment of seborrhoeic dermatitis there has been a renewed interest in the role of *Malassezia* yeasts now known as *Pityrosporum ovale* in the disorder. A number of recent studies have investigated the efficacy of antifungals in the treatment of seborrhoeic dermatitis [27-32]. A recent study by Zani MB et al, shows that ketoconazole does not reduce the fungal amount in seborrhoeic dermatitis [33].

1.7.1 Non-Specific Agents:

1.7.1.1 Topical:

- Coal Tar
- Selenium sulphide/sulphur
- Benzyl Peroxide
- Propylene Glycol
- Lithium succinate
- Corticosteroids

The non-specific topical agents are described below:

Selenium Sulphide:

Is an organic compound, with antifungal properties and is available in a shampoo preparation (e.g. selsun shampoo). It is a keratolytic agent that relieves pruritus and flaking of the scalp [5]. Scalp irritation, hair discolouration and increased hair loss are common side effects of the shampoo [35].

Lithium Succinate:

Has anti-inflammatory properties and is a successful treatment in HIV negative and positive patients with seborrhoeic dermatitis [5]. Minor skin irritations have been reported [35].

Coal Tar:

Has antinflammatory, antifungal, antiproliferative and decreased sebum secretion properties [5,23]. Studies have also found that tar has fungal properties similar to ketoconazole [23].

Corticosteroids:

Due to its anti-inflammatory and antimitotic properties, corticosteroids remains a popular choice in the treatment of seborrhoeic dermatitis. Side effects include atrophy, hypertrichosis and telangiectasia and prolonged use should be avoided.

Several studies have evaluated the use of steroids and antifungals [28-30], and there is still controversy over the efficacy of the two agents.

Two studies have found that there was no superiority between hydrocortisone and 2 % ketoconazole cream [28,29]. Additionally, the combination of steroids and antifungals is beneficial in the treatment of moderate to severe seborrhoeic dermatitis [30].

Topical steroids are indeed equal in efficacy to topical imidazoles in reducing symptoms and signs but due to the unavoidable tachyphylaxis that develops to steroids, due to the proliferation of *Malassezia furfur*, imidazoles are a much better long term option in the treatment of this chronic disease.

Other agents that have been successful in the management of seborrhoeic dermatitis include propylene glycol (a synthetic liquid substance that absorbs water), benzoyl peroxide and PUVA therapy [5].

Propylene glycol:

Propylene glycol is also called 1,2-propanediol or propane 1,2-diol. It is an odourless, colourless viscous liquid and has a lower toxicity compared to ethylene glycol. Propylene glycol functions as an emulsifier, solvent, vehicle, preservative, humectant and or penetration enhancer due to its high affinity for water and being freely miscible with water, methyl and ethyl alcohols, ether, glycerol, chloroform and ethyl acetate. It can found in antifungals, antibacterials, emollients and topical corticosteroids [39]. Vehicles for topical corticosteroid preparations commonly include propylene glycol for enhancing stratum corneum penetration [5,39].

Benzoyl Peroxide:

Benzoyl peroxide efficacy is against superficial inflammatory lesions as it is lipophilic and allows penetration of the pilosebaceous unit. It is a powerful antimicrobial agent, destroying both surface and ductal bacterial organisms and yeasts [40]. When applied topically to the skin it releases free oxygen radicals that have strong bactericidal activity in the sebaceous follicles and anti-inflammatory properties. It also reduces follicular hyperkeratosis. Topical retinoids and benzyl peroxide have no effect on sebum production [5,40].

1.7.2 Specific Antifungal Agents:

1.7.2.1 Topical:

- Zinc pyrithione
- Bifonazole
- Miconazole
- Ketoconazole
- Fluconazole
- Metronidazole
- Ciclopirox

The specific topical antifungal agents are described below:

Zinc pyrithione:

Has antibacterial and antifungal properties and is available as a 1% and 2% shampoo [5]. Its mechanism of action is its ability to disrupt membrane transport by blocking the proton pump that energises the transport mechanism [23].

Azoles:

Azole antifungals have broad-spectrum activity and are classified into two groups: the triazoles and the imidazoles. It inhibits the cytochrome P450 dependent enzyme lanosterol 14-alpha-demethylase, which converts lanosterol to ergosterol, the main sterol in fungal cell membrane. Depletion of ergosterol damages the cell membrane resulting in cell death [23].

The most common topical azole is ketoconazole.

Several randomised trials have been evaluated:

- A double blind study conducted in Europe showed 80% of the patients were cured with the use of topical 2% ketoconazole cream [29]. Although there was a higher cure rate in patients that used 1% hydrocortisone, topical ketoconazole can still be

considered as an alternative to topical steroids. Similar results were also found in another study [28].

- In a 4 week trial, 20 patients with scalp seborrhoeic dermatitis were treated with 2% ketoconazole shampoo, twice weekly for 4 weeks. Significant improvement of the severity of seborrhoeic dermatitis ($p < 0.001$) and negative mycological tests in 19 (95%) of patients were observed [41].
- 2 % Ketoconazole foaming gel was found to be significantly more effective than bethamethasone dipropionate 0.05% lotion in the treatment of seborrhoeic dermatitis. A total of 62 patients were included in this study and a substantial decrease in the Malasszia yeasts were also noted [30].

Metronidazole:

Has anti-inflammatory properties such as inhibition of free radical generation and oxidative tissue damage and is well documented in the treatment of rosacea [42]. A study conducted in Turkey evaluated the use of pimecrolimus cream 1%, methylprednisolone aceponate 0.1% cream and metronidazole 0.75% gel [42]. In this study metronidazole was as effective as methylprednisolone aceponate in the treatment of seborrhoeic dermatitis however it did cause marked side effects such as erythema, burning/tingling sensations and scaling [42].

1.7.2.2 Oral Antifungals:

- Ketoconazole
- Itraconazole
- Fluconazole

The oral antifungal agents are described below:

Itraconazole:

Is an azole with antifungal and has anti-inflammatory properties [31]. Due to its high lipophilicity it acts as a therapeutic reservoir and can be used in pulse therapy as it persists in skin for 2-4 weeks [31].

- In a randomised study evaluating topical steroids and itraconazole, 32 patients were enrolled, where all topical and oral treatments were stopped 2 weeks prior to the study. 1% hydrocortisone cream was applied twice daily for 1 month. In addition itraconazole 200mg/day was given during the first week of the first month. The steroid was then topical steroid was stopped and itraconazole 200mg/day was given on the first 2 days of the following 11 months. This study showed that itraconazole is effective in the treatment of seborrhoeic dermatitis. Furthermore, itraconazole can be used to prevent recurrence of the disease [27].
- In an open non comparative study, 60 patients with moderate to severe seborrhoeic dermatitis were treated initially with itraconazole 200mg day for a week, followed by a maintenance single dose of 200mg every two weeks for 18 weeks. After the initial treatment all patients reported improvement in itching, scaling and erythema without additional improvement during the maintenance period [32].
- Other studies have also confirmed that itraconazole is successful in the treatment of seborrhoeic dermatitis [43].

Fluconazole:

There is a limited number of studies available evaluating the use of fluconazole.

Gupta et al conducted a systemic review of oral treatments for seborrhoeic dermatitis and found that the efficacy outcome of fluconazole varied greatly from no difference with placebo therapy to clinical improvement in all patients [44]. There is definitely a need to evaluate the efficacy of fluconazole in seborrhoeic dermatitis.

CHAPTER 2

AIMS AND OBJECTIVES

2.1 Aims: To assess the quality of life of patients with seborrhoeic dermatitis using the Dermatology Life Quality Index (DLQI) and to assess the clinical severity of seborrhoeic dermatitis.

2.2 Objectives:

2.2.1 Primary:

- Physician's assessment: To objectively assess the clinical severity of seborrhoeic dermatitis
- Patients' assessment of their quality of life: To quantify their quality of life as a result of seborrhoeic dermatitis.

2.2.2 Secondary:

- a) To correlate clinical severity with quality of life.
- b) To evaluate the demographic and clinical parameters of patients with SD.

i) Demographic:

- Age
- Gender
- Ethnic Background
- Occupational status/ Employment status
- Marital status
- Rural or urban residence
- Other medical conditions
- HIV status
- Alcohol
- Smoking
- Level of education

ii) Clinical:

- Percentage Body Surface Area Involvement
- Severity of Seborrhoeic Dermatitis Lesions
- Site of involvement
- Type of Treatment

2.3 Hypotheses:

1. Patients with seborrhoeic dermatitis have a quality of life that does correlate with a clinician's assessment of clinical severity.
2. Demographic parameters do play a significant role when comparing quality of life between patients.
3. Clinical parameters are significant when assessing quality of life.

CHAPTER 3

LITERATURE REVIEW

There is a limited number of studies done on the quality of life of patients with seborrheic dermatitis, notably most of the studies were conducted in the European countries [1,45,46]. Although quality of life studies on South African patients with acne and psoriasis have been done [47,48] to our knowledge none have been conducted on patients with seborrhoeic dermatitis. Skin diseases can have a severe effect on the quality of life of affected individuals [47-51]. Diseases such as psoriasis or eczema, for instance, have been observed to have an impact comparable to that of cardiovascular diseases [52].

When compared to other dermatological skin diseases, seborrhoeic dermatitis has a lower dermatology quality of life index than that of atopic eczema, psoriasis, urticaria and rosacea [49,50]. In a study performed by Harlow *et al.*, mean dermatology of life index scores were assessed to be 5.9 points in seborrhoeic dermatitis; however, the group of patients was limited to only 20 subjects [49]. Compared with seborrhoeic dermatitis, these authors demonstrated higher scores of the dermatology life quality index for patients suffering from atopic dermatitis, psoriasis, urticaria and rosacea [49]. Similar impact on quality of life as in seborrhoeic dermatitis individuals was found for patients with acne, lichen planus and leg ulcers. Fungal infections, viral warts and moles influenced quality of life less than seborrhoeic dermatitis [49]. Öztas *et al.* also found that quality of life in seborrhoeic dermatitis patients is significantly decreased compared with healthy controls [53].

In a study done in Cape Town, higher dermatology quality of life scores were obtained for patients with dermatitis, prurigo and papular urticaria [51]. This study demonstrated that social class and language group influenced the impact of skin disease on overall quality of life.

Studies have confirmed that seborrhoeic dermatitis adversely impacts QOL [1,4,45,52,54]. Often there is no correlation between objective disease severity as assessed by the clinician and patients perspectives of their QOL and daily functioning.

One of the largest surveys of patients with seborrhoeic dermatitis in Europe had shown that seborrhoeic dermatitis has a negative impact on quality of life ^[1]. In this study 2159 patients participated, 98% of patients reported a trigger factor for outbreaks, namely stress, depression, fatigue and seasonal variation. The most common treatments were topical steroids, imidazole antifungals and hydrating skin products. In this study it is documented that the disease severity determines quality of life as patients with mild or moderate seborrhoeic dermatitis had significantly better QOL than those with severe or very severe disease. The quality of life was significantly affected by all the symptoms of seborrhoeic dermatitis including the severity of erythema, flaking, infiltration, oily skin and pruritus.

A Polish study of 3000 patients had shown that quality of life of patients suffering from seborrhoeic dermatitis is significantly altered, although the measured quality of life varied depending on age, sex and educational level. In this study younger patients, subjects with higher educational level and women were more affected by the disease than the rest of patients ^[45].

Some researchers have reported that there is a belief that stress is a causal factor or exacerbates seborrhoeic dermatitis and this is associated with poorer life quality ^[1,4,54].

Depression is not associated with a life threatening disorder only, but is also strongly prevalent in patients with seborrhoeic dermatitis ^[4]. Patients with seborrhoeic dermatitis also experience feelings of stigmatisation, social rejection and social limitations ^[4].

This study aims to highlight those aspects that are impossible to measure clinically by mere physician-centred methods, by assessing the patient's quality of life and providing their perspective of this debilitating condition.

CHAPTER 4

METHODOLOGY

4.1 Patients:

This was a cross sectional study conducted at the dermatology outpatients department at Stanger Regional Hospital. It is located in Kwa-Dukuza within the ILembe Health District, KwaZulu Natal, South Africa and has 500 beds. The hospital is a referral hospital for more than four districts and serves an estimated population of 600 000. Consenting participants over the age of 18 years, with a clinical diagnosis of seborrhoeic dermatitis were invited to take part in the study. The nature of the study was explained to every patient in their preferred language and confidentiality and anonymity was maintained. Patients signed written informed consent. To calculate the sample size needed for the study, the following equation was used.

$$n_0 = \frac{z^2 p(1-p)}{\varepsilon^2}$$
 : z is the value for a selected alpha level of 0.025 in each tail, giving a value of 1.96 (the overall significance level was set a priori at 5 percent); $p(1-p)$ is the estimate of variance, with a maximum possible proportion of $p=0.03$ and $1-p=0.97$ which generates a maximum possible sample size; ε is set at 0.05 and indicates the acceptable margin of error (Bartlett *et al.*, 2001).

After substituting our values in the above formula our sample size was 45. This study was conducted over a 6 month period from the 28th of August 2014 until the 17th of February 2015.

4.1.1 Inclusion Criteria

- Male and female
- Patients older than 18 years
- Clinical diagnosis of seborrhoeic dermatitis

4.1.2 Exclusion Criteria

- Patients less than 18 years of age
- Other dermatological comorbid skin diseases
- Patients with pityriasis sicca (dandruff) only. The study was focused on a moderate to severe form of seborrhoeic dermatitis therefore pityriasis sicca (milder disease) was excluded.

4.2 Methods:

4.2.1 Quality of Life Tools:

Quality of life was assessed using the Dermatology Life Quality Index (DLQI) [54]. This validated tool is a 10-item self-administered questionnaire. It comprises of 6 domains, including symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. Patients answered questions regarding their skin during the preceding week on a three point scale.

Scoring:

The scoring of each question is as follows:

Very much scored 3

A lot scored 2

A little scored 1

Not at all scored 0

Not relevant scored 0

Question 7, 'prevented work or studying' scored 3

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

The DLQI score is divided into the following five categories:

0-1 = no effect at all on patient's life

2-5 = small effect on patient's life

6-10 = moderate effect on patient's life

11-20 = very large effect on patient's life

21-30 = extremely large effect on patient's life

Approval for use of these questionnaires, which are under copyright, was formally granted from Prof A Finlay. See Appendix A.

English literate patients completed the original English questionnaires and isiZulu speaking patients completed the isiZulu translated questionnaires that was available on the DLQI website. See Appendix B, C. A comprehensive demographic questionnaire was completed for each patient. Refer to Appendix D.

4.2.2 Clinician's Assessment:

Severity of the lesions was assessed by one clinician to evaluate the lesions and the extent of involvement. On clinical assessment the patients were examined in four different areas (head, upper extremities, trunk, lower extremities) and were graded at each site for erythema, thickness, scaling and pruritus on a scale from 0 to 3 (0-absent, 1-mild, 2-moderate, 3-severe).

The area of involvement was measured on a scale of 1 to 5 (1: less than 10%, 2:11-30%, 3:31-50%, 4:51-70%, 5 more than 70%). The severity score for each area was obtained as follows: for the head, if erythema was mild (score 1), thickness was severe (score 3), scaling was moderate (score 2), pruritus mild (score 1), and the area of involvement was 35% (score 3), the severity score was $(1+3+2+1) \times 3 = 21$. The severity scores of the other areas (upper extremities, trunk, lower extremities) was added. See Appendix E, F.

This is not a validated scoring system and has been adapted from the Psoriasis Area and Severity Index (PASI) scoring system and several studies [27,44]. A higher severity score will indicate a more severe form of seborrhoeic dermatitis.

4.2.3 Statistical Analysis:

Data was analyzed using IBM SPSS Statistics 22 software and the results were interpreted with assistance from the statistician.

Descriptive statistics in the form of frequency tables, percentages, median, minimum and maximum values were used to assess the clinical severity of seborrhoeic dermatitis and to assess the relationship between quality of life and demographic factors. Scores were calculated to quantify the patient's quality of life as a result of seborrhoeic dermatitis.

The Spearman's rank correlation was used to correlate clinical severity with quality of life and age with quality of life. This is a nonparametric measure of rank correlation

(statistical dependence between the ranking of two variables). It assesses how well the relationship between two variables can be described using a monotonic function.

The Spearman correlation between two variables is equal to the Pearson correlation between the rank values of those two variables; while Pearson's correlation assesses linear relationships, Spearman's correlation assesses monotonic relationships (whether linear or not). If there are no repeated data values, a perfect Spearman correlation of +1 or -1 occurs when each of the variables is a perfect monotone function of the other.

Intuitively, the Spearman correlation between two variables will be high when observations have a similar (or identical for a correlation of 1) rank (i.e. relative position label of the observations within the variable: 1st, 2nd, 3rd, etc.) between the two variables, and low when observations have a dissimilar (or fully opposed for a correlation of -1) rank between the two variables.

4.3 Ethical Considerations:

As this is a quality of life study, there was no perceived harm, injury or discomfort to participants. Only those patients, who had consented to participate in the study, were included. All participants were 18 years and older and had signed written prior informed consent. See Appendix G and H. A participant information leaflet was given to each participant in their language of choice. See Appendix I. Formal consent was granted from the KZN Health Research and Knowledge Management to conduct the study at Stanger Provincial Hospital. See Appendix J. Full ethics approval was granted by the Biomedical Research Ethics Committee UKZN. See Appendix K.

CHAPTER 5

RESULTS

A total of 45 patients were enrolled in the study. All patients agreed to participate. Ages ranged from 18 to 70 years with a mean age of 37 years, with 26 (57.8%) females and 19 (42.2%) males. A detailed demographic profile is presented in Table 5.3.

Table 5.3: Demographic Profile of Study Sample and DLQI Scores

N=45			
Mean age	37 years		DLQI
Gender			
Males	42.2%	(n = 19)	11
Females	57.8%	(n = 26)	17,5
Ethnic Origin			
Black	88.9%	(n = 40)	17
Asian	6.7 %	(n = 3)	10
White	4.4 %	(n = 2)	4,5
Marital Status			
Single	68.9%	(n = 31)	17
Married	8.9 %	(n = 4)	13
Divorced	2.2 %	(n = 1)	6
Widowed	4.4 %	(n = 2)	9,5
Living Together	15.6%	(n = 7)	18
Home Language			
IsiZulu	86.7%	(n = 39)	17
English	13.3%	(n = 6)	8
Residence			
Urban	75.6%	(n = 34)	17
Rural	20,0%	(n = 9)	19
Level of Education			
Primary	20,0%	(n = 9)	17
Secondary	60,0%	(n = 27)	17
Tertiary	8.9 %	(n = 4)	19,5
No Schooling	11.1%	(n = 5)	22

The demographic profile of the patients was analysed using frequency tables. The percentages reported are the valid percentages. N stands for the number of patients in each demographic category. The DLQI scores in Table 5.3 represent median scores.

With regards to medical history, 5 (11.1%) had diabetes, 6 (13.3%) hypertension, 1 (2.2%) history of heart disease, 1 (2.2%) asthma, 14 (31.1%) tuberculosis and 1 (2.2%) depression. No patients had a previous history of epilepsy or Parkinson's disease.

The median Severity Score was 24 and the median DLQI score was 17. The greatest impairment in the DLQI was Symptoms and Feelings. Comparison of QOL between men and women revealed that female patients were more negatively influenced by the disease (women: n=26, median of 17.5 vs men: n=19, median of 11). Black participants had a higher DLQI score than other ethnic groups. Assessing the educational level of participants, it was interesting to note that patients that had no form of schooling were more adversely affected by the disease (n=5, median 22). Regarding marital status, single patients (n=31, median 17) and patients living together (n=7, median 18), had a worse QOL when compared to married (n=4, median 13), divorced (n=1, median 6) and widowed patients (n=2, median 9.5). Patients that resided in a rural area (n=9, median 19) had a higher DLQI score than urban patients (n=34, median 17). Refer to Table 5.3.

The relationships between severity scores and DLQI score are shown in Table 5.4. The correlation coefficient severity score of 1 in Table 5.4 reflects the perfect monotonic relationship. However when compared to the DLQI the correlation coefficient is .307. Thus there was no linear correlation between severity of the lesions and the DLQI. Similarly there was no obvious correlation between age and DLQI score as seen in Table 5.5.

Table 5.4: Correlation between Clinical Severity and DLQI

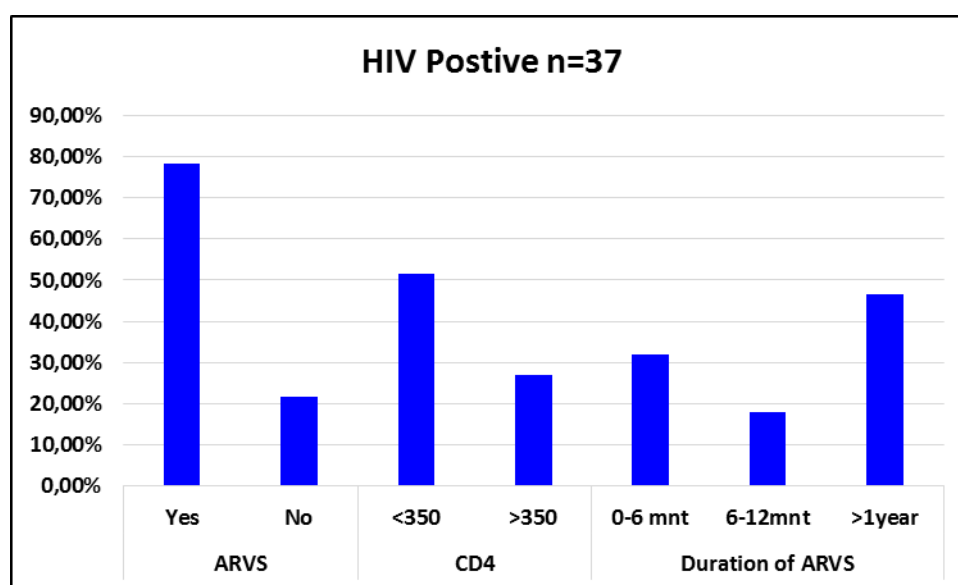
			Severity score	Total score
Spearman's rho	Severity score	Correlation Coefficient	1.000	.307*
		Sig. (2-tailed)	.	.040
		N	45	45
	Total score	Correlation Coefficient	.307*	1.000
		Sig. (2-tailed)	.040	.
		N	45	45

*. Correlation is significant at the 0.05 level (2-tailed).

Table 5.5: Correlation between Age and DLQI

			Total score	Age
Spearman's rho	Total score	Correlation Coefficient	1.000	-.036
		Sig. (2-tailed)	.	.813
		N	45	45
Age	Age	Correlation Coefficient	-.036	1.000
		Sig. (2-tailed)	.813	.
		N	45	45

HIV is a prominent health concern in Kwa-Zulu/Natal, notably 37 patients (82.2%) were HIV positive, 29 (78.4%) were on antiretrovirals, 19 (51.4%) had a CD4 count less than 350 cells/mm³ and 13 (46.6%) had been on antiretrovirals for more than a year. Patients that had a positive HIV result, with a CD4 count of less than 350 cells/mm³ had a higher DLQI score and severity score. See figure 5.2. There was no significant associations between HIV positive patients that were on ARVS vs those that were not on ARVS and QOL (on arvs n=29, median 18 vs not on arvs n=8, median 17). The severity score was higher in patients that were not on ARVS. Patients that had been on ARVs for greater than 1 year were more adversely affected by the disease (n=13, median 19) and had a higher severity score. See Figure 5.1 and Figure 5. 2.

**Figure 5.1: Demographic profile of HIV positive patients**

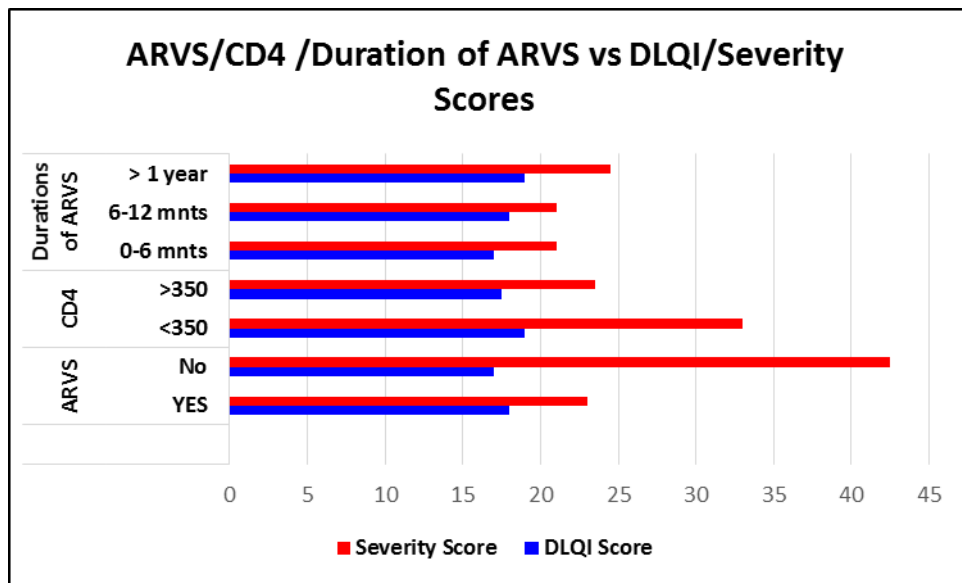


Figure 5.2: Correlation between ARVs, CD4 count, Duration of ARVS vs DLQI and Severity Score

Site of involvement also affected the QOL. Patients that had scalp, pinna/external auditory canal, neck, umbilicus, groin, intergluteal, axillary, inframammary, posterior trunk, upper limbs and lower limbs had higher DLQI scores. See Figure 5.3.

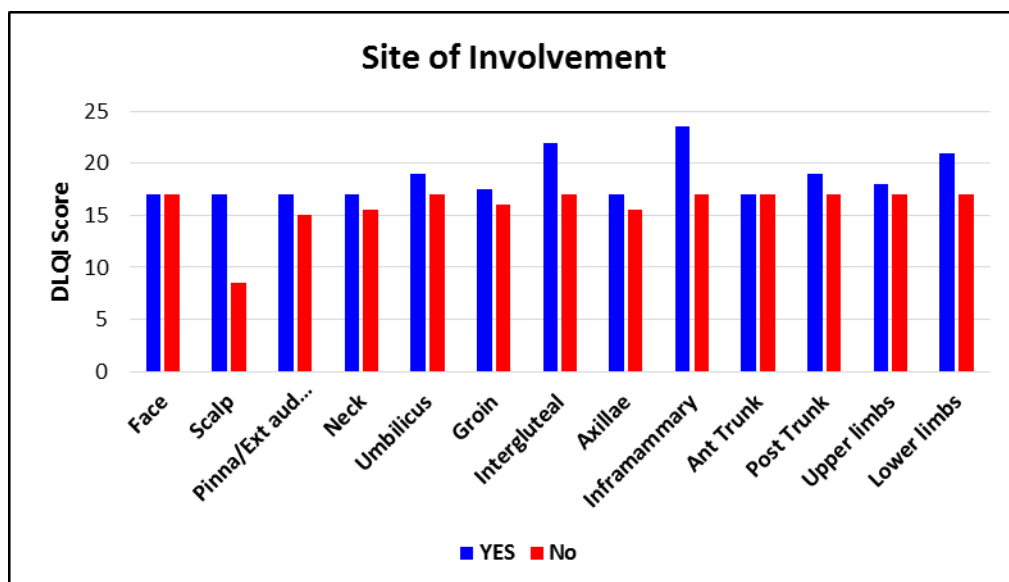


Figure 5.3: Site of Involvement vs DLQI

Although 26 (57.8%) of patients were on treatment for seborrheic dermatitis, those patients that were not on treatment were equally affected by the disease (not on treatment n=19, median 17 vs on treatment n=26, median 17). The most frequently used treatments are illustrated in Figure 5.4. Other pharmacological treatments for seborrheic dermatitis included the use of systemic antihistamines.

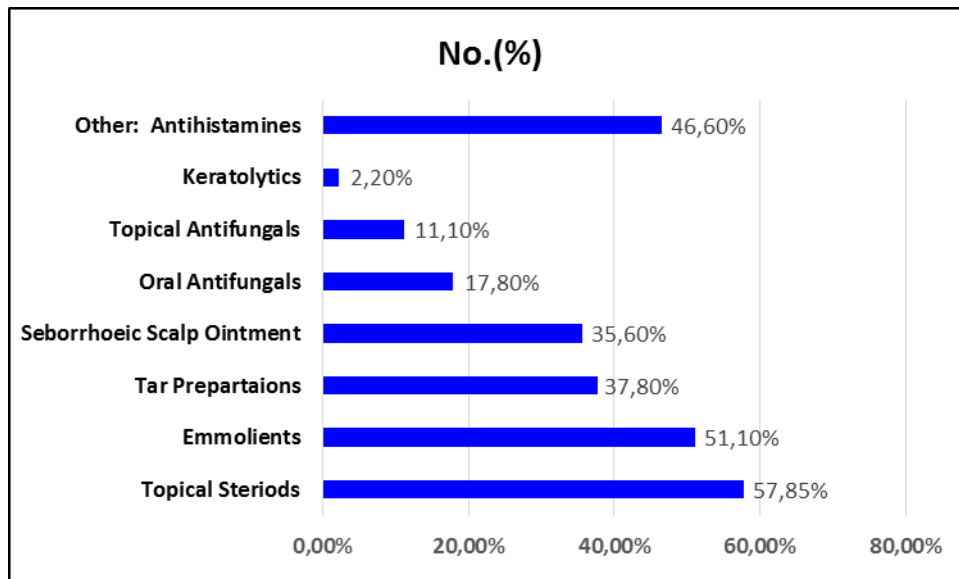


Figure 5.4: Treatment for Seborrheic Dermatitis

CHAPTER 6

DISCUSSION

In this study we clearly demonstrated that QOL of patients suffering from seborrhoeic dermatitis is greatly altered. The DLQI questionnaire consists of ten items and covers six domains including symptoms (question 1) and feelings (question 2), daily activities (question 3 and 4), leisure (questions 5 and 6), work and school (question 7), personal relationships (questions 8 and 9), and treatment (question 10). Response categories include "not at all," "a little," "a lot," and "very much," with corresponding scores of 0, 1, 2, and 3 respectively; the response "not relevant" (and unanswered items) are scored as "0". A total score is calculated by summing the score of all items, resulting in a maximum score of 30 and a minimum score of 0. The higher the score, the more quality of life is impaired [55]. Interpretation of the scores are: 0 – 1 no effect at all on patient's life, 2 – 5 small effect on patient's life, 6 – 10 moderate effect on patient's life, 11 – 20 very large effect on patient's life, 21 – 30 extremely large effect on patient's life [55]. In this study the median DLQI score was 17, which equated to a "very large effect on the quality of life". The greatest impairment in the DLQI was Symptoms (valid percentage of 40%) and Feelings (valid percentage of 51.1%), thus reiterating that patients with seborrhoeic dermatitis have significant psychological distress.

There was no linear correlation between age and QOL, which confirms that dermatological disability can be a burden at any age. A study however conducted in Poland found that younger patients were more affected by the disease [45]. This can be explained by the fact that younger patients are more socially active and always in contact with their peers [45]. Seborrhoeic dermatitis is more common in men [9], however this study and other studies [1,10,11,45], have reported a higher prevalence in females. Women place much more emphasis on their outward appearance and are therefore more likely to seek medical attention than their male counterparts.

Demographic parameters do play a significant role when comparing QOL between patients as shown in Table 5.3. The QOL varied depending on gender, educational level, ethnic origin, home language, marital status, residence, HIV status and site of involvement. Patients with no formal schooling were more adversely affected by the

disease. The interpretation of the questions despite careful translations and the perception of disability may explain the differences in DLQI between the educational groups. IsiZulu speaking patients had a higher DLQI score of 17, as compared to a DLQI score of 8 in English speaking patients. This can be attributed to the preponderance of Black African participants. Visible body areas and groin involvement had a greater impact on a patient's QOL than those without the involvement of these sites [47]. As appearance plays an important role in our society, patients with seborrhoeic dermatitis felt more embarrassed and self-conscious. In addition groin involvement may affect intimacy with a partner.

SD has a higher prevalence in patients with HIV disease and has been found in up to 40% of seropositive patients [55], notably, HIV positive patients (n=37, 82.2%), with a CD4 count less than 350 cells/mm³ (n=19, 51.4%, DLQI score:19, severity score:33), and patients that had been on antiretrovirals (ARVs) for greater than 1 year (n=13, 46.6%, DLQI:19, severity score:24.5), had higher DLQI scores and severity scores as represented in Fig. 2. Although the introduction of ARVs has reduced the amount of opportunistic dermatological conditions seen, there has been no change in the prevalence of primary HIV related inflammatory diseases [55]. This is illustrated by a lack of significant associations between HIV positive patients on ARVs versus those who were not on ARVs and QOL (on ARVs n=29, median 18, not on ARVs n=8, median 17).

There was no linear correlation between clinical severity and QOL (Spearman's rank correlation coefficient of 0.307). In contrast, one of the largest surveys of patients with SD in Europe had shown that the disease severity determines QOL, as patients with mild or moderate disease had significantly better QOL than those with severe disease [1].

Limitations of this study include the small number of patients included and that data was collected at a single public hospital, thus may not be fully representative of our population. The protocol also did not allow for capturing drug related and, in the management, the discontinuation of possibly offending drugs was not included. We did not allow for capturing factors that may trigger outbreaks (e.g. seasonal changes, sun exposure, changes in eating habits etc.) as described by Peyri J et al [1].

CHAPTER 7

CONCLUSION

In South Africa, skin diseases pose a significant problem and an understanding of the impact on QOL is crucial particularly with the limited resources at our disposal. There is a high demand on dermatological services and hospital managers may not regard dermatology as a priority when allocating services. Disability measurements can be used in debates regarding resource allocations. Seborrhoeic dermatitis rarely causes serious complications, however it has an impact on appearance and this may lead to emotional and social difficulties for the affected individual. The results of this study highlight that QOL tools are imperative in providing holistic, comprehensive management and offers a patient's perspective of their debilitating skin condition.

Therefore, the following recommendations are proposed:

1. A psychological assessment be sought and included in the treatment of seborrhoeic dermatitis
2. A further larger population based study be conducted in multiple public hospitals with all data correlated into one study.

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APPENDICES

APPENDIX A: Permission for use of the Dermatology Life Quality Index

From: Faraz Ali <AliFM@cardiff.ac.uk>
Date: 10 June 2013 at 14:04:25 SAST
To: nerissazn@yahoo.com
Cc: Andrew Finlay <FinlayAY@cardiff.ac.uk>
Subject: DLQI, Seborrhoeic Dermatitis, Zulu, South Africa

Dear Nerissa,

I am writing this email on behalf of Professor Finlay. Thank you for your interest in the DLQI. We are happy to give you formal permission to use the DLQI in the Seborrhoeic Dermatitis Study as you have described. There will be no charge. It is a requirement that the copyright statement must always be reproduced at the end of every copy of the DLQI. You can find the validated translations of the DLQI, as well as further information, at www.dermatology.org.uk (click on Quality of Life).

Best Wishes,
Faraz

Dr Faraz Mahmood Ali MBBCh MRCP
Clinical Research Fellow in Dermatology

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School of Medicine, Cardiff University
3rd Floor Glamorgan House
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APPENDIX B: Dermatology Life Quality Index

DERMATOLOGY LIFE QUALITY INDEX

Hospital No:
Name:
Address:

Date:
Diagnosis:

Score:

DLQI

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

- | | | | | |
|-----|---|------------|---|----------------|
| 1. | Over the last week, how itchy, sore, painful or stinging has your skin been? | Very much | r | |
| | | A lot | r | |
| | | A little | r | |
| | | Not at all | r | |
| 2. | Over the last week, how embarrassed or self conscious have you been because of your skin? | Very much | r | |
| | | A lot | r | |
| | | A little | r | |
| | | Not at all | r | |
| 3. | Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden ? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 4. | Over the last week, how much has your skin influenced the clothes you wear? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 5. | Over the last week, how much has your skin affected any social or leisure activities? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 6. | Over the last week, how much has your skin made it difficult for you to do any sport ? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 7. | Over the last week, has your skin prevented you from working or studying ? | Yes | r | |
| | | No | r | Not relevant r |
| | If "No", over the last week how much has your skin been a problem at work or studying ? | A lot | r | |
| | | A little | r | |
| | | Not at all | r | |
| 8. | Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 9. | Over the last week, how much has your skin caused any sexual difficulties ? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |
| 10. | Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time? | Very much | r | |
| | | A lot | r | |
| | | A little | r | Not relevant r |
| | | Not at all | r | |

Please check you have answered EVERY question. Thank you.

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APPENDIX C: Dermatology Life Quality Index in Zulu

UHLA OLUSEZINGENI ELIPHEZULU LWEMPILO NGE-DERMATOLOGY

Inombolo yesibhedlela:

Usuku:

Isamba:

Igama:

Ikheli:

Isifo esitholakele emva kokuhlolisisa:

Inhloso yalolu hla lwemibuzo ukuthola ukuthi inkinga yakho yesikhumba iyiphazamise kanjani impilo yakho ESONTWENI ELEDLULE

Uyacelwa ukuba ubeke uphawu ebhokisini ngalinye embuzweni ngamunye obuziwe.

1. Esontweni eledlule isikhumba sakho besiluma, sinezilonda, sibuhlungu noma sincinza kanjani?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho

2. Esontweni eledlule uphoxeke noma uzenyeze kanjani ngenxa yesikhumba sakho?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho

3. Esontweni eledlule isikhumba sakho singenelele kanjani kwinqubo yakho ejwayelekile yokuyokwenza igilosa, ukubheka ikhaya lakho kanye noma isivande sakho?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

4. Esontweni eledlule, isikhumba sakho sibe nomthelela ongakanani ezingubeni ozigqokayo?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

5. Esontweni eledlule, isikhumba sakho siziphazamise kanjani izinto ozenza ukuzithokozisa ngokwenhlalo?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

6. Esontweni eledlule, isikhumba sakho sikwenze kwalukhuni kangakanani ukuthi udlale nanoma yimuphi umdlalo?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

7. Esontweni eledlule, kungabe isikhumba sakho sikuvimbele ukuba usebenze noma ufunde?

- Yebo
- Cha
- Akubalulekile

Uma uthi “cha”, esontweni eledlule isikhumba sakho sibe yinkinga kangakanani kuwena emsebenzini noma ekufundeni kwakho?

- Kakhulu
- Kancane
- Asibanga yinkinga

8. Esontweni eledlule, isikhumba sakho sizidale kangakanani izinkinga kumlingani wakho noma nanoma yibaphi abangane noma izihlobo ezisondelene zakho?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

9. Esontweni eledlule, isikhumba sakho sizidale kanjani izinkinga kwezocansi?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

10. Esontweni eledlule, ukuthatha kwakho unyango lwesikhumba kudale inkinga engakanani, isib. Ngokwenza ikhaya lakho lingcole noma ukuthatha isikhathi sakho?

- Kakhulu impela
- Kakhulu
- Kancane
- Bekungenzeki lutho
- Akubalulekile

Uyacelwa ukuthi ubheke ukuthi uphendule YONKE imibuzo. Siyabonga
AY Finlay, GK Khan, Ephreli 1992. Akumele leli pheshana likopishwe ngaphandle
kwemvume yababhali balo.

APPENDIX D: Demographic Questionnaire

DEMOGRAPHIC QUESTIONNAIRE INVESTIGATOR'S SIGNATURE:

DEMOGRAPHIC QUESTIONNAIRE

PATIENT FILE NUMBER :

1. DATE OF BIRTH

DD / MM / YYYY

----/-----/-----

2. AGE

YEARS

3. GENDER

(a) MALE (b) FEMALE

4. ETHNIC ORIGIN

(a) BLACK (b) WHITE
 (c) ASIAN (d) COLOURED

5. MARITAL STATUS

(a) SINGLE (b) MARRIED
 (c) DIVORCED (d) WIDOWED
 (e) LIVING TOGETHER

6. HOME LANGUAGE

(a) ENGLISH (b) ISIZULU (c) OTHER

7. LEVEL OF EDUCATION

(a) PRIMARY (b) SECONDARY
 (c) TERTIARY (d) OTHER

8. URBAN OR RURAL

(a) URBAN (b) RURAL

9. OCCUPATION

(a) LABOURER (b) OFFICE WORKER
 (c) PROFESSIONAL (d) HOUSEWIFE
 (f) UNEMPLOYED (g) OTHER: -----

10. ALCOHOL

(a) YES (b) NO

11. SMOKING

(a) YES (b) NO

12. OTHER MEDICAL CONDITIONS

(a) DIABETES (b) HYPERTENSION (c) HEART DISEASE
 (d) ASTHMA (e) EPILEPSY (f) TB
 (g) DEPRESSION (h) PARKINSON'S (i) OTHER

13.HIV STATUS

(a) POSITIVE (b) NEGATIVE (c) UNKNOWN

IF POSITIVE: (i) ON ARVS (ii) NOT ON ARVS

CD 4 COUNT (i) <350 (ii) >350 (iii) UNKNOWN

DURATION OF ARVS?

a) <6MONTHS b) 6-12 MONTHS c) >1 YEAR

14 .DURATION OF SEBORRHOEIC DERMATITIS?

a) <3 MONTHS b) 3-6 MONTHS c) 6-12 MONTHS d) > 1 YEAR

15. IS THE PATIENT ON TREATMENT FOR SEBORRHOEIC DERMATITIS?

(1)YES (2) NO

16. WHAT TREATMENT IS THE PATIENT TAKING FOR SEBORRHOEIC DERMATITIS?

- (1) TAR PREPARATIONS
- (2) TOPICAL STEROIDS
- (3) KERATOLYTICS
- (4) EMMOLIENTS
- (5) ORAL STEROIDS
- (6) ORAL ANTIFUNGALS
- (7) TOPICAL ANTIFUNGALS
- (8) SEBORRHOEIC SCALP OINT (Salicylic Acid/Sulphur/Epizone E)
- (9) OTHER :Specify:.....

INVESTIGATOR'S SIGNATURE:.....

DATE: / /

APPENDIX E: Site of Involvement Questionnaire

AN ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS LIVING WITH SEBORRHOEIC DERMATITIS

STUDY NO:

DATE: / /

1.SITE OF INVOLVEMENT

- (a) FACE
- (b) SCALP
- (c) PINNA/EXTERNAL AUDITORY
MEATUS /POSTAURICULAR REGION
- (d) NECK
- (e) UMBILICUS
- (f) GROIN
- (g) INTERGLUTEAL
- (h) AXILLAE
- (i) INFRAMAMMARY
- (j) ANTERIOR TRUNK
- (k) POSTERIOR TRUNK
- (l) UPPER LIMBS
- (m) LOWER LIMBS

INVESTIGATOR'S SIGNATURE:.....

DATE: / /

APPENDIX F: Severity Score of Lesions

AN ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS LIVING WITH SEBORRHOEIC DERMATITIS

STUDY NO:

DATE: / /

	HEAD	UPPER EXTREMITIES	TRUNK	LOWER EXTREMITIES
1.REDNESS				
2.THICKNESS				
3.SCALE				
4.PRURITUS				
5.SUM OF ROWS 1,2,3,4				
6.AREA SCORE				
7.SCORE OF ROW 5 X ROW 6				
7.SUM ROW 6 FOR EACH COLUMN FOR SEVERITY SCORE	SEVERITY SCORE =			

Erythema,thickness and pruritus scale:0-Absent, 1-mild, 2-moderate, 3-severe

Area scoring criteria (score: % involvement)

0: 0 (clear)

1: <10%:

2: 11–30%

3: 31–50%

4: 51-70%

5: >70%

INVESTIGATOR’S SIGNATURE:.....

DATE: / /

APPENDIX G: Informed Consent for Participation in Study
INFORMED CONSENT

STUDY NO:

DATE:...../...../.....

CONSENT TO PARTICIPATION IN RESEARCH STUDY: AN ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS LIVING WITH SEBORRHOEIC DERMATITIS

I,, hereby consent to participate in the research study entitled : An assessment of the quality of life of patients living with Seborrhoeic Dermatitis - which is being conducted at Stanger Regional Hospital-Dermatology Out-patient clinic, by Dr N Moodley.

I have received, read and understood the patient information sheet. I know that participation in this study is voluntary and confidential. I am aware that there are no risks to my health and life and that this study is not to test any medication on me.

I agree to fill the anonymous questionnaires. I agree to the study doctor examining me and recording the findings both in my file and the study record sheets.

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
University of KwaZulu-Natal
Private Bag X 54001, Durban, 4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

STUDY PARTICIPANT'S SIGNATURE:

DATE:...../...../.....

INVESTIGATOR'S SIGNATURE:

DATE:...../...../.....

WITNESS:

DATE:...../...../.....

APPENDIX H: Informed Consent for Photographs

INFORMED CONSENT FOR PHOTOGRAPHS

STUDY NO:

DATE:...../...../.....

CONSENT TO PARTICIPATION IN RESEARCH STUDY: AN ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS LIVING WITH SEBORRHOEIC DERMATITIS

I,, hereby consent to participate in the research study entitled : An assessment of the quality of life of patients living with Seborrhoeic Dermatitis - which is being conducted at Stanger Regional Hospital-Dermatology Out-patient clinic, by Dr N Moodley.

I hereby consent to be photographed by the study doctor, Dr N Moodley. I am aware that my photographs will be for the purpose of the study. Further, these photographs will be anonymous and I will not be identified.

STUDY PARTICIPANT'S SIGNATURE:

DATE:...../...../.....

INVESTIGATOR'S SIGNATURE:

DATE:...../...../.....

WITNESS:

DATE:...../...../.....

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
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APPENDIX I: Patient Information Pamphlet**PATIENT INFORMATION****STUDY NUMBER** :**DATE**:.../...../....**TITLE OF STUDY : AN ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS LIVING WITH SEBORRHOEIC DERMATITIS**

I, Dr N MOODLEY, am inviting you to participate in a research study conducted at the Dermatology out-patient clinic, Stanger Regional Hospital.

I am registered as a postgraduate student at the University of Kwa-Zulu Natal and this study is for a Masters Degree i.e. Masters of Science Degree in Dermatology. My student number is 201295866. This study is being supervised by Dr K HOOSEN, specialist dermatologist and lecturer, at the Nelson R. Mandela School of Medicine.

In this study, I want to learn how seborrhoeic dermatitis affects you as a person, your daily activities and your life quality. I cannot assess these aspects when I examine you so I am asking you to complete anonymous questionnaires.

By completing these questionnaires, you will help me to learn if assessing your quality of life is important in your treatment.

VOLUNTARY PARTICIPATION AND CONFIDENTIALITY:

Participation in this study is voluntary. Should you decide not to participate, you will not be discriminated against and you will still receive all your usual treatment. Further, you may withdraw from participation from this study at any stage.

CONFIDENTIALITY AND ANONYMITY:

Should you agree to participate in this study, I require from you the following: You will need to give consent to participating in the study by signing a consent form, a copy of which you will receive. At your consultation, I will examine you and record the findings in your file and on anonymous record sheets for the study. You will then be asked to complete questionnaires, which are anonymous and confidential. These questionnaires will take an average about three minutes to complete. You may be required to be photographed, but only with your written consent.

RISKS:

There are no risks involved or discomforts in this study. However, should you experience any emotional distress when completing the questionnaires, you may withdraw from the study should you want to, and you will be referred to a psychologist if you wish.

I am NOT conducting this study to test any medications or drugs on you. You will still receive your usual medication and you will still continue with your normal treatment regimen. If your medication is adjusted, it is because your skin condition has changed and is not related to the study.

BENEFITS:

There are no benefits to you in terms of receiving “new” medication, as this study is not testing medications/drugs on you. Further, you will not be paid for completing the questionnaires. We only hope that the knowledge gained from this study, will help you and others with seborrhoeic dermatitis in the future.

CONTACT PERSONS:

For more information or queries regarding the study, please feel free to contact the following: The study doctor: Dr N MOODLEY – (032) 437 6119 / 0837892607.

The study supervisor: Dr K HOOSEN - (031) 3603546 /0837861805

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
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Tel: 27 31 2604769 - Fax: 27 31 2604609
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APPENDIX J: Approval of Research from the Kwa Zulu Natal Department of Health



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM 209/14
Enquiries : Mr X Xaba
Tel : 033 – 395 2805

Dear Dr N. Moodley

Subject: Approval of a Research Proposal

1. The research proposal titled '**Quality of life in patients with seborrheic dermatitis**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Stanger Hospital.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely



Dr E Lutge
Chairperson, Health Research Committee
Date: 14/08/14

APPENDIX K: Approval from the Biomedical Research Ethics Committee



25 August 2014

Dr Nerissa Moodley
No 6 Nonoti Gardens
15 Nonoti Avenue
Musgrave, 4001
nerissazn@yahoo.com

PROTOCOL: Quality of life in patients with Seborrhoeic Dermatitis. REF: BE235/14

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 23 April 2014.

The study was provisionally approved pending appropriate responses to queries raised. Your responses received on 15 August 2014 to queries raised on 25 July 2014 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 25 August 2014.

This approval is valid for one year from 25 August 2014. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on **09 September 2014**.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D. R. Wassenaar
Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee

Professor D R Wassenaar (Chair)

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APPENDIX L: Journal Decision

From: Professor Janet Seggie <janets@hmpg.co.za>

Sent: 20 January 2016 12:08

To: Nerissa Moodley

Cc: Koraisa Hoosen; Ncoza Dlova

Subject: [SAMJ] Editor Decision

Dear Nerissa Moodley:

We have reached a decision regarding your submission to South African Medical Journal, "Quality of life in Patients with Seborrhoeic Dermatitis in KwaZulu Natal, South Africa".

Our decision is to accept.

Kind regards,

Professor Janet Seggie

Phone 021 532 1281

Fax 072 635 9825

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APPENDIX M: Publication

SAMJ CORRESPONDENCE

Quality of life in patients with seborrhoeic dermatitis in KwaZulu-Natal, South Africa

To the Editor: Skin diseases may have a severe effect on the quality of life (QOL) of affected individuals,^[1,2] but their impact has rarely been investigated in the developing world. In South Africa, there have been no studies conducted on patients with seborrhoeic dermatitis (SD). A cross-sectional study was undertaken in the ILembe District, KwaZulu-Natal Province, assessing the QOL of patients presenting with SD, correlating clinical severity and demographic parameters.

Forty-five consenting participants, with a clinical diagnosis of SD, were invited to participate. QOL was assessed using the Dermatology Life Quality Index (DLQI).^[3] The severity of the condition was assessed by a dermatologist and graded at individual sites for erythema, thickness, scaling and pruritus on a three-point scale. Body surface area involvement was calculated using the rule of nines and the sites of involvement were recorded.

A detailed demographic profile was completed for each patient (Table 1). The median severity score was 24 and the median DLQI score was 17, which equates to a very large effect on the QOL.^[3] The QOL varied depending on sex, educational level, ethnic origin, home language, marital status, residence, HIV status and site of involvement. Female patients were more negatively influenced by the disease, confirming the findings in three other studies.^[4-6] Patients with no formal schooling were more adversely affected. The way the questions were interpreted and the perception of disability may explain the differences in DLQI between the groups. Visible body areas and groin involvement had a greater impact on a patient's QOL. As appearance plays an important role in

Table 1. Demographic profile of study sample and DLQI scores (N=45)

	n (%)	DLQI
Mean age (years)	37	
Sex		
Male	19 (42.2)	11
Female	26 (57.8)	17.5
Ethnic origin		
Black	40 (88.9)	17
Asian	3 (6.7)	10
White	2 (4.4)	4.5
Marital status		
Single	31 (68.9)	17
Married	4 (8.9)	13
Divorced	1 (2.2)	6
Widowed	2 (4.4)	9.5
Living together	7 (15.6)	18
Home language		
isiZulu	39 (86.7)	17
English	6 (13.3)	8
Residence		
Urban	34 (75.6)	17
Rural	9 (20.0)	19
Level of education		
Primary	9 (20.0)	17
Secondary	27 (60.0)	17
Tertiary	4 (8.9)	19.5
No schooling	5 (11.1)	22

our society, patients felt more embarrassed and self-conscious. In addition groin involvement may affect intimacy with a partner.

SD has a higher prevalence in patients with HIV and has been found in up to 40% of seropositive patients,^[7] notably, HIV-positive patients ($n=37$, 82.2%), with a CD4 count <350 cells/mm³ ($n=19$, 51.4%), and

patients who had been on antiretrovirals (ARVs) for >1 year ($n=13$, 46.6%) had higher DLQI and severity scores. Although the introduction of ARVs has reduced the number of opportunistic dermatological conditions seen, there has been no change in the prevalence of primary HIV-related inflammatory diseases.^[7] This is illustrated by a lack of significant associations between HIV-positive patients on ARVs v. those who were not on ARVs and QOL (on ARVs $n=29$, median 18; not on ARVs $n=8$, median 17).

This study highlights that QOL tools are valuable in understanding the impact of skin disorders and will help in providing holistic, comprehensive management, offering a patient's own perspective of their debilitating skin condition.

Nerissa Moodley

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