Malaysian Psoriasis Registry – Preliminary Report of a Pilot Study Using a Newly Revised Registry Form

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SUMMARY

The Malaysian Psoriasis Registry, established in 1998, is the first skin disease clinical registry in Malaysia. It aims to provide useful data on various aspects of psoriasis. Following an extensive revision of the registry form in 2007, a total of 509 psoriasis patients from 10 government dermatologic centres were reviewed in a three month pilot study. The onset of psoriasis was during the second to fourth decade of life in the majority of patients. There was no sexual and ethnic predilection. A positive family history was present in 21.2%, and more common in patients with younger disease onset. The main aggravating factors of psoriasis were stress, sunlight and infection. Plaque psoriasis was the commonest clinical type (80.9%). Joint disease was present in 17.3% of patients, among which mono-/oligoarticular type being the commonest. Nail changes occurred in 68%. More psoriasis patients were overweight and obese compared to the normal population. The mean Dermatologic Life Quality Index (DLQI) score was 8.08 ± 6.29, and changes during subsequent follow-up may reflect therapeutic effectiveness. This study enabled evaluation of the revised registry form and helped in identifying shortcomings in the implementation of the registry.

KEY WORDS:
Psoriasis, Clinical Registry

INTRODUCTION

Psoriasis is a common chronic inflammatory disease affecting the skin, nails and joints with significant physical, psychosocial and economic impact. There has been a worldwide effort to obtain comprehensive epidemiological and clinical data on psoriasis in different populations[1,2,3,4]. However, published reports of successful clinical registries on psoriasis are few[6,7].

The Malaysian Psoriasis Registry (MPR) is the first skin disease clinical registry in Malaysia. Pioneer efforts towards establishing a clinical registry for psoriasis was started in 1998 by a group of dermatologists under the umbrella body of the Dermatological Society of Malaysia. Following nationwide data collection from public and private dermatologic centres from March 2000 to July 2005, a preliminary report was published in August 2005[5]. However, the continuity of this registry was challenged by the limitations in budget and resources, as well as the lack of a stable secretariat and steering committee.

With strong financial and technical support from the Ministry of Health and Clinical Research Centre, MPR was given a new lease of life in 2007. A permanent Steering Committee based in the Department of Dermatology Hospital Kuala Lumpur (HKL), and an Advisory Committee represented by senior consultant dermatologists from government, private and university hospitals were formed. The registry case report form was extensively revised.

OBJECTIVE

The primary objective the MPR is to obtain more accurate data on various aspects of psoriasis in Malaysia.
Secondary objectives are :

1. To determine the socio-demographic profiles of patients with psoriasis.
2. To determine the disease burden attributed to psoriasis.
3. To provide information for planning of medical services, facilities, manpower and training related to the management of psoriasis.
4. To stimulate and facilitate research on psoriasis and its management.

These objectives are planned to be achieved in two phases.

The first phase begins with a pilot study limited only to a number of government hospitals with dermatologic services.

The second phase expands the coverage to include university hospitals, private hospitals and private dermatologists throughout the country. This paper reports the finding of the pilot study.

MATERIALS AND METHODS

The MPR is an ongoing systematic collection of data pertaining to patients who have psoriasis. All patients clinically diagnosed to have psoriasis by a registered dermatologist or by a medical practitioner under the supervision of a dermatologist are included. Confirmation of mdiagnosis by histopathologic examination is optional. Patients whose diagnosis is in doubt are excluded.

The study involves collection of data on the patient's first visit to the participating centre and thereafter every six monthly on follow-up visits. The Case Report Form (CRF) consists of a clinical data form and multilingual Dermatology Life Quality Index (DLQI) forms separately for adult and children. The DLQI is a widely used and validated

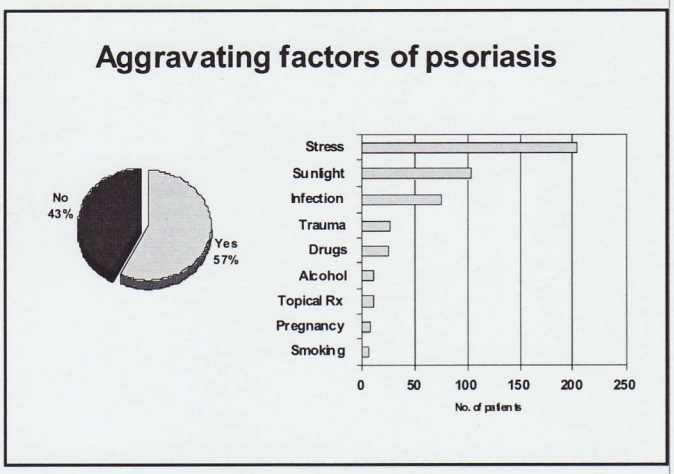

Fig. 1: Aggravating factor of psoriasis reported by patient

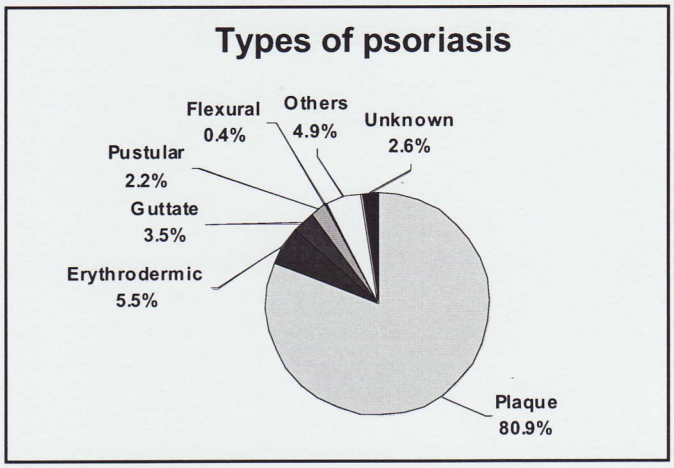

Fig. 2: Clinical types of psoriasis

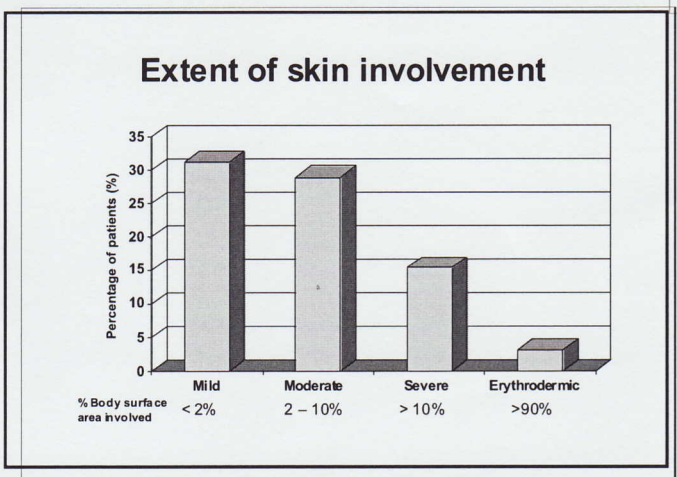

Fig. 3: Extent of skin involvement in Psoriasis patient

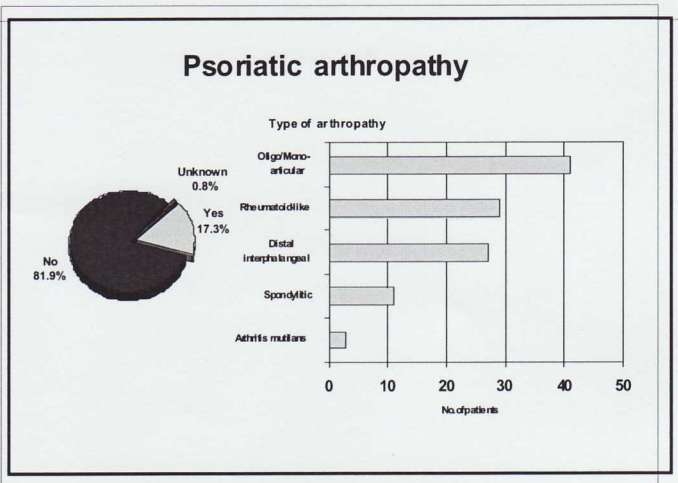

Fig. 4: Joint involvement in Psoriasis patient.

dermatology-specific questionnaire consisting of 10 questions concerning health-related quality of life (QOL) relating to the previous one week. The total DLQI score ranges between 0 (no impairment of QOL) and 30 (maximum impairment of QOL)[11,12].

The clinical data form in the CRF is to be completed by the doctor in-charge while the DLQI form is to be completed by the patient (parent or guardian for young patient) with guidance from trained staff if necessary.

One set of CRF is to be completed for each new patient during consultation at the participating centre. A new set of CRF is to be completed for the same patient every six months to record the progress of the patient. Data collected is analysed, interpreted and presented in regular reports to be disseminated to the users.

During this current pilot phase of the registry, all CRFs were sent to the Psoriasis Registry Unit (PRU) based in HKL for data entry. A centralized computer database with web application has been set up and a research assistant employed to perform data entry for all centres. With the availability of additional resources, future plans include data entry performed directly using online electronic CRF at individual centres.

RESULTS AND DISCUSSION

This preliminary report contains the results and analysis of data over collected over a three-month period from 1st October to 31st December 2007. Data was collected from new and follow-up patients of psoriasis from ten participating centres on a voluntary basis. However, all completed CRFs received by the PRU upto 31st January 2008 were also included. Hence the number of cases might not reflect the true burden of psoriasis in each centre.

A total of 509 patients with psoriasis (80 new cases and 429 follow-up cases) were reported. Male-to-female ratio was 1.26:1. Ethnic distribution was similar to that of government clinic attendance: Malays 51.1%, Chinese 26.3%, Indians 17.3% and other ethnic groups 5.3%. Previous registry reported a higher male-to-female ratio of 3:2 and a similar ethnic distribution[5]. There is no sexual or ethnic predilection reported worldwide.

In the majority of patients (59.7%), the disease onset was during the second to fourth decade of life. Overall mean age of onset was 32.9 years with a wide range from two to 80 years. Females had slightly earlier onset compared to males (mean age of onset 30.2 years vs. 35 years, t=3.255, p=0.001). Most patients (70.4%) knew about the diagnosis within a year from the onset of the disease.

About one-fifth (21.2%) of patients had at least one family member suffering from psoriasis. Of those patients with a positive family history, about half (48.9%) had either of their parents affected. Siblings were affected in 26.9%, and children in 15.7%. In four patients, family members of both preceding and succeeding generations were affected by psoriasis. Positive family history seemed to be more common in patients with younger onset of disease (aged 40 and below), 24.8% vs. 13.9% (OR=2.05, 95%CI=1.24-3.39, p<0.01).

These findings are consistent with previous reports from the European countries which proposed a subdivision of psoriasis into Type 1 and Type 2. Type 1 has early onset, stronger family history, more severe disease and association with HLA-Cw[6]. While the less common Type 2 has a later onset (fifth decade of life) and less common family history[2,3,4,8].

The majority of patients (57%) reported one or multiple factors which aggravated their psoriasis. The most common aggravating factor was stress (70.3%), followed by sunlight (36.2%), infection (25.5%), trauma (9%), drugs (8.6%), alcohol (4.1%), topical medication (3.8%) and pregnancy (2.7%). (Figure 1) Similarly, stress has been found to be an important aggravating factor in up to 60% of psoriasis patients in other reports[3,4,5]. This is thought to be due to stress related immune dysregulation and abnormal neuroendocrine response.

The commonest clinical type of psoriasis was plaque psoriasis (80.9%) and its variant which involved the scalp only (4.7%). A minority of patients had other types of psoriasis namely erythrodermic (5.5%), guttate (3.5%), pustular (2.2%), flexural (0.4%), and palmo-plantar non-pustular (one patient). (Figure 2) On evaluation of percentage body surface area (BSA) involvement of psoriasis, 31.2% had less than 2% BSA involved, 28.9% between 2 to 10%, 15.3% more than 10%, and 3.1% were erythrodermic (>90% BSA involved), while the remaining 21.4% was unknown. (Figure 3) The commonest body region involved was the lower limbs (81.1%), followed by the scalp (78.8%), upper limbs (74.1), the trunk (72.7%), and the face and neck (49.7%).

Psoriatic arthropathy occurred in 17.3% of patients. The commonest clinical pattern of arthropathy was oligo-/monoarticular type (46.6%), followed by symmetrical polyarthropathy involving proximal hand joints orRheumatoid-like type (33%), distal hand joints arthropathy (30.7%), spondylitic type (12.5%), and arthritis mutilans (3.4%). (Figure 4) Two patients had only morning stiffness of > 30 minutes duration, and one patient developed enthesopathy alone. Only 15.9% patients with joint disease had rheumatoid factor tested, and all of them were negative. More than one-third (36.8%) of patients with arthropathy had joint deformities.

About two-third of patients (68%) had nail changes related to psoriasis. The majority of these patients had nail pitting (50.9%), followed by onycholysis (38.5%), nail discolouration (28.7%), subungual hyperkeratosis (13.4%), and total nail dystrophy (4.3%).

Body mass index (BMI) was determined in 461 (90.8%) patients. In adult patients (age above 18 years), the mean body mass index was 25.8. Using the standard World Health Organization (WHO) Classification, 33.6% adult patients were overweight (BMI 25 to 29.9), and 21.3% were obese (BMI 30 and above). These figures are high compared to the corresponding figures of 20.7% and 5.8% in normal Malaysian population according to the National Health and Morbidity Survey[13]. A number of psoriasis patients had one or multiple concomitant diseases such as hypertension (21%), hyperlipidaemia (16.3%), diabetes mellitus (15.3%), and ischaemic heart disease (4.9%). These findings echoed the concern on recent association of psoriasis with obesity, dyslipidaemia, and cardiovascular diseases[2,4,9].

In terms of treatment, almost all patients were treated with topical medications which are the first line therapy in psoriasis. The most widely used topical treatments were emollients (82.5%), followed by tar preparations (79.6%), topical corticosteroids for areas other than face and flexures (72.3%), keratolytics (67.8%), vitamin D analogues such as calcipotriol (22.4%), and dithranol (0.8%). Phototherapy was used in 6.1% of patients. Narrowband UVB was used in the majority (67.7%). Other types of phototherapy used were broadband UVB (9.7%), oral PUVA (two patients), and topical/bath PUVA (3 patients). Systemic treatment as third-line therapy had to be given to 26.3% of patients. The most commonly used drug was methotrexate (69.4%), followed by acitretin (23.9%), systemic corticosteroids (7.5%), sulphasalazine (4.5%), cyclosporine (3.7%), and hydroxyurea (1.5%).

Patients with psoriasis have been reported to have a reduction in the quality of life similar to or worse than other chronic diseases[3,12]. In this pilot study, the measurement of quality of life using DLQI was performed in 505 patients. The mean DLQI score was 8.08 ± 6.29 (Min 0, Max 29). As this is an on-going registry, changes in DLQI scores can be measured during subsequent follow-up visits of these patients as part of an evaluation of therapeutic effectiveness.

Quality control measures are important in ensuring data quality of a registry. In this study, an audit of data entry revealed an accuracy rate of 99.9%. Rate of missing data was less than 3% in most data fields except for weight and height (up to 9%). Periodic re-training of source data providers have been planned to further reduce the missing data. Further refinement of the CRF and guidelines have been proposed to improve reporting.

CONCLUSION

This pilot study provides a great opportunity to evaluate the newly revised registry form, and provides an excellent starting point for what will be a large scale nationwide continuous data collection effort. Apart from revealing several interesting findings about psoriasis, more importantly the study helped to identify short- comings in the implementation of this registry. Our next steps should focus on resolving these issues in order to ensure greater benefit and future success of the registry.

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