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Economic Burden and Cost Effectiveness Analysis of Psoriasis Treatment Modalities in Malaysian Public Hospitals: A Study Protocol

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Abstract

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There is limited evidence on the economic burden and cost effectiveness of psoriasis treatment modalities in this region. This study aims to evaluate the economic burden and cost effectiveness analysis of four Psoriasis treatment modalities in Malaysian public hospitals. This is a prospective cohort study involving a total of 523 moderate to severe psoriasis patients (Psoriasis Area Severity Index (PASI)>10 and/or Body Surface Area (BSA)>10 and/or Dermatology Life Quality Life (DLQI)>10) recruited from five public hospitals in Malaysia via consecutive sampling technique. The duration of the data collection is 12 months (6 months recruitment and 6 months follow up). Inclusion criteria include new or existing moderate to severe psoriasis patients who started with new treatment modalities at the time of the recruitment period, Malaysians, aged 18 years and above and who are willing to participate. The costs are calculated from the societal perspective. Provider costs are calculated by estimating recurrent costs (emolument, consumables, utility, maintenance and training) and direct costs (drugs, laboratory investigation, procedural examination). Patient costs components are direct and indirect costs. Direct costs include treatment cost (traditional medicines), out of pocket expenses (over the counter drugs, skin supplements and products). Indirect costs covers transportation and loss of productivity. Economic burden is measured by multiplying the total cost with the prevalence of psoriasis. Effectiveness of the treatment modalities is assessed based on PASI, BSA and DLQI scores (outcomes). PASI-75 (75% reduction of PASI score from baseline score), BSA<5 and DLQI≤5 (disease has no or minimal impact on quality of life) is considered effective. The least cost per outcome is the most cost effective treatment.

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Keywords: Psoriasis; Cost effectiveness; Economic burden.



1. Introduction

Psoriasis is chronic inflammatory skin disease described by formation of papules, and silvery scale plaques that occur primarily at skin and joint (Langley et al. 2005; Affandi & Adnan 2012; Griffiths & Barker 2007). Recent study suggests that the immune system plays a vital role in the disease presentation by responding inappropriately to an environmental trigger, triggering inflammation within the skin. Psoriasis occurs worldwide but the prevalence varies among countries, cultures, risk and age of onset. It affects 1.5-3% of the world population, 2% in US (Langley et al. 2005; Griffiths et al. 2007), 1.3-2.2% of the UK population (Burfield & Burden 2013), 8.5% in Norway, 3.1% in Italy (Parisi et al. 2013), 1.5% in Spain (Ferrándiz et al. 2002), 2.3-6.6 % in Australia and 2%-6% of the Malaysian population (Affandi & Adnan 2012). In Malaysia, the most common type of psoriasis is plaque psoriasis, followed by guttate, erythrodermic, pustular, flexural, and palmoplantar non-pustular. More than half the psoriasis patients were male, representing 56.4% of 4445 patients. Malays were the majority, with 48.5% of the total patients, followed by Chinese, 24.3% and Indians 17.8%. The majority of patients (66.3%) reported to the Malaysian Psoriasis Registry had age of onset at age 40 years old (Affandi & Adnan 2012).

Psoriasis is a disease with no definite cure. Available therapeutic options are therefore aimed at controlling the extent of lesion and making it tolerable for the patient because it is not possible for complete clearance. Current treatments available for psoriasis are topical therapy (first line treatment), phototherapy (second line therapy), systemic therapy (third line management) and biologic therapy (severe cases). Topical therapy is given to patients with mild psoriasis and with minimal effect on quality of life ($DLQI \leq 10$), $PASI \leq 10$ or less than 5% Body Surface Area (BSA). Topical corticosteroids and vitamin D analogues are the agents most regularly given to the patients (Lebwohl 1995; Wakkee 2010; Affandi & Adnan 2012). Moderate to severe psoriasis will be treated by phototherapy, systemic therapy and biologic treatment. Phototherapy is indicated for patients who have failed topical therapy before starting them on systemic therapy. Phototherapy Ultraviolet B (UVB) for example, has been revealed to be safe, efficacious and cost effective. In cases where the patients did not respond well to UVB monotherapy, a combination of UVB and acitretin is given regularly (Bhosle et al. 2006; Vañó-Galván et al. 2012).

1.1 Problem Statement

Although psoriasis is rarely fatal, it has been recognized as a challenging disease from several perspectives such as patients, health care providers and health insurance companies. The issues might differ among these perspectives, but some problems related to costs are especially relevant to all. Because of the chronic nature of psoriasis, patients require lifelong care which equals to lifetime expenses (Radtke & Augustin 2008). With an increased incidence of psoriasis in Malaysia yearly, a great economic burden can be expected, particularly from providers' perspective, as the Malaysian public health care sector is heavily subsidized by the government. A study found that the estimated cost of illness for psoriasis in Malaysia in 2007 was RM1307.47 per patient per year excluding inpatient

costs. This amount was far lower than other countries because the government subsidized treatment cost, therefore it does not reflect the true cost of treating psoriasis in Malaysia (Tang et al. 2013).

Psoriasis is also associated with reduced work capacity, productivity and a greater number of missed work days than individual without psoriasis; incurring substantial indirect costs and adding to the financial burden of the disease. Since the treatment options are given at the hospital as either inpatient or outpatient, considerable loss of income can be expected. In Taiwan, loss of productivity (NT\$60,823) was higher than direct medical costs (NT\$54,620) among those enduring moderate to severe psoriasis. Loss of productivity (indirect costs borne by patient) accounts for 30-50% of the total cost with an average of 2.2 hours were lost from work attributed to psoriasis in Canada. The cost associated with loss of productivity were 2.26 times higher in moderate psoriasis than mild cases (Chen et al. 2014). Emergence of the new interventions such as biologic and systemic have been found to be highly effective than other modalities and improve patient's quality of life (Affandi & Adnan 2012; Kurian, 2011), but, its high costs limit its use to very severe patients, particularly in hospitals which are highly subsidized. High costs associated with biologics and systemic agents are associated with their side effects. As pre-treatment assessment and screening tests are required to be conducted to identify those at risk of developing toxicity, the cost of therapy will accumulate (Ahn et al. 2013; Affandi & Adnan 2012). For example, the most common Acitretin (systemic agent) related side effect is hyperlipidemia which may develop in 33% of patients treated with acitretin. Use of antilipid drugs, weight loss management and dietary changes require patients to spend more of their income to counter this effect (Hankin et al. 2010).

1.2 Justification

The findings of this study are expected to provide benefits to the healthcare system, clinician and public health. Economic analysis of psoriasis is especially important as it requires lifelong care, which equals to greater spending for healthcare system and high medical resource utilization. In line with the growing need of economic evaluation in healthcare, increasing demand in all areas of healthcare system and costs associated with pharmaceuticals, this study is initiated to compare cost and effectiveness as well as to report current costs and trends of psoriasis treatments including expensive treatments such as systemic and biologic in Malaysia. A comprehensive study on the economic burden of psoriasis provides useful information to the clinicians with better insight about the resource utilization for psoriasis management. This will help to justify and provide the necessary resources for further research and deployment of better treatments. It is important to consider patient's self-reported treatment effectiveness. This study includes Dermatology Life Quality Index (DLQI) together with the clinical assessment, Psoriasis Area Severity Index (PASI) and Body Surface Area (BSA) as the study outcomes. It is imperative to contain DLQI assessment as patients may underestimate the objective assessments of the clinical severity. Cost-Effectiveness Analysis (CEA) is the technique used to compare treatment options of a particular disease to investigate which modality offers the best outcome with the least amount of cost. The intervention is considered cost effective when the treatment resulted in health benefit which is at an equal or lower cost than the opposing treatment (Parisi et al. 2013). To our knowledge, cost effectiveness of four psoriasis treatments has never been evaluated in this region.

1.3 Study purpose

The study aims to evaluate economic burden and cost effectiveness of four psoriasis treatment modalities namely; topical, topical and phototherapy, topical and systemic, and topical and biologic.

1.4 Research question

The study aims to answer the following research questions:

- i) How much is the cost borne by provider, patient and society because of psoriasis in Malaysia?
- ii) What is the most effective treatment for psoriasis in Malaysia?
- iii) What is the most cost effective treatment for psoriasis in Malaysia?

2. Research Methods

Design: This a prospective cohort study involving a moderate to severe psoriasis patient (PASI>10and/or BSA>10 and/or DLQI>10) recruited from five public hospitals in Malaysia; Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Hospital Kuala Lumpur (HKL), Hospital Sultanah Aminah, Johor Bahru, Hospital Sultanah Bahiyah, Alor Setar and Hospital Pulau Pinang. a sample size is calculated using Power Sample (PS) software. A total of 523 is to be recruited (all hospitals) in 6 months duration, and another six months is the follow up phase, gives the duration of the data collection is one year. **Instrument:** Data is collected using several instruments; clinical pathway (to be filled by dermatologist/doctors), PASI form (to be filled by dermatologist/doctors), DLQI form (to be filled by patient) and patient cost instrument. Respondents are recruited via consecutive sampling technique. Inclusion criteria includes; age 18 years and above, Malaysian citizenship, moderate to severe Psoriasis ((PASI>10, BSA>10 and DLQI>10) who started with new treatment modality at the study settings at the time of the data collection. The case definition was similar to the Malaysian Clinical Practice Guideline on the Management of Psoriasis Vulgaris (Affandi & Adnan 2012), Australian Consensus on the Treatment Goals for Moderate to Severe Psoriasis (Baker et al. 2013), Treatment Psoriasis in New Zealand, British Association of Dermatology on the Diagnosis and Clinical Management of Psoriasis (Cohen et al. 2012: Smith et al. 2009) and European Consensus on The Treatment Goals For Moderate to Severe Psoriasis (Mrowietz et al. 2011) and willing to participate. Costs are calculated from societal perspective (patient and health provider). Costs borne by provider are recurrent cost (cost of hospitalization) and direct cost (medications, laboratory investigation and procedural examination). Component of cost borne by patient are direct (traditional/supplementary medicines/private hospitals, over the counter drugs, skin supplement) and indirect cost (transportation and loss of productivity).

3. Findings

This economic analysis study is conducted from societal perspective (provider and patient). Table 1 shows the component of costs borne by provider and patient. Cost borne by provider are classified into

recurrent cost and direct costs. Recurrent cost includes hospital expenditures on emolument for all staffs, utility, maintenance and training for a year 2015. Direct costs include drugs, laboratory investigation, procedural examination. Direct costs includes ; i) drugs are classified into four treatment: For topical therapy; drugs are classified into a) emollient; aquos cream, vaseline, ung emulsificant, aqueous cream + vaseline, urea, liquid paraffin and others, b) steroid: hydrocortisone, clobetasone butyrate, mometasone, betamethasone valerate, clobetasol propionate and clobetasol shampoo, c) tar: liquor picis carbonis, sebitar shampoo, cerascalp, ung cocois, 20% coal tar bath, d) keratolytic agents: dithranol, salicylic acid, e) calcipotriol: daivonex, daivonet, xamiol, daivonex scalp solution, f) combination; diprosalic ointment, g) adjunctive therapy: antihistamine, oral antibiotic, topical antibiotic. For phototherapy, the agents include narrowband ultraviolet B (UVB), oral psoralen ultraviolet A (PUVA), topical PUVA and bath PUVA. For systemic treatment, the agents are methotrexate, sulphasalazine, acitretin and cyclosporine. For biologic treatment, the agents are ustekinumab, adalimumab, etanercept, secukinumab and infliximab. ii) cost of laboratory investigation which includes, liver function test (LFT), fasting blood sugar (FBS), full blood count (FBC), renal profile (RP), antinuclear antibody (ANA), rheumatoid factor (RF), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), Hepatitis B, Hepatitis C, HIV, Quantiferon gold, Mantoux. iii) cost of procedural includes chest x-ray. Cost borne by patients are classified into direct and indirect cost. Direct costs consist of treatment costs at private clinics/hospitals, traditional medicines, over the counter drugs, skin supplements. Meanwhile, indirect costs are identified as transportation cost (to and fro) and loss of productivity.

Table 2 shows calculation model used in this study. The calculation is done based on one-year utilization (data collection). Two costing methods are used in the study: Step Down and Activity Based Costing (ABC) methods as suggested by Drummond et al. (1999). For the step down method, costs of running the related departments that involved in psoriasis management are allocated. Cost of hospitalization is estimated using step down costing. It starts with average recurrent costs (5 hospitals) then divides with the total output (cost per patient per day and cost per patient per visit). Average recurrent cost is allocated to inpatient (60%) and outpatient (40%). Then, it is divided with the number of inpatient and outpatient days to obtain average cost per patient per day and average cost per patient per visit. Other costs such as laboratory, procedural examination and drug is estimated using ABC method. Drug cost is obtained by multiplying drug cost per test with test utilization to give average cost drug per patient per treatment. Cost of laboratory investigation is obtained by multiplying cost per unit laboratory test with utilization to give average cost laboratory investigation per patient per treatment. Cost of procedural examination is obtained by multiplying cost per unit procedural examination with utilization to give average cost of procedure examination per patient per treatment. Analysis involves; a) economic burden, b) effectiveness and c) cost effectiveness. Economic burden is measured by multiplying the total cost (societal) with the prevalence of psoriasis (year 2015) to give average cost per patient. Effectiveness is measured based on the PASI, BSA and DLQI score (outcomes). Effectiveness is expressed in terms of percentage; the number of patients achieving PASI 75 (75% reduction of PASI score from baseline) and/or BSA<5 and/or DLQI≤5 (the disease has minimal impact

on quality of life), 6 months after treatment is initiated. Cost effectiveness is expressed in terms of the average cost per PASI 75 (75% reduction of PASI score from baseline) and/or BSA<5 and/or DLQI≤5. The least cost per outcome is considered the most cost effective treatment.

Table 1. Component of costs borne by provider and patient.

Component of cost		Description
Provider cost		
Recurrent costs		emolument cost (salary, allowances and bonuses in year 2015) consumable cost (medical utilities and non-medical such as stationaries) utility cost (water, electricity and phone bill) maintenance cost (hospital building) training
Direct cost		
Drug	topical	a) emollient; aquos cream, vaseline, ung emulsificant, aquous cream + vaseline, urea, liquid paraffin and others, b) steroid: hydrocortisone, clobetasone butyrate, mometasone, betamethasone valerate, clobetasol propionate and clobetasol shampoo, c) tar: liquor picis carbonis, sebitar shampoo, cerascalp, ung cocois, 20% coal tar bath, d) keratolytic agents: dithranol, salicylic acid, e) calcipotriol: daivonex, daivonet, xamiol, daivonex scalp solution, f) combination; diprosalic ointment, g) adjunctive therapy: antihistamine, oral antibiotic, topical antibiotic
	phototherapy	narrowband UVB, oral PUVA, topical PUVA, bath PUVA
	systemic	methotrexate, cyclosporine, acitretin , sulphasalazine
	biologic	ustekinumab, infliximab, adalimumab , secukinumab and etanercept
Laboratory investigation		LFT, FBS, FBC, RP, ANA, RF, ESR, CRP, Hepatitis B, Hepatitis C, HIV, Quantiferon gold, Mantoux
Procedural examination		chest x-ray
Patient cost		
Direct cost		
Treatment		treatments at private clinic/hospitals, traditional medicine, expenses on over the counter drugs, skin products and skin supplements
Indirect cost		
Transportation		transportation cost to hospital (to and fro)
Loss of productivity		loss of income because of psoriasis

Table 2. Calculation model

Perspective	Component of cost	Approach	Measure	Calculation model
Provider	cost of hospitalization	Step down	average cost of hospitalization per patient per day	(60% x average recurrent cost) / total number of inpatients day
		Step down	average cost per patient per visit	(40% x recurrent cost) / number of patient's visit at outpatient clinics
	drug cost	ABC	average cost per drug per patient per treatment	average cost per unit drug x utilization
	cost laboratory investigation	ABC	average cost per laboratory investigation per patient per treatment	average cost per test x utilization
	cost of procedural examination		average cost per examination per patient per	average cost per test x utilization

		treatment		
Patient	transportation cost	ABC	average transportation cost per patient per treatment	expenses of transportation (to and fro)
	loss of productivity	ABC	average loss of productivity per patient per treatment	income (daily) x days of patients unable to work because of psoriasis in a month
Societal	Component cost provider + component cost patient	Step down + ABC	average cost per patient per treatment	average cost borne by patient + average cost borne by patient
Economic burden	-	-	average cost per patient	total cost (societal) x prevalence of psoriasis (year 2015)
Effectiveness analysis	-	-	percentage of patients achieving PASI-75 and/or BSA<5 and/or DLQI≤5, 6 months after treatment is initiated	number of patients achieving PASI-75 and/or BSA<5 and/or DLQI≤5 / total number of patients treated with particular treatment
Cost effectiveness analysis	-	-	Average cost per PASI-75 and/or BSA<5 and/or DLQI≤5	average cost per treatment / effectiveness

*calculation is based on one-year utilization (data collection).

4. Conclusion

Psoriasis occurs worldwide, affects 2-3% of the total population. Being an incurable disease, psoriasis imposes great economic burden to both patients and health provider. Patient with Psoriasis needs lifelong care which equals to lifetime expenses and higher medical resources. Emergence of newer interventions such as biologic increased awareness of the cost of therapy.

5. Implication and policy recommendation

The main purpose in this study is to evaluate both economic burden and cost effectiveness of four treatment modalities which is the first study conducted in Malaysia. The findings provide evidence based information to the policy makers in determining a proper resource allocation for psoriasis management in Malaysia including better deployment of cost effective psoriasis interventions in Malaysia. Also, it will help clinicians to evaluate to what extend the current treatments are effective and improve patient's quality of life. In addition, it provides information about the cost borne by provider, patient and society because of psoriasis, hence, it will assist in developing appropriate strategies in the future psoriasis management.

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