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Health-related quality of life and disease burden of psoriasis in Iran

Ph.D. thesis

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I. Theoretical background and aims of the dissertation

Iran, as a developing country, is an upper middle-income country located in the southwest of Asia – the Middle East. Based on the latest reports of the World Bank, its population is 79.1 million people, its GDP (current US\$) is 393.7 billion (year 2015), and its total expenditure on health is 6.9 percent of GDP (year 2014). The Iranian health care financing system is organized through a number of public and non-public insurance schemes. Access to services and choice of provider is determined largely by the type of insurance coverage.

Iran has one of the first national Health Technology Assessment program, established in 2007, in the Eastern Mediterranean Region. Health technology assessment (HTA) is a form of policy research that systematically examines the short- and long-term consequences, in terms of health and resource use, of the application of a health technology, a set of related technologies or a technology related issue. HTA involves health economic evaluation that requires input data considering local aspects such as characteristics of the health care system, clinical practice, patients' clinical status and health-related quality of life (HRQOL), individual and societal preferences and costs in a given country. HTA has been introduced in Iran, however country-specific input data both HRQOL and cost for health economic evaluation are often missing.

For HRQOL research, it is fundamental to understand people's notion on health. The concept of health has been dynamically changing by rise of new needs and diversity in human preferences. Also by improvement of life expectancy from the beginning of the 20th century, the concept of health for the person and the society has evolved. Advancements in science and technology have made this possible and have changed human needs. The fear of dying has changed to dedication to survival and living healthier in a better quality of life for a longer time. Hence the importance of HRQOL

in determining the burden of a disease as well as the value of healthcare interventions has increased.

Psoriasis is a chronic inflammatory disease affecting approximately 2% of the population globally. It represents a social and financial burden for patients and the healthcare system. Patients often suffer from disfigurement and from social stigmatization. Because the disease is usually persistent, patients usually need lifelong care, which also means a lifetime of expenses. Several questionnaires have been used to measure HRQOL in patients with psoriasis in Iran. However, to our knowledge there cannot be found any studies in the literature that assessed HRQOL of psoriasis patients with the EQ-5D, a preference-based tool that can provide utility data for quality-adjusted life year (QALY) calculations in cost-effectiveness analyses. Furthermore, there has not been published any cost-of-illness study in psoriasis from Iran or the Middle East region. Comparison of the findings in Iran with other countries can provide a basis for analyses of transferability of health economic evaluations.

The thesis involves three major research topics, and the structure of the chapters follows these points:

1. Health policy and Health Technology Assessment in Iran
2. An empirical investigation into the concept of health
3. Health-related quality of life and cost-of-illness of psoriasis in Iran

I.1 Objectives

I.1.1 Health policy and Health Technology Assessment (HTA) in Iran

- (1) To provide an overview on the health system and healthcare financing in Iran with special focus on the development of HTA.

I.1.2 An empirical investigation into the concept of health

- (1) To explore laymen's opinions concerning the everyday notions of health.

I.1.3 Health-related quality of life and cost-of-illness of psoriasis in Iran

- (1) To measure HRQOL of psoriasis patients in Iran with the general measure of EQ-5D and several disease-specific instruments.
- (2) To compare HRQOL of psoriasis patients to the age-matched general population in Iran.
- (3) Mapping EQ-5D index scores and EQ visual analogue scale (EQ VAS) scores from Dermatology Life Quality Index (DLQI) to provide utility values for economic evaluations.
- (4) To estimate annual per patient direct and indirect costs associated with psoriasis in Iran from a societal perspective.
- (5) To compare HRQOL and cost-of-illness in patients with psoriasis between Iran and Hungary.

II. Methodology

II.1 Review on the health policy and HTA in Iran

Characteristics of the health status of the population, healthcare system, healthcare financing system, health insurance system and HTA in Iran are reviewed and discussed based on the available literature.

II.2 A survey exploring the importance of a set of factors in the concept of health

In a cross-sectional survey 34 factors usually associated with the domain of health according to the literature were listed. Participants were asked to rate the importance of each factor in respect of health in general and also to add factors which they think are important. The degree of importance was measured on a Likert-type scale from 0 to 6 (most irrelevant, irrelevant, not at all relevant, neutral, less relevant, relevant, and most relevant), and responses were scored from 1 to 7. Scoring of each factor was calculated by counting how many times participants marked each response level to each factor, then the total number of each factor was multiplied by the score we gave to each degree, and finally we add up all the numbers. The formula is: (numbers choosing most irrelevant x 1) + (numbers choosing irrelevant x 2) + (numbers choosing not at all relevant x 3) + (numbers choosing neutral x 4) + (numbers choosing less relevant x 5) + (numbers choosing relevant x 6) + (numbers choosing most relevant x 7). Finally, factors were sorted in descending order in the basis of the sums explained above.

II.3 Cross-sectional survey to assess health-related quality of life and cost-of-illness of patients with psoriasis in Iran

A cross-sectional questionnaire survey including 262 patients has been carried out. Overall, 200 patients from Hungary and 62 from Iran enrolled to the study. The Iranian study was performed from May to August 2013 at Moradi Skin Laser Clinic in Shiraz, Iran. We used a questionnaire that incorporated self-designed items and validated HRQOL and disease severity measures (Balogh et al., 2014, Heredi et al., 2014). The questionnaire consisted of two parts; the first was filled out by the patients and the second by their dermatologist. HRQOL was assessed by EQ-5D, EQ VAS and DLQ). All the patients were managed by the same dermatologist who provided data on clinical type of psoriasis, psoriasis treatment in the last 12 months, and moreover, completed the Psoriasis Area Severity Index (PASI).

II.3.1 Outcome measures

EQ-5D questionnaire

In our study, the validated Farsi version of the EQ-5D was administered. The EQ-5D consists of two pages - the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system comprises of the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression) (EuroQol Group, 1990). Each of these dimensions can be rated as 1 (no problems), 2 (some problems) or 3 (extreme problems). Due to absence of local value set in Iran, the UK weights were applied to calculate EQ-5D scores (i.e. utilities) that can range from -0.594 to +1, with higher scores referring to better HRQOL (Dolan, 1997). EQ-5D is accompanied by a visual analogue scale (EQ VAS) on which patients are asked to provide a self-assessment of their own health in a range from 0 (worst imaginable health state) to 100 (best imaginable health state).

Dermatology Life Quality Index (DLQI)

Dermatology Life Quality Index (DLQI) is the most commonly used dermatology-specific HRQOL questionnaire (Finlay&Khan, 1994). It consists of 10 questions covering symptoms, feelings, daily activities, leisure, work and school, personal relationships and treatment side effects that assess patients' perception of the impact of skin condition on their HRQOL last week. Each question is scored on a 4-point Likert scale (0, not at all/not relevant; 1, a little; 2, a lot; 3, very much). DLQI score is calculated by summing up the score of each question and therefore, total scores range between 0 (least impact on HRQOL) and 30 (maximum impact on HRQOL).

II.3.2 Costing

The cost calculation was performed from societal perspective based on resource utilization data provided by the patients and their dermatologist in the questionnaire. Data were collected about direct and indirect costs (productivity loss). Official unit costs of the Iranian Ministry of Health were applied, where available. Timeframe of the cost analysis was 12 months, and the year of costs was 2016.

Direct costs

Data were collected from patients on the number of GP visits in the past one month, the number of dermatologist visits in the past three months and the number of hospitalizations over the past 12 months. According to the Iranian General Physicians' Association, the cost of a GP visit and a dermatologist outpatient visit were €5.34 and €8.21, respectively. The daily average cost of hospitalization was considered at a public hospital rate (€45.95/day). On average fourteen days of inpatient stays were calculated for each hospitalization.

The patients' dermatologist provided data on the treatments applied in the past 12 months. Costs of drugs and topical treatments (i.e. ointments) were based on official pharmacy list prices. Where multiple generic products were available, the drug with the lowest price was considered. Furthermore, patients answered questions about spa

and a neuropath visits or any other treatments/services used, and also indicated the monthly amount payed for these.

To estimate costs of informal care, patients were asked to indicate how many hours of help they receive from informal caregivers such as family members or friends on a weekly average. Cost of informal care was calculated at a rate of €3.42/hour.

Indirect costs

The costs of productivity loss due to psoriasis were estimated by employing the Human Capital Approach based on patients' responses on the Work Productivity and Activity Impairment questionnaire (WPAI) (Reilly et al., 1993). Psoriasis patients indicated the hours they actually worked in the past week, the hours missed by cause of psoriasis and other reasons and indicated the degree to which psoriasis affected productivity while working on an 11-point rating scale. Both costs of absenteeism (working hours missed due to psoriasis) and presenteeism (reduced productivity while at work due to psoriasis) were estimated. The average gross hourly wage (€3.74/hour) was applied for the cost calculation.

III. Main results

III.1 Health policy characteristics and development of HTA in Iran

The total population of the Islamic Republic of Iran is dynamically growing, as it increased by 10 million between 2000 and 2011 and was 79,109,000 in 2015. A dominance of age-group 25-54 years can be observed (47.6%) indicating a typically young population. Life expectancy at birth is increasing and it was 72.1 years for males and 74.6 years for females in 2011. The leading causes of death are non-communicable diseases, namely ischaemic heart disease and cerebrovascular diseases. The most frequent health problems causing disability are low back and neck pain, depressive disorders, sense organ diseases, and diabetes. Skin disorders are in 5th place in the causes of disability.

The Iran health system consists of both public and private sectors, and currently all Iranians have access to a government-supported health insurance system. However, due to the lack of sufficient resources in public health sectors and national health insurance schemes, in the past years and up to 2012, out-of-pocket payments of patients have substantially increased, it was 55% in 2008 (although the Iranian Development Plan set the goal for out-of-pocket payment to as low as 30% in 2008) and has topped to over 81.3% of the costs of medical services.

Government pays for general revenue financing health care. General revenue financing of health care mostly gives primary health care (PHC) to the people and focuses on several secondary care services, such as expensive-to-manage diseases. In addition to that, public hospitals' infrastructure is mostly paid out of government general revenue. Medicine production benefits from significant government subsidies. Social health care insurance covers around 90% of the population, and it focuses on non-PHC 'treatment' services, which includes most ambulatory, diagnostic and hospital services. The number of services they provide varies depending on the service and setting, and to some extent on who is the insurer. However, an important share of

health care bill is paid by people as out-of-pocket payments at the time of service utilization. Total health expenditure has increased very rapidly in the past decade, the per capita health expenditure has risen from \$68 in 1995 to \$229 in 2000 to \$351 in 2014.

HTA began its activities as a secretariat in the Deputy of Health in 2007 in Iran and it continued as a Health Technology Assessment Office at the Management of Health Technology Assessment, Standardization, and Tariff at the Deputy of curative affairs of Ministry of Health and Medical Education (MoHME) in the beginning of 2010 with structurally enhanced objectives and goals to promote evidence based policy making. Between 2007 and 2010 altogether 22 HTA evaluations were conducted in Iran, 14 of which focused on medical equipment and eight pharmaceutical drug-related HTA were completed. These HTAs were funded through governmental budgets. Between 2010-2015 more than 50 projects were conducted in various clinical fields and were used to inform Health Transformation Plan. Nonetheless, reimbursement does not depend on the results of the HTA. Further research is needed on how to increase the usefulness and efficacy of the HTA-backed decision making in Iran.

III.2 Laymen' opinion on the concept of health

Survey questionnaires were completed by a convenience sample of 105 participants (66.7% female) with mean age of 31 (SD 9.1; minimum: 19, maximum: 63) years. The highest education level was as follows: 2 % had completed secondary school, 45.7 % had a Bachelor's degree, 35.2% a Master's degree, 13.3% a PhD and 3.8% others.

The five most relevant factors in the concept of health were (scores): Positive emotional feeling (659), Optimism (633), Fitness, Goal and harmony (630), and Love (627), respectively, while the five most irrelevant factors were Machine-like (327), Religiousness and beliefs (380), Flow (382), Reproduction of society (415), and Beauty (440). Other important aspects of health, such as Discipline, Ability to relax, Innovativeness and Maturity, were placed by participants in the middle of our rank

order (scores were 539, 530, 527, 522, respectively). Participants added further relevant factors, namely no stress, patience, security, proper partner relations, education, healthy diet, social responsibility, motivation, loving animals, spiritual well-being, internal and external balance, faithful and reliable friends. The fact that people attach less importance to beauty in the concept of health may have implications for priority setting and in the evaluation of skin diseases, including psoriasis that affects physical appearance.

III.3 Disease burden of psoriasis in Iran and comparisons with Hungary

III.3.1 Patient characteristics

Mean age of the Iranian psoriasis patients was 40.40 (SD 17.53, range 16-86), with 76 % males. The mean disease duration was 13.60 (SD 11.37) years. In total, 66% of the patients were diagnosed with chronic plaque psoriasis followed by scalp psoriasis 36%, palmoplantar involvement 27%, inverse 26%, guttate 19%, and nail psoriasis 19 %. Overall, 48% of the patients used only topical therapy in the last 12 months, and 39% received systemic non-biological therapy.

III.3.2 Health-related quality of life and disease severity results

Mean EQ-5D, EQ VAS, DLQI and PASI scores were 0.62 (SD 0.37), 60.18 (27.26), 10.19 (SD 6.46) and 12.94 (SD 8.28), respectively. In terms of the five underlying dimensions of EQ-5D, 18%, 26%, 28%, 63%, and 63% marked having some or severe problem in mobility, self-care, usual activities, pain/discomfort and anxiety/depression, respectively.

III.3.3 Mapping EQ-5D index scores and EQ VAS scores from DLQI to provide utility values for economic evaluations

Linear relationships of DLQI onto both EQ-5D and EQ-VAS were estimated: EQ-5D= $0.88 - 0.02 \cdot \text{DLQI}$ (adjusted $r^2=0.213$, F-test $p<0.001$), EQ-VAS= $80.14 - 1.98 \cdot$

DLQI (adjusted $r^2=0.206$, F-test $p<0.001$). Thus, 1 point increase in the DLQI results in 0.02 point decrease in the EQ-5D and 1.98 points decrease in EQ VAS. The DLQI score explained 22.6% of variance of EQ-5D and 22 % of the variance of EQ-VAS.

III.3.4 Comparison of EQ-5D results with the Iranian general population

In Iran, an EQ-5D population norm was published in 2016 (Karyani et al., 2016). They surveyed overall 600 members of the general population who had health insurance in Tehran, Iran. The rate of reporting problems regarding mobility was approximately equal among psoriasis patients and the age-matched general population (40-49 years): 18% vs. 22%. In the other four dimensions, considerably more problems occurred among psoriasis patients (self-care 27% vs. 3%, usual activities 27% vs. 9%, anxiety/depression 63% vs. 39%, pain/discomfort 63% vs. 38%). Whereas few members of the general population reported severe problems in any dimension, psoriasis patients more often had such problems; for example, 16% in anxiety depression and 13% in pain discomfort.

III.3.5 Comparison of HRQoL findings between Iran and Hungary

A comparison between the findings of Iranian and Hungarian studies is provided in Table 1. Iranian patients were, on average, 10 years younger. More than half of the Hungarian patients used systemic biological therapy in the last 12 months but none in the Iranian study. The Iranian patients were in a worse health status assessed by any outcome measure (EQ-5D, DLQI and PASI).

Table 1. Health-related quality of life and disease severity of Hungarian and Iranian patients

Variables	Iran (2016)	Hungary (2012)
	This study	(Balogh et al., 2014)
N	62	200
Age (mean, SD)	40.4 (17.5)	51.2 (12.9)
Males %	76%	69%
BMI (mean, SD)	25.66 (3.29)	29.89 (5.44)
Disease duration (mean, SD)	13.60 (11.37)	21.96 (11.67)
<i>Health-related quality of life and disease severity (mean, SD)</i>		
EQ-5D (-0.594 to 1)	0.62 (0.37)	0.69 (0.3)
DLQI (0-30)	10 (6.5)	6.29 (7.3)
PASI (0-72)	13 (8.3)	8.1 (10)
<i>Treatment (during the last 12 months)</i>		
None or topical therapy	48%	18%
Systematic non-biological	39%	31%
Biological	0%	51%

III.3.6 Cost-of-illness of psoriasis in Iran

Total annual per patient cost of psoriasis in Iran in 2016 was €3,373 (SD €4,757) (Table 2). The shares of direct medical, direct non-medical and indirect costs were 23%, 11% and 65% of the total costs, respectively. Hospitalizations were responsible for the majority of direct medical costs, which accounted for about one-fifth of the total per patient costs of psoriasis. Costs of drugs and ointments took less than 6% of direct medical costs. Informal care represented 11% of the total costs. The highest

costs were related to productivity loss. Total indirect costs amounted to €2,209, with a share of €700 (32%) and €1,509 (68%) between absenteeism and presenteeism, respectively.

Table 2. Comparison of annual cost in psoriasis in Iran and Hungary

Cost items	Mean EUR (SD)	
	Iran (2016)	Hungary (2012) (Balogh et al., 2014)
	N=62	N=200
TOTAL COSTS	3,373	9,254
Direct medical costs	789 (23%)	7,595 (82%)
GP visit	26 (0.8%)	22 (0.2%)
Outpatient dermatologist visit	42 (1%)	36 (0.4%)
Hospitalizations	674 (20%)	136 (1%)
Topical and systemic non-biological therapy	46 (1%)	256 (3%)
Biological therapy	-	7,339 (79%)
Spa	0.05 (0.001%)	-
Other	0.36 (0.01%)	60 (0.7%)
Direct non-medical costs	376 (11%)	148 (2%)
Informal care	376 (11%)	117 (1%)
Transportation	N/A	31 (0.3%)
Indirect costs (productivity loss)	2,209 (65%)	1,255 (14%)

N/A = not applicable

III.3.7 Conclusions

This is the first study from Iran that assesses HRQOL of psoriasis patients with EQ-5D and EQ VAS and the first cost-of-illness study in psoriasis patients. HRQOL impairment measured with either EQ-5D or EQ VAS was considerable; some or

severe problems were most frequently emerged in anxiety/depression and pain/discomfort dimensions. Psoriasis patients have significantly decreased HRQOL measured by the EQ-5D compared to the general public in Iran. Moreover, EQ-5D scores evaluated in this study provide country-specific data for cost-utility analyses. Annual total costs of psoriasis in Iran exceeded €3,000 per patient, which is considerably higher than that of diabetes, gastroesophageal reflux disease or irritable bowel syndrome. The major cost drivers were productivity loss, hospitalizations and informal care.

IV. Implications for practice

Results of the research presented in this thesis have various economic and health policy implications for Iran. Although biological drugs have brought the potential to dramatically change the management of patients with psoriasis, in Iran, the access to biological treatment is limited, mostly due to the high costs of biological drugs. Lack of insurance coverage of the biological drugs can lead to economic problems for the patients in obtaining them. Private companies (not related to the state) import these kinds of medicines and due to the frequent change of the currency value, the price of imported drugs are fluctuating. I believe that our findings can contribute to the improvement of psoriasis care by highlighting that this chronic skin disease imposes a great burden on the individuals and has a significant economic impact to the society. Moreover, our study provides reliable input data for cost-effectiveness analyses that can support sustainable financing decisions and long-term health planning. Our experiences with adapting a disease burden survey from another country to Iran can serve as a useful experience for other clinical fields with lack of HRQOL and disease burden data.

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VI. Publications of the author related to the thesis

VI.1 Published papers

MORADI, M., RENCZ, F.: GULÁCSI, L., MORADI, A., BROSZKY, V. (2015): Health status and quality of life in patients with psoriasis: Iranian cross-sectional survey. Arch Iran Med. 18(3), pp. 153-9. IF 0.931

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VI.2 Poster presentations

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BRODSZKY, V., MORADI, M., GULÁCSI, L., BAJI, P., BALOGH, O., PÉNTEK, M. (2013): Indirect comparison of the biologics in patients with psoriasis; a meta-analysis of randomized, double blind clinical trials in bayesian framework. Value in Health 16(7), pp. A501-A502. Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 16th Annual European Congress, 2-6 November 2013, Dublin, Ireland

MORADI, M., RENCZ, F. (2014): A comparative cross-sectional study on health-related quality of life in psoriasis from Hungary and Iran. Value in Health, 17(7), p. A612., Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 17th Annual European Congress, 8-12 November 2014, Amsterdam, The Netherlands

VI.3 Conference papers

MORADI, M. (2013): Health system in Iran. PhD student conference at Corvinus University of Budapest, 30 May 2013

MORADI, M. (2014): Evaluation of the quality of life in patients with psoriasis; cross sectional study from Iran. Corvinus Health Policy and Health Economics Conference Series 2014/2, at Corvinus University of Budapest, 31 March 2014

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