

Economic costs incurred by the patients with Multiple Sclerosis at different levels of the disease: a cross-sectional study in northwest Iran

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Research article

Keywords: Multiple Sclerosis, disease cost, disease levels, Iran

Posted Date: January 2nd, 2020

DOI: <https://doi.org/10.21203/rs.2.16370/v2>

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Version of Record: A version of this preprint was published at BMC Neurology on May 23rd, 2020. See the published version at <https://doi.org/10.1186/s12883-020-01790-5>.

Abstract

Background Multiple sclerosis (MS) causes significant economic burden to the patients, families, health systems and society. This study aimed to estimate the economic costs incurred by patients with multiple sclerosis at different levels of the disease. **Method** This was a cross-sectional study, using the Expanded Disability Status Scale (EDSS) tool for assessing the disease level of 300 (=N) patients in East Azerbaijan province, Iran. To estimate the cost of MS, a questionnaire with its validity and reliability (CVR 92% and CVI 87%) and pilot test (Cronbach's alpha score 0.89) was used. The data were collected by interviewing patients and reviewing their clinical records. Linear regression and ANOVA were used to assess the relationship between disease levels and incurred costs. **Results** The results revealed that the mean annual cost for patients is 97,521,740 IRR (equivalent to 2,321.94 USD) and the mean score of EDSS in patients was 3.14. The annual cost incurred by patients with mild, moderate and severe levels of disease were 83,918,150 IRR (998.05 USD), 137,772,660 IRR (3,280.30 USD) and 119,962,670 IRR (2,856.25 USD) respectively. Also, there was a significant relationship between total cost and disease severity in such a way that any increase in EDSS degree is led to 8,139,260 IRR (193.79 USD) added cost for patients. **Conclusion** The study results could be helpful for Iranian health managers to solve problems which are facing patients and their families.

Introduction

Multiple sclerosis (MS) is a complex inflammatory disease associated with the central nervous system, resulting in several health problems including muscle stiffness, diplopia, sensory loss, limb weakness, gait ataxia, loss of bladder control, epilepsy, functional impairment and disability (1). MS leads to a wide range of psychological disorders, including depression, disappointment, cognitive impairment, loss of independence, pain, fatigue, anxiety, lack of confidence, and social problems (2). It causes significant economic burden to patients and societies (1, 3-5). A study has shown that during 2016, worldwide 2.22 million people were suffering from MS with an increase of prevalence of 10.4% during the last 26 years (1). MS has emerged as a major public health problem with its noteworthy prevalence (1, 6), long survival time (7), affecting the high productivity age (8), resulting in devastating socioeconomic effects (1, 9, 10).

Besides its physical, psychological and social effects, MS incurs huge economic costs for the patients and their families and health systems (11). Depending on the duration of the disease, the level of neuro-degeneration MS results with various level of productivity loss including unemployment (12). With a mean affecting age of MS around 30 years, studies indicated that even the working persons have lost their jobs after five to ten years of diagnosing MS resulting severe burden of unemployment (1, 13). The prevalence of MS in Iran varies between different geographical locations (14). There are 5 -13 cases per 100,000 population in southeast Iran (15) and 33.5 - 51.9 cases per 100,000 population in central Iran (16). Literatures indicate that MS is increasing in Iran like other Middle East countries (14, 17).

Studying the disease status in MS patients and the costs incurred by them is one of the essential requirements for managing this disease. There is a dearth of materials in low and middle-income countries, especially focusing on economic costs (1, 18-20). With 304 death and 26395 DALYs lost due to MS during 2016, Iran has a lack of health economics studies estimating the cost of MS (1). The current study aimed to investigate the economic costs incurred by MS patients at different levels of the disease.

Methods

Participants

This is a cross-sectional study, conducted in May 2018 with the participation of 300 registered MS patients in East Azerbaijan province of Iran. The study subjects were patients with medical records in the East Azerbaijan MS Association who had spent at least one year from initiating treatment. Random sampling method was used in this study and the sample size was determined based on the total number of patients registered in this association (1200) and using the Morgan table

(21). The participation rate was 97%. Nine patients had inappropriate health condition and could not agree to participate in study (3% decline rate).

Study tools

The Expanded Disability Status Scale (EDSS) questionnaire was used for calculating the clinical status of patients (22, 23). For economic cost estimation, a cost questionnaire including demographic and related variables were designed and standardized during the study. In the first step of developing the instrument for evaluating the cost of MS, comprehensive literature reviews were conducted. Content validity and face validity of the questions were examined by 10 field experts in terms of five aspects of necessity, relevance, transparency, simplicity, and feasibility of measurement. Then, content validity ratio (CVR) was evaluated based on necessity scores. After confirming the questions in CVR index, the mean score of four other indicators or content validity index (CVI) was reviewed and confirmed. The acceptance score of 70% was selected as the decision criterion according to the responses of 10 experts (24). In this study, the CVR score (92%) and CVI score (87%) were obtained. The reliability of the questionnaire was also confirmed by the data obtained from a sample of 50 patients in a pilot study and the Cronbach's alpha score (α) of 0.89.

Data collection

A pre-tested questionnaire was used for interviewing the MS patients for estimating costs along with reviewing their medical records. Patients/family perspective was used to calculate the costs of the disease, which includes a set of direct and indirect costs incurred by patients and their families (25, 26). Given that the MS patients had received their required healthcare service in determined healthcare facilities (clinicians, pharmacy, hospitals and rehabilitation centers), their health records were assessed precisely towards more accurate data. Direct costs are consisting of direct medical costs including diagnosis, treatment and rehabilitation costs; and non-medical costs including supportive equipment costs (wheelchair), equipping the home with needed medical facilities, regular transfer costs to/from care centres (27, 28). Indirect costs refer to the patient's lost time and related productivity loss (29, 30). In absence of any formal record keeping system there is lack of relevant clinical and managerial information for MS patients in Iran, especially for non-medical and indirect cost elements. Multiple sources were used for necessary information generation. For example, for employed MS patients we had used their medical and/or job records. For self-employed MS patients we had used self-reported information.

The disease status score was calculated by the EDSS questionnaire and a neurological examination by the neurologist, during which the patient's condition and grade of disease progression are determined on a scale between 0 and 10; these numbers represent the best and the worst possible conditions for the patient, respectively.

Data analysis

Frequency, mean and standard variables were used. Linear regression and ANOVA tests were used for assigning the relationship between the disease condition and various costs imposed on patients. These costs are based on the exchange rates of the Central Bank of Iran, expressed in US dollars (a dollar equivalent to 42,000 IRR, on 30 May 2018) (31). The reference year was May 2017 to May 2018 for cost estimation. Due to sanction, we could not provide international Dollar for 2018. All analyses were performed using SPSS18. Significance level was considered at $P < 0.05$.

Ethical considerations

The study has received ethical permission from the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1396.101). Each participant was informed and explained by the researchers about the study objectives. Freedom of participation, privacy, anonymity, and rights to withdraw during study were explained and assured. Written informed consent was obtained from each participant.

Results

Characteristics of the patients

The mean age of the patients was 37.15 (± 9.68) years old. The youngest and oldest patients were 16 and 68 years old, respectively. Most of the patients were middle-aged and more than two-thirds of them were women. The mean age of the onset of the symptoms was 27.18 (± 7.64) years and on average, 9.95 (± 7.06) years were passed since the onset of symptoms. These patients were mostly married, housekeeper, native to the city of Tabriz, and with low education level. All patients had basic insurance and the majority of them were covered by social welfare, but only one-third of the patients had a supplementary insurance. (Table 1)

Direct medical expenses

A neurologist had examined almost all of the MS patients during the past year while other specialists had examined only one percent of the patients. A large number of patients (73%) had brain MRI. Among the rehabilitation care services, physiotherapy was the only service that was received by the patients. The medicines Betaferon, Diphosel and CinnoVex had the highest intake for the MS patients, respectively. Only 26% of the patients used drug supplements. Results showed that 42% of the patients were hospitalized in the past year, and about 5% of them had made some unofficial payments (bribery) to the health care staff (Table 2).

Direct non-medical costs

Four percent of the patients received non-therapeutic and home care. Also, 8% of the patients used walking aids devices, and only 2% of them considered safety and comfort issues at their homes. Patients commuted mostly for receiving care services of private clinics, and no costs were incurred for accommodation and meals at the time of visiting health centers (Table 3).

Indirect costs

Most of the patients (84%) and their caregivers (77%) had to be absent from work due to the disease and receiving medical care. Accordingly, patients and their families lost 32 and 5 working days in a year on average, respectively and 15% of the patients and 1% of their families lost their jobs due to the disease.

The cost of disease

Investigating the amount of costs imposed on patients showed that the highest proportion of the costs is related to direct medical costs and the lowest part to indirect costs. On average, these patients paid 70,106,490 IRR (1,669.20 USD) in a year for medical/clinical services, with the cost of medicine, rehabilitation services and diagnostic services having the highest

shares, respectively. The amount of direct non-medical costs for patients was 22,201,750 IRR (528.61 USD); the highest cost was related to commuting to care centers. These results also estimated the indirect costs of patients to be 5,213,500 IRR (124.13 USD); these costs were mainly due to the patient's absence from his/her job for medical and treatment reasons. In total, the mean amount of 97,521,740 IRR (2,321.94 USD) was the cost for the MS patients in a year (Table 4).

The status of disease progression based on EDSS score

Reviewing the status of patients' disease indicated that the mean score of EDSS was 3.14. Also, 70% of the patients had mild illness (life quality score less than 4) and each group of the patients with moderate and severe disease comprised about 15% of the total. Nearly one-third of the patients had suffered a recurrence of the disease during the past year, and the mean recurrence rate for this period was 0.58 times (Table 5).

The relationship between costs and patients' status

Regression analysis showed that there is a significant relationship between patients' disease status and direct medical costs and total cost. Degree of increase in EDSS score (worsening of patients' condition), enhance the direct medical costs and the total cost increase significantly as 7,462,080 and 8,139,260 IRR, respectively (equivalent to 177.66 and 193.79 USD). The relationship between EDSS score and direct non-medical costs and indirect costs was not significant (Table 6). B indicates occurring changes in various types of cost due to one unit change in EDSS score.

The results also indicated that patients with mild illness (EDSS score less than 4) spent 83,918,150 IRR (1,998.05USD); patients with moderate illness (EDSS score between 4 to 6.5) spent 137,772,660 IRR (3,280.30 USD); and the cost for patients with severe illness (EDSS score 7 and above) was 119,962,670 IRR (2,856.25 USD) annually. Also, using ANOVA test to determine the statistical relationship between the disease condition (mild, moderate and severe) and illness costs, it was found that the status of patients had a significant relationship with direct medical costs and the total cost (Table 7).

Discussion

The current study indicated that, on average, MS patients spent an annual amount of 97,521,740 IRR (2,321.94 USD). The highest share of expenses (almost 72% of total cost) was related to direct medical costs and the lowest share (5%) to indirect costs. In a study by Imani et al. (2013) in Iran, the mean annual total cost per patient was estimated to be 24,475 USD and direct medical costs accounted for the largest share of the costs too (32). In the studies by Svendsen et al. (2012) in Norway and Berg et al. (2006) in Sweden, the annual cost of the disease was estimated to be 65,000 and 53,600 euros, respectively. In both studies, direct medical costs accounted for the largest share of costs (3, 23). Therefore the current study from Iran is in the line of findings from high-income countries (10, 33). The direct medical cost, direct non-medical cost, and indirect cost were 71.89%, 22.77% and 5.34% respectively in this study, in Iran. While the direct medical cost, direct non-medical cost, and indirect cost were 22.45%, 16.59% and 60.69% respectively in Norway (3); and were 46.91%, 21.10% and 31.99% respectively in Sweden (23). The cost of disease in different countries with varying contexts could not make comparable as the health systems, healthcare provider organizations, health status, structures, and mechanisms for payments, as well as healthcare utilization and the caregivers' perspectives are different (23, 33). It is important to consider issues such as low and declining value of Iranian national currency, the economic sanctions and, consequently, the scarcity of drugs, and high prices of the drugs due to the lack of manufactures in Iran.

Reviewing the conditions of MS suggested that the average score of EDSS in patients was 3.14, and about 70% of patients were in the mild group, and each of the groups of patients with moderate and severe illness comprised 15% of the sample. In Sweden, the mean EDSS score was 5.1, and the mild, moderate and severe levels of disease included 29, 46, and 25% of the

total patients, respectively (23). In Norway, the mean score of EDSS was 4.3, and the mild, moderate and severe levels of the disease included 43.5%, 43% and 13.5% of total patients, respectively (3). The reason for the better status of the disease in this study may be attributed to early diagnosis and treatment because the mean age of the patients at the time of diagnosis in Sweden was 39 and it was 37 in Norway. But in the present study, the mean age of the patients of MS was 27 years. This has led to the fact that, despite ten years since the onset of the disease, patients are still in mild condition in Iran. Undoubtedly, part of this difference in the condition of illness can be attributed to the limitation of the present research, which could not access patients in severe condition because of their reluctance to participate in the study.

The current study supports the literature that there is a significant correlation between the severity of the disease (EDSS score) and various types of costs imposed on patients (23). The reason could be seen in insurance systems, social security and poor financial support for patients in Iran than in high-income countries (10, 33). For example, providing proper insurance system and necessary social security which cover all of required services with reasonable and payable cost for patients with MS and their families (Universal Health Coverage / effective coverage) could lead to proper financial protection and healthcare access. In this situation, the patients with MS can receive their required medical services in appropriate quality and quantity; consequently, the disease progress and its negative effects could be controlled. Also, costly care increases patients' concern on direct medical costs (as the major cost) and obliges them to neglect other indirect costs associated with the disease. A recent study from Germany demonstrated that healthcare costs increases with severity but the in-patient costs decreases (31). Our study actually demonstrated the same but in different context.

Comparison of the amount of costs imposed on patients at different levels of quality of life showed that direct medical costs in patients with severe disease were higher than those with mild illness and lower than those with moderate type of disease. The reason for high direct medical costs imposed on patients with severe condition is that they need more diagnostic, therapeutic and rehabilitation facilities. Moreover, the lower costs of disease in patients with severe conditions compared to moderate patients can be associated with bad economic conditions of the first group due to a high amount of total cost as well as a decrease in their earnings because of absence from work and losing their jobs. All these factors make the patients with severe disease take cheaper drugs with low efficiency or put some essential treatment services aside resulting decrease in productivity and extreme situation unemployment. This might be another reason why the severe MS patients were unwilling to participate in the current study.

The assessed characteristics majority (68%) patients in the current study were women (mean age 37.15 years) which is in line of a Norwegian study (3), where, 65.1% patients were women (mean age 37.7 years) and a Swedish study (23), where 73% of participants were women (mean age 53.4 years). The majority of the patients were not employed in the current study which is supported by earlier studies from Scandinavian countries (3, 23). Middle aged unemployed women are mostly affected by the MS. MS patients in Iran has more (42.7%) university education than Swedish (25.8%) patients (23).

The lack of similar studies which assess disease costs from the patient/family perspective (analyzing incurred cost by the patients and their families, not the incurred cost by the health systems or society) in Iran or other developing countries especially in Eastern Mediterranean Region is noteworthy. The research propose some executive suggestions, including: strengthening the basic and supplementary insurance system for patients, strengthening their social security system, increasing governmental and charitable support, enhancing social work for patients, in particular, creating jobs and income generation for patients in proportion to their physical capacity, establishing comprehensive caring centers for MS patients to provide one-stop-shop type of services for all necessary cares, providing full coverage of patient cares by insurers, and providing government planning to ensure timely delivery of medicines and equipment to healthcare managers in Iran. Further studies in Iran and other developing countries are essential for estimating a national level cost of illness of MS. Also, to assess the share of MS costs in the household budget (% of average income spent on healthcare expenses or MS-related expenses) to estimate the scale and level of catastrophic expenditure and its induced impact on poverty in the MS patients and their families are warranted.

The current study is a cost of illness study which may have some criticism (10, 26, 33). However, it can provide important information as direct costs being the main cost driver, to ensue with marginal analyses which in turn help inform priority setting for MS for scarce resource allocation in economically struggling Iran by decision-makers.

Conclusions

The results of this study showed that by increasing the severity of illness in MS patients, higher costs are incurred by them due to their need to receive medical services. This is considered to be catastrophic because economic power and income generation of the patients and their families dramatically decrease due to MS. This study also showed that the amount of costs imposed on patients with MS in East Azerbaijan province was very high and it was in no way proportionate to the mean income of Iranian families. The results of this study can pave the way for Iranian healthcare managers to provide financial, social and psychological support to MS patients and their families.

Abbreviations

MS: Multiple sclerosis

EDSS: The Expanded Disability Status Scale

CVR: Content Validity Ratio

CVI: Content Validity Index

MRI: *Magnetic Resonance Imaging*

Declarations

Acknowledgement

The researchers would like to thank all patients for their active participation in the study. Also, the research team would like to thank all the experts for their sincere collaboration in the development of the questionnaire.

Funding

The study was supported from Tabriz Health Services Management Research Center and Mid Sweden University.

Availability of data and materials

The study data and Persian questionnaire are available and will send to made accessible by the corresponding author.

Authors' contributions

Ali Imani: proposal writing, data analyzing, article writing

Farid Gharibi: literature review, proposal writing, data collection, data analyzing, article writing

Ali Khezri: proposal writing, data collection, data analyzing, article writing

Nasrin Joudyian: proposal writing, data collection, data analyzing, article writing

Koustuv Dalal: proposal writing, data analyzing, article writing, critical review

Competing interest

Declared none.

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Tables

Table 1: Demographic and background characteristics

Variable	Category	Frequency	Percentage
Age	Childhood and adolescence (under 20 years)	14	4.7
	Youth (20-35 years)	128	42.6
	Middle age (35-60 years)	156	52
	Elderly (over 60 years)	2	0.7
Gender	Male	96	32
	Female	204	68
Mean age at first symptoms	Under 20 years	67	22.3
	20-29 years	122	40.7
	30-39 years	92	30.7
	40-50 years	19	6.3
Years of illness	1-5 years	96	32
	6-10 years	90	30
	11-15 years	53	17.7
	More than 15 years	61	20.3
Marriage status	Single	99	33
	Married	188	62.7
	Divorced and spouse died	13	4.3
Education	Illiterate	15	5
	Diploma and lower	157	52.3
	B.Sc.	103	34.3
	M.Sc.	20	6.7
	Ph.D.	5	1.7
Employment	Employed (public or private sector)	27	9
	Self employed	10	3.3
	Student	22	7.3
	Housewife	152	50.7
	Retired	11	3.7
	Unemployed	24	8
	Other	54	18
Basic medical insurance		300	100
Insurance type	Social Welfare (Tamine Ejtemaei)	193	64.3
	Health Services (Khadamat darmani)	73	24.4
	Other (Armed Forces, Banks, Broadcasting, ...)	34	11.3
Supplementary medical insurance		105	35
Locality	Tabriz	254	84.7
	Other cities	46	15.3

Table 2: Status of receiving medical care by patients related to direct medical costs

Service type	Category	Patient use of resources		Frequency of use	
		Number of patients	Percentage (rate)	Mean	SD
Visit	Specialist visit	294	98.3	7.1	3.77
Diagnosis	Laboratory	214	71.3	2	2.36
	MRI	219	73	1.01	0.86
	CT Scan	20	6.7	0.07	0.26
	Other	20	6.7	0.08	0.34
Rehabilitation	Physical therapy	40	13.3	3.55	13.89
	Occupational therapy	0	0	0	0
Medicine	Avonex	6	2		
	Betaferon	68	22.7		
	Rebief	4	1.3		
	CinnoVex	49	16.3		
	ReciGen	12	4		
	Diphosel (Dimethyl fumarate)	65	21.7		
	Other MS drugs	67	22.3		
Supplements	79	26.3			
Hospitalization	First time	126	42	2.94	5.62
	Second time	43	14.3	0.50	1.61
	Third time	3	1	0.03	0.28
Other	Informal paid	14	4.7	0.05	0.34
	Complementary/alternative therapies	8	2.7	0.08	0.37
	Home care (medical)	5	1.7	0.15	0.42

- Continuous and daily consumption

Table 3: Status of direct non-medical costs imposed on patients

Service type	Patients		Frequency of receiving service		
	Frequency	Percentage	Mean	SD	
Home care (non-medical)	13	4.3	14.23	21.66	
Walking aids devices	24	8	0.12	0.42	
Modification of home, care and ...	2	0.7	0.02	0.13	
Travel	Hospital	174	58	24.29	22.55
	Physician office	211	70.3	480.7	28.18
	Other centers	99	33	7.23	13.24
Accommodation and food	0	0	0	0	

Table 4: The overall costs incurred by patients under study

Cost type	Category	Cost amount (IRR)		Cost amount (USD)	
		Mean	SD	Mean	SD
Medical Direct Costs	Physician visit	2519500	1745300	59.97	41.55
	Diagnosis	4727000	5804350	112.54	138.19
	Rehabilitation	9481830	99625340	225.75	2372.03
	Medicine	50757550	61977004	1208.51	1475.64
	Hospitalization	2010200	4062930	47.86	96.73
	Home care (medical)	328660	4866630	7.82	115.87
	Complementary/alternative therapies	163330	1267360	3.88	30.17
	Informal paid	118400	629500	2.81	14.98
	Total	70106490	121767380	1669.20	2899.22
Direct Non-Medical Costs	Home care (non-medical)	2812010	24696900	66.95	588.02
	Walking aids devices	5354330	58966640	127.48	1403.96
	Modification of home, care and ...	216660	2657050	5.15	63.26
	Travel to healthcare centers	13818730	13110770	329.01	312.16
	Total	22201750	73513150	528.61	1750.31
Indirect Costs	Patients' absence cost	4398870	22167790	104.73	528.80
	Relatives' absence cost	2618160	8388760	62.33	199.73
	Total	5213500	18987350	124.13	452.07
Total		97521740	145680370	2321.94	3468.58

Table 5: Status of the disease in the patients under study

Variable	Category	Frequency	Percentage
EDSS score	1	139	46.3
	1.5	1	0.3
	2	29	9.7
	3	13	4.3
	3.5	1	0.3
	4	27	9
	4.5	2	0.7
	5	20	6.7
	5.5	3	1
	6	21	7
	6.5	1	0.3
	7	17	5.7
	7.5	1	0.3
	8	17	5.7
9	5	1.7	
10	3	1	
Disease severity	Mild disease	210	70
	Moderate disease	47	15.7
	Severe disease	43	14.3
Relapses during last year	Yes	93	31.3
	No	204	68.7
Relapses during last 3 months	Yes	85	28.9
	No	209	71.1

Table 6: The relationship between EDSS score and various costs imposed on patients

Cost type	USD		IRR		β	P-value
	B	Std. Error	B	Std. Error		
Direct medical costs	7462080	27233210	177.66	648.40	0.157	0.007
Direct non-medical cost	1426870	1662640	33.97	39.58	0.050	0.391
Indirect cost	-749700	427760	-17.85	10.18	-0.101	0.081
Total cost	8139260	3265050	193.79	77.73	0.143	0.013

Table 7: The relationship between patients' status and types of costs imposed on them

Cost type	Mild disease			Moderate disease			Severe disease			P-value
	Mean (SD)		% of total cost	Mean (SD)		% of total cost	Mean (SD)		% of total cost	
	IRR	USD		IRR	USD		IRR	USD		
Direct medical costs	57330010 (61057540±)	1365 (1453.75±)	68.31	111768420 (±255325660)	2661.16 (±6079.18)	81.12	86965810 (112051120±)	2070.61 (±2667.88)	72.49	0.013
Direct non-medical cost	19949800 (±80598510)	474.99 (±1919.01)	23.78	25227650 (±57750230)	600.65 (1375±)	18.23	29892200 (±48967780)	711.71 (1165.89±)	24.92	0.690
Indirect cost	6638330 (±22281580)	158.06 (±530.27)	7.91	776590 (±3544450)	18.49 (±84.39)	0.56	3104650 (6910610±)	73.92 (±164.53)	2.59	0.118
Total cost	83918150 (±103164530)	1998.05 (±2456.29)	100	137772660 (±264022250)	3280.30 (±6268.24)	100	119962670 (±136103800)	2856.25 (±3240.56)	100	0.039