

Cost of an episode of diabetic foot ulcer in Spain

Marinel Io J¹, March J², Blanes JI³, Martínez-Aguilar E⁴, Escudero JR⁵, Masegosa A⁶, Lizano C⁷, Massó JM⁷, Yébenes M⁸, Casado MA⁸

¹Hospital de Mataró, Barcelona, ²Hospital de Getafe, Madrid, ³Hospital Dr. Peset, Valencia, Spain; ⁴Hospital de Navarra, Pamplona, ⁵Hospital Sant Creu I Sant Pau, Barcelona, ⁶Complejo Hospitalario Universitario, Albacete, ⁷Praxis Pharmaceutical S. A., Spain; ⁸Pharmacoeconomics & Outcomes Research Iberia, Spain

INTRODUCTION

Diabetes mellitus is a chronic disease, which has become one of the major health problems in the world due to its high prevalence and socioeconomic impact. (Maticrali 2007, Oliva 2004, O'Brien 2003). In 1995, the World Health Organization calculated that 135 millions adult people had diabetes and estimated that this figure would increase to 360 millions in 2005. One of the most frequent complications of diabetes is the diabetic foot syndrome. The economic burden of diabetic foot is substantial, due to the requirement of long term treatments for lesion healing, its high recurrence rate and the high risk of lower extremity amputation (LEA) associated. Diabetes mellitus increases 10 to 20 times the risk of lower extremity amputation (van Houtum 1996, Wrobel 2001). It is estimated that between 15-25% of diabetic patients show foot problems due to the appearance of ulcers. 14-20% of these patients will suffer a LEA which approximately represents one in every fifteen diabetic people. Approximately 80 % of lower extremities amputations are preceded by diabetic foot ulcers (Apelqvist 2000, Ortegón 2004) and 30-40% of patients suffering an amputation, will lose the contralateral lower extremity in 3 years (Group TG 2000, Gomis 1995), which make diabetes mellitus the major cause of non-traumatic amputation in the world. In addition to their social and sanitary costs, diabetic foot ulcers cause high disability and decrease the health related quality of life of these patients (Group TG 2000). The development and implementation of appropriate prophylactic programs, mainly focused on the self-care of this type of patients, could diminish the amputation rates by 49-85% (Moreno 1997, Apelqvist 2000). Several studies have analysed the costs of diabetic foot or its complications in development countries as Sweden, Australia and Austria (Apelqvist 1995, Davis 2006, Habacher 2007). In addition, a study performed in 14 European centres has been recently published (Prompers 2008), although the Spanish contribution was very low (only one centre). This study examined the use of resources and costs of diabetic foot treatment. Apart from this, there are no data available in the literature about the costs of diabetic foot in the Spanish population. Thus, the objective of the present study was to obtain data concerning resource consumption in patients with diabetic foot syndrome and to estimate the direct sanitary costs per patient associated to an episode of non-complicated superficial full-thickness neuropathic ulcer of diabetic foot in Spain.

METHODS

Design of analysis

This study has an observational, retrospective and multicenter design. Adult patients (older than 18 years) of both genders, with a previous history of non-complicated superficial neuropathic ulcer of at least 10 cm² or non-complicated deep diabetic foot ulcer; without lower extremity ischemia (ankle brachial index (ABI) between 0.75 and 1.3), and with the study ulcer completely resolved due to wound healed or amputation were included. The complete ulcer episode should have occurred between January 2007 and December 2008. Patients with ischemic or neuro-ischemic ulcers or with foot infection at the time of inclusion were excluded. When patients had more than one ulcer episode during the study period, the most recent ulcer episode to the date of data collection was selected. After Ethics Committee approval and following the respective data confidentiality regulations, patient recruitment was performed from February 1st 2009 to June 15th 2009. The study period for each patient was the duration of the complete selected ulcer episode, i.e. the period from the diagnosis of the diabetic foot ulcer in the hospital to the definitive hospital discharge of that patient, due to complete ulcer healing or amputation. Collection of study data was performed in an unique visit, at which information on the demographic variables (date of birth, sex and employment status at the time of the ulcer), clinical ones (concomitant diseases, aspects referred to the study ulcer and previous ulcers) and data from resources consumption associated to the diagnosis and treatment of the episode of diabetic foot lesion was compiled. For collection of this information, the hospital computerised clinical database systems, medical records and discharge reports were used.

Cost Estimation

The estimation of costs was performed by identification and subsequent quantification of health resources used in the treatment of the diabetic foot episode, assigning a specific unitary cost to each of these resources. Table 1 shows the more relevant unitary costs employed for assessment of the used resources, with their respective references. Analysis was carried out according to the perspective of the National Health System, taking into account direct sanitary costs, exclusively. Results are shown as total cost per ulcer episode. All costs are expressed in Euros (€) from year 2009.

For estimation of direct sanitary costs, the following resources related to the diabetic foot episode were quantified: a) hospital services: hospital stays and visits to the hospital emergency department; b) surgeries: number and type of surgery required for the treatment of the ulcer under study, c) medical and nurse visits: visits carried out to hospitals, specialists, outpatients clinics and private clinics (in all cases, they have been considered as consecutive visits); d) laboratory and microbiological tests: tests performed to the patients for the diagnosis and treatment of the neuropathic ulcer; e) antibiotics and pharmacological treatment following medical prescription; f) dressings of neuropathic ulcer; type of dressings and place where it was carried out, g) orthotic devices: use required of orthotic devices as consequence of the diabetic foot ulcer. No other costs as loss of productivity, time or money inverted by patients or caregivers were evaluated in this study.

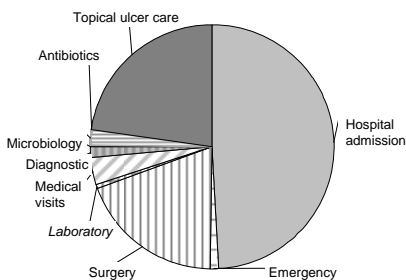
The costs of health resources were obtained from the e-Salud database of health costs (Oblikue Consulting), updated to January 1st 2009. The Drug Catalogue (Consejo General de Colegios Oficiales de Farmacéuticos de España 2009) was used for assessing the costs of pharmacological treatments. In order to calculate the average daily cost of antibiotic treatment, the standard dosage established in the technical Summary of Product Characteristics of each speciality was used. The statistical software SPSS (Statistical Product and Service Solutions, Chicago, Ill) 15.0. was used for the performance of the statistical analysis of cost evaluation. For description of the continuous variables the mean was used, for the description of categorical variables the number and percentage of patients per response category were used. For the global score 95% confidence interval was used.

RESULTS

Patients demographics and comorbidities	
Number of patients	92
Gender, %	
Male	76.9
Female	23.1
Age, years (range)	65 (36-88)
Age, %	
30-39 years	1.1
40-49 years	8.8
50-59 years	23.0
60-69 years	30.4
More than 70 years	35.9
Employment status, %	
Employed worker	13.0
Unemployed	1.1
Housewife	6.5
Retired	50.0
Unknown	28.4
Average age at the time of diabetes diagnosis, years (range)	48 (33-74)
Mean time from the diagnosis of diabetes to the ulcer diagnosis, years	16,8
Comorbidities, %	
Stroke	41.3
Dyslipemias	25.0
Hypertension	61.9
Myocardial infarction	19.5
Chronic Renal Insufficiency	30.4
Others	64.1

Patients resource consumption by episode of diabetic foot ulcer				
	Unit	Mean	95% IC LI	95% IC LS
Hospital Stays				
Hospital admission	Admission number	1.37	1	5
Inhospital stay	days	23.86	19.15	28.57
Emergency room	visits	1.14	0.87	1.40
Visits to Specialists				
Primary Care Physician	visits	2.16	2.80	3.13
General Surgery	visits	0.58	0.25	0.92
Vascular Surgery	visits	1.22	0.72	1.73
Endocrinology	visits	2.58	1.12	4.04
Orthopedist	visits	0.98	0.29	1.67
Rehabilitation	visits	0.67	0.36	0.98
Laboratory tests, diagnosis and microbiological				
Sample culture	tests	1.94	1.47	2.41
Doppler	tests	0.34	0.24	0.45
Hemogram	tests	3.63	2.78	4.47
X-ray	tests	1.25	1.07	1.42
Surgical procedures				
Amputation	surgeries	0.69	0.56	0.82
Debridement	surgeries	0.19	0.008	0.38
Skin Graft	surgeries	0.01	0	0.03
Antibiotic therapy				
Ertapenem	cost/day	1.33	0.52	2.15
Piperacilin – Tazobactam	cost/day	0.27	0	0.65
Vancomicin	cost/day	0.79	0.17	1.40
Ulcer care / dressings				
Dressing at the outpatient clinics and hospital	times	28.87	14.52	43.22
Dressing at home by health professionals	times	4.03	0	9.97
Orthotic devices				
Shoes	cost/patient	0.15	0.14	0.16
Orthesis, insoles and discharge filters	cost/patient	0.22	0.21	0.23
Prosthesis	cost/patient	0.08	0.07	0.08

Average direct sanitary cost per episode of diabetic foot ulcer (€2009)			
	Average	95% CI LI	95% CI LS
Hospital Stays			
Hospital admission	5749.82	3527.78	7971.85
Visit to the Emergency Unit	116.90	89.72	144.09
Total	6314.15 €	3694.25	9022.36 €
Visits to Specialists			
Primary Care	49.90	64.64	72.41
General Surgery	28.14	12.11	44.17
Vascular Surgery	56.73	33.36	80.09
Endocrinology	147.79	64.45	231.12
Orthopedist	38.04	11.47	64.60
Rehabilitation	47.26	25.60	68.93
Total	447.15 €	215.67 €	750.60 €
Laboratory, diagnostic and microbiological tests			
Sample culture	10.51	7.99	13.03
Doppler	23.58	16.62	30.54
Hemogram	25.63	19.66	31.60
X-rays	21.98	18.86	25.09
Total	312.95 €	186.44 €	444.18 €
Surgical procedures			
Amputation	1.649.49	1344.90	1954.08
Debridement	648.32	27.42	1269.23
Graft	49.40	0	146.81
Total	2410.90 €	1372.33 €	3522.56 €
Antibiotic therapy			
Ertapenem	84.79 €	33.01	136.58
Piperacilin Tazobactam	12.54 €	0.00	30.42
Vancomicin	23.48 €	5.32	41.65
Total	239.37 €	48.17 €	472.59 €
Ulcer care and dressings			
Cures in outpatient clinics and hospital	1079.32	543.08	1616.06
Cures at home by health professionals	264.90	0.00	655.53
Total	2864.16 €	1127.40 €	4758.92 €
Orthotic devices (€ per patient)			
Shoes	0.15	0.14	0.16
Orthesis, insoles and discharge filters	0.21	0.20	0.22
Prosthesis	0.07	0.07	0.08
Total	0.45 €	0.42 €	0.47 €
Total cost per episode of diabetic foot	12525.12	6644.68	18619.24



DISCUSSION

Diabetes mellitus represents a great social and sanitary cost. Also, in spite of the fact that more resources are being used for prevention and treatment of the disease, its prevalence increases constantly. On the other side, the costs associated to the treatment of diabetes has been increased by the costs associated to its complications. One of the most frequent complication is the diabetic foot ulcer, which entailed high expenses. In the present study, the average cost per patient with an episode of diabetic foot ulcer in Spain is estimated at 12525.12€.

Up to now, with the exception of the Eurodiale Study (Prompers 2008), no extensive studies are available in Spain to examine the sanitary costs of diabetic foot treatment. Thus, the present study will introduce new data in this context. Comparison of this study with those published in the literature evaluating the cost of diabetic foot is complex, due to differences in the study design, study perspective, unitary costs of the procedures, treatment at the different studied scenarios and methodology for calculation the costs. In the Eurodiale study, the costs (Euros 2005) and the use of direct as well as indirect resources (loss of productivity) are differentiated between individuals with and without peripheral arterial disease (PAD) and infection. In the group of diabetic patients without PAD and without infection, the total costs (4514€ per patient) are lower than the ones obtained in the group of patients with PAD and infection (16835€ per patient). In all groups, the hospital admissions and the antibiotic treatment represent the highest percentages of the direct costs, with the exception of the patients with PAD and infection, in which hospitalisations and amputations represent the highest percentages, 40% and 14%, respectively. The indirect costs represented the highest cost in the group of patients with infection but without PAD, 1160€ and 13% over the total costs. Considering all the patients, the average total cost including direct and indirect costs was estimated as 10091€ per patient. In that study, the costs were presented according to the different groups of patients based on the ulcers outcome (healing, non healing-death, amputation or non healing in a follow up period of 12 months). The group of patients with LEA showed the highest costs, 25222€ considering direct as well as indirect costs. Hospitalisations represented 10953€ and 43%, the highest cost, followed by amputations as surgical procedures, with 6907€ per patient and representing 27% of the total costs.

Ulcer related surgeries and, specially, amputations represented one of the most important resources within the total cost of the diabetic foot management. In a review on the costs of diabetes complications in different countries the cost of lower extremity amputations, among others, was estimated (Ray 2005). In Spain, the average cost per amputation (Euros 2003) using values from the Diagnosis-related groups (DRG) was estimated in 14787€. Updating this value in € from year 2009, the cost of an amputation would correspond to 17419.09€. In our study the average cost of amputations as unitary resource cost, and considering the DRG values obtained on the basis of e-Salud sanitary cost (Oblikue 2009), was estimated as 7.730,14€. Taking into account the percentage of patients in the sample that suffered an amputation, this cost represent 1649.49€ per amputation (surgery procedure only) and ulcer episode. In consequence, our study could be underestimating the cost of amputations, one of the costs with highest impact in the average cost per patient.

When considering the generalisation and transferability of results, one of the possible limitations might be the use of the hospital perspective in our study. This means that only the direct sanitary costs have been considered and not the indirect costs related to the loss of productivity of patients and caregivers. In order to consider the magnitude of these costs it has to be taken into account, for example, that in the study by Prompers the indirect costs in the group of amputated patients represented 3% of the total costs of diabetic foot management and 681€ (Prompers 2008). So, it is possible that the costs estimated in the present study could be underestimating the total costs of diabetic foot ulcer.

In summary, diabetic foot is one of the complications of diabetes mellitus that produces a high economic impact in the health systems. In consequence, after estimation in this study and others published in different countries, of the costs that its management involves, it would be necessary to carry out primary and secondary prophylaxis programs in order to decrease the occurrence of diabetic foot ulcers in patients with diabetes. By doing this, the decrease in health related quality of life of these patients would be avoided, as well as the risk of losing the extremity and also the use of the high number of sanitary resources its treatment involves.