Endocrinol Diabetes Nutr. 2017;64(4):188–197

Endocrinología, Diabetes y Nutrición

www.elsevier.es/endo

ORIGINAL ARTICLE

Trends in the incidence of lower limb amputation after implementation of a Multidisciplinary Diabetic Foot Unit☆

Sara Jiménez[a,b,*], **José Antonio Rubio**[a,b,c], **Julia Álvarez**[a,b,d], **Fernando Ruiz-Grande**[a,e], **Carlos Medina**[a,f]

[a] *Unidad de Pie Diabético, Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Madrid, Spain*
[b] *Departamento de Endocrinología y Nutrición, Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Madrid, Spain*
[c] *Departamento de Ciencias Biomédicas, Universidad de Alcalá, Alcalá de Henares, Madrid, Spain*
[d] *Departamento de Medicina y Especialidades Médicas, Universidad de Alcalá, Alcalá de Henares, Madrid, Spain*
[e] *Departamento de Cirugía Vascular, Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Madrid, Spain*
[f] *Departamento de Cirugía General, Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Madrid, Spain*

Received 20 December 2016; accepted 20 February 2017
Available online 11 June 2017

KEYWORDS
Diabetic foot;
Diabetes mellitus;
Lower limb amputation;
Diabetic foot clinic

Abstract
Backgrounds and objective: Incidence of lower extremity amputations (LEA) in the population with and without diabetes mellitus (DM) was assessed after implementation of a Multidisciplinary Diabetic Foot Unit (MDFU) during 2008.
Material and methods: Non-traumatic LEA were analyzed, and those performed before (2001–2007) and after (2008–2014) introduction of the MDFU were compared. LEA were grouped by age and sex. Their incidence was expressed as a rate per 100,000 population per year, adjusted to the standard European population.
Results: A total of 664 LEA were performed during the 2001–2014 period, 486 (73%) of them in patients with DM. Total LEA incidence was $11.2/10^5$ population in DM versus $3.9/10^5$ in the population without DM. Incidence of major LEA in patients with DM significantly decreased from $6.1/10^5$ population in the 2001–2007 period to $4.5/10^5$ in the 2008–2014 period ($p = 0.03$). Joinpoint regression analysis also showed a reduction in the trend of incidence of major LEA in patients with DM, with an annual percentage change of −3.3% [95% CI, −6.2–0.3] ($p = 0.025$). No significant differences were found for all other incidences and trends in the diabetic and non-diabetic populations.

☆ Please cite this article as: Jiménez S, Rubio JA, Álvarez J, Ruiz-Grande F, Medina C. Tendencia de la incidencia de amputaciones de miembro inferior tras la implementación de una Unidad Multidisciplinar de Pie Diabético. Endocrinol Nutr. 2017;64:188–197.

* Corresponding author.
E-mail address: sjimenezg@salud.madrid.org (S. Jiménez).

Conclusions: Implementation of a MDFU has been shown to be associated with a significant reduction in major amputation rate in the diabetic population, although the results are not optimal yet. Both results and work at the MDFU should be improved.

PALABRAS CLAVE
Pie diabético;
Diabetes mellitus;
Amputación miembro inferior;
Unidad de pie diabético

Tendencia de la incidencia de amputaciones de miembro inferior tras la implementación de una Unidad Multidisciplinar de Pie Diabético

Resumen
Antecedentes y objetivo: Evaluamos la incidencia de amputaciones de miembro inferior (AMI) en población con y sin diabetes mellitus (DM) tras la implementación en nuestro centro de una Unidad Multidisciplinar de Pie Diabético (UMPD) durante el año 2008.
Material y métodos: Analizamos las AMI de causa no traumática y comparamos las realizadas antes del inicio de la UMPD, 2001-2007; vs. las realizadas después, 2008-2014. Las AMI se agruparon por edad y sexo. Su incidencia se expresó por 100.000 habitantes y año, ajustada a la población europea estándar.
Resultados: Se realizaron 664 AMI, 486 (73%) en población con DM durante el período 2001-2014. La incidencia de todas las AMI en DM fue de $11,2/10^5$ habitantes vs. $3,9/10^5$ en población sin DM. La incidencia de AMI mayores en DM se redujo de manera significativa de $6,1/10^5$ habitantes en el período 2001-2007 a $4,5/10^5$ en el período 2008-2014 ($p = 0,03$). El análisis de regresión jointpoint, también demostró una reducción en la tendencia de la incidencia de AMI mayores en la población con DM, observándose un cambio porcentual anual del -3,3% [IC 95%, -6,2-0,3] ($p = 0,025$). No encontramos diferencias significativas en el resto de incidencias y tendencias en población con y sin DM.
Conclusiones: La puesta en funcionamiento de una UMPD en nuestro centro ha demostrado que se asoció a una reducción significativa en la tasa de amputaciones mayores en la población diabética, si bien estos resultados aún no son óptimos. Se precisa mejorar estos resultados y el funcionamiento de la UMPD.

Introduction

The population with diabetes mellitus (DM) has a 15- to 45-fold greater risk of suffering lower extremity amputation (LEA) than the population without DM.[1] It is estimated that up to 25% of all patients with DM will develop foot ulcer at some point in life, and this precedes amputation in up to 80% of cases.[2]

Infection and peripheral artery disease are the two conditions most commonly leading to amputation,[3] but these factors, along with others such as ethnicity or socioeconomic parameters, are unable to fully explain the differences in amputation rates seen in diabetic populations from different geographical areas.[4] Amputation is not simply a phase in the natural history of diabetic foot, but should rather be regarded as a treatment option. In addition, aspects such as differences in access to healthcare and the way in which care is provided for this complication are determinant factors for the incidence of LEA in the population with DM.[5]

Different scientific position statements, such as those of the ADA, NICE and IDF, make it clear that patients with diabetic foot and at a high risk of ulceration should be seen by multidisciplinary teams including specialists in different areas: podiatrists, surgeons, internists (specialists in infectious diseases) and endocrinologists, among others.[6–8] This strategy has been shown to decrease the incidence of LEA by up to 60%.[9,10] The incidence of LEA in the diabetic population has therefore been established as an indicator of the adequate intervention of healthcare systems.[11]

In 2008, Príncipe de Asturias University Hospital (HUPA, Madrid, Spain) inaugurated a diabetic foot clinic served by an endocrinologist and a podiatrist to provide care for patients with diabetic foot. Over the following 8 years, coordination with different related disciplines was established and gradually improved. This has resulted in a Multidisciplinary Diabetic Foot Unit (MDFU) involving different specialties: vascular surgery, general surgery, vascular and interventional radiology, orthopedic surgery, infectious diseases, and physical medicine and rehabilitation.[12]

Awareness of the trend in the incidence of LEAs during the period of implementation of the MDFU and how it has changed as compared to historical series is important when assessing the outcomes of the Unit. This study examines how LEA has evolved in the population with or without DM during the period 2001–2014, its distinctive features, and the associated hospital mortality.

Table 1 Census-based population in the HUPA catchment area.

Year	Males	Females	Total
2001	144,723	147,789	292,512
2002	153,894	153,894	307,788
2003	160,069	161,507	321,576
2004	164,816	164,966	329,782
2005	171,223	170,188	341,411
2006	175,479	174,034	349,513
2007	175,725	174,588	350,313
2008	182,377	180,408	362,785
2009	184,043	181,330	365,373
2010	184,307	182,403	366,710
2011	186,414	185,035	371,449
2012	125,275	124,855	250,130
2013	126,186	125,977	252,163
2014	123,915	124,758	248,673

Source: Institute of Statistics of the Community of Madrid.[13]

Patients and methods

A retrospective cohort study of LEAs of non-traumatic origin was conducted in the population of our healthcare area from 1 January 2001 to 31 December 2014. This population initially comprised those people living in the town of Alcalá de Henares (Madrid, Spain) and in 12 nearby localities who historically and for reasons of proximity have preferentially attended the reference hospital (HUPA), though since 2010 the Madrid Department of Health regards the entire Community of Madrid as a single healthcare area. During the study period, the registered population decreased from 292,512 inhabitants in 2001 to 248,673 inhabitants in 2014 (Table 1).[13]

Identification of amputations

Data on LEAs were collected from the Minimum Basic Data Set (MBDS) of the Madrid Department of Health. The MBDS records information regarding hospital discharges (in our case those corresponding to all Madrid hospitals), and the data on admissions include details for identification purposes and the codes corresponding to the diagnoses and surgical procedures performed during the hospital stay,[14] with a mean coding incidence of 98%.

The captured procedure codes were 84.11–84.18 of the International Classification of Diseases (ICD-9-CM). Minor LEA was defined as amputation distal to the ankle joint (codes 84.11–84.12), while major LEA was defined as amputation through or proximal to the ankle joint (codes 84.13–84.17). Traumatic and cancer-related amputations, corresponding to codes 895–897, 905.9, 213.7, 213.8, 170.7, 170.8, and 195.5, and the major diagnostic categories 14 (pregnancy, delivery, and puerperium) and 15 (newborns and perinatal conditions) were excluded. Episodes corresponding to the diabetic population were identified by code 250.xx in any diagnostic field. When more than one amputation was coded in the same episode, only the highest level amputation of each hospital discharge was taken into account. The codes were reviewed by two independent observers.

Selection of the individuals belonging to the population census of the catchment area of the HUPA was carried out using the Healthcare Identification Code (CIAS_pro): 1603.XX for the period 2001–2011, and 1603.01XX-1603.10XX, 1603.17XX, 1603.18XX and 1603.21XX for the period 2012–2014, because in the last three years the reference population of the HUPA decreased (Table 1). The CIAS_pro identifies those subjects usually attending the basic healthcare areas of the localities dependent upon the HUPA.

Data reporting and statistical analysis

Quantitative data were reported as median (P25, P75), while qualitative data were given as absolute value and percentage (%). LEA incidence (mean and 95% confidence interval [95%CI]) was calculated globally, as well as for major LEA and minor LEA, per year and taking into account whether the subject had DM or not. Data were adjusted for age and sex, expressed as ratios per 10^5 inhabitants (according to census data), and adjusted to the standard European population using the direct method.[15]

Differences in the incidence of LEA were evaluated by comparing the incidence during the period 2001–2007, before the start of the activity of the MDFU, to data for the period 2008–2014, during the implementation of the Unit, in individuals with and without DM. Quantitative variables were compared using a Student's *t* test or a Mann–Whitney *U* test depending on whether the data exhibited were normally or non-normally distributed (as determined by the Kolmogorov–Smirnov test). A Chi-squared test was used to compare qualitative variables. Trends in amputations were also explored by a joinpoint regression analysis, using a Poisson distribution. This analysis allows for the identification of points where the distribution significantly changes direction, and these changes were quantified by means of the annual percentage change (APC). SPSS version 15.0 statistical software and Joinpoint Regression, version 4.2.0.2, June 2015 software were used.[16] Values of $p < 0.05$ were considered statistically significant.

Functioning of the Multidisciplinary Diabetic Foot Unit (Fig. 1)

Diabetic patients with foot lesions are preferentially referred to the MDFU from any primary or specialized care center, or emergency room. The MDFU determines the diagnostic and management approach in each case, according to the International Diabetic Foot Consensus guidelines,[17] and coordination with other specialties is established where required, with preferential referral to the departments of general and vascular surgery on an outpatient basis or for hospital admission. Regardless of whether assessment by other specialties is required or not, all patients are followed up at the MDFU until the end of the episode. Once the lesions have healed, the need for regular monitoring by the MDFU is evaluated.

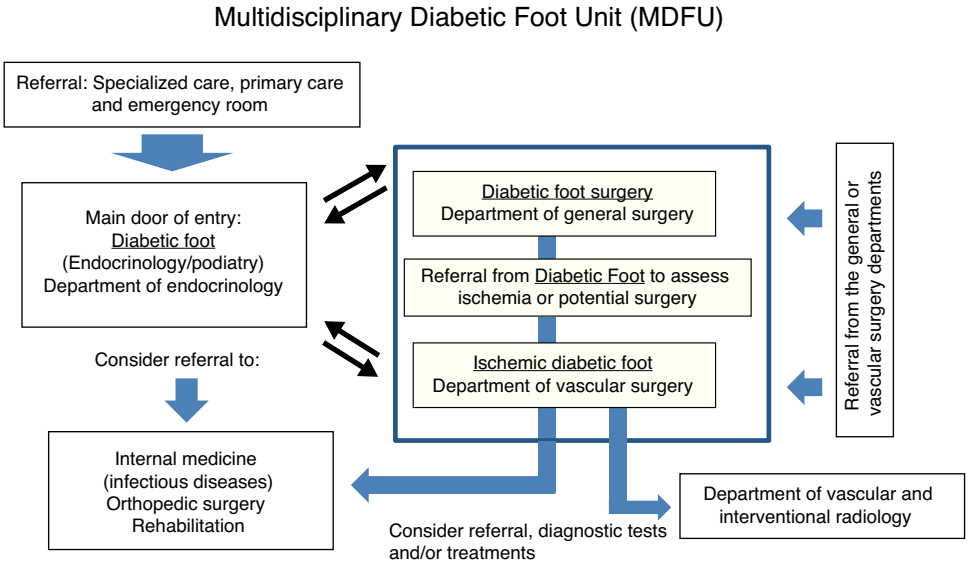

Figure 1 Schematic representation of the functioning of the MDFU of the HUPA.

Table 2 Data on amputations, with differentiation between patients with and without diabetes.

	LEAs in patients with DM, n = 486	LEAs in patients without DM, n = 178	*p*
Age, median (P25–P75)	73 (64–79.2)	75.5 (60.7–85)	0.141
Males, n (%)	338 (69.5)	127 (71.3)	0.654
Females, n (%)	148 (30.5)	51 (28.7)	0.654
Minor/major LEAs	255/231	73/105	0.009
Minor/major LEA ratio	1.10	0.69	0.009
In-hospital mortality, n (%)	42 (8.6)	29(16.3)	0.005
Hospital stay, median (P25–P75)	15 (9–26)	17 (9–31)	0.007

LEA: lower extremity amputation; DM: diabetes mellitus. *p*-value patients with versus without DM.

Results

A total of 664 LEAs of non-traumatological and non-oncological origin were recorded; 486 of them in patients with DM (73%). Table 2 shows the clinical characteristics of the population with or without DM subjected to LEA. Amputation was more frequent in individuals over 60 years of age, with no differences in age distribution between the population with and without DM. Analysis of LEAs by sex revealed no significant differences between patients with DM and without DM, though amputation was more frequent in males in both groups. The minor/major amputation ratio was greater among the diabetic population, i.e. minor amputations were more frequent in patients with DM. In-hospital mortality and length of hospital stay were greater in the population without DM.

Table 3 shows the incidence of LEA in diabetics and non-diabetics during the overall study period (2001–2014) and the two individual periods (2001–2007 and 2008–2014). The table shows a significant decrease in major LEAs in patients with DM, from $6.1/10^5$ inhabitants/year [95% CI 4.9–7.2] in the period 2001–2007 to $4.5/10^5$ inhabitants/year [95% CI 3.6–5.5] in the period 2008–2014 ($p = 0.030$). All other analyses of incidences, corresponding to total and major LEAs, showed no significant differences between the two periods.

The analysis of LEA incidence by sex in the populations with and without DM (Tables 4 and 5) revealed a significant decrease in the total incidence of LEAs in women with DM from $7.6/10^5$ inhabitants/year [95% CI 5.2–10.1] to $4.4/10^5$ inhabitants/year [95% CI 3.3–5.5] ($p = 0.013$) during the period 2001–2007 versus 2008–2014 respectively. The decrease was not significant in males. An increase was also seen in the minor/major LEA ratio in the DM population during the study period, which was significant in males: 1 [95% CI 0.7–1.4] during the period 2001–2007 versus 1.6 [1.1–2.2] during the period 2008–2014 ($p = 0.049$).

Fig. 2 shows the change over time in LEA incidence in the populations with (Fig. 2A) and without DM (Fig. 2B). The joinpoint regression analysis only showed significant changes in trend in major LEAs during the study period in patients with DM, with an APC of −3.3% [95% CI −6.2–0.3) ($p = 0.025$). No significant changes in trend were seen in minor and total LEAs in the diabetic population or in any LEAs in the population without diabetes.

Discussion

The results of this study suggest that implementation of a multidisciplinary team for the diagnosis and treatment of diabetic foot, coordinated by an endocrinologist and

Table 3 Incidence of lower extremity amputations in patients with and without diabetes per 100,000 inhabitants/year.

Period	LEAs in patients with DM, n = 486			LEAs in patients without DM, n = 178		
	All	Minor	Major	All	Minor	Major
2001–2014	11.2 [6.8.9.9–12]	5.9 [4.8–6.9]	5.3 [1.4–6]	3.9 [1–3.3.4.6]	1.5 [1.2–1.8]	2.3 [1.7–2.9]
2001–2007	11.8 [3.3–9.9–14]	5.7 [3.9–7.5]	6.1 [4.9–7.2]	4.3 [2.3.3–5.5]	1.5 [1.0–2.1]	2.6 [1.5–3.76]
2008–2014	10.7 [6.7.7.8.8–12]	6.1 [4.4–7.7]	4.5 [3.6–5.5]	3.4 [2–5]	1.5 [1.0–2.0]	1.9 [1.1.2.7]
p-value	0.405	0.715	0.030	0.182	0.893	0.235

LEA: lower extremity amputation; DM: diabetes mellitus. Data are given as mean [95% CI]. *p*-value period 2001–2007 vs 2008–2014.

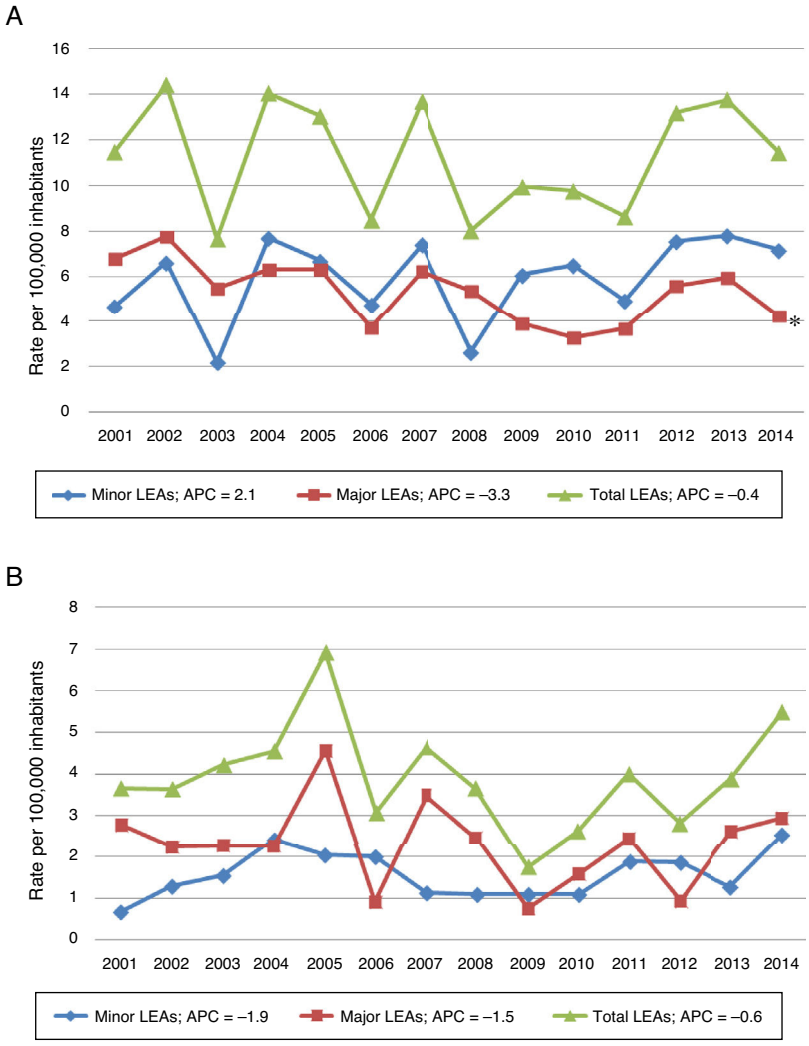

Figure 2 Change over time in the incidence of minor, major, and total LEAs in diabetics (A) and patients without diabetes (B), expressed per 100,000 inhabitants in the catchment area of the HUPA during the period 2001–2014. *$p = 0.025$ (joinpoint regression analysis). The annual percentage change (APC) was calculated during the study period (2001–2014). The population was taken from the census data of the Community of Madrid.[13]

a podiatrist, who in turn coordinate different specialties, is associated with a significant decrease in major LEA incidence in diabetic patients. The care of patients with diabetic foot and subjects at high risk of recurrent ulceration (such as those who have already suffered an amputation) by multidisciplinary teams coordinated to provide integral and multifactorial care is vital in order to reduce the suffering caused by diabetic foot problems.[15]

The main differences in amputations between patients with and without DM are well known[5], and include a greater minor/major amputation ratio among diabetic patients. Particular mention should be made of the greater in-hospital

Table 4 Incidence adjusted to age and standard European population per 100,000 inhabitants in the population with DM.

Year	Both sexes				Males				Females			
	All	Minor	Major	Minor/ major ratio	All	Minor	Major	Minor/ major ratio	All	Minor	Major	Minor/ major ratio
2001	11.51	4.69	6.82	0.69	12.49	6.63	5.87	1.13	10.03	2.79	7.25	0.38
2002	14.43	6.65	7.77	0.86	17.25	9.02	8.22	1.10	11.61	4.28	7.33	0.58
2003	7.69	2.19	5.50	0.40	10.28	3.22	7.06	0.46	5.86	1.26	4.60	0.27
2004	14.07	7.72	6.34	1.22	20.43	9.22	11.21	0.82	7.98	6.04	1.94	3.11
2005	13.05	6.72	6.33	1.06	18.57	9.59	8.97	1.07	8.51	4.08	4.42	0.92
2006	8.51	4.79	3.72	1.29	13.52	8.51	5.01	1.70	3.85	1.42	2.43	0.59
2007	13.71	7.44	6.27	1.19	22.54	13.12	9.42	1.39	5.90	2.23	3.67	0.61
2008	8.03	2.65	5.38	0.49	12.48	4.11	8.37	0.49	4.38	1.64	2.74	0.60
2009	9.99	6.10	3.89	1.57	18.42	11.95	6.47	1.85	3.16	1.17	1.98	0.59
2010	9.8	6.52	3.28	1.99	17.81	11.64	6.17	1.89	3.13	1.90	1.23	1.55
2011	8.66	4.97	3.69	1.35	13.20	9.09	4.11	2.21	4.84	1.63	3.21	0.51
2012	13.21	7.59	5.62	1.35	20.80	13.63	7.17	1.90	6.48	2.34	4.14	0.57
2013	13.78	7.82	5.96	1.31	23.80	13.99	9.82	1.42	5.23	2.25	2.98	0.76
2014	11.47	7.20	4.28	1.68	19.41	12.77	6.64	1.92	3.97	1.79	2.18	0.82
2001–2014	11.2	5.9	5.3	1.1	17.2	9.7	7.4	1.4	6	2.4	3.5	0.8
	[9.8–12.6]	[4.8–6.9]	[4.5–6.1]	[0.9–1.4]	[14.8–19.6]	[7.7.7–9]	[6.3–8.6]	[1–1.7]	[4.5–7.56]	[1.6–3.2]	[2.5–4.6]	[0.4–1.2]
2001–2007	11.8	5.7	6.1	0.9	16.4	8.4	7.9	1	7.6	3.1	4.5 [2.4–6]	0.9
	[9.3–14.3]	[3.9–7.5]	[4.9–7.2]	[0.6–1.2]	[12.2–20.5]	[5.6–11.2]	[5.9–9.9]	[0.7–1.4]	[5.2–10.1]	[1.5–4.7]		[0.01–1.8]
2008–2014	10.7	6.1	4.5	1.3	17.9	11	6.9	1.6	4.4	1.8	2.6	0.7
	[8.6–12.7]	[4.4–7.7]	[3.6–5.5]	[0.9–1.8]	[14.2–21.7]	[7.8–14.2]	[5.3–8.6]	[1.1–2.2]	[3.3–5.5]	[1.4–2.1]	[1.7–3.5]	[0.4–1.1]
p-value	0.405	0.715	0.03	0.066	0.509	0.166	0.362	0.049	0.013	0.070	0.053	0.709

Results are given as mean or mean [95% CI].

Table 5 Incidence adjusted to age and standard European population per 100,000 inhabitants in the population without DM.

Year	Both sexes				Males				Females			
	All	Minor	Major	Minor/ major ratio	All	Minor	Major	Minor/ major ratio	All	Minor	Major	Minor/ major ratio
2001	3.66	0.89	2.77	0.32	1.11	1.88	4.59	0.41	1.35	0.00	1.11	–
2002	3.64	1.40	2.24	0.62	0.52	2.79	3.97	0.70	0.65	0.00	0.52	–
2003	4.23	1.96	2.27	0.86	0.78	4.07	4.13	0.99	0.62	0.00	0.78	–
2004	4.55	2.28	2.27	1.00	1.50	5.54	2.87	1.93	1.82	0.00	1.50	–
2005	6.91	2.34	4.57	0.51	2.19	5.56	6.95	0.80	2.35	0.00	2.19	–
2006	3.07	2.16	0.91	2.36	3.01	2.87	0.77	3.72	2.87	1.76	1.25	1.41
2007	4.66	1.16	3.50	0.33	3.12	2.82	3.67	0.77	4.01	0.00	3.12	–
2008	3.66	1.19	2.47	0.48	0.00	2.83	5.59	0.51	0.00	0.00	0.00	–
2009	1.76	0.99	0.76	1.31	0.89	1.19	1.94	0.61	1.10	0.89	0.00	–
2010	2.62	1.04	1.58	0.66	1.00	1.68	2.38	0.71	1.64	0.33	0.67	0.50
2011	4.01	1.56	2.45	0.64	3.59	2.22	2.33	0.96	5.40	1.17	2.41	0.49
2012	2.81	1.88	0.94	2.00	1.17	3.04	1.58	1.92	1.60	0.74	0.42	1.76
2013	3.89	1.27	2.62	0.49	2.66	1.50	4.18	0.36	3.97	1.13	1.53	0.74
2014	5.49	2.54	2.95	0.86	3.59	4.22	3.64	1.16	4.81	1.09	2.50	0.44
2001–2014	3.9 [3.1–4.6]	1.6 [1.2–1.9]	2.3 [1.7–2.9]	0.8 [0.5–1.2]	6.4 [5–7.9]	3 [2.2–3.8]	3.4 [2.5–4.4]	1.1 [0.5–1.6]	1.8 [1.0–2.4]	0.5 [0.1–0.8]	1.2 [0.7–1.8]	0.8 [0.3–1.4]
2001–2007	4.3 [3.2–5.5]	1.7 [1.2–2.2]	2.6 [1.5–3.7]	0.8 [0.2–1.5]	7.4 [4.9–9.9]	3.6 [2.3–4.9]	3.8 [2.1–5.5]	1.3 [0.2–2.4]	1.7 [0.7–2.7]	0.2 [−0.3–0.8]	1.4 [0.6–2.3]	–
2008–2014	3.4 [2.3–4.5]	1.5 [0.9–2]	1.9 [1.1–2.7]	0.9 [0.4–1.4]	5.4 [3.6–7.3]	2.4 [1.4–3.3]	3.1 [1.7–4.4]	0.8 [0.5–1.2]	1.8 [0.5–3.1]	0.7 [0.3–1.1]	1.0 [0.1–2.0]	0.7 [0.09–1.4]
p-value	0.183	0.436	0.235	0.857	0.136	0.087	0.410	0.376	0.889	0.116	0.442	–

Results are given as mean or mean [95% CI].

mortality in the population without DM, shown by historical series in Spain during the 2001–2012 period[18] and which may be related to the greater frequency of major amputations in the non-diabetic population and, thus, to a greater extent of vascular disease in such individuals. Some authors reported a greater frequency of cerebrovascular disease in patients who have suffered a first amputation, a situation that was more prevalent among non-diabetic subjects and which could reflect the fact that this is a population at greater cardiovascular risk[19].

In Spain, the most recent data on LEAs in diabetics are not encouraging. During the period 2001–2008, López-de-Andrés et al. found that age- and sex-adjusted major LEA rates had increased in patients with type 2 from 7.12 to 7.47 per 10^5 inhabitants.[20] Using the same methodology, there was a decrease in LEAs in patients with type 1 diabetes. However, in patients with type 2 diabetes, which accounted for 95% of all the amputations performed, no major changes were seen in the historical series corresponding to 2001–2012.[18]

Few global data comparing LEA rates in diabetics from different countries are available. The Organization for Economic Cooperation and Development (OECD) has published these data for years, reporting LEA rates in Spain that are double the average of the OECD, and with major LEA rates that are double the average found in neighboring countries such as Ireland, Italy, and the United Kingdom,[11,21] with virtually no changes in the historical series covering the 2000–2013 period. This situation indicates the urgent need for measures to deal with this complication.[22]

The Diabetic Foot Group of the Spanish Diabetes Society examined the reasons for these poor results, and attributed them to several factors.[23] First of all, there is an important shortage of diabetic foot units in Spain, and second, there is only limited access to podiatrists in the national health system because they are not among the professionals contracted by the public health system. This study estimated that only one out of every four Spanish patients with DM is able to benefit from the care available in MDFUs,[23] as recommended by the International Diabetic Foot Consensus.[17]

Our group reported LEA incidence in diabetics in our healthcare area during two consecutive periods, 1997–2000[24] and 2001–2006,[25] during which a progressive increase was seen in amputation rates. This prompted a change in the approach to, and in the management of these complications. The first (i.e. preliminary) results four years after the implementation of the MDFU showed a 33% decrease in the amputation rate in patients with DM, from $6.1/10^5$ inhabitants/year to $4/10^5$ inhabitants/year during the 2001–2007 and 2008–2011 periods respectively, with no significant changes in minor amputations or in amputations in the non-diabetic population.[26] It seems reasonable to infer that these good outcomes achieved in only four years, which are at variance with the overall Spanish data, are a consequence of the adoption of this new approach.

However, there have been changes in the operation of the MDFU that require knowledge of the long-term LEA trends in the diabetic population attending the healthcare area of the HUPA, which has been performing vascular surgery for the past four years, and more recently vascular and interventional radiology. As a result, in the last three years our hospital has been responsible for almost all admissions due to this disease (data not shown), while previously, until 2011, patients who required hospital admission for some vascular surgical or interventional radiology procedure attended some other center in the Community of Madrid.

Another aspect to be taken into account is the methodology involved. In this regard, changes in LEA incidence between different years may be very striking if the population from which the data are taken is not very large. In our study, the population ranged from 248,673 to 252,163 inhabitants in the last three years. However, larger populations ensuring greater stability of the rates or longer study periods are required.[5]

This study recorded 25% reductions in the major LEA rate among diabetic patients, but no significant reductions in the population without diabetes. These findings are consistent with those reported by other multidisciplinary teams in diabetic foot management (40%–60% decreases in major LEA rates),[9,10,27] but are noticeably poorer than those previously reported by our group.[26] It should also be taken into consideration that the mean incidence of major LEAs in this study was $5.3/10^5$ inhabitants/year, which is markedly lower than the rate reported during the same period in Spain for the population with type 2 diabetes,[18] which was slightly greater than $7/10^5$ inhabitants/year.

LEA incidence significantly decreased in females, but not in males. This data does not appear in most studies analyzing this quality indicator. We have no explanation for this finding. Aspects such as sex differences in the severity of peripheral artery disease and smoking may possibly contribute to a greater difficulty in achieving greater reductions in males. An increase was seen in the minor/major LEA ratio during the study period, reflecting a significant decrease in major amputations. The joinpoint regression analysis, revealing a significant decrease in APC in major amputations in the diabetic population, was consistent with this observation.

Overall, these data demonstrate that the results in terms of the LEA rate obtained following the implementation of the MDFU have been positive, though the outcomes are still not optimum, and there is still room for improvement. Aspects in need of improvement include: a) coordination and communication within the team, reducing delays in the care of patients with foot lesions. A key element in this sense is communication between the professionals of the team and between primary and specialized care; b) the optimization of revascularization in the ischemic patient; and c) increased preventive efforts in the case of feet at risk, particularly in patients at risk but with no prior foot lesions, because prevention is currently not being applied in a structured manner.[28,29]

The present study has the following limitations:

- The data source of the MBDS is an administrative database that does not include all clinical history variables, such as chronic complications, year of diagnosis, treatment or laboratory test results, among others. These variables could have explained the changes in LEAs during the study period.
- We were unable to differentiate between type 1 diabetes and type 2 diabetes; although the two conditions are stated with different codes, these are not always accurately specified.

The present study has the following strengths:

- The period of the study was long (14 years), and methods standardized in previous studies were used.
- The MBDS codifies 98% of LEAs performed in the public healthcare system of the Community of Madrid, and since the coding system is standardized and the same in all centers, our study included the great majority of amputations performed in our healthcare area in the period 2001–2014.
- Selection of hospital admissions for LEAs based on the CIAS_pro allowed us to enroll only those subjects who routinely used the healthcare services provided by the HUPA, including the MDFU.

In conclusion, implementation of the MDFU has been shown to be associated with a significant decrease in the major amputation rate in the diabetic population of our healthcare area. Although the results are positive, they are still far from optimum, and additional strategies and the combined efforts of all the professionals involved are still needed.

Conflicts of interest

The authors state that they have no conflicts of interest.

References

1. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. Diabetic foot disorders. A clinical practice guideline (2006 revision). Foot Ankle Surg. 2006;45 Suppl.:S1–66.
2. Boulton AJ. The pathway to foot ulceration in diabetes. Med Clin North Am. 2013;97:775–90.
3. Barshes NR, Sigireddi M, Wrobel JS, Mahankali A, Robbins JM, Kougias P, et al. The system of care for the diabetic foot: objectives, outcomes, and opportunities. Diabetic Foot Ankle. 2013;4:21847, http://dx.doi.org/10.3402/dfa.v4i0.21847.
4. Margolis DJ, Hoffstad O, Nafash J, Leonard CE, Freeman CP, Hennessy S, et al. Location, location, location: geographic clustering of lower-extremity amputation among medicare beneficiaries with diabetes. Diabetes Care. 2011;34:2363–7.
5. Margolis DJ, Jeffcoate W. Epidemiology of foot ulceration and amputation: can global variation be explained. Med Clin North Am. 2013;97:791–805.
6. American Diabetes Association. Microvascular complications and foot care. Diabetes Care. 2016;39 Suppl. 1:S72–80.
7. National Institute for Clinical Excellence. Diabetic foot problems: prevention and management, NG 19. Available from: https://www.nice.org.uk/guidance/ng19 [accessed 06.12.16].
8. Schaper NC, Van Netten JJ, Apelqvist J, Lipsky BA, Bakker K, International Working Group on the Diabetic Foot. Prevention and management of foot problems in diabetes: a Summary Guidance for Daily Practice 2015, based on the IWGDF Guidance Documents. Diabetes Metab Res Rev. 2016;32 Suppl. 1:7–15.
9. Krishnan S, Nash F, Baker N, Fowler D, Rayman G. Reduction in diabetic amputations over 11 years in a defined U.K. population: benefits of multidisciplinary team work and continuous prospective audit. Diabetes Care. 2008;31:99–101.
10. Canavan RJ, Unwin NC, Kelly WF, Connolly VM. Diabetes and non diabetes related lower extremity amputation incidence before and after the introduction of better organized diabetes foot care: continuous longitudinal monitoring using a standard method. Diabetes Care. 2008;31:459–63.
11. Carinci F, Massi Benedetti M, Klazinga NS, Uccioli L. Lower extremity amputation rates in people with diabetes as an indicator of health systems performance. A critical appraisal of the data collection 2000–2011 by the Organization for Economic Cooperation and Development (OECD). Acta Diabetol. 2016;53:825–32.
12. Implementación de una Unidad de Pie Diabético coordinada desde un Servicio de Endocrinología. Available from: http://www.msps.es/organizacion/sns/planCalidadSNS/BBPP_DIABETES_2014.htm [accessed 06.12.16].
13. Instituto de Estadística de la Comunidad de Madrid. Población interpolada por municipios según edad simple, para cada sexo. Available from: http://www.madrid.org/iestadis/fijas/estructu/demograficas/censos/ipob_ref_1.htm [accessed 06.12.16].
14. Instituto de Estadística de la Comunidad de Madrid. Altas hospitalarias registradas en la Comunidad de Madrid. Available from: http://www.madrid.org/iestadis/fijas/estructu/sociales/descarga/alh12me.pdf [accessed 08.12.16].
15. Ahmad OB, Boschi-Pinto C, Lopez AD, Murray CJL, Lozano R, Inoue M. Age standardization of rates: a new WHO standard (GPE Discussion Paper Series No. 31.EIP/GPE/EBD). Geneva, Switzerland: World Health Organization; 2001.
16. Kim HJ, Fay MP, Feuer EJ, Midthune DN. Permutation test for joinpoint regression with applications to cancer rates. Stat Med. 2000;19:335–51.
17. Bakker K, Apelqvist J, Lipsky BA, Van Netten JJ, International Working Group on the Diabetic Foot. The 2015 IWGDF guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus. Diabetes Metab Res Rev. 2016;32 Suppl. 1:2–6.
18. López-de-Andrés A, Jiménez-García R, Aragón-Sánchez J, Jiménez-Trujillo I, Hernández-Barrera V, Méndez-Bailón M, et al. National trends in incidence and outcomes in lower extremity amputations in people with and without diabetes in Spain, 2001–2012. Diabetes Res Clin Pract. 2015;108:499–507.
19. Aragón-Sánchez J, Hernández-Herrero MJ, Lázaro-Martínez JL, Quintana-Marrero Y, Maynar-Moliner M, Rabellino M, et al. In-hospital complications and mortality following major lower extremity amputations in a series of predominantly diabetic patients. Int J Low Extrem Wounds. 2010;9:16–23.
20. López-de-Andrés A, Martínez-Huedo MA, Carrasco-Garrido P, Hernández-Barrera V, Gil-de-Miguel A, Jiménez-García R. Trends in lower-extremity amputations in people with and without diabetes in Spain, 2001–2008. Diabetes Care. 2011;34:1570–6.
21. OECD (2015), Major lower extremity amputation in adults with diabetes, 2013 (or nearest year), in Health at a Glance 2015. OECD Publishing: Paris. Available from: http://dx.doi.org/10.1787/health-data-en [accessed 06.12.16].
22. Gérvas J. Diabetes: cost, process and results in Spain. Quality with amputations. Aten Primaria. 2011;43:174–5.
23. Rubio JA, Aragón-Sánchez J, Lázaro-Martínez JL, Almaraz MC, Mauricio D, Antolín Santos JB, et al. Diabetic foot units in Spain: knowing the facts using a questionnaire. Endocrinol Nutr. 2014;61:79–86.
24. Rubio JA, Álvarez JA, Cancer E, Peláez N, Maqueda E, Marazuela M. Amputaciones de miembro inferior en población con diabetes mellitus en el área 3 de la Comunidad de Madrid. Av Diabetol. 2003;19:25–30.
25. Rubio JA, Salido C, Albarracín C, Jiménez S, Álvarez J. Incidencia de amputaciones de extremidades inferiores en el área 3 de Madrid. Estudio retrospectivo del período 2001–2006. Rev Clin Esp. 2010;210:65–9.
26. Rubio JA, Aragón-Sánchez J, Jiménez S, Guadalix G, Albarracín A, Salido C, et al. Reducing major lower extremity

amputations after the introduction of a multidisciplinary team for the diabetic foot. Int J Low Extrem Wounds. 2014;13:22–6.
27. Anichini R, Zecchini F, Cerretini I, Meucci G, Fusilli D, Alviggi L, et al. Improvement of diabetic foot care after the implementation of the International Consensus on the Diabetic Foot (ICDF): results of a 5-year prospective study. Diabetes Res Clin Pract. 2007;75:153–8.
28. Plusch D, Penkala S, Dickson HG, Malone M. Primary care referral to multidisciplinary high risk foot services – too few, too late. J Foot Ankle Res. 2015;8:62.
29. Aragón-Sánchez J. Are useful the diabetic foot units? Med Clin (Barc). 2014;142:208–10.