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SEX DIFFERENCES IN LOWER EXTREMITIES AMPUTATIONS IN PATIENTS WITH DIABETES - FIVE YEAR NATIONWIDE FOLLOW-UP USING DRG DATA IN ROMANIA

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Abstract

Background and Aims. *The present study represents the first nationwide evaluation of lower extremities amputations (LEA) in diabetes patients in Romania.* ***Material and Methods.*** *We used the disease related groups (DRG) data provided by the National School for Public Health, Management and Health Education, for the years 2006-2010 and stratified according to diabetes type, sex and age group.* ***Results.*** *There were 16873 patients with diabetes who underwent a total number of 24312 non traumatic LEA. A total of 22.55% of the patients had type 1 diabetes (T1DM) and 70.26 % had type 2 diabetes (T2DM). The rate of amputations decreased in T1DM and increased in T2DM, especially in elderly people. Male-to-female ratio of amputations was ~2:1 in T1DM and ~2.4:1 in T2DM. The predictions for the number of amputation episodes was approximated by the regression line y=286.8x-572728 r=0.97, p=0.005, d=0.95 in men, and by y=91.1x-181511, r=0.98, p=0.004, d=0.95 in women (where x is years and y is number of amputation episodes).* ***Conclusions.*** *Identifying certain age and sex groups of patients with diabetes in whom higher increase of LEA rates are observed imposes a change of strategy concerning prevention and curative measures.*

key words: *lower extremity amputations, diabetes, sex distribution*

Background and Aims

Lower extremities amputations (LEA) represent a major handicap for the patients with diabetes in them, these procedures represent a continuously worsening condition, leading to subsequent, higher anatomical level interventions and an increased mortality risk. The burden of this chronic diabetes complication outcome lies on the patient itself and also on the family and the whole society. There is a well known difference in epidemiology of amputations between sexes in people without diabetes. In diabetes these differences tend to be lower due to the similar underlying mechanisms of the disease in both sexes [1,2].

The aim of this study was to provide –for he first time at national level - an evaluation of the prevalence, incidence and trends of LEA in male and female patients with diabetes from Romania using data provided through the Disease Related Groups (DRG) coding system.

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Materials and Methods

For the five year duration of the study, comprising the years between 2006 and 2010, all amputations in Romania were performed during a hospital admission and reported using the DRG coding system and centralized by the National School for Public Health, Management and Health Education (Școala Națională de Sănătate Publică, Management și Perfecționare în Domeniul Sănătății) [3] which was our data provider. For the year 2006, the International Classification of Diseases 10 (ICD 10) was used whereas from 2007 to 2010 the ICD 10 AM (the Australian version - diagnostic and procedures) [4] was used. The selection criteria for the national database search were: patients with all primary or secondary DRG diagnosis codes for diabetes E09-E14 at discharge, and any of the amputation procedure codes: codes 1484 – 44367.00 for thigh amputations, code 1484 – 44370.00 for hip amputations, codes 1505 – 44367.02, for leg amputations and all codes between1532 – 1533 for feet and toes amputations.

The total (absolute) number of patients as well as the number of hospital admissions and procedures / patient was assessed every 6 months. Data were summarized in report tables for groups of patients (type of diabetes, age decades, sex) and not individually due to patient confidentiality reasons. Identification data were encrypted. Data on sex and age (decades between 20-90 years), were available only for the years 2008, 2009, 2010 and were reported separately for different diabetes types. Demographic data for the Romanian population was obtained from the annual reports of the National Institute of Statistics [5].

Statistical analysis was performed with the Microsoft Excel, SPSS 19.0 and STATISTICA 8.0 softwares and consisted of descriptive statistics and linear regression analysis. Due to the fact that we had access to the data of the entire population (not just a representative sample), significance level (P) was not required. In most cases absolute numbers and mean ± standard deviation (SD) were given. Incidence was expressed as number / 10^5 person-years in general population.

Results

The total number of non traumatic LEA performed in Romania during the five years study duration was 48106, with a mean incidence rate of 23.3 amputations / 10^5 persons / year in the general population. Of the total number of LEA, 24312 (50.54%), were performed in diabetes patients.

A total of 16873 patients with diabetes mellitus were identified. Of them, 3805 (22.55%) had type 1 diabetes DRG coded diabetes (T1DM) and 11855 (70.26 %) had type 2 DRG coded diabetes (T2DM). The remaining 1213 (7.19%) were patients with “specified” and “non specified” types of DRG coded diabetes diagnosis at discharge.

The absolute numbers of non traumatic LEA episodes performed each year over the five year study period are presented in Table 1.We found a mean of 4584.4 ± 612.42 amputations / year; 1628.8 ± 240.7 in T1DM and 3066.0 ± 854.6 in T2DM patients. The increase of the absolute number of amputations over the five years interval was due to an increasing number of amputations in T2DM, but not in T1DM.

The predictions of the number of non traumatic LEA showed an increase in both men and women, steeper in men (Figure 1) and were approximated by: the regression line y= -572728+286.8x r=0.97, p=0.005, d=0.95 in men, and by y= -181511 + 91.1x, r=0.98, p=0.004, d=0.95 in women, where x is the year and y is the number of episodes of amputation.

Table 1. Absolute number and incidence of non traumatic amputations in patients with diabetes.

	2006	2007	2008	2009	2010	Total
Absolute number of amputations	4123	4343	4927	5092	5827	24312
Number of amputations due to diabetes /10^5 persons (in general population) / year	18.15	19.07	21.56	22.23	25.52	-

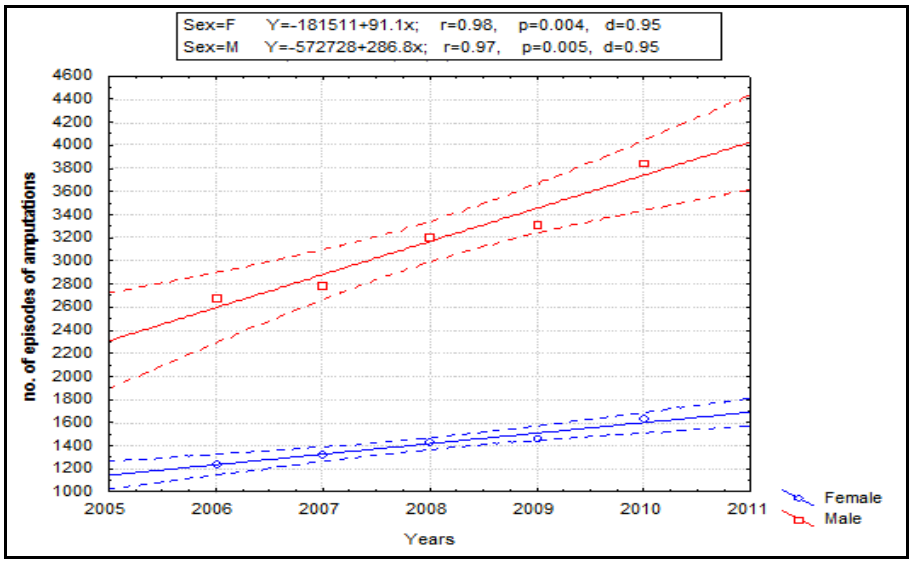

Figure 1. *Prediction of number of amputations in men and women(x=year, y=no. of episodes of amputation).*

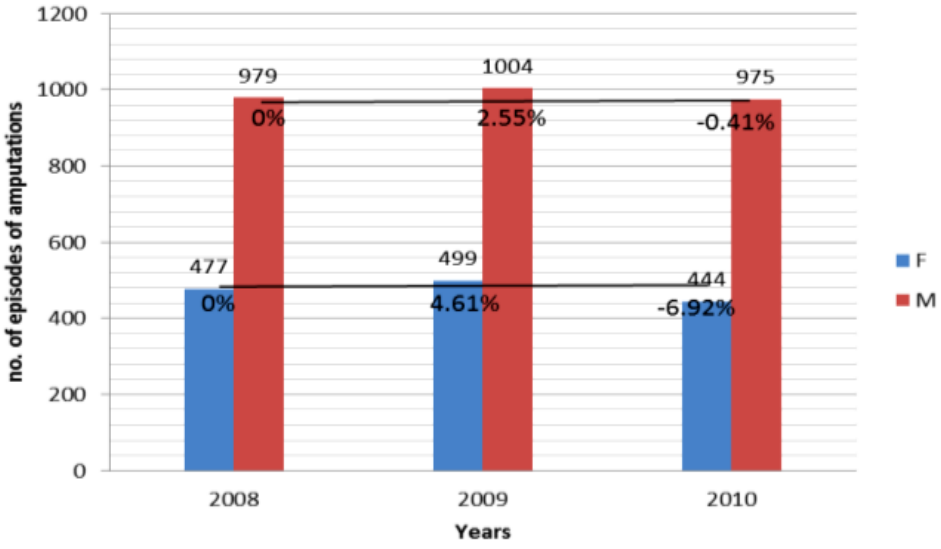

Figure 2. *Total number of LEA episodes stratified by sex in type 1 diabetes patients (Absolute numbers and % change from 2008).*

When stratifying for type of diabetes the absolute number of amputations/year for the years 2008, 2009, 2010 in T1DM men was 979, 1004, 975, with a male-to-female sex ratio of 2.05, 2.01 and 2.19 as shown in Figure 2. In T2DM men, the total number of LEA was 2304, 2403, 2951, with a male-to-female ratio of 2.34, 2.37, 2.39 for the respective years (Figure 3).

We found a mean of 473.3 ± 22.6 amputations/year in T1DM women and 986.0 ± 12.8 amputations/year in T1DM men, whereas for T2DM patients, there were 1077.7 ± 112.5

amputations/year in women and 2552.7 ± 284.6 amputations/year in men (for years 2008-2010).

The absolute number of amputation episodes showed a slight reduction between 2008 and 2010 in T1DM patients in both sexes, being more important in women (Figure 2) whereas there was a marked increase in amputations in T2DM patients in both sexes (Figure 3).

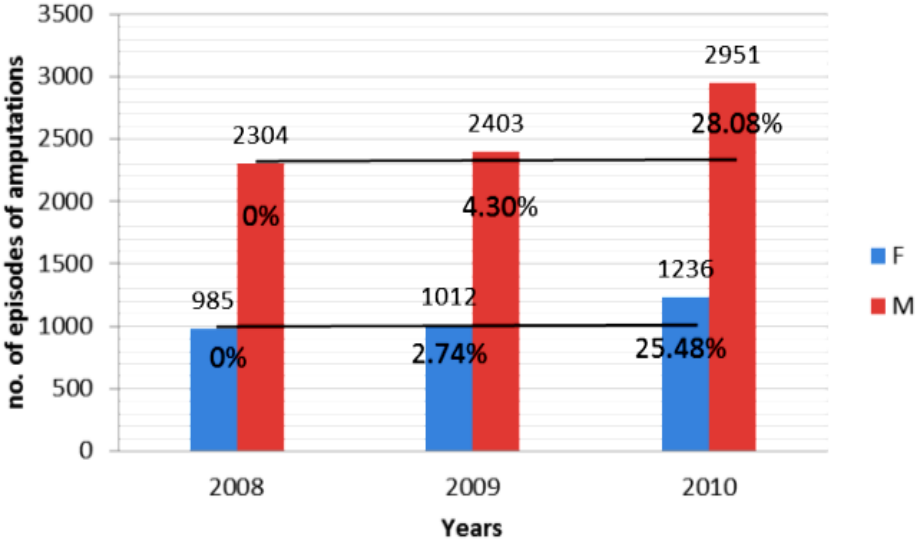

Figure 3. *Total number of LEA episodes stratified by sex in type 2 diabetes patients (Absolute numbers and % change from 2008).*

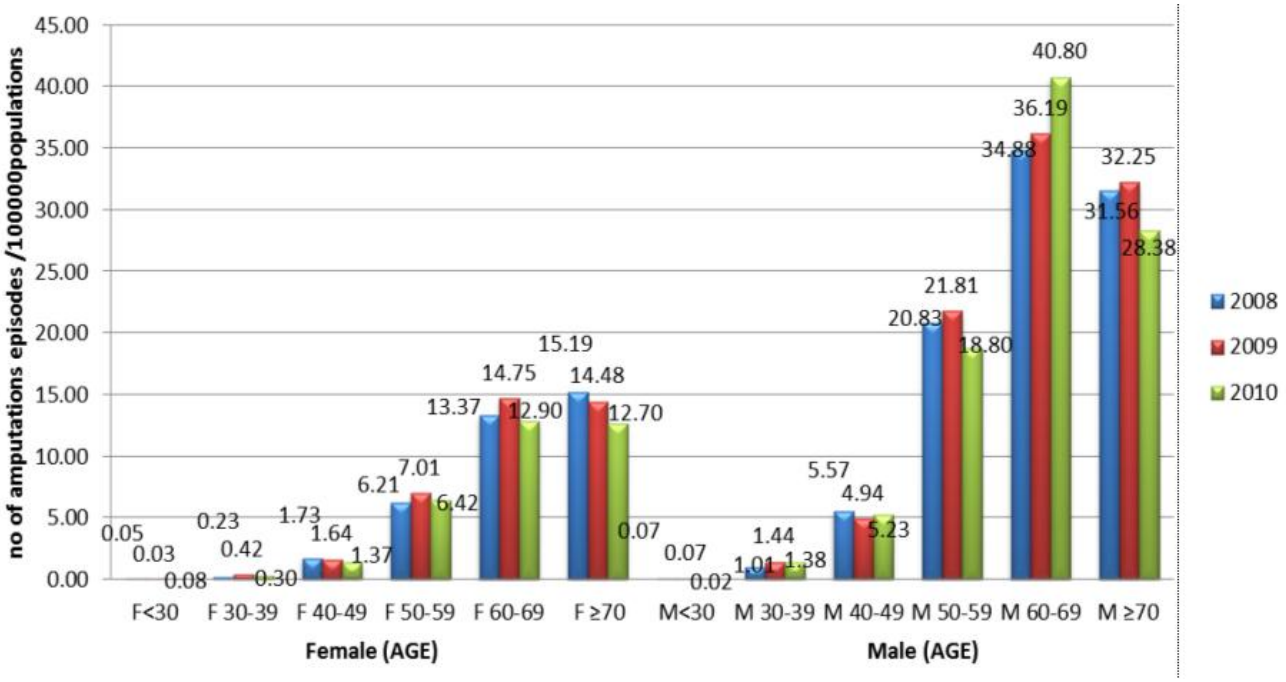

Figure 4. *Crude incidence of amputations in type 1 diabetes patients stratified by sex and age groups /10^5 persons of the same age decade in general population.*

Differences between sexes were further evaluated by taking into account the decade specific incidence rates in both type 1 and type 2 diabetes (age related data were available only for years 2008-2010). Crude incidence rates of LEA stratified by age group and sex (per 10^5 persons in the general population) in T1DM patients are shown in Figure 4 and for T2DM patients are shown in Figure 5. Calculations were made using as nominator the total number of persons

of the same age decade reported in the general population for the three years period of the study.

Overall we found a slight decrease in LEA incidence in T1DM, in both sexes and in all decades, except for a noticeable increase in men aged 60-60 years, this population subgroup thus representing a target for improvement of foot care in type 1 diabetes patients in Romania.

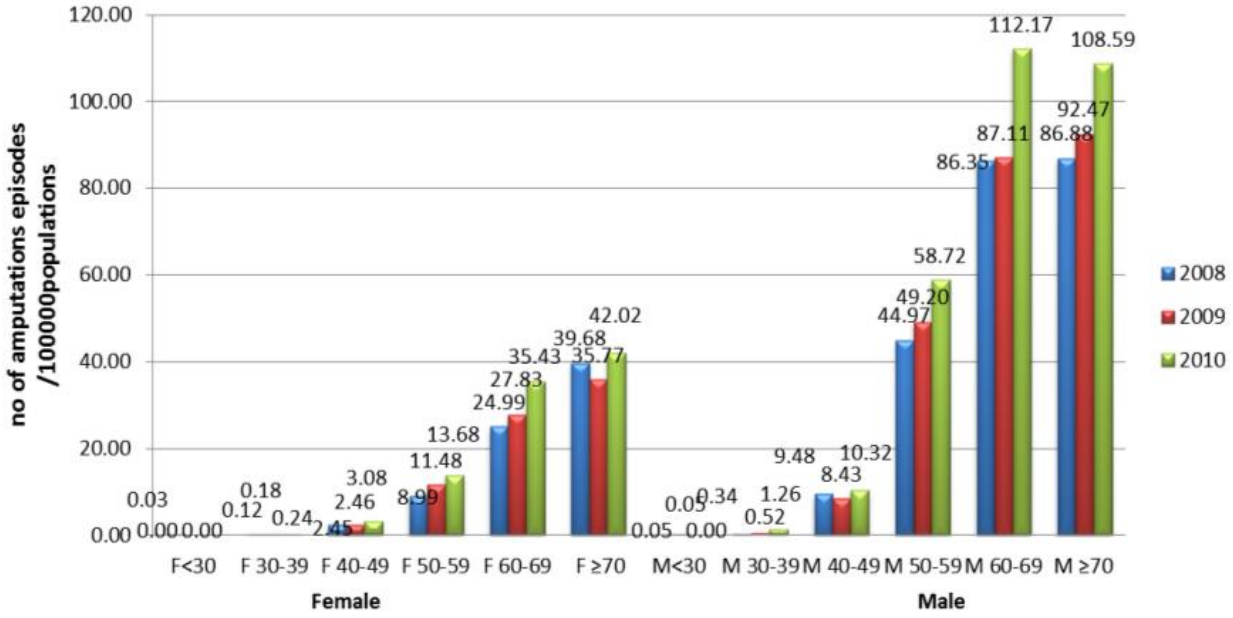

Figure 5. *Crude incidence of amputations in type 2 diabetes patients stratified by sex and age groups /10^5 persons in the general population.*

In type 2 diabetes men as well as in women we found there was an increase in LEA incidence rates along all age groups, the most affected was the decade 60-69 years in both sexes, although in all advanced age patients (all patients over 60 years) an important increase of LEA incidence rates was observed, contributing to the general positive trend in both sexes.

Discussions

The objectives of reducing the number of preventable amputations in diabetes patients were set since 1989 by The St. Vincent Declaration [6] although today they may seem quite ambitious at national or local level. In order to achieve any of these objectives a well documented, reliable evaluation is obviously needed and to this need the present study represents a first preliminary answer.

An important increase of LEA rates in Romania between 2006-2010 was observed despite the implementation/improvement of standards of foot care for diabetic patients, including screening, primary and secondary prevention of ulcerations through educational measures, increased availability of special shoe ware, medication, surgical interventions (like revascularization, etc). However, despite the fact that the majority of these measures are supported by the national medical insurance system, they are not uniformly applied in all regions or at all levels, thus needing more attention and a change of strategy.

Comparing the data for the Romanian population with data published by a Spanish group [7], that used data from hospital discharge files and who reported a significant decrease in amputations in T1DM patients, whereas the incidence increased in T2DM over an 8 year study period (2001-2008) we found similar trends, negative for type 1 diabetes and positive for type 2 diabetes patients.

Another evaluation from Ireland [8], performed during the same period(2005-2009), showed a small variation of non traumatic amputation rates in the general population but a non significant increase in the rates of LEAs in the diabetes population: from 144 to 175 LEA /10^5diabetes persons /year. In our study we found an ample, steady increase in amputation rates in men and women with diabetes during approximately the same observation period.

Data on LEA in T1DM patients from Sweden [1] demonstrate a decrease of the risk for amputations during the last five years of the study, but still with a much higher amputation risk in type 1 diabetes than in the general population, the risk being twice as high in men than in women. In our population with type 1 diabetes the rate of males to females LEA was between 2.01 to 2.19. Similar trends were found by a study from England analyzing the 1985-2005 period [9] when the amputation rates decreased in T1DM patients but increased by 43% in T2DM subjects.

In a diabetic population (including ~ half a million patients) from Taiwan [2], the estimated incidence of non-traumatic LEA in diabetic men was 410.3 per 100.000 diabetes patient-years. The corresponding data for women with diabetes were relatively low at 115.2 per 100.000 diabetes patient-years, corresponding to an approximated male-to-female ratio of 4:1, indicating greater difference between sexes when compared to the Romanian population.

In Germany [10], the overall incidence of LEA in the diabetes population was 176 per 10^5 person years. Approximately 66% of those with a first amputation are diabetes patients and of them 76% are males. In our study we found an overall percentage of 50.54% amputations performed in diabetes patients, with a male-to-female ratio of 2:1 in T1DM and 2.4:1 in T2DM.

Concerning the limitations of the study, we stress that there is great variability in LEA reporting methods, a problem already mentioned by several authors [11,12], as well as a lack of standardized methods, thus making comparisons difficult. We should also mention that for the period when the study was performed, the accuracy of reporting using the DRG coding system remains questionable for some centers. Improving of coding can offer a valuable tool for further longitudinal evaluations and adjustments of health policies

Conclusions

We found a high incidence in LEA rates in diabetes patients in Romania. There is a worrying positive trend of LEA in T2DM, especially in the elderly, both in men and women. The age-group 60-69 years presented the higher increase in amputation rates. In T1DM patients we recorded a slight tendency of decrease in the number of LEA over the study period, especially in women but not in men aged 60-69 years.

The increase of LEA rates in patients with diabetes identifies the need for improvement of prevention strategies (screening and educational therapy towards awareness of foot problems) and also curative measures (both medical and surgical). Re-evaluation of amputation rates should be performed regularly and with standardized parameters.

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