An economic evaluation of the cost of diabetic foot ulcers: results of a retrospective study on 239 patients

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SUMMARY
Objective: To evaluate the cost of foot ulcers in diabetic patients.

Methods: Retrospective pharmacoeconomic study using direct and indirect costs (sick leave days) from the perspective of French social security system.

Results: 239 patients were included in the study by 80 physicians who treat diabetic patients suffering from foot ulcers. Initially identified by telephone survey, these physicians were primarily endocrinologists/diabetologists, general practitioners and surgeons. Average monthly costs in the treatment of foot ulcers were €697.50 for outpatient care, €1556.20 for hospital care (day treatment and short stays), and €34.76 for sick leaves. When hospitalization was required, it represented approximately 70% of the average cost for foot ulcers. The portion of outpatient costs was principally generated by medical and paramedical treatments, and interventions carried out by healthcare personnel. On the other hand, medication only represented 10% of total costs. The initial severity of the pathology was a determinant clinical factor of high healthcare costs. In addition, the more recent the lesion was, the higher the cost of treatment. Amputation and follow-up by specialists were correlated to high costs as well, a logical result of these clinical factors.

Conclusion: This analysis is the first to evaluate the cost of treating foot ulcers in such a large population of diabetic patients. The economic outcomes should help direct public authorities in their choices, particularly as regards the interest of treating these diabetes-related complications as early as possible.

Key-words: Diabetic Foot - Diabetes - Medical costs - Amputations.

Resumen
Evaluación económica de la prise en charge des lésions trophiques des pieds chez des patients diabétiques: résultats d’une étude rétrospective chez 239 patients

Objetivo: Evaluar los costos de los úlceras del pie en los pacientes diabéticos.

Métodos: Estudio médico-económico retrospetivo; incluyendo los costos directos e indirectos (faltas de trabajo) para la seguridad social. 

Resultados: 239 pacientes fueron incluidos en el estudio por 80 médicos que tratan a los pacientes diabéticos con úlceras del pie. Inicialmente identificados por encuesta telefónica, estos médicos fueron principalmente endocrinólogos/diabétólogos, generalistas y cirujanos. Los costos mensuales promedio de la atención de las úlceras del pie eran de €697.50 para el cuidado ambulatorio, €1556,20 para el hospitalización (atención diurna y corta estancia), y €34,76 para las faltas de trabajo. Cuando se requirió hospitalización, representaba aproximadamente el 70% del costo promedio de un ulcer del pie. La parte de los costos ambulatorios fue principalmente generada por los gastos en tratamientos médicos y paramédicos, e intervenciones hechas por el personal de atención. Por otro lado, los tratamientos medicamentosos solo representaban el 10% de los costos. Los factores clínicos identificados como predecibles de un costo de tratamiento elevado fueron el carácter reciente de la lesión y su gravedad inicial. La amputación y el sueldo por un especialista fueron correlacionados a los costos más importantes, en línea lógica con los factores clínicos.

Conclusion: Esta evaluación de costos de la enfermedad es la primera a evaluar el costo de cuidado de las úlceras del pie en un tel número de pacientes diabéticos. Los resultados económicos obtenidos contribuyen a esclarecer los fondos públicos en sus elecciones cuant a su interés de una el costos de cuidado de estas complicaciones ligadas al diabético.

Mots-clés: Pied diabétique - Diabète - Coûts des soins - Amputations.
Despite considerable progress made over the past fifteen years in the treatment and prevention of diabetes, chronic cardiovascular, renal, ocular and neurological complications still represent a major public health problem. One complication in particular, chronic foot lesions, has been the subject of various epidemiology studies worldwide, highlighting how frequently this disorder occurs. In the United States, it is estimated that 15% of all diabetic patients are afflicted by this condition during the course of their lives [1], and in Sweden and Great Britain, 4.4% to 9% of diabetic patients are affected [2-5]. In France, between 75,000 and 150,000 diabetic patients suffer from this condition, with an annual incidence of between 40,000 and 80,000 [6]. Between 10% and 15% of all diabetics develop trophic foot lesions during the course of their lives [7]. The treatment of this disorder generates potentially high healthcare expenses, particularly in developed countries where the number of diabetic patients increases due to lifestyle and ageing populations [8]. Foot ulceration is at the origin of 20% of diabetes-related hospitalizations, with a risk of amputation 15 times higher than among non-diabetic subjects [9]. In the United States, 46% of annual hospitalizations for foot ulcers concern diabetic patients [1], these patients representing between 30% and 70% of all non-traumatic amputations [8, 10-11]. Costs relevant to the treatment of diabetic foot ulcer attain an average 2,687 US$ per patient and per year, or 4,565 US$ per outbreak, over 80% of which correspond to hospitalization costs [12].

In France, little data exists concerning the economic impact of diabetic foot ulcer [8]. Only one cost evaluation of this pathology, published in 1993 [6], contains estimations of direct medical costs (outpatient care and hospitalization) and indirect costs (namely sick leave days). This work, based on ranges of values, highlighted the public health aspect of this diabetes complication and emphasized the need for further prospective studies using methodologies adapted to the complex management of these patients within the French healthcare system.

It was in this context that we decided to carry out a retrospective economic evaluation of diabetes-related foot ulcers, which was then coupled with a cross-sectional observational quality of life study. The primary objective was to estimate the cost of the care as well as the quality of life of patients suffering from diabetic foot ulcers. However, this article focuses only on the economic objective, while the quality of life results are presented in another article [13].

Material and methods

Make-up of sample of investigating physicians

The recruitment of physicians (general practitioners, endocrinologists/diabetologists, general/orthopedic and vascular surgeons, dermatologists, geriatricians and internists in charge of patients suffering from foot ulcers) was carried out through a telephone survey among a representative sample of French medical practitioners. The physicians who were contacted were chosen at random within a medical provider database. Proportions of each medical specialty and their characteristics such as age, sex, location and exercise mode were verified to conform to these officially published by the SESI National Statistics.

Patient inclusion criteria

Each doctor who agreed to participate in the study was asked to recruit consecutive diabetic patients (aged ≥ 18 years) during medical consultations. The patients had either to have undergone treatment for trophic lesions (grade 1 to 5 according to the Wagner classification [14]) for at least one month, or be healing from an amputation related to a trophic foot lesion.

Study plan

This retrospective cost evaluation of diabetic patients suffering from trophic foot lesion(s) was associated with a cross-sectional observational quality of life study (QoL) carried out in France from April to July, 1999. The protocol was registered with the French National Consumer Commission (Commission Nationale Informatiques et Libertés — CNIL), and the principal survey elements were declared to the French Medical Association (Conseil National de l’Ordre des Médecins — CNOM).

Investigators were asked to fill out forms concerning their socio-demographic and professional characteristics.

For the study population, investigators gathered patients’ socio-demographic and clinical characteristics during medical consultations. Additional economic data was collected for the “patient” group: direct medical costs, outpatient and hospital healthcare costs, and indirect costs linked to loss of productivity (sick leave) for working patients.

A list of resources consumed was drawn up:
- from the appearance of the lesion: general treatment, surgery, consultations with specialists, para-clinical exams, orthopedic equipment, hospitalization and sick leave;
- for the month preceding study inclusion: laboratory analyses, medical care, local treatment and physical reeducation.

At the same time, a generic self-administered quality of life questionnaire (SF-36) was completed by all subjects. Subjects in the “patient” group also filled out a specific quality of life questionnaire (DFS: Diabetic Foot Ulcer) [13].

Valuation of resource consumption and pharmacoeconomic analysis

The methodology in this economic evaluation follows the good practice guidelines elaborated by the French College of Health Economists for the economic evaluation of
therapeutic strategies [15]. An evaluation of healthcare costs was carried out on the “patient” group only.

The perspective chosen for the economic analysis was that of the French social security system, with no adjustment for reimbursement rates. This choice was related to the fact that diabetic patients included in the study were all medically recognized as suffering from diabetes mellitus and also registered by the social security as “long-term disease” patients. Consequently, all diabetes-related treatment, including treatment of diabetic foot ulcer, were fully reimbursed by the French healthcare system.

The healthcare resource utilization collected in the “patient” case report form are as follows:
- medical consultations;
- outpatient care: para-clinical exams, surgery, local treatment, physical reeducation;
- prescription: medication and orthopedic equipment;
- hospitalization;
- sick leave (for working patients only).

In order to cost the acts carried out by healthcare staff, such as podiatry, local treatments and physical reeducation, panels of physical therapists and nurses were set up. This allowed us to elaborate a qualitative and quantitative description of their activities, and then estimate the value of these acts and their costs to the French Social Security. Similarly, a panel of pharmacists and medical suppliers was set up to identify medical and orthopedic equipment used, as well as the corresponding reimbursement rates.

Medico-technical and biological acts, consultations, para-clinical exams and outpatient surgery were valued according to official 1999 French Social Security rates (published by Union des Caisses Nationales de Sécurité Sociale — UCANSS), and the following coding classifications: Nomenclature des Actes de Biologie Médicale (NABM) and Nomenclature Générale des actes professionnels (NGAP). The average daily costs for reimbursed general and local treatments were elaborated with regard to therapeutic indications, applying the average recommended dosages listed on the Vidal® 1999 (French Formulary). Hospitalization (day treatment and short stays), valuation was based on the French Hospital Information System (Programme de Médicalisation du Système d’Information — PMSI). The reasons for hospitalization reported in the patient case report form (Wound care, Excresis of an ostitis focus, Abscess treatment, Skin graft, Endarteriectomy, Angioplasty, Bypass, Amputation of one or more toe(s), Transmetatarsian amputation, Amputation at a higher site, Reeducation), were considered as the principal diagnosis. Therefore, we were able to identify patients according to Diagnosis Related Groups (DRG), and to cost these groups by applying the national 1999 cost scale for DRGs.

Sick leave days were costed according to public health insurance daily-allowance tables, which correspond to 1/720 of the Social Security ceiling for 1999.

All cost outcomes relevant to the disease were adjusted to one month of average resource consumption per patient. Two types of monthly averages were calculated:
- for the population of patients included in the study;
- for the real population of patients who require this type of healthcare resource utilization.

Statistical analyses

Statistical analyses were performed using SAS software system for Windows (Version 6.12).

Descriptive analyses are presented as average values ± standard deviation, median values and percentages. For quantitative values, sub-groups of patients defined according to socio-demographic and clinical parameters (age, sex, type of diabetes, initial severity of disease, oldness of lesion, amputation for current lesion, recruiting physician’s medical specialization and exercise mode), were compared by means of T-tests, ANOVA analyses and non-parametrical tests (Mann-Withney Wilcoxon and Kruskal-Wallis). Qualitative parameters were compared by means of the Chi-2 or Fisher Exact Test. The significance threshold was fixed at 0.05. Searches for correlation between quantitative parameters were carried out using Pearson and Spearman correlation coefficient calculations.

Results of the resource-consumption descriptive analysis and relative monthly costs were presented according to healthcare categories, under the following headings:
- outpatient treatment and medical follow-up;
- hospitalization (day treatment and short stays);
- sick leave (for working patients only).

Hospitalization for convalescence/physical reeducation was not valued.

Furthermore, in order to simultaneously include certain clinical and socio-demographic factors in monthly healthcare costs (including hospitalization costs), a step-by-step logistic regression was carried out, making monthly costs qualitative in relation to median values by means of two modalities (“less than” or “equal to” and “greater than”).

Results

Characteristics of participating physicians

Among the 1,090 physicians who were contacted by telephone, 900 (82.6%) agreed to answer the study questions and 562 (62.4%) declared treating patients who suffered from foot ulcers. At the end of the telephone survey, 119 physicians (out of the 562) agreed to participate in the study and recruit subjects for the “patient” group. Following this, 80 of the 119 physicians (67.2%) each recruited between one and eight patients (three on average). “Control” subjects were recruited by 18 other physicians, none of whom were involved in the medical treatment of diabetic foot ulcer.

The 80 recruiting physicians were for the large part male (75%), their average age was 43.6 years, and they practiced in...
urban environments (small or large cities: 67.6%). The physicians were principally endocrinologists/diabetologists (28.8%), general practitioners (27.5%), and surgeons (orthopedic, vascular and general: 22.5%) (Tab I). Ten of these physicians (12.5%) belonged to a healthcare network, while 11 (13.8%) practiced at a specialized diabetic foot center.

Socio-demographic and clinical characteristics of “patient” group

A total of 239 patients were included in the study. Most patients were male (66.5%), with an average age of 65.5 (± 11.2) years, the majority of them living with a partner (58.2%). Patients had known about their diabetes for approximately 17.3 years on average. Most of them (73%) had type 2 diabetes. Among the various foot ulcer risk-factors, it is important to note a high frequency of associated neuropathy (79.5%) and hypertension (61.9%) (Tab II). Retinopathy (56.9%) and nephropathy (47.3%) were also noted as frequent among these patients; 33.9% of them had a coronary disease or arteritis of the lower limbs, and 23.4% had had an arteriopathy which led to an amputation.

Two-thirds of the patients (67.0%) declared that they monitored their glycemia levels and 44% had followed educational programs in specialized centers.

Characteristics of foot ulcers

More than one out of two patients (59%) had previously suffered from one or more foot ulcers, and over one out of three (38.5%) had already been amputated.

At the time of inclusion in this study, patient’s main lesion had been present for an average of 13.5 months (median: 5 months), and they had been undergoing specific treatment for their lesion for an average of 12 months (median: 4 months) (Tab III). For 59% of the patients, this main lesion was progressive; for 33% it was associated with another progressive lesion. The triggering factor remained unknown in 30% of cases. The origin of the main lesion was of multiple etiology in two-thirds of cases: most frequently, neuropathy, arteriopathy of the lower limbs or infection. Lesions were most commonly found on the toes (50.5%), or the sole of the foot (24.3%).

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**Table I**

Characteristics of the 80 physicians having recruited the diabetic patients suffering from foot ulcer.

<table>
<thead>
<tr>
<th>Frequency (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age:</strong> mean (years)</td>
<td>43.6 ± 6.9</td>
</tr>
<tr>
<td><strong>Sex:</strong> male/female/missing data</td>
<td>60 (75.0%)/16 (20.0%)/4 (5.0%)</td>
</tr>
<tr>
<td><strong>Specialty</strong></td>
<td></td>
</tr>
<tr>
<td>- General Practitioners</td>
<td>22 (27.5%)</td>
</tr>
<tr>
<td>- Endocrinology/diabetologists</td>
<td>23 (28.8%)</td>
</tr>
<tr>
<td>- Surgeons</td>
<td>18 (22.5%)</td>
</tr>
<tr>
<td>- Others (internists, dermatologists, geriatric specialists, angiologists)</td>
<td>8 (10.0%)</td>
</tr>
<tr>
<td>- Missing Data</td>
<td>9 (11.2%)</td>
</tr>
<tr>
<td><strong>Exercise mode</strong></td>
<td></td>
</tr>
<tr>
<td>- Hospital</td>
<td>34 (42.5%)</td>
</tr>
<tr>
<td><strong>Place of practice</strong></td>
<td></td>
</tr>
<tr>
<td>- Small cities</td>
<td>31 (38.8%)</td>
</tr>
<tr>
<td>- Large cities</td>
<td>23 (28.8%)</td>
</tr>
</tbody>
</table>

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**Table II**

Characteristics of the diabetic patients having foot ulcers (N = 239).

<table>
<thead>
<tr>
<th>Frequency (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Socio-demographic characteristics</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sex:</strong> Male/Female</td>
<td>159 (66.5%)/79 (33.0%)</td>
</tr>
<tr>
<td><strong>Mean Age (years)</strong></td>
<td>65.5 ± 11.2</td>
</tr>
<tr>
<td><strong>Familiar status</strong></td>
<td></td>
</tr>
<tr>
<td>- Single</td>
<td>73 (30.5%)</td>
</tr>
<tr>
<td>- Living with a partner</td>
<td>139 (58.2%)</td>
</tr>
<tr>
<td>- In community</td>
<td>25 (10.5%)</td>
</tr>
<tr>
<td>- Missing data</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td><strong>Characteristics of the diabetes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type:</strong> 1/2</td>
<td>62 (25.9%)/174 (72.8%)</td>
</tr>
<tr>
<td><strong>Mean duration (years)</strong></td>
<td>17.3 ± 11.1</td>
</tr>
<tr>
<td><strong>Duration of diabetes treatments</strong></td>
<td></td>
</tr>
<tr>
<td>- Duration of first insulin treatment (years) (N = 150)</td>
<td>10.1 ± 12.6</td>
</tr>
<tr>
<td>- Duration of first oral treatment (years) (N = 193)</td>
<td>15.4 ± 9.7</td>
</tr>
<tr>
<td><strong>Current treatment of diabetes</strong></td>
<td></td>
</tr>
<tr>
<td>- Insulin treatment</td>
<td>154 (64.4%)</td>
</tr>
<tr>
<td>- Oral treatment</td>
<td>96 (40.17%)</td>
</tr>
<tr>
<td><strong>Risk factors of foot ulcer</strong></td>
<td></td>
</tr>
<tr>
<td>- Neuropathy</td>
<td>190 (79.5%)</td>
</tr>
<tr>
<td>- Arteritis of the lower limb or coronary disease</td>
<td>81 (33.9%)</td>
</tr>
<tr>
<td><strong>Others complications linked to diabetes</strong></td>
<td></td>
</tr>
<tr>
<td>- Retinopathy</td>
<td>136 (56.9%)</td>
</tr>
<tr>
<td>- Nephropathy</td>
<td>113 (47.3%)</td>
</tr>
<tr>
<td>- Arteritis with amputation, infarct or stroke</td>
<td>56 (23.4%)</td>
</tr>
<tr>
<td>- Arterial Hypertension</td>
<td>148 (61.9%)</td>
</tr>
<tr>
<td><strong>Habits</strong></td>
<td></td>
</tr>
<tr>
<td>- Smokers</td>
<td>61 (25.5%)</td>
</tr>
<tr>
<td>- Alcohol consumers</td>
<td>73 (30.5%)</td>
</tr>
</tbody>
</table>
Patients discovered lesions themselves in 63.2% of cases, in which case the average lapse of time before starting treatment was approximately 22 days (median: 10 days). This timeframe decreased when lesions were discovered by physicians (21 days on average), or family members (14 days on average).

During the first consultation for the lesion, the surface of the lesion was greater than 5 cm² in 20% of cases, and less than 1.4 cm² in 50% of cases. Lesions were considered severe in 28% of patients: grade 3, 4 or 5 according to the Wagner classification (Tab III). During the study inclusion consultation, 16% of patients presented main lesions that were over 5 cm², and 50% presented ones that were less than 1 cm². A breakdown of patients according to the Wagner classification showed that 5.9% were healed (classified grade 0). In effect, between the initial consultation and study inclusion, 16% of patients presented main lesions that were over 1.4 cm² in 50% of cases. Lesions were considered severe in 28% of patients: grade 3, 4 or 5 according to the Wagner classification (Tab III). During the study inclusion consultation, 16% of patients presented main lesions that were over 5 cm², and 50% presented ones that were less than 1 cm². A breakdown of patients according to the Wagner classification showed that 5.9% were healed (classified grade “0”). In effect, between the initial consultation and study inclusion, 16% of patients presented main lesions that were over 1.4 cm² in 50% of cases. Lesions were considered severe in 28% of patients: grade 3, 4 or 5 according to the Wagner classification (Tab III).

### Stages of severity of lesions and type of physician consulted

The distribution of the severity of the main lesion upon diagnosis (initial consultation) and at the moment of study inclusion differed significantly, depending on the medical specialization of the physician consulted (Chi-2 test, \( p = 0.0001 \) and \( p = 0.0001 \)). During the initial consultation, general practitioners and endocrinologists/diabetologists mainly saw patients who presented grade 1 and 2 ulcers (82.0% and 81.7%, respectively), whereas only 50% of the patients who consulted a surgeon presented this type of lesion. Likewise, upon inclusion in the study, most patients treated by general practitioners or endocrinologist/diabetologists presented grade 0 to 2 lesions (78.0% and 68.3%, respectively), whereas this category represented only 23% of patients seen by surgeons. On the other hand, 70% of patients treated by surgeons were healing from secondary amputations of lesions.

### Resource consumption related to foot ulcers

Resource consumption for the medical treatment of foot ulcers can be broken down as follows:

#### Outpatient treatment since appearance of lesion
- consultations with specialists: more than half of the patients (53.5%) had consulted an endocrinologist/diabetologist at least once, one-third had consulted an angiologist, and over one-quarter (28.5%) a cardiologist;
- medico-technical exams specifically related to the lesion: almost two-thirds of patients (62.7%) had had at least one foot X-ray and 60% an arterial ultrasound examination;
- surgery: 25% of patients had required an opening and 18.8% a debridement;
- general medical treatments (oral or parenteral): 72% of patients had taken at least one oral antibiotic treatment, 45% vasodilators, 27% LMWH anticoagulants, and 26% platelet antiaggregants;
- orthopedic equipment prescribed: orthopedic shoes, shoes with partial support, and soles for 31%, 22% and 21% of patients, respectively.

#### Outpatient treatment during month preceding study inclusion
- biological exams of which, due to the lesion, the frequency has been increased during the month preceding inclusion: fasting glycemia was measured among 63% of patients, blood cell count among 58%, creatinine among 57%, and glycated hemoglobin among 55%;
- physical reeducation: prescribed for over 11% of patients (3.5 ± 1.4 weekly sessions);
- local medical treatments: 83.3% of patients were treated with local antiseptic treatments, prescribed for an average of 9.5 weeks, and 22.2% with local antibiotic treatments, prescribed for an average of 12 weeks;
- medical follow-up: 59% of patients consulted a general practitioner 1.34 (± 0.95) times per week during the month, 34% consulted a specialist 1.60 (± 1.20) times per week, and 17% a debridement 1.73 (± 1.62) times per week;
- local treatments were carried out by various healthcare providers: general practitioners for 33% of patients (once a week on average), specialists for 27% of patients (almost twice a week on average), surgeons for 14% (once a week on average), and nurses for over 82% (5 times a week on average).

#### Hospital treatment required since appearance of lesion
Eighty percent of patients had been hospitalized at least one time (average of 3.28 hospitalizations per patient): 35%
had required hospital day treatment (mainly for wound care), and 71% had required a short hospital stay (17 ± 18.4 days) for an amputation or wound care. Twenty-five percent of patients hospitalized for short periods were reoriented to long stays for reasons related to wound care, convalescence and physical reeducation.

Sick leave days required since appearance of lesion

Eleven percent of patients were required to take sick leave for periods ranging from 2 to 82 days.

Costs of treating foot ulcers

Costs related to the treatment of foot ulcers per patient included were 697 € on average per month for outpatient treatment, 1556.28 € per month for hospitalization (day treatment and short stays), and 34.76 € (± 148.94) per month for sick leave (Tab IV). The average monthly costs for each type of treatment were also calculated per patient consumer (Tab IV). Thus, the average monthly cost for a diabetic patient treated for foot ulcers was 730.55 € (± 596.00) if hospitalization was not required, and 2260.12 € (± 2717.71) if hospitalization was required.

The three principal cost categories for outpatient treatment were: local treatment (269.10 € on average per patient included and per month, 248.80 € of which went for interventions by nursing staff and 18.30 € for prescribed products), medical follow-up by general practitioners, specialists and surgeons (132.63 € on average per patient included and per month), and biological exams (114.95 € on average per patient included and per month). An analysis of all outpatient expenditure directly imputable to the lesion showed that costs related to medical and paramedical treatment represented more than 65% of this expenditure. Medication (general and local) represented only 10% of these costs and orthopedic equipment 4%.

An analysis of the average monthly expenditure for hospitalization (day treatment and short stays) showed that the main portion of this cost category corresponded to short hospital stays, which represented more than 90% of all hospital costs (1458.17 € ± 2463.58 per patient included vs. 88.57 € ± 294.84).

Cost determinants for foot lesions

A relation was found between the grade of the lesion and the cost of outpatient and/or hospital care (Kruskal-Wallis tests, p = 0.0403 and p = 0.0001, respectively) (Tab V). As regards hospital costs, the average monthly cost for a patient with a grade 4/5 lesion was 2.5 times higher than for a grade 1 lesion (2,744.28 € vs. 1,132.80 €). This was also found to be true, though to a lesser degree, for outpatient treatment (945.35 € vs. 582.22 €). On the contrary, only a small difference was observed between grade 2 and 3: outpatient and hospital costs of care were quite similar and sick leave inferior for grade 3 patients. This non-significant difference shows that the treatment of the most severe category of patients (i.e. grade 3) was not hospital-oriented but rather in outpatient care. A cost analysis per type of physician involved in medical follow-up provided parallel results: monthly expenditure for follow-up by a surgeon (804.02 € on average per patient), or by an endocrinologist/diabetologist (616.50 € on average per patient), was significantly higher than for follow-up by a general practitioner (548.21 € on average per patient) (Kruskal-Wallis test, p = 0.0017). When analyzing these figures, it is important to remember that differences in treatment depend upon the severity of lesions: high-grade lesions being more frequently treated by surgeons than by general practitioners.

Depending on how long ago the lesion appeared, the type of treatment also varied. The average monthly costs for outpatient and hospital follow-up were significantly higher for patients suffering from recent lesions (Kruskal-Wallis tests, p = 0.0293 and p = 0.0012, respectively), as the first two months of treatment are the most expensive. The need to amputate a current lesion had a significantly positive impact (Kruskal-Wallis tests, p = 0.0001) on outpatient expenditure.
No significant relation was noticed between the cost of treating foot ulcers and the type of diabetes presented by the patient, nor with the sex of the patients.

Costs for sick leave only showed significant variations in relation to the patient’s age: the cost of sick leave obviously decreasing among elderly patients due to retirement (Spearman correlation, p = 0.0001).

Search for factors related to high costs

A step-by-step logistic regression was carried out on the following independent variables: patient’s age, initial severity of lesion according to Wagner (grades 1/2 vs. grades 3/4/5), amputation for current lesion, oldness of lesion, physician’s specialization (general practitioner vs. others), number of lesions (1 vs. multiple), and hospitalizations. The outcomes show that our final model was adequate, for it presented an agreement coefficient of 86.9% and a sensitivity rate for predicting the event of 88.5%.

Patients amputated for current lesions presented a greater risk of generating high monthly costs when lesion oldness and type of hospitalization were equal (odd ratios (OR) [IC 95%] = 3.731 [1.64-9.03], p = 0.0023). Likewise, short hospital stays were also associated with a greater risk of high monthly costs when lesion oldness and level of amputation were equal (OR = 16.434 [6.72-45.38], p = 0.0001). However, for an equal level of amputation and type of hospitalization, one additional month of lesion oldness decreased average monthly expenditure (OR = 0.926 [0.89-0.96], p = 0.0001).

These outcomes indicate that treatment costs are higher among patients who require hospitalization or amputation and yet, conversely, such costs decrease during the course of treatment, the first months of treatment being the most costly.

Discussion

The objective of this study was to evaluate the cost of treating foot ulcers in diabetic patients. It is the second cost study carried out in France on this pathology, following the one published in 1993 by Halimi et al. [6]. This type of study is an essential preliminary to all economic evaluations in healthcare, for it relies on descriptive epidemiology data and known treatments in current medical practice. In addition to direct and indirect costs [16], pharmacoeconomic evaluations define a third type of costs, intangible costs, which corresponds to the cost of pain and suffering for the patient.

Table V

Costs per item and total costs, according to initial grade of the lesion severity according to the Wagner classification [16], per patient included in the study and per patient who required the type of healthcare.

<table>
<thead>
<tr>
<th>Consumed resources</th>
<th>Monthly healthcare costs per included patient (€)</th>
<th>Monthly healthcare costs per patient consumer (€)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Grade 1</td>
<td>Grade 2</td>
</tr>
<tr>
<td>Item</td>
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</tr>
<tr>
<td>Outpatient care</td>
<td>N</td>
<td>95</td>
</tr>
<tr>
<td>Mean</td>
<td>582.22</td>
<td>660.59</td>
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<tr>
<td>Median</td>
<td>483.16</td>
<td>582.84</td>
</tr>
<tr>
<td>p = 0.0403, Kruskal-Wallis test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization</td>
<td>N</td>
<td>95</td>
</tr>
<tr>
<td>Mean</td>
<td>1,132.80</td>
<td>1,479.12</td>
</tr>
<tr>
<td>Median</td>
<td>102.51</td>
<td>707.29</td>
</tr>
<tr>
<td>p = 0.0001, Kruskal-Wallis test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sick leave</td>
<td>N</td>
<td>95</td>
</tr>
<tr>
<td>Mean</td>
<td>6.71</td>
<td>67.18</td>
</tr>
<tr>
<td>Median</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>p = 0.0569, Kruskal-Wallis test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (with hospitalization)</td>
<td>N</td>
<td>95</td>
</tr>
<tr>
<td>Mean</td>
<td>1,709.59</td>
<td>2,213.12</td>
</tr>
<tr>
<td>Median</td>
<td>734.64</td>
<td>1,364.62</td>
</tr>
<tr>
<td>p = 0.0001, Kruskal-Wallis test</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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These costs were not evaluated here [15]. In order to evaluate the repercussions of foot ulcers in diabetic patients, a specific quality of life study was coupled with this evaluation [13].

As diabetic foot ulcer is a complication of diabetes mellitus, it is recognized as a “long-term disease” by the social security (i.e. treatments are fully reimbursed). Therefore, it was meaningful to adopt the point of view of the French Social Security system in the cost evaluation of this pathology, which enabled us to use official recommended cost sources [15] without adjustment for patient participation and reimbursement rates. On the one hand, due to the partial coverage rate of the diabetic patients (around 70%), one of the limitations of the study is to have considered only patients who were fully reimbursed by the Social Security system. In this way, we can guarantee the precision of cost data and offsets any eventual weaknesses related to information collection.

In effect, as the study is retrospective, the quality of the data gathered depended directly on the information the physicians had in their patient files: 1) since the appearance of the lesion, and 2) for the month preceding study inclusion. Exhaustiveness of the recorded resource consumption is therefore not guaranteed and cost evaluations are a minima. Nonetheless, this type of data collection has the advantage of producing reliable outcomes, for it combines budget constraints and limited timeframes.

All aspects of the treatment of diabetic foot ulcer were identified (healthcare staff, treatment and acts carried out, hospitalization, etc.) in order to provide a pragmatic approach to the costs of disease. Panels of practitioners were set up to reflect real-life medical practices. As such, the outcomes of this study — though probably somewhat underestimated due to the data-gathering method — can be directly taken into account by all of the actors involved in the treatment of diabetic foot ulcer in France.

Indirect costs were defined according to loss of productivity and leisure time: sick leave, disability, premature mortality and early retirement. In this study, only sick leave days were taken into consideration, resulting in an underestimation of these costs, which are relatively low in comparison with direct costs. The diabetic patients from this study received a sick-leave compensation of 34.76 € per month in average. This low amount is also related to the fact that only few patients (24 out of 239) declared having a professional activity (most of the others were retired). This was already touched upon by Halimi et al. [6] in their estimation of the cost of diabetic foot in France. To estimate indirect costs, which are usually equal to direct costs, the authors applied a multiplier coefficient of 0.5 to direct costs to take the age of the patient population suffering from diabetic foot into consideration, as well as their generally inactive work status.

Epidemiology studies have shown that diabetic patients who present ulcers are generally over 60 years of age [17, 23] and therefore no longer professionally active. This is also linked to the fact that the percentage of professionally active persons in the diabetic population is lower than among the general population: only 28% of type2 60-year-old diabetic patients work, compared with 43% among the general population in the same age bracket [19]. In the present study, only 27 patients out of 239 (11%) reported taking sick leave and the cost of sick leave was calculated according to information concerning 16 patients. Age appeared to be negatively correlated to the cost of sick leave, with younger patients generating greater costs.

The greatest cost category in the treatment of diabetic patients is linked to direct costs, hospital expenditure in particular. On average, one diabetic patient suffering from foot ulcer costs Social Security more than 1,555 € per month in hospital day treatment and short stays alone. Other studies have also shown that the treatment of diabetic patients suffering from ulcers is more costly when patients are hospitalized [20].

The motive for hospitalization has an impact on the length of the hospital stay and subsequently on associated costs. Thus in 1990, Gibbons et al. showed that revascularization was less costly than amputation, and at the same time improved the quality of healthcare as compared with the same hospital in 1984 [21]. In the United Kingdom, Panayiotopoulos et al. showed that revascularization, when possible, was the most economic alternative to amputation in diabetic patients [22].

In effect, the treatment of diabetic patients presenting foot lesions involves various healthcare actors, as well as complementary medical and paramedical acts. Outpatient treatment in suitable healthcare facilities by coordinated multidisciplinary teams, thus reducing the number of hospitalizations, could be a less costly alternative. In Sweden, Apelqvist et al. estimated that the average cost of treatment, through to the healing stage, without amputation was 6.5 times less than following after amputation [20]. “The Swedish example” as Carpentier et al. [8] recently qualified it, constitutes an efficient model for the coordinated healthcare of foot ulcers.

As regards outpatient costs, this study confirmed that the principal cost category for Social Security was due to local treatments (evaluated at 267.09 € per month on average), which were principally carried out by nursing staff (93%). Medical interventions were the second most costly category: on average 132.63 € per month and per patient are spent on consultations with general practitioners and specialists. Improving outpatient care appears to be a potential source of cost savings, and could also be generated by increasing prevention and improving patient education [23]. In this study, the initial severity of the lesion was identified as a determining clinical factor in treatment-related costs. This correlation has already been described in literature [20], concluding that early detection would be economically advantageous. Likewise, in this study, the cost of treatment appears to be
negatively correlated to the oldness of the lesion, as the most costly treatments are administered at the onset of the treatment, then progressively diminish, both in frequency and character.

Early detection and medical treatment are principally ensured by general practitioners, the first physicians to be consulted: they make over 80% of all diabetes diagnoses [19]. In France, in effect, surveys [17-19, 24] carried out by public health insurance funds in different regions showed that diabetic patients are principally treated by general practitioners: in 97% of type2 diabetes, and in 74% of diabetes treated with insulin [19]. In May 1999, public health measures concerning the application of recommendations made by the French Agency for the Accreditation and Evaluation of Healthcare (Agence Nationale d’Accréditation et d’Évaluation en Santé — ANAES) were implemented in France. Since then, the detection of type2 diabetes complications has improved: in 1999, 41.5% of diabetic subjects saw an ophthalmologist, nearly 30% had cardiovascular follow-up, and almost 60% had regular check-ups for cholesterolemia, an overall increase of close to 2% in comparison with 1998. As regards screening for nephrological complications, creatininemia and urinary albumin secretion rate were measured in 69.2% and 14.3% of diabetic patients, respectively [25]. Several years ago, the French Social Security system estimated that 50% to 75% of patients (depending on the study) never examine their feet and are not checked for this during medical consultations [24].

The improved treatment of diabetic foot ulcer will require a reduction of hospitalization, and in particular of amputation, an act which, according to our multivariate analysis, results in a statistically independent additional expenditure risk of approximately 3.7. This act constitutes the main portion of expenditure for Social Security and, furthermore, alters patients’ quality of life to a considerable degree [13]. Early medical follow-up combined with increased, coordinated screening by multidisciplinary teams would optimize healthcare and, consequently, the associated costs, as the oldness of the lesion and its initial severity are determining clinical factors of high healthcare costs.

These results will provide health authorities with important elements for public health decision-making in a realm where therapeutic alternatives are rare and consequences for patients potentially serious.

References