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Burden of Infected Diabetic Foot Ulcers on Hospital Admissions and Costs in a Third-Level Center

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Abstract: Diabetic foot is a common complication of diabetes that affects quality and prognosis of life for patients and often requires hospitalization. Infection, alone or in association with ischemia, is the main cause of hospital admission and impacts prognosis. The aim of this study is to analyze the costs of diabetic foot lesions and assess factors that influence the economic impact, focusing on infection. We included all people with diabetes with a first visit for diabetic foot during 2018 in our diabetic foot center. Database interrogation identified 422 patients. Diabetic foot treatment required hospitalization for 242 patients (58%), while 180 (42%) were treated in outpatient services. Healing time was different between the two groups: it was 136 ± 124 days (mean ± SD) for outpatients and 194 ± 190 days for patients that require hospitalization ($p < 0.001$). Costs: Treatment of 422 patients for diabetic foot globally costs 2063 million EUR and the mean cost for patients is 4888 EUR, with hospital stay having a high impact on this, accounting for 88% of the costs. Infection impacts hospitalization duration and ischemia impacts healing time. Ischemia and infection prolonged hospitalization duration and costs. Our work underlines that hospital treatment costs have a high impact on total costs.

Keywords: diabetic foot ulcer; infection; hospitalization; peripheral arterial disease costs

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1. Introduction

Diabetes mellitus has become a critical pandemic. According to the International Diabetes Federation [1], approximately 700 million people will live with diabetes until the year 2045.

According to the Italian National Institute of Statistics [2], there are more than 3 million people living with a diagnosis of diabetes in Italy, 5.3% of the total Italian population, and approximately another 1 million people who do not know that they have the disease.

Diabetic foot disease is a frequent complication of diabetes, with a high impact on patients' quality of life, and diabetic foot ulcer (DFU) is the main cause of non-traumatic limb amputation, an event that impacts the life of the patient and their family.

Distal peripheral neuropathy and peripheral arterial disease (PAD) are the two complications of diabetes underlying the development of diabetic foot. The risk of developing a lesion increases with one or both of these complications, particularly if associated with foot deformities or if the foot has already had ulcerations or previous amputations [3,4]. Recent data have highlighted that the annual incidence of diabetic foot ulcers has increased to 2% of patients, and up to 34% of patients with type 2 diabetes develop DFU at least once in their lifetime [5].

According to the Global Burden of Disease study [6], it was estimated that in 2016, 131.0 million (1.77%) people worldwide had lower-limb complications, equal to 34% of the diabetic population, of which 105.6 million had neuropathy alone, 18.6 million had DFU, and 6.8 million had lower-extremity amputations. These conditions account for 16.8 million years lived with disability (YLD) (2.07% of all YLDs), including 12.9 million for neuropathy, 2.5 million for foot ulcers, and 1.6 million for amputations [6].

These prevalence data are exacerbated by another dramatic fact: the risk of recurrence after healing of the ulcer. Ulcer recurrence is very frequent, and literature data highlight a risk of ulcer recurrence of 40% in the first year and 65% or more after 3 years [5]. For this reason, a previous injury or amputation constitutes a very high-risk factor for ulceration and in these conditions, the patient must be monitored frequently, a structured therapeutic education program must be started and indications must be given for the use of therapeutic footwear.

Diabetic foot disease not only impacts patients' quality of life [7,8] but is associated with a negative prognosis with a high mortality rate. Several studies reported that the five-year mortality rate due to DFU was 30.5%, while the five-year mortality rate due to minor and major amputation was 46.2% and 56.6%, respectively [9–13]. Infection, alone or in association with ischemia, is the main cause of hospital admissions and impacts prognosis [5,10].

These data justify all efforts to avoid major amputations, an event that impacts both patients' quality of life and results in a negative prognosis. The high impact of diabetic foot disease has resulted in this pathology being placed in the top 10 medical conditions [14].

In addition to the clinical impact, the diabetic foot has high management costs. The analysis of the Eurodiale study [15] highlights that the estimated cost of the treatment of a DFU is approximately EUR 10,000. In the UK, the National Health Service (NHS) spends between GBP 837 and 962 million annually on the treatment of ulcers and amputations [16], while direct costs for diabetic foot disease in the US in 2017 alone reached 80 billion USD [9–17], almost equal to the attributable cost of cancer in 2015 [18]. The aim of this study is to analyze the costs of healed foot lesions in people with diabetes and assess factors that may influence the economic impact, specifically diabetic foot infection (DFI).

2. Materials and Methods

This is a retrospective cross-sectional study using the administrative databases of the Monfalcone Hospital as the source of information. This study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments. We used a general consent system that was signed by patients on first visit, in which they agreed to their clinical data being used for clinical research, epidemiology, disease study and training, with the aim of improving knowledge, treatment and prevention. This study was based on the analysis of anonymous health administrative databases for which ethical committee approval was not required in Italy. Subjects included in our study were those with diabetes and DFUs recorded in our database from January to December 2018. All patients were treated in a third-level center in the presence of a multidisciplinary team directed by diabetologists and composed of vascular surgeons, orthopedists, nurses specializing in wounds, specialists in infectious diseases, interventional radiologists and orthopedic shoe technicians.

All of them were treated according to the local protocol in line with the International Working Group on Diabetic Foot Guidance [19] and the Italian consensus for treatment of PAD in diabetes [20]. These protocols include surgical debridement wound dressings, treatment of infection PAD, off-loading via irremovable or removable knee-high and ankle-high casts, and education. Regarding the cost analysis, we analyzed total costs and costs for hospital and community treatment. We also grouped patients based on the presence or absence of PAD and/or infection (according to the wound classification system of the University of Texas [21]) and the need for hospital stay.

3. Cost

Financial aspects were evaluated according to two main health conditions: inpatient and outpatient care. Extra hospitalization costs included first medical visit, control visit, wound care and dressing change, temporary shoes for acute-phase off-loading, and definitive therapeutic shoes. To each parameter, we assigned the unit costs based on Health Care System (HCS) evaluation.

Hence, the unit cost of any procedure, drug or visit included the total cost, regardless of whether expenses were for the HCS, patient, insurance, etc. Indirect costs, loss of working activity, time spent on visits, inability, etc., were not evaluated. We calculated costs individually for each patient based on resource utilization.

Clinical medical evaluation. Each patient received a first visit and 1 or more control visits. Costs of first visit (46.5 **EUR)** and control (21.5 EUR) are calculated based on HCS reimbursement.

Medications and topical treatment. The costs of medications (5 **EUR)** for topical treatment were calculated with HCS reimbursement independently of the setting for use of medications, i.e., home or hospital, and of the kind of dressing/therapy used.

Off-loading: Off-loading costs were calculated considering the total number of footwears, insoles, orthoses and casts prescribed for a patient and the unit cost of each type of off-loading. We maintain separate off-loading in the acute and chronic phases (Table 1).

Table 1. Summary of costs involved.

Acute-Phase Orthosis	Cost EUR	Chronic-Phase Definitive Orthosis	
Medical shoe	70	Preformed shoe	300
Brace	150	Brace	1800
Half cast	14	Prothesis	4000
Shoe + half cast	84	Custom made	900

Hospitalization cost was based on the diagnosis-related group (DRG) on hospitalization. Diagnoses recorded in hospital discharge records and specified in the International Classification of Diseases, 9th Revision [22], were examined and analyzed.

Hospital discharges with DRG (24th version) codes 213, 217, 218, 225, 226, 227, 233, 238, 263 and 264 were considered in the case of DFU.

The use of this parameter enabled easy comparison of costs (Table 2).

Table 2. Comparison of costs oh hospital discharges.

DRG	Description	Cost (EUR)	Occurrence	Cost Day Surgery (EUR/day)	Occurrence
113	Amputation for circulatory disease	13145	1		
213	Amputation for bone disease	8141	16		
217	Debridement and graft	11334	40	495	8
218	Surgical procedure on legs	7858	3		
225	Surgical procedure on foot	3164	12	3164	5
226	Surgical procedure on soft tissue with complications	6364	174	495	47
227	Surgical procedure on soft tissue without complications	1809	3	1809	2
233	Other procedures on bone/soft Tissue	9709	7		

Table 2. *Cont.*

DRG	Description	Cost (EUR)	Occurrence	Cost Day Surgery (EUR/day)	Occurrence
238	Osteomyelitis	5714	4		
263	Skin graft with complications	9690	10	453	1
264	Skin graft without Complications	5714	37	453	11
270	Other procedures on skin	1725	12		
Others			12		

Statistical analysis and cost calculations were performed using the SPSS statistical package, version 12.0.2 (SPSS, Chicago, IL, USA). Continuous variables are described as the mean and SD, whereas categorical variables are reported as the percentage.

4. Results

Of the 445 patients recruited, 23 were patients on secondary prevention without an active wound and thus excluded from this study. The remaining 422 patients were included and examined—127 (30%) were women, and 10 (2%) patients had type 1 diabetes while the remaining 412 (98%) had type 2 diabetes. The main baseline characteristics of the whole population are described in Table 3—a long history of diabetes, quite good metabolic control, obesity, and a high level of creatinine.

Table 3. Clinical characteristics of the whole population and groups of inpatients and outpatients.

Parameter	Total Population (n = 422) Mean ± SD	Hospitalized (n = 242 (57%)) Mean ± SD	Not hospitalized (n = 180 (43%)) Mean ± SD	*p*
Age (years)	72 ± 11	71 ± 12	74 ± 11	$p < 0.01$
Female n. (%)	127 (30%)	70 (29%)	57 (32%)	n.s.
BMI (m/kg^2)	27 ± 6	26 ± 6	28 ± 7	n.s.
Years of diabetes	19 ± 12	20 ± 11	18 ± 12	n.s.
HBA1c%	7.8 ± 2	8.1 ± 2	7.5 ± 1.5	n.s.
Creatinine (mg/dL)	1.96 ± 1.4	2.1 ± 1.5	1.56 ± 1.6	n.s.
Dialysis n.	16 (4%)	14 (6%)	2 (1%)	$p < 0.01$
CAD n.	178 (42%)	124 (51%)	54 (30%)	$p < 0.01$

CAD: Coronary Artery Disease. HbA1c: Glycated Haemoglobin. BMI: Body Max Index

The incidence of peripheral arterial disease with ischemia was very high. We found 213 people with this condition (50% of whole population), while infection was present in 121 patients (28% of the whole population).

We divided the population into two groups based on whether hospitalization was necessary: 57% required hospitalization, while 43% were managed on an outpatient basis. Hospitalization was required for peripheral ischemia and/or infection. All ischemic patients required hospitalization and 43% patients had infection. Hospitalized patients had a higher incidence of CAD, dialysis and were older. Control and history of diabetes, BMI, creatinine levels and sex were not associated with higher hospitalization rates.

Ulcer classification: Ulcer characteristics were completely different in the two groups. Inpatients presented with an ulcer of grade 3 Texas in 90% of cases—14% were 3A, 8% were 3B, 64% were 3C, and 14% were 3D. The remaining 10% presented ischemic lesions with grade 1 (74%) and 2 (26%). Outpatients did not show deep (grade 3) and/or ischemic ulcers (C), and lesions were classified as grades 1 (58%) and 2 (42%).

Among hospitalized patients, 242 patients accounted for 330 hospitalizations—191 for ischemia; 40 for ischemia and infection; 25 for infection without ischemia; 74 for surgical reconstruction, skin and dermal flap, and arthrodesis.

Clinical outcome: A total of 8 patients underwent major amputation while 38 patients underwent minor amputation (forefoot amputation). In 161 patients, surgical removal of metatarsal infected bone was performed, and 39 surgical procedures were limited to fingers.

The difference in the severity of the lesions between hospitalized and non-hospitalized patients also significantly affected the difference in the recovery time between the two groups—the recovery time was 136 ± 124 days (mean ± DS) for outpatients, and 194 ± 190 days for patients requiring hospitalization ($p < 0.001$).

The hospitalization rate resulted in a 1.37 hospitalization/patient ratio. While 25 were readmissions, new hospitalizations within 30 days of discharge from an acute care hospital accounted for 10% of the rate. The total cost of diabetic foot treatment of 422 patients was 2063 EUR, with the hospitalization cost of 1811 EUR accounting for 88%. We separately analyzed and compared patients treated only in the outpatient setting and patients managed in the hospital setting. For the 180 patients treated only in outpatient services, a first visit, a mean of 2 control visits, 47 for dressing applications, 1 for acute-phase orthosis and 1 chronic-phase orthosis were recorded. The individual extra hospitalization cost was 579 ± 293 EUR. The outpatient service costs of patients that also needed hospitalization were higher, as they required more control visits and higher costs for acute- and chronic-phase orthosis, with a total cost of 818 ± 603 EUR, as shown in Table 4.

Table 4. Outpatient service related costs.

	Patients Treated Only In Outpatient Services (n = 180)		**Patients Treated in In- and Outpatient Services (n = 242)**		
Parameter	**Mean ± DS**	**Cost (EUR) ± SD**	**Mean ± SD**	**Cost (EUR) ± SD**	**Test T**
First visit	1 ± 0	46,5 ± 0	1 ± 0	46,5 ± 0	n.s.
Control visits	2 ± 3	42 ± 59	4 ± 3.7	82 ± 80	<0.01
Dressing	47 ± 37	235 ± 184	48 ± 40	238 ± 200	n.s
Acute phase Orthosis	1 ± 0	44 ± 39	1 ± 0	70 ± 67	<0.01
Chronic phase Orthosis	1 ± 0	212 ± 207	1 ± 0	372 ± 517	<0.01
Total		579 ± 293		811 ± 603	<0.01

The 330 hospitalizations were divided into 256 ordinary hospitalizations and 74 day surgery appointments. The mean duration of hospital stay was 10 ± 10 days (mean ± SD), and the mean cost was 6855 ± 2393 euros (mean ± SD). The mean duration of day surgery was 1 day, and the mean cost was 761 ± 764 euros (mean ± SD). Hospitalization analysis based on clinical characteristics causative of hospitalization such as ischemia and infection highlights that DFI impacts hospitalization length, while ischemia impacts healing time—together, ischemia and infection prolong hospitalization duration and costs (Table 5).

In our group, eight patients underwent major amputation, and the DRG cost of major amputation in vascular patients was 11,127 EUR. The total costs for these patients were not analyzed because they were treated through another surgical service at our hospital.

Table 5. Hospital stay, healing time and hospitalization costs.

Parameter	No Ischemia Infection (n = 25)	Ischemia Not Infection (n = 191)	Ischemia and Infection (n = 40)	Test T Ischemia With/Without Infection	Test T Infection With/Without Ischemia
Hospital stay (days), mean ± DS	12.5 ± 9.7	9 ± 9	16 ± 13	< 0.01	n.s
Healing time (days), mean ± SD	135 ± 121	263 ± 243	268 ± 287	n.s.	0.04
Hospitalization costs (EUR) ± DS	6486 ± 2860	6514 ± 2632	7657 ± 2175	0.01	n.s.

5. Discussion

This study highlights a year of activity involving the diabetic foot at a reference center, and presents a large series of cases—422 cases included. Data show that a high percentage of patients (57%) have complicated injuries that require treatment in hospital. Furthermore, in addition to having serious injuries, these patients are more fragile—they are older with the ischemic heart disease and dialysis. These conditions impact prognosis and recovery times, which are significantly longer than for patients treated on an outpatient basis. The cost analysis also highlights a great impact of this complication from an economic point of view. Hospitalization accounts for most of the costs in the management of diabetic foot syndrome, 88% of the total cost. Ischemia and infection, combined or alone, are the causes of hospitalization—they impact the duration of hospital stay, healing time and costs.

This is the first economic evaluation of diabetic foot care at Monfalcone Hospital. The present study, carried out at a third-level center with a multidisciplinary team, highlights that dedicated care for diabetic foot has better clinical outcomes and lower costs compared to standard treatments. The clinical advantage of optimal care can be clearly seen through the reduction in the frequency of foot complications or negative evolution such as amputation. In fact, DFD causes an increase in morbidity and frequent hospital admissions, worsening recovery times and the possibility of particularly disabling sequelae, such as amputation of the lower limbs.

Diabetes represents a pathology with high treatment costs—approximately 11 billion—per year for the Italian National Health Service [23], accounting 10% of the annual budget (111 billion euros in 2018) [24]. The study based on the ARNO Diabetes Observatory analyzed the average cost of healthcare for diabetic patients in 2018—the average cost for each patient was 2833 euros and the greatest impact on overall costs was the cost of hospitalization, which represented 40% of the total costs (1152 euros) [23]. As regards specific analyses on the costs of diabetic foot, a recent study, conducted in Tuscany, evaluated healthcare costs for a large population cohort [25]. Of the 730 patients who developed a DFU in the period 2015–2018, the analysis found that 114 had an amputation (15.6%) with an annual per capita cost calculated at EUR 12,146, compared to a patient without amputation and a cost of EUR 7864 [25].

The burden of diabetes is represented in particular by hospital admissions. Diabetic foot is one of the most expensive complications of diabetes and can be a major economic and public health burden. Wound resolution is not an immediate target and data from this study, with a mean healing time longer than 5 months, confirm the important impact on public health as well as underlining the efforts to obtain wound resolution.

Considering that the hospitalization cost is the main cost in the treatment of diabetic foot, efforts must be made to optimize hospitalization times and management of the hospitalized patient. To achieve this, in our center, we use a multidisciplinary approach dedicated to diabetic foot, with close coordination between specialists to optimize patient treatment and reduce the duration of hospital stay. The average length of hospital stay was

10 days and the average cost of each hospitalization was less than EUR 7000, confirming the effectiveness of this approach compared to approaches presented in other studies [26–28].

The readmission rate, i.e., new hospitalizations within 30 days of discharge from an acute hospital, represents a qualitative index that can be used to evaluate the approach to diabetic foot lesions. A treatment with frequent re-admissions is not clinically effective not cost-effective. The readmission rate obtained in this study was 10%, which is relatively low compared to the readmission rate reported in the literature, higher than 20–30% [29]. Reasons for this outcome include complete resolution of ischemia and infection before hospital discharge including acute surgical treatment of infection and definitive surgical treatment as well as the combination of revascularization and subsequent surgical treatment of the foot.

In one year, the expenditure for 422 patients suffering from diabetic foot was 2 million euros, with a significant impact of hospitalization (87%) on the total cost, confirming the literature data. Hospitalization was necessary in 58% of patients, a very high percentage that can be explained by the fact that our third-level center receives the most complex cases, which most frequently require hospitalization. Furthermore, by analyzing the hospitalized patients, we found a high incidence of vascular and cardiovascular diseases (90%), so we included more fragile patients requiring hospitalization.

Our analysis then evaluated the factors influencing the cost of hospitalization by evaluating the impact of infection, ischemia or both conditions. The more complicated patients, who presented a combination of ischemia and infection, had significantly higher hospitalization costs. Likewise, the length of hospitalization for these patients was significantly longer. Analyzing the clinical effects of infection and ischemia by evaluating them individually, it appears that infection significantly increases the duration of hospitalization while ischemia negatively affects recovery time. Thus, ischemic patients have significantly longer recovery times. These data can be used for preventive treatment. In particular, the data indicate the importance of preventing infectious evolution in patients with diabetic foot lesions, especially if they are also ischemic. Avoiding infection could have a huge impact on saving the foot and treatment costs.

An American study, based on data from medical and pharmaceutical claims from 2000 and 2001, included outpatients and inpatients with or without peripheral arterial disease. The results of the work showed an average cost per lesion of 13,179 USD (approximately EUR 10,914), ranging from 5218 USD (4321 EUR) for patients without PAD compared to 23,372 USD (19,357 EUR) for patients with PAD [30]. In our work, we did not find this high difference between vascular and non-vascular patients, as PAD had a significant impact on recovery times but not on costs. The possible explanation for our results is the usually chronic and not acute ischemia, therefore enabling planning hospitalization without resorting to urgent hospitalization. Planned hospitalization with short revascularization and surgical treatment times enables a reduction in hospitalization times and, therefore, a relative reduction in costs.

On the other hand, higher costs were involved for the treatment of patients with PAD and infection. The increase in costs in these cases is justified not only by the need for hospitalization, with higher rates of hospitalization, but also by the use of antibiotics, the need for amputation, revascularization, the need for multiple surgical interventions and the duration of hospitalization.

As the data in our work show, outpatient services account for approximately 8% of the total costs. The largest outpatient service costs relate to preventive footwear provided to the patient. This is a device used to prevent relapses, given the high rate reported in the literature. We also know that a new injury has a decidedly significant impact on quality of life and costs. It therefore becomes essential to educate the patient, who is at high risk of ulceration having already had a lesion, on the correct use of these devices. Reducing ulcer recurrence represents a challenge in the treatment of diabetic foot.

6. Limitations

We must also analyze the limits of our work. In this study, we included a white European population without racial/ethnic diversity, which raises concerns regarding the generalizability of our findings to other ethnic groups. Consequently, our results would benefit from verification in diverse populations. The use of data from an administrative database may present coding errors, so we integrated administrative data with clinical data to minimize the occurrence of missing data. In any case, it is possible that some of the diagnoses of foot ulceration identified by the ICD-9 (International Classification of Disease, 9th Revision) codes are not entirely representative of the pathological state of interest. The direct costs were calculated on the basis of the 2018 reimbursement rates, which remained unchanged in Italy but could be different from current costs in other countries. Finally, our analysis only concerns direct costs, as we have not calculated indirect costs, which include sickness absence, loss of production, temporary disability and early retirement. A systematic review [31] reported that indirect costs for diabetic foot ulcers in Europe range from USD 1027 [15] to 1476 [32], and those for amputations range from USD 1043 [15] to 1442 [32], while indirect costs per ulcer with infection were not available.

The clinical outcome could be influenced by other factors not evaluated in this study, for example patient compliance, but this is a one-year real-life study with a large cohort and prospective monitoring aimed at evaluating clinical practice daily without predetermined intervention options.

7. Conclusions

This study confirms the complexity of the treatment of diabetic foot, with the need for inpatient and outpatient treatments with long times to achieve healing of the lesions. This study also highlights the need for a multidisciplinary approach to optimize treatment times and patient outcomes [33].

This complexity is confirmed by the high costs. In particular, our analysis confirmed that hospital treatment has a significant impact on the costs of diabetic foot treatment. These data provide reference points in the analysis of diabetic foot treatment.

We have highlighted that clinical conditions such as ischemia and infection are increasingly responsible for hospitalizations, influence the duration of hospitalization and impact the outcome. We believe that strategies aimed at avoiding delays in patient referral are able to reduce the impact on costs and improve clinical outcome, especially if combined with timely institution of antibiotic therapy and early vascular intervention. The goal must be to prevent limb loss.

The presence of multidisciplinary diabetic foot centers can reduce disease progression and amputation [34]. In these centers, there should be limb salvage teams that deal with prevention, as the surveillance and management of foot ulcers through a multidisciplinary approach can improve outcomes [35,36].

Our data suggest that among the various competing factors, infection affects the need for hospitalization, also increasing the economic health burden associated with the treatment of diabetic foot ulcers. Efforts should therefore be made to avoid this impactful event. Further research and multicenter prospective studies are recommended to identify more variables that influence cost management.

In conclusion, the present study clearly suggests that an optimal multidisciplinary approach can limit costs for the treatment of DFUs. A preventive approach with a reduction in infections and rapid referral to reference centers could also be even more effective in reducing the clinical and economic impacts of diabetic foot.

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Informed Consent Statement: We used a general consent system that was signed by patients on first visit, in which they agreed to their clinical data being used for clinical research, epidemiology, disease study and training.

Data Availability Statement: The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author/s.

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