The effect of foot ulcers on costs of care for people with diabetes in Ireland

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In order to estimate the effect of foot ulcers on costs of care for diabetes in Ireland, a cost analysis of 220 people with diabetes in the west of Ireland was carried out. A provider perspective was adopted in that only costs to the healthcare system were considered for analysis. Resource activity over a follow-up period of 18 months was identified via structured patient questionnaires and chart searches, and valued using a vector of unit costs to calculate individual resource and total care expenditure. The mean healthcare cost over the 18-month follow-up was €9566 for people who developed foot ulcers compared to €2785 for those who did not. Costs of care were statistically significantly higher for people with foot ulcers, with total healthcare costs estimated to be, on average, 175% higher over 18 months. It is concluded that foot ulcers add considerably to costs of care for diabetes. Preventive interventions to reduce the risk of foot disease in diabetes may be associated with significant economic as well as clinical benefits.

The worldwide cost of strategies to treat and prevent diabetes and its associated complications was estimated to total at least US$376 billion in 2010 and is projected to exceed US$490 billion by 2030 (International Diabetes Federation, 2010).

Foot ulcers are among the most serious and costly complications associated with diabetes, and these in turn may lead to lower limb amputation (Matricali et al, 2007). International evidence on the incidence of foot ulceration indicates that approximately 2% of patients with diabetes develop new foot ulcers each year (Ramsey et al, 1999; Abbot et al, 2002).

Recent evidence from the West of Ireland Diabetes Foot Study (WOIDFS) reflects these estimates, with a reported annual incidence of 2.6% (Hurley et al, 2013).

Another Irish study reported an annual incidence of diabetes-related lower extremity amputation between 145 and 176 per 100 000 people with diabetes (Buckley et al, 2012). The emergence of such evidence highlights the impact of diabetic foot disease in the Irish setting and the resultant need for preventive strategies to address this issue.

Because complications associated with diabetes-related foot disease can be prevented, the focus of clinical policy is moving towards early recognition and preventive care. Indeed, it is recommended that all patients with diabetes should be given a complete foot examination at least annually (NICE, 2004). These recommendations are supported by a growing evidence base of clinical and cost effectiveness (Matricali et al, 2007).

In Ireland, the National Clinical Programme for Diabetes recommends annual screening for foot disease to be implemented in general practice with subsequent multidisciplinary care determined by the patient's assigned risk status (National Diabetes Programme, 2011). Nonetheless, diabetic foot screening in the primary care setting is not routinely undertaken in Ireland.

To inform the ongoing process of translating such policy goals into practice, a range of data is required on the resource implications, costs, clinical and cost effectiveness of proposed strategies aimed at meeting this clinical need (Drummond et al, 2005). Within this context of evidence-based policy, economic information is becoming increasingly

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Article points

1. This study estimates the effect of foot ulcers on costs of care for diabetes in Ireland.
2. Healthcare resource activity for 220 people with diabetes was identified to calculate costs of care over 18 months.
3. Mean healthcare cost at 18 months was €9566 for patients who developed foot ulcers compared to €2785 for patients who did not.
3. Costs were significantly greater for patients with foot ulcers, with total healthcare costs estimated to be, on average, 175% higher.
4. Preventive interventions that reduce the risk of diabetic foot disease may be associated with significant economic as well as clinical benefits.

Key words

- Cost analysis
- Foot ulcers
- Ireland

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relevant given the projected increases in national diabetes prevalence levels (Balanda et al, 2010), as well as commitments by policymakers in Ireland and elsewhere to shift the focus of chronic disease management from the hospital sector to primary and community care (Department of Health and Children, 2008).

Data on the excess costs associated with preventable conditions can be used to strengthen arguments for investment in prevention for those clinical areas. In this study, we apply this framework to explore the excess costs associated with diabetic foot ulcers in Ireland.

A number of international studies have highlighted the excess costs associated with foot ulcers in diabetes (Currie et al, 1998; Ramsey et al, 1999; Harrington et al, 2000). A single study has examined costs for Ireland, reporting that inpatient admissions for foot ulcers cost substantially more than the average cost per inpatient admission (Smith et al, 2004). However, no evidence exists on the wider cost burden of foot ulcers beyond hospitalisation.

In this study, we use data from a subsample of participants in the WOIDFS to explore costs of care associated with diabetes-related foot ulcers in Ireland. In doing so, we aim to provide evidence that will be of interest to those involved in the management of diabetes and its complications in Ireland and elsewhere.

Methods

Study sample

Data collected as part of the WOIDFS, conducted from 2008 until 2011 and described in detail elsewhere (Hurley et al, 2013), were used for the analysis.

In brief, 12 general practices in the west of Ireland, and the patients on their diabetes registers, were recruited into the study. Inclusion criteria required patients to be aged at least 18 years and to have a diagnosis of type 1 or type 2 diabetes. Patients were excluded if they had significant learning difficulties, cognitive impairment or a history of bilateral amputation. Ethical approval for the study was obtained from the Irish College of General Practitioners and Galway University Hospitals.

A total of 563 participants attended a baseline clinic appointment at their local surgery or health centre. This consisted of a set of screening tests and the collection of range of clinical and demographic data. Over an 18-month follow-up period, the onset of new foot ulcers were recorded as they occurred. A total of 383 of those recruited completed study follow-up, of whom 4.2% developed a new foot ulcer over 19.4 months, giving an annual incidence rate of 2.6%. Two patients underwent an amputation, one transmetatarsal and one below knee. Further information on the study design and its clinical results are provided by Hurley et al (2013).

The cost analysis was conducted on a subsample of 220 (39% of the total sample), for whom an extensive range of additional data were collected on healthcare resource utilisation patterns over the study follow-up period of 18 months. This included 15 people who developed an ulcer, in addition to an opportunistic sample of the 205 people who completed follow-up without ulceration.

Notably, the baseline patient characteristics for the subsample included in the cost analysis did not systematically differ from the full sample apart from in the case of educational status and comorbidity status; with a higher percentage in the former having completed secondary or higher level education and having one or more comorbidities (*Table 1*).

Summary statistics for the characteristics of the cost study participants, classified by ulceration status, are presented in *Table 2*. Compared with those in the subsample who did not develop a foot ulcer, those who did develop a new ulcer were more likely to be male and had higher rates of previous ulceration and amputation.

Cost analysis

Healthcare costs were estimated for a set of activities including general practitioner, practice nurse, public health nurse, diabetes nurse, dietitian and podiatrist consultations, in addition to hospital inpatient admissions, outpatient clinic visits, and accident and emergency visits.

Data on resource utilisation over 18 months were collected by the research podiatrist via structured questionnaires completed with the patient, in addition to a review of patient charts. Individual resource costs were estimated by applying the

appropriate unit cost for each resource activity and summed to estimate total costs or care. Unit costs were estimated from a variety of national Irish data sources (*Table 3*) and were adjusted to constant Euros in 2009 prices using an appropriate inflation index (Central Statistics Office, 2013).

Statistical analysis

Given that resource use and costs of care form the central focus of the analysis, these variables are analysed in a number of ways. First, descriptive statistics, specifically means and standard deviations (SD), were used to compare resource activity and costs for the two cohorts of interest: (a) people without foot ulcers at follow up; and (b) people with foot ulcers at follow up. Second, univariate analysis, consisting of independent sample t-tests was undertaken for each of the resource cost and total cost variables. Third, multivariate analysis, comprising of a generalised linear regression model (GLM) was estimated to explore the effect of developing a foot ulcer on total costs, while controlling for a range of other potentially important cost drivers.

In addition to a binary variable for ulceration status at follow up, the regression model was estimated for age, sex, marital status, education status, employment status, medical card status, diabetes type, duration of diabetes in years, HbA_{1c}, body mass index, comorbidity status including diabetic retinopathy, diabetic nephropathy, cardiovascular disease, peripheral vascular disease, cerebrovascular disease, and hypertension, previous ulceration, and previous amputation.

To reflect the non-normal nature of the cost data (Mihaylova et al, 2011), a GLM with a Gamma variance function and a log-link was adopted (Glick et al, 2007). As a result, the regression coefficient for ulceration status estimates the percentage difference in total costs that is attributable to the new ulcer over the course of follow up. Model specification was based on Akaike Information Criterion and log likelihood statistics. All analyses were performed using STATA 11.

Results

The descriptive results for resource activity and costs are presented in *Table 4*. The mean healthcare cost over 18 months was €2785 (SD €6472) for patients who did not develop foot ulcers compared to €9566 (SD €18753) for patients who did develop foot ulcers. *Table 4* also presents the results from the univariate analysis, using independent sample t-tests, to compare individual resource costs and total costs across the patient groups.

These results indicate that costs of care were significantly higher for people with foot ulcers for GP, public health nurse, diabetes nurse, dietitian and podiatrist consultations, in addition to hospital inpatient admissions and accident and emergency visits. Total costs of care were also significantly greater for the group who developed foot ulcers.

The results for the multivariate regression analyses indicate that, after controlling for a range of potential important cost drivers, patients with foot ulcers had statistically significantly greater total costs over the course of follow up. Notably, no other independent variable reached statistical significance in the regression analysis. The interpretation of the regression coefficient for ulceration status is that total healthcare costs were, on average, 175% higher for people who developed foot ulcers than for those who did not.

Table 1. Baseline characteristics for full sample and sub sample

Variable	Full sample, *n*=563 (mean [SD]/%)	Sub-sample *n*=220 (mean (SD)/%)	*P*-value
Age	64.1 (13.4)	63.8 (13.4)	0.637
Male	60%	61%	0.570
Married or cohabiting	66%	68%	0.385
Completed secondary education	54%	59%	0.013
Currently in employment	31%	31%	0.823
Type 1 diabetes	10%	12%	0.209
Duration of diabetes	7.7 (8.2)	8.1 (8.7)	0.462
HbA_{1c}	7.3 (1.5)	7.3 (1.4)	0.291
Body mass index	31.2 (6.1)	31.3 (6.3)	0.739
One or more comorbidities	65%	71%	0.004
Previous ulcer	4%	4%	0.583
Previous amputation	1%	2%	0.255

Statistical analysis – Chi-square tests for discrete variables; independent t-tests for continuous variables

Discussion

Foot ulcers are one of the most serious diabetes-related complications and there is a widespread

Table 2. Baseline characteristics by ulceration status

Variable	No foot ulcers at follow up, *n*=205 (mean (SD)/%)	Foot ulcers at follow up, *n*=15 (mean (SD)/%)	*P*-value
Age	63.7 (13.6)	69.9 (7.7)	0.640
Male	60%	87%	0.032
Married or cohabiting	67%	53%	0.148
Completed secondary education	55%	27%	0.369
Currently in employment	31%	33%	0.129
Medical card holder	70%	78%	0.879
Type 1 diabetes	10%	13%	0.329
Duration of diabetes	7.9 (8.3)	11.2 (13.4)	0.224
HbA_{1c}	7.2 (1.4)	7.8 (0.9)	0.730
Body mass index	31.4 (6.3)	29.3 (6.0)	0.914
One or more comorbidities	65%	87%	0.359
Previous ulcer	2%	53%	0.000
Previous amputation	1%	33%	0.000

Statistical analysis – Chi-square tests for discrete variables; independent t-tests for continuous variables

consensus internationally of the need for strategies for early recognition and targeted preventive care. In the context of increasingly resource constrained health systems, data on costs and cost effectiveness are increasingly required to inform policy decisions relating to investments in prevention. This study estimates the excess costs associated with foot ulcers over and above standard costs of care for diabetes in Ireland.

Our results indicate that foot ulcers add significantly to the burden of diabetes in the Irish healthcare setting. From a policy perspective, these findings support the promotion of screening and management programmes for foot disease for patients with diabetes.

Current guidelines in Ireland recommend that people with diabetes should be screened annually (Department of Health and Children, 2011); however, diabetic foot screening in the primary care setting is not routinely undertaken. Our results suggest that the implementation of such a policy would be unlikely to place a considerable financial burden on the healthcare system.

While people with foot ulcers in this study were screened appropriately, our findings do highlight the potential cost savings that could be achieved through prevention. Nonetheless, such potential savings would need to be considered against the additional resources required to adequately provide and deliver preventive interventions in the community care setting.

Strengths of the study included the extensive range of data on resource activity collected for each participant, which facilitated a comprehensive cost analysis to be undertaken. Appropriate statistical approaches were adopted for the analysis of the cost data, which is complicated in nature. Furthermore, the participating practices are members of a primary care research network which is broadly representative of the Irish national general practice profile (Kavanagh et al, 2010).

Limitations include the cross-sectional nature of the data, which precludes the drawing of definitive

Table 3. Unit cost estimates

Resource activity	**Activity**	**Unit cost***	**Data sources**
General practitioner consultation	Per visit	€50	Gillespie et al (2012)
Practice nurse consultation	Per visit	€12	Gillespie et al (2012)
Public health nurse consultation	Per visit	€27	Salary Scales, Department of Health and Children
Inpatient night	Per inpatient night	€832	Casemix Unit, Department of Health and Children
Outpatient consultation	Per visit	€169	Casemix Unit, Department of Health and Children
Accident and emergency consultation	Per visit	€289	Casemix Unit, Department of Health and Children
Diabetes nurse consultation	Per visit	€27	Salary Scales, Department of Health and Children
Dietitian consultation	Per visit	€24	Salary Scales, Department of Health and Children
Podiatrist consultation	Per visit	€24	Salary Scales, Department of Health and Children

* Unit costs are presented in 2009 prices. Where necessary, unit costs were inflated using the medical component of the consumer price index (www.cso.ie)

Table 4. Univariate cost analysis results

Descriptive analysis Resource item/cost*	Patients without foot ulcers (*n*=205)		Patients with ulcers (*n*=15)		Statistical analysis†
	Resource use, mean (SD)	Cost, mean (SD)	Resource use, mean (SD)	Cost (€), mean (SD)	*P*-value
General practitioner visits	7.8 (12.5)	€390 (€624)	18.6 (21.6)	€932 (€1079)	0.009
Practice nurse visits	1.6 (6.0)	€19 (€72)	2.4 (6.0)	€28 (€72)	0.667
Public health nurse visits	2.2 (12.4)	€60 (€333)	24.4 (27.5)	€659 (€743)	0.000
Diabetes nurse visits	1.1 (1.8)	€30 (€49)	3.6 (6.3)	€98 (€169)	0.001
Podiatrist visits	2.7 (14.1)	€65 (€339)	14.0 (9.6)	€336 (€230)	0.010
Outpatient visits	1.7 (3.9)	€290 (€653)	2.5 (2.6)	€415 (€443)	0.534
Accident and emergency visits	0.2 (0.6)	€44 (€167)	2.5 (6.9)	€709 (€1979)	0.000
Hospital inpatient days	2.5 (7.8)	€2093 (€6492)	11.5 (2.4)	€9530 (€18650)	0.003
Total cost		**€2785 (€6472)**		**€9566 (€18753)**	**0.009**

* Unit costs are presented in 2009 prices. †Statistical analysis of cost variables – independent t-tests for continuous variables

conclusions regarding causality. That is, more comprehensive analysis of the effect of foot ulcers on costs of care would require, for example, the analysis of longitudinal data. Furthermore, the sample size, in particular with respect to the number of ulcerated patients, was small. This limited the scope of our analysis and the statistical approaches we could adopt with respect to estimation.

Nonetheless, the effect of foot ulceration on costs was robustly detected in both the univariate and multivariate regression analyses. Indeed, and notwithstanding the limited number of affected cases, the development of a foot ulcer was strongly significant, even after controlling for a range of other potentially important cost drivers in the final regression model. Nonetheless, future studies with larger sample sizes and longitudinal data would go some way to address some of the issues which arose in our analysis.

Importantly, data on resource use, while supplemented by chart searches, were self-reported by patients and is thereby open to bias. Notably, patients in the subsample had higher baseline levels of education and comorbidity than those lost to follow up, which may bias results. Some costs, such as those relating to ophthalmologist and medications were not collected.

Finally, the process of conducing economic analysis in Ireland is complicated by the lack of a national database of unit cost data. All unit costs are best estimates of the cost per activity.

In conclusion, the incidence of foot ulcers adds considerably to the overall costs of care for people with diabetes in the Irish setting. It follows that preventive interventions which reduce the risk and progression of foot disease in diabetes have the potential to yield significant economic as well as clinical benefits.

The current analysis provides information that will be of interest to future research which examines the cost and cost effectiveness of such strategies. Furthermore, it contributes to the international literature on costs of care in this area by providing data on these as they arise in an Irish setting.

As the healthcare service in Ireland is re-steering diabetes care towards general practice, our data can help inform policy and resource planning in this area. ■

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Table 5. Multivariate cost analysis results

Multivariate analysis		Total cost	
Covariate/factor	Coefficient	95% confidence intervals	*P*-value
New ulcer at follow up	1.75	(0.21, 3.29)	0.026
Age	–0.00	(–0.04,0.03)	0.986
Gender: male	0.17	(–0.75,0.73)	0.981
Marital status: married or cohabiting	0.31	(–0.54,1.15)	0.479
Education status: completed secondary level	–0.32	(-1.08,0.43)	0.402
Employment status: currently in employment	–0.20	(–1.01,0.62)	0.636
Medical card status: card holder	0.57	(–0.39,1.52)	0.245
Diabetes type: type 1	–0.20	(–1.84,1.45)	0.815
Duration of diabetes	–0.01	(–0.04,0.06)	0.757
HbA_{1c}	–0.04	(–0.32,0.31)	0.962
Body mass index	0.04	(–0.02,0.11)	0.201
Diabetic retinopathy	–0.44	(–2.21,1.34)	0.631
Diabetic nephropathy	–0.66	(–2.78,1.46)	0.539
Cardiovascular disease	0.18	(–0.65,1.01)	0.671
Peripheral vascular disease	–1.67	(–4.03,0.68)	0.164
Cerebrovascular disease	–0.26	(–1.77, 1.25)	0.734
Hypertension	–0.43	(–1.15,0.28)	0.236
Previous ulcer	–0.45	(–2.13,1.23)	0.597
Previous amputation	0.51	(–3.46,4.49)	0.800
Constant	6.30	(2.02,10.59)	0.004
Akaike Information Criterion		*17.76*	
Log likelihood		*-1134.61*	

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