Health-related Quality of Life in Type 2 Diabetes (T²ARDIS-2)

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ABSTRACT

Background: Type 2 diabetes is now recognized as a major public health concern but its burden on society is under-researched.
Methods: T²ARDIS was a postal survey of 1578 people with type 2 diabetes across four UK centres, incorporating measures of resource use, treatment satisfaction and health-related quality of life (HrQoL). The findings included data on the EQ-5D that enabled the HrQoL burden of the disease to be established by comparison with equivalent data for the general population and the diabetic population as a whole from the 1996 Health Survey of England.

Results: The results indicate a significant deficit experienced by people with type 2 diabetes vs. their age group peers in the general population. The proportion of T²ARDIS respondents reporting problems increases in relation to the presence of complications, and microvascular complications appear to have more impact than macrovascular complications.
Conclusions: This confirms the need for treatment policies to focus on reducing the risk of such complications and hence improve patients' HrQoL.
Keywords: Burden of illness, Diabetic complications, EuroQol, Patient survey, Quality of life, Type 2 diabetes.

Introduction

Type 2 diabetes is associated with significant morbidity and mortality and is now recognized as a major public health concern [1]. Complications of the condition include retinopathy, heart disease, stroke and kidney damage. However, few studies have attempted to identify the overall costs of diabetes to society [2] and type 2 diabetes has been particularly under-researched in this respect.

The Type 2 Diabetes: Accounting for a Major Resource Demand In Society in the UK (T²ARDIS) survey was undertaken to investigate the direct, indirect and intangible costs associated with the condition in order to improve understanding of the overall burden it imposes. The direct and indirect cost findings are being reported elsewhere; the overall cost to the NHS of people with type 2 diabetes is in the region of £2 billion per year, driven predominantly by in-patient care [3].

This paper reports on the intangible costs of type 2 diabetes expressed in terms of the impact on HrQoL. In particular, for the first time it estab-

lishes the burden of disease by comparing T²ARDIS findings with equivalent data from the UK general population and the diabetic population as a whole from the Health Survey of England (HSE 1996) [4].

The T²ARDIS findings also allow examination of the impact of complications on HrQoL to supplement that reported by the UKPDS Group [5]. While the UKPDS analysis found that therapeutic policies known to reduce the risk of complications had no effect on HrQoL, the current paper reinforces the need for further attention to be paid to this issue in order to reduce the significant quality of life burden of the condition.

Methods

A postal survey of 1578 people with type 2 diabetes was undertaken in the period April to August 1999 across four UK centres with local diabetes registers: Brighton, Hemel Hempstead, Newcastle and Lanarkshire. Each of these registers encompassed data from at least 80% of local GP practices, and included diabetic patients seen only in primary care as well as those seen in secondary care.

Identification of patients with type 2 diabetes was based on a confirmed type 2 diagnosis recorded on the register (Hemel Hempstead and La-

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narkshire) or diagnosis of unspecified type at age 30 or over (Brighton and Newcastle). Using this definition, a random sample of 750 patients from each centre was identified and a total of 3000 questionnaires distributed.

A battery of four instruments was included in the T²ARDIS questionnaire for self-completion by the patient and/or their informal carer: a 3-month retrospective review of resource use, the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [6], the Caregiver Strain Index (CSI) [7] and the EQ-5D.

The EQ-5D is a two-part questionnaire developed by the EuroQol Group and designed as a generic measure of health-related quality of life [8]. EQ-5D defines health in terms of five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Within each dimension there are three levels of response indicating no problems, some problems or extreme problems on that dimension. Taken together, this descriptive system defines a total of 243 unique health states. Responses to the first part of EQ-5D can be presented separately for each dimension in the form of a profile (EQ-5D$_{profile}$) or converted into a single weighted index score (EQ-5D$_{index}$) using population preference scores [9]. The second part of EQ-5D consists of a 20-cm visual analogue scale with endpoints of 0 denoting the worst imaginable state and 100 denoting the best imaginable state used to record the respondents perception of their overall health status (EQ-5D$_{VAS}$).

Approximately three weeks following distribution of questionnaires to the T²ARDIS sample, each centre carried out a telephone follow-up to nonrespondents. Response bias checks were carried out using data available on the center registers, namely the proportion of males vs. females, the proportion aged over 65, and the proportion receiving insulin. The respondents did not differ significantly from the nonrespondents on any of these variables.

Comparison was made with the EQ-5D$_{index}$ data reported in the Health Survey for England (HSE) [3]; EQ-5D$_{VAS}$ data was not reported in the HSE. The HSE is an annual series of national surveys of the population living in England. The 1996 survey sample was based on 12,960 addresses selected from the national Postcode Address File. Interviews were obtained from 20,328 persons in total, of whom 16,443 were aged 16 and over. The data obtained on chronic illnesses included diabetes, although this was not broken down according to type or complication status.

Diabetic complications in T²ARDIS were categorized as follows: no complications, $n = 864$ (57%);

microvascular complications (i.e., eye problems associated with diabetes, kidney damage, amputation, foot or leg ulcers), $n = 364$ (24%); macrovascular complications (i.e., stroke and/or heart attack), $n = 178$ (12%); and both macro-and microvascular complications, $n = 104$ (7%).

The data on complications were taken from the survey questionnaires, i.e., self-reported, based on prompts. Terminology used to capture this information was designed to assist ease of completion and to avoid unnecessary complexity. Responses are therefore more likely to reflect patients' own perceptions of their overall complication status rather than objective clinical diagnoses. Nevertheless, the authors consider that the prompts were sufficiently clear that respondents would know if they suffered from any of the respective complications.

Results

Of the 3000 T²ARDIS questionnaires distributed across the four study centres, 1578 were returned, yielding a 53% response rate (Table 1).

The mean age ranged between 63 and 69 across all four centres. However, in Lanarkshire and Newcastle a smaller proportion of respondents were aged over 65. There were more males in Hemel Hempstead and Lanarkshire, and proportionately more smokers in Lanarkshire. Differences in treatment regimen are illustrated by the higher proportion of respondents in Newcastle receiving insulin, either alone or in combination with oral antidiabetic tablets.

For the purposes of examining HrQoL, these data have been aggregated. A total of 68 (4%) respondents did not provide data on all five dimensions of the EQ-5D$_{profile}$ and these were excluded from the analysis. There was no evidence of bias arising from these exclusions.

Table 1   T²ARDIS sample characteristics by centre

	BT	HH	NC	LS	All
Type 2 diabetics on register	3602	1600	2501	7523	15226
T²ARDIS sample	750	750	750	750	3000
T²ARDIS respondents	414	373	420	371	1578
	(55%)	(50%)	(56%)	(50%)	(53%)
Mean age (yrs) and (SD)	68	69	66	63	67
	(10.7)	(11.1)	(12.0)	(11.2)	(11.5)
Age >65 (%)	66	64	54	48	58
Male (%)	53	59	52	59	56
Smokers (%)	15	13	16	20	16
Insulin (%)	19	19	28	15	20
Mean years since diagnosis and (SD)	9 (7.2)	9 (7.1)	8 (9.5)	8 (6.0)	8 (7.6)

BT = Brighton; HH = Hemel Hempstead; NC = Newcastle; LS = Lanarkshire.

Comparison with HSE data

The percentage of patients reporting problems (either some problems or extreme problems) across the five dimensions of the EQ-5D$_{index}$, is shown in Table 2. Comparison was made with both the overall population data from the HSE and with the diabetic subpopulation from the HSE.

The most commonly reported problem areas are on the mobility and pain/discomfort dimensions. Overall, there is a strong similarity between the EQ-5D$_{profile}$ for the T²ARDIS study population and that for the HSE diabetic population.

A chi-square test indicated that both the T²ARDIS and the HSE diabetic population demonstrate significantly more problems (some plus extreme) than the general population across each of the five dimensions ($P < .01$). However, a lower proportion of the T²ARDIS population report problems on the pain/discomfort dimension, as compared with the HSE diabetic population, and a higher proportion report problems on the anxiety/depression dimension.

Figure 1 plots the T²ARDIS findings against the age-standardized EQ-5D$_{index}$ for the HSE diabetic respondents and the HSE general population. Across all four age groups the 95% confidence intervals for the T²ARDIS patients and the HSE diabetic population overlap, providing evidence of the overall similarity of the two sets of EQ-5D data. *P*-values ranging from 0.10 for the 45–64-year-old age group to 0.96 for the <45-year-old age group indicate that the T²ARDIS findings for type 2 diabetes are not significantly different to those for the overall diabetic population of England (which includes both type 1 and type 2 diabetes).
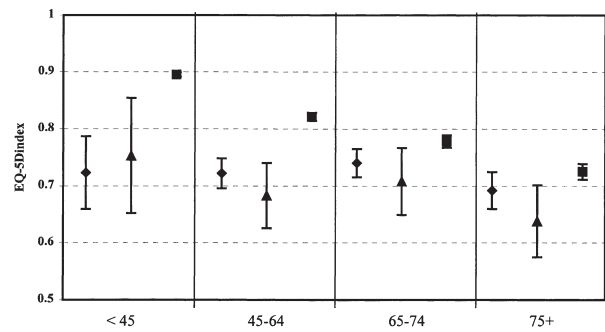

Figure 1 EQ-5D$_{index}$ in diabetics and the general population, by age group (mean scores and 95% confidence intervals). ◆ = T²ARDIS Population (*n* = 1510). ▲ = HSE 1996 Diabetics (*n* = 360). ■ = HSE 1996 General Population (*n* = 17076).

Figure 1 also illustrates a significant HrQoL deficit for type 2 diabetes when compared with EQ-5D$_{index}$ data for the general population. This deficit is most marked in the youngest age group where T²ARDIS respondents record a differential of 0.15 on the EQ-5D$_{index}$. This represents a loss of 0.15 of a year of full health (i.e., without problems on any EQ-5D dimension) or 1.5 years of full health over a 10-year period.

However, the mean EQ-5D$_{index}$ values tend to converge with increased age. The mean value for the T²ARDIS population appears reasonably stable across the age groups, whereas in the general population this value decreases markedly. *P*-values indicate a significant difference between the general population and the T²ARDIS population ($P < .01$) for the <45, 45–64 and 65–74 year old age groups. Only the 75+-year-olds show no significant difference ($P = .0489$).

Analysis by Complication Status

Table 3 shows the EQ-5D$_{profile}$ associated with each of the complications categories. Patients with no complications record lower rates of problems on all EQ-5D dimensions than patients with complications. Those patients suffering from both microvascular and macrovascular complications report problems far more frequently than those with only one category of complications. There is also a tendency for those with microvascular complications to report problems more often than those with macrovascular complications. This is most pronounced on the usual activities dimension.

In order to standardize for other factors known to influence EQ-5D responses, a subset of patients across all four complications categories was matched in terms of 10-year age group, gender and smoking status (EQ-5D$_{index}$, *n* = 89; EQ-5D$_{VAS}$, *n* = 94). The

Table 2 EQ-5D$_{profile}$ for T²ARDIS and HSE samples (percentage of respondents in each sample reporting problems)

EQ-5D Level of problems	T²ARDIS All Patients (*n* = 1510)	HSE 1996	
		Diabetics (*n* = 360)	General population (*n* = 17076)
Mobility			
Some	47.2%	45.7%	17.1%
Extreme	0.4%	0.3%	0.1%
Self-care			
Some	14.8%	17.1%	4.6%
Extreme	1.2%	1.8%	0.4%
Usual activities			
Some	35.0%	36.4%	15.9%
Extreme	6.6%	9.1%	2.4%
Pain/discomfort			
Some	40.9%	48.7%	32.8%
Extreme	7.7%	10.9%	3.3%
Anxiety/depression			
Some	34.7%	29.9%	20.9%
Extreme	5.3%	4.4%	1.8%

Table 3 EQ-5D$_{profile}$ by diabetic complication category (percentage of respondents in each category reporting problems)

EQ-5D Level of problems	No complications (n = 864)	Microvascular complications (n = 364)	Macrovascular complications (n = 178)	Both micro & macrovascular complications (n = 104)
Mobility				
Some	34.0%	60.2%	56.7%	83.7%
Extreme	0.2%	0.3%	0.6%	1.9%
Self-care				
Some	7.9%	20.9%	19.1%	36.5%
Extreme	0.5%	2.5%	0.6%	3.8%
Usual activities				
Some	27.1%	46.2%	37.1%	55.8%
Extreme	2.9%	9.1%	10.1%	20.2%
Pain/discomfort				
Some	35.0%	47.5%	43.8%	58.7%
Extreme	4.9%	11.8%	7.9%	15.4%
Anxiety/depression				
Some	28.8%	39.6%	36.5%	55.8%
Extreme	2.9%	7.1%	5.1%	10.6%

difference in the mean score of each complication category vs. no complications was significant ($P < .01$).

A chi-square test indicated that the presence of complications was also associated with a higher number of reported problems across four of the five individual dimensions which comprise the EQ-5D$_{index}$. The exception was self-care; this may be linked to the fact that more respondents with complications reported that they have a regular informal carer, 141 (37%) in the microvascular category, 79 (43%) in the macrovascular category and 60 (56%) in the both micro- and macrovascular category, as compared with 217 (24%) for patients with no complications.

Reported problems with anxiety/depression were only associated with the combination of both micro- and macrovascular complications. This is relevant to the high level of problems reported on this dimension compared to the HSE diabetic population shown in Table 2, and may be particularly pronounced in the type 2 diabetic population.

Respondents on insulin reported problems more often ($P < .01$) on the mobility, usual activities and pain/discomfort dimensions than those on other treatment regimens.

Discussion

Although drawn from only four selected UK centres, the T^{2}ARDIS survey responses may be considered broadly representative of the national picture on the HrQoL burden of type 2 diabetes. Comparison with the HSE data indicates a strong similarity with the overall diabetic population (including both type 1 and type 2) and confirms the significant deficit experienced by people with type 2 diabetes vs. their age group peers in the general population.

The proportion of T^{2}ARDIS respondents reporting problems on the EQ-5D$_{index}$ increases in relation to the presence of self-reported complications. Microvascular complications appear to have more impact than macrovascular complications, and over half the respondents with the former report problems on mobility, usual activities and pain/discomfort. However, this comparison is amongst survivors and consequently does not take into account the impact of macrovascular complications on mortality. Within this survivor population, the cumulative nature of complications in type 2 diabetes may also lie behind the high level of reported problems on anxiety/depression.

T^{2}ARDIS has shown that type 2 diabetes is a serious condition in terms of reduced HrQoL, and is costly both to the NHS [3] and to the individual patient. The Audit Commission [2] has reinforced the scale of the challenge faced in the provision of diabetes services in the UK in order to alleviate this burden. The UKPDS has confirmed that aggressive management of the risk factors of diabetes through blood glucose control prevents complications [10] and we now have evidence that complications are directly linked to intangible costs in the form of HrQoL. There is consequently a need for increased emphasis on therapeutic policies that are specifically targeted at reducing the risk of complications. This would have substantial benefits in terms of improved quality of life for people with type 2 diabetes.

and their patients at each of the four centres involved in the T²ARDIS survey.

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