Economic Burden of Diabetic Patients with Established Atherosclerotic Cardiovascular Disease or Risk Factors for Atherosclerotic Cardiovascular Disease

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BACKGROUND

Atherosclerotic cardiovascular disease (ASCVD), defined as coronary heart disease (CHD), cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin, is the leading cause of morbidity and mortality for individuals with diabetes [1], especially in patients with diabetes mellitus type 2 in which the disease typically occurs 14.6 years earlier [2]. Common conditions coexisting with type 2 diabetes (e.g., hypertension and dyslipidemia) are clear risk factors for ASCVD, and diabetes itself confers independent risk [1]. Heart failure is another major cause of morbidity and mortality from cardiovascular disease. The presence of this intersection between diabetes, ASCVD and heart failure, make essential the development of diabetes therapies that can be safe but also effective in reducing cardiovascular risk [3-5]. Moreover, several studies have shown that the increase in complexity in diabetic patients inevitably leads to an increase in the healthcare resources used which translates into an increase in costs [6, 7]. Reducing the burden associated with ASCVD in diabetes mellitus should be a priority goal in order to reduce premature mortality, improve quality of life and reduce individual and economic burdens resulting from associated morbidity [8].

OBJECTIVE

The analysis aimed to quantify the number and costs of patients with type 2 diabetes and ASCVD or with risk factors for ASCVD from the Regional Health Service (RHS) perspective of the Marche Region.

METHODS

A Cost of Illness (CoI) model was developed to estimate the economic burden associated with diabetes and ASCVD or risk factors for ASCVD. Data were extrapolated from the administrative database of the Marche Region and specific inclusion criteria for enrolling patients were adapted from DECLARE–TIMI 58 clinical trial. RHS perspective (drugs, hospitalizations, monitoring cost) and 1 and 4-year time horizons were considered.

Data source

The analysis was conducted using the following administrative databases of the Marche region:

• Hospital Information System (HIS), which records all admissions to public and private accredited hospitals in the region;

• Pharmaceutical Prescription Information System, containing all prescriptions sent to municipal and private pharmacies within the region and reimbursed by the Italian National Health Service;

• Specialist Service Information System, containing all outpatient appointments for diagnostic and therapeutic services in the region.

A deterministic linkage was performed at individual user level between the different administrative sources through anonymous ID number.

Population selection

Diabetic patients were identified by selecting all persons aged ≥ 40 years with the presence of:

• at least one admission for "diabetes mellitus" (ICD-9-CM code 250) as primary or secondary diagnosis with discharge date between January 1, 2014 and December 31, 2014;

- at least one prescription of hypoglycemic drugs (ATC A10) between 1 January 2014 and 31 December 2014;
- exemption 013 (diabetes mellitus) between 1 January 2014 and 31 December 2014.

Patients with ASCVD were identified by selecting diabetic patients with at least one hospitalization with discharge date between January 1, 2014 and December 31, 2014 for:

- Acute Coronary Syndrome (ACS);
- Peripheral Arterial Disease (PAD);
- Stroke (ischemic or TIA).

Patients at risk of ASCVD were identified by selecting diabetic patients with none of the previous diseases but who reported the following risk factors:

- age \geq 55 for men and \geq 60 for women and at least one of:
- a. hypercholesterolemia, defined as at least one prescription of lipid-lowering drugs;
- b. hypertension, defined as at least one prescription of antihypertensive drugs.

Costs

A cross-sectional and longitudinal analyses were carried out by considering costs associated with patients with ASCVD or at-risk of ASCVD incurred within 365 days from the index date (first hospitalization or prescription for diabetes) or up to 4 years from the index date, respectively.

The following costs were considered: drugs for diabetes delivered within 365 days from the index date (first hospitalization/prescription in the period 2010-2013) or within 4 years from the index date (first hospitalization/prescription in the period 2008-2010); concomitant drugs for co-morbidities delivered within 365 days (or 4 years) from the index date;

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hospitalization for heart failure, identified by DRG 127, with discharge date within 365 days (or 4 years) from the index date; other hospitalizations with discharge date within 365 days (or 4 years) from the index date; specialist services provided within 365 days (or 4 years) from the index date.

RESULTS

The analysis estimated a total number of 92,205 diabetic patients in Marche Region in 2014. Of these, 66,306 patients (5.9% of the resident population) were with established atherosclerotic cardiovascular disease (13,104 patients) or risk factors for atherosclerotic cardiovascular disease (53,202 patients). Tables 1 and 2 show average costs per patients estimated at 1 and 4 years from the index date. The annual expenditure associated with patients analyzed amounted to \notin 98.8 million (average cost per patient \notin 1,480) in Marche region (Table 3). Of these, 52% was associated with hospitalizations. Considering a 4-year time horizon, the overall economic burden rises to over \notin 301 million per year with an average cost per patient of \notin 4,545 (Table 4). Stratifying patients between patients hospitalized for heart failure and patients not hospitalized for heart failure, the average annual cost per patient was equal to \notin 15,896 and equal to \notin 3,998, respectively.

Table 1: Average costs per patient (1 year from the index date)

Patients hospitalized for heart failure						
	Heart failure	Other hospitalizations	Diabetes drugs	Other drugs	Specialist services	Total
At risk	€ 3 <i>,</i> 853	€ 1,168	€138	€ 379	€ 295	€ 5,833
With CVD	€ 4,066	€ 4,894	€166	€ 452	€ 484	€ 10,063
Patients not hospitalized for heart failure						
	Heart failure	Other hospitalizations	Diabetes drugs	Other drugs	Specialist services	Total
At risk	€0	€ 240	€ 157	€ 292	€ 196	€ 885
With CVD	€0	€ 2,151	€183	€ 391	€ 388	€ 3,113

Table 2: Average costs per patient (4 years from the index date)

Patients hospitalized for heart failure						
	Heart failure	Other hospitalizations	Diabetes drugs	Other drugs	Specialist services	Total
At risk	€ 4,653	€ 2,785	€ 503	€ 1,295	€ 497	€ 9,733
With CVD	€ 5,163	€ 11,456	€ 692	€ 1,693	€ 1,265	€ 20,269
Patients not hospitalized for heart failure						
	Heart failure	Other hospitalizations	Diabetes drugs	Other drugs	Specialist services	Total
At risk	€0	€ 819	€ 557	€ 1,055	€ 445	€ 2,877
With CVD	€0	€ 5,633	€ 659	€ 1,347	€ 827	€ 8,466

Table 3: COI at 1 year from index date

Cost items	Subjects at risk	Subjects with CVD	Total
Hospitalization for heart failure	€ 3,824,542	€ 3,121,158	€ 6,945,700
Diabetes drugs	€ 8,343,120	€ 2,385,383	€ 10,728,504
Other hospitalizations	€ 13,663,310	€ 30,296,274	€ 43,959,584
Other drugs	€ 15,646,344	€ 5,168,354	€ 20,814,698
Specialist services	€ 10,524,263	€ 5,156,430	€ 15,680,693
Total	€ 52,001,580	€ 46,127,600	€ 98,129,179

Table 4: COI at 4 years from index date

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Cost items	Subjects at risk	Subjects with CVD	Total
Hospitalization for heart failure	€ 12,279,569	€ 8,422,800	€ 20,702,369
Diabetes drugs	€ 29,509,172	€ 8,691,924	€ 38,201,096
Other hospitalizations	€ 48,782,240	€ 83,312,667	€ 132,094,907
Other drugs	€ 56,739,578	€ 18,217,674	€ 74,957,252
Specialist services	€ 23,828,435	€ 11,548,981	€ 35,377,417
Total	€ 171,138,994	€ 130,194,047	€ 301,333,041

CONCLUSIONS

An important epidemiological and economic burden associated with type 2 diabetes patients were estimated from the analysis due to the disease and the associated comorbidities. The ability to prevent comorbidity risks, especially cardiovascular ones, represents not only a clinical advantage but also a positive reduction in expenditure. Early and effective intervention represents the best strategy to avoid or slow down the evolution of complications of the disease.

AUTHOR INFORMATION

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ABSTRACT

Objective: The analysis aimed to quantify the number and costs of patients with type 2 diabetes and atherosclerotic cardiovascular disease from the Italian Regional Health Service (RHS) perspective.

Methods: A Cost of Illness (CoI) model was developed to estimate the economic burden associated with diabetes and established atherosclerotic cardiovascular disease or risk factors for atherosclerotic cardiovascular disease. Data were extrapolated from the administrative database of the Marche Region and specific inclusion criteria for enrolling patients were adapted from DECLARE–TIMI 58 clinical trial. RHS perspective (drugs, hospitalizations, monitoring cost) and 1 and 4-year time horizons were considered.

Results: The analysis estimated a total number of 92,205 diabetic Patients in Marche region in 2014. Of these, 66.306 patients (5.9% of the resident population) with established atherosclerotic cardiovascular disease (13,104 patients) or risk factors for atherosclerotic cardiovascular disease (53,202 patients). The annual expenditure associated with patients analysed amounted to \notin 98.8 million (average cost per patient \notin 1,480) in Marche region. Of these, 52% was associated with hospitalizations. Considering a 4-year time horizon, the overall economic burden rises to over $\notin \notin$ 301 million per year with an average cost per patient of \notin 4,545. Stratifying patients between patients hospitalized for heart failure and patients not hospitalized for heart failure, the average annual cost per patient was equal to \notin 15,896 and equal to \notin 3,998 respectively.

Conclusion: An important epidemiological and economic burden associated with type 2 diabetes patients were estimated from the analysis due to the disease and the associated comorbidities. The ability to prevent comorbidity risks, especially cardiovascular ones, represents not only a clinical advantage but also a positive reduction in expenditure. Early and effective intervention represents the best strategy to avoid or slow down the evolution of complications of the disease.

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