

Management of patients with type II diabetes: a Budget Impact Analysis

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Abstract

Type II diabetes has a high prevalence rate worldwide, especially in industrialized countries. By requiring increasing health expenditures and resources, the disease and its complications generate a considerable economic burden.

Since many years several institutions promote awareness and information programs regarding the most effective strategies to prevent and control diabetes. By reducing the severity of the disease and its complications, Adapted Physical Activity (APA) represents an ideal instrument to remodulate the Therapeutic Healthcare Management Protocol (THMP) of patients with type II diabetes and may be defined as a new health technology.

On the basis of these considerations, a Budget Impact Analysis (BIA) was carried out from the healthcare management perspective to evaluate advantages deriving from the introduction of a structured program of APA for diabetics in Campania, one of the Italian regions with the highest prevalence of diabetes.

Key words: Type II Diabetes; Adapted Physical Activity; Health Technology Assessment; Therapeutic Healthcare Management Protocol; Budget Impact Analysis

Introduction

In the last few decades, the growth and the progressive ageing of population, the urbanization and the diffusion of unhealthy lifestyles caused a rapid increase of the prevalence of type II diabetes (1, 2, 3). Projections for the future show a higher increase of the disease, until to a prevalence rate almost doubled in 2030 respect to that estimated in 2000 (2, 3, 4). In Italy, 4.9% of the population is affected by diabetes, which represents one of the main cause of death and a social epidemic involving healthcare services and facilities, as well as work and family settings (5).

In order to contain this epidemic, it is necessary to define its magnitude and its determinants and to implement effective paths for screening, diagnosis and treatment of the disease. To this

aim, specific cultural interventions are needed in the context of prevention and health promotion initiatives.

Type II diabetes, which accounts for the 90% of diabetes cases, is related to behavioral risk factors, such as overnutrition and inactivity; about 58% of diabetic patients shows a Body Mass Index >21 (19).

Substantial modifications in lifestyles such as diet and physical activity may represent the best strategy to prevent and control this disease. Physical inactivity is a significant risk factor for type 2 diabetes, and several studies have shown that the development of this disease can be prevented through exercise training combined with dietary guidelines. Furthermore, regular exercise training in type 2 diabetics leads to an increase in the insulin sensitivity of the tissues even at rest (6, 7). Therefore, regular physical activity is an important part of the treatment of type 2 diabetes (8, 9, 10, 11, 12, 13, 14, 15); by contributing to generate a good metabolic control, it can also reduce the development of late diabetic complications.

On the basis of our previous findings (progetto CCM 2012 “*Counseling motorio ed Attività Fisica Adattata quali azioni educativo-formative per ridefinire il percorso terapeutico e migliorare la qualità di vita del paziente con diabete mellito tipo II*”) and literature reports, a structured and regular exercise program may reduce complications of type II diabetes of about 30% (6, 22, 23, 24, 25, 26).

As for economic aspects, it was showed that health expenses for the management of subjects with type II diabetes can exceed 4 times those for subjects without the disease of the same age and gender (19). For example, this happens in the case of insulin treatment failure, or in presence of some complications, such as cardiopathy, retinopathy, nephropathy, stroke, which account for 38% of exceeding healthcare expenses (7, 20, 19, 27).

Since many years, several institutions promote awareness and information programs regarding the most effective strategies to prevent and control diabetes. By reducing the severity of the disease and its complications, Adapted Physical Activity (APA) represents an ideal instrument to remodulate the Therapeutic Healthcare Management Protocol (THMP) of patients with type II diabetes. Therefore, APA may be defined as a new health technology and may undergo economical evaluations in a Health Technology Assessment (HTA) setting.

The integration of structured movement programs for diabetics in healthcare management plans should be considered of utmost importance in order to produce health and improve the quality of life of patients, with a positive impact on related expenses.

On the basis of these concepts, a Budget Impact Analysis (BIA) was carried out from the healthcare management perspective to evaluate economic advantages deriving to the local healthcare system from the introduction of a structured program of APA for diabetics in Campania, one of the Italian regions with the highest prevalence of diabetes. The aim was to evaluate if this new integrated DTHMP could give economic advantages, in addition to those specifically health-related.

As a support instrument, the BIA was aimed to provide detailed information to decision makers in order to address the use of resources and enhance health advantages for the local population.

Methods

The model employed for the evaluation of APA program was based on the guidelines of the International Society of Pharmacoeconomics and Outcome Research (ISPOR) (17).

The BIA was carried out on a time frame of five years, by considering the National Health System perspective, that is only fundamental direct costs such as hospitalizations, medications and specialized services costs (expressed in euros) (18, 19).

Two scenarios were analyzed: a base scenario, which did not include any physical activity program, and an alternative scenario, which included an APA course integrated in the traditional DTHMP. The difference between costs sustained in both scenarios represents the potential savings.

- *Reference population*

The population of type II diabetics aged 50-70 years living in Campania region was considered (20). They were 115,871 individuals (7.91% of the total population), 53,7% of which males and 46,3% females. In particular, 61,004 cases were associated with complications (cardiovascular, ocular or kidney complications) (Table 1).

On the basis of literature (21), different annual incidence values were considered per age class: 9.1x1,000 persons aged 50-59/year; 11.9x1,000 persons aged 60-69/year and 9.5x1,000 persons aged 70/year.

At the end of the fifth year, without the implementation of an APA program, the population examined will be composed by 236,234 cases, 121,372 of which complicated.

- *Efficacy data*

Considering the efficacy data, we estimated a reduction of complications equal to 30% in the case of APA adoption respect to the base case (CCM 2012).

The implementation of the new DTHMP could produce a modification in the estimated number of diabetics with or without complications during the five years examined, and a significant reduction of complicated cases.

- *Costs data*

In Italy, in 2005, the total annual expense for type II diabetes exceeded 5 billion euros (about 7% of the national health fund), corresponding to 3,000 euros/year per patient. About 60% of this amount was employed for hospitalizations due to complications, the 22% for medication use and the remainder for specialized services (7).

More recent estimates indicate that the direct costs produced by a diabetic patient with complications are almost similar, that is 2,921 euros; 57% of these are employed for hospitalizations, 29% for medications (about 16% of the total national public pharmaceutical expense) and 14% for specialized services (28). The annual expense for a non-complicated patient is equal to 1,461 euros, with 832, 425 e 204 euros invested in hospitalizations, medications and services, respectively.

The unit cost for the regional health system was multiplied for the estimated number of complicated cases in both scenarios.

The analysis considered a time period of five years from a National Health System perspective (2013 direct costs expressed in euros).

- *Sensitivity analysis*

A one-way sensitivity analysis was carried out to evaluate the robustness of the results and the impact of the sensitivity on them. Efficacy was assumed from a minimum value of 20% to a maximum of 40%.

Results

Table 2 shows the estimated numbers of diabetics from the reference population in the time frame considered (years 2013-2017), with or without complications.

The difference between costs for complicated diabetes cases with or without APA represents the possible economic benefit for region fund (Table 3).

We considered APA as delivered for zero costs.

The results of the projection show at the end of the five years a possible saving of 27,205,286 euros, distributed among the three cost items (Table 4).

The results of the sensitivity analysis support the economic potentiality of the integrated DTHMP as a new health technology (Table 5).

Conclusions

Diabetes is one of the main chronic diseases in the global population. Given its progress and complications, it accounts for a reduction of expectancy and quality of life in diabetic patients and for considerable health cost items (19, 23). In order to improve its control compatibly with the National Health System resources, the collection of information about healthcare flows and related costs is fundamental.

The presence of complications affects notably the burden of disease: about one third of total resources employed for the management of cases are needed to treat comorbidities. Therefore, this seems the more adequate setting to which address interventions for expense rationalization.

Further improvements can be obtained through the promotion and prescription of healthy lifestyles with preventive and therapeutic aims.

In a previous experience, we evaluated the decrease of complications in diabetic patients who undergo a structured APA program inside their THMP.

Findings from the BIA performed in the present study allow to affirm that a diabetes DTHMP remodulated through the integration of APA could be not only efficacious for health outcomes, but also effective and able to create "value" for both patient and healthcare system in a management and economic perspective.

Furthermore, it has to be noted that our analysis was conservative: estimated savings are limited to direct costs and do not refer to indirect cost items, such as loss of productivity.

Finally, savings were referred to a time period of five years, but the potential economic return could be extended to the following years, increasing the advantages deriving from this healthcare approach.

This study testifies the importance of HTA to obtain an optimal healthcare management in economic terms and to guarantee effective services for the health and wellbeing of individuals. In fact, the consideration of all the fields involved – scientific, economic, organizational and social fields – represents the strongest element to endorse policy-maker in promoting and supporting physical activity as a strategy to integrate the DTHMP of chronic diseases such as diabetes and to promote individual and community health. In this way, HTA can play its role of connection between the scientific model, oriented to the analysis of new technologies, and the decision-making process, addressed to evaluate the efficacious and effective employ of the lacking resources available (29, 30, 31).

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Table 1. Estimated numbers of subjects with type II diabetes and diabetics with complications per age, referred to the population of Campania region in 2014

age	subjects with diabetes	stroke	vascular complications	cardiac complications	ocular complications	kidney complications	total
50	2,512	39	101	203	474	169	986
51	2,453	38	99	198	462	165	962
52	2,405	37	98	194	453	162	945
53	2,310	36	93	187	435	155	906
54	2,273	35	92	184	428	153	892
55	3,116	48	126	252	587	210	1,223
56	4,648	72	188	376	876	313	1,824
57	4,427	68	179	358	835	298	1,737
58	4,493	69	182	363	847	302	1,763
59	4,434	68	179	358	836	298	1,740
60	6,323	182	328	681	1,435	900	3,526
61	6,126	176	318	660	1,390	872	3,416
62	6,132	177	318	660	1,391	873	3,419
63	6,250	180	324	673	1,418	889	3,485
64	6,252	180	324	673	1,419	890	3,486
65	10,035	289	521	1,081	2,277	1,428	5,596
66	9,682	279	503	1,043	2,197	1,378	5,399
67	9,782	282	508	1,054	2,220	1,392	5,454
68	8,018	231	416	863	1,819	1,141	4,471
69	6,834	197	355	736	1,551	972	3,811
70	7,366	354	552	1,034	1,771	2,252	5,963
total	115,871	3,036	5,805	11,831	25,121	15,212	61,004

Source: elaboration from ISTAT data (20)

Table 2. Estimated numbers of type II diabetes cases with or without complications predicted for the base scenario or in the case of APA implementation

	base scenario (without APA)		alternative scenario (with APA)	
	cases with complications	cases without complications	cases with complications	cases without complications
year 1	61,004	54,867	61,004	54,867
year 2	76,096	69,959	71,437	74,618
year 3	91,188	85,051	81,871	94,368
year 4	106,280	99,957	92,305	113,932
year 5	121,372	114,862	102,738	133,496

Source: elaboration from ISTAT data (20)

Table 3. Direct costs (euros) for hospitalizations, medications and specialized services with or without the APA program on a period of five years

YEAR 1		YEAR 2	YEAR 3	YEAR 4	YEAR 5
hospitalizations 147,098,492	without APA	184,753,374	222,408,256	259,907,675	297,407,094
	with APA	180,882,211	214,665,930	248,294,185	281,922,441
medications 75,171,617	without APA	94,414,092	113,656,567	132,819,628	151,982,690
	with APA	92,434,255	109,696,893	126,880,118	144,063,343
specialized services 36,082,376	without APA	45,318,764	54,555,152	63,753,422	72,951,691
	with APA	44,368,443	52,654,509	60,902,457	69,150,405
TOTAL 258,352,485					

Table 4. Savings (euros) obtainable in a period of five years predicted through BIA

BUDGET IMPACT ANALYSIS					
	year 1	year 2	year 3	year 4	year 5
hospitalizations	0	3,871,163	7,742,326	11,613,489	15,484,653
medications	0	1,979,837	3,959,674	5,939,510	7,919,347
specialized services	0	950,322	1,900,643	2,850,965	3,801,287
TOTAL	0	6,801,322	13,602,643	20,403,965	27,205,286

Table 5. Savings (euros) obtainable in a period of five years predicted through BIA and sensitivity analysis

BIA (efficacy 20%)					
	year 1	year 2	year 3	year 4	year 5
TOTAL	0	4,406,904	8,813,808	13,220,712	17,627,616
BIA (efficacy 40%)					
	year 1	year 2	year 3	year 4	year 5
TOTAL	0	8,792,188	30,231,045	51,746,720	72,666,733