



THE COST-EFFECTIVENESS ANALYSIS OF VILDAGLIPTIN IN TYPE 2 DIABETES IN POLAND

**Walczak J, Nogas G, Gebus E, Pawlik D, Pacocha K.
Arcana Institute, Cracow, Poland**

INTRODUCTION:

Type 2 diabetes mellitus (T2DM) constitute about 90% of all diabetes mellitus [1, 2]. T2DM occurs more often in persons who are older and have a high body mass index. Most often T2DM appears between the fifth and seventh decade of life [3].

In 2000, according to the World Health Organization, at least 171 million people worldwide suffer from diabetes, or 2.8% of the population. Its incidence is increasing rapidly, and it is estimated that by the year 2030, this number will almost double [4]. In Poland more than 2 million people suffer from type 2 diabetes mellitus, from those above 50% remain undiagnosed [1, 2].

OBJECTIVES:

The aim of the analysis was to estimate the cost-utility of vildagliptin in the treatment of diabetes mellitus type 2, in combination with metformin, compared to the standard strategy of treatment in Poland: combination of metformin and sulphonylurea.

METHODS:

The cost-utility analysis is based on Markov decision model which was constructed using *TreeAge Pro 2008*.

The cost-utility analysis (CEA) was conducted from the both payers' perspective (National Health Fund and patient), using clinical data from published sources and Polish cost data assuming a lifelong time horizon. The cycle length is six months. In line with Polish guidelines, the costs and health benefits were discounted at 5% annual rate. To estimate the robustness of results, one-way and multi-way sensitivity analyses were performed.

The target population consisted of adult patients with diagnosed diabetes mellitus type 2, inadequately controlled with metformin in mono-therapy.

The units of effectiveness in the analysis were "quality adjusted life years" (QALY) and "life years gained" (LYG). The outcome of the analysis was an incremental cost-effectiveness ratio (ICER), which presents the cost of gaining one additional unit of QALY or LYG in the case of using the therapy with vildagliptin instead of the comparator.

Data concerning clinical effectiveness of compared interventions and also of other strategies of treatment (used after oral antidiabetic drugs (OAD) treatment) were taken from RCT studies, long term studies and systematic reviews.

The following strategies of treatment were compared:

- Vildagliptin (50 mg twice daily) versus Glimepiride (mean dose 4.5 mg/day) both added to metformin (mean dose 1 892 mg/day).

In the analysis, direct medical costs were considered using Polish cost data:

- Costs of OAD (vildagliptin, metformin, glimepiride),
- Costs of insulin,
- Additional costs of treatment of type 2 diabetes (test strips, lancets, glucometers),
- Costs of general practitioner,
- Costs of specialist visits,
- Costs of complications of type 2 diabetes mellitus treatment, i.e. hypoglycaemia, ischaemic heart disease, myocardial infarction, congestive heart failure, stroke, retinopathy, neuropathy, nephropathy).

To calculate resource use data of Polish costs, Polish guidelines were used regarding T2DM treatment, expert opinion and data from RCT studies.

Model (Figure 1) was based on Eastman Model and UKPDS Model [5-8].

RESULTS:

Average costs of the treatment for T2DM (including pharmacotherapy, insulinotherapy, treatment of complications, health state monitoring) were: 47 735 PLN for vildagliptin + metformin and 44 681 PLN for glimepiride + metformin.

Based on VILD + MET treatment effects (per patient) were 11.57552 LYG vs. 11.57034 LYG respectively for GLIM + MET. Based on VILD + MET treatment effects (per patient) were 7.69512 QALY vs. 7.64290 QALY respectively for GLIM + MET.

Cost of gaining one additional unit of QALY and one additional unit of LYG in the case of using combination therapy vildagliptin + metformin instead of therapy glimepiride + metformin is 58 483 PLN and 589 575 PLN, respectively.

The robustness of the models was tested in the sensitivity analyses which proved stability of the results.

CONCLUSIONS:

Assuming the Polish acceptable threshold which is 91 914 PLN, treatment with combination of vildagliptin and metformin is a cost-effective strategy in comparison with glimepiride added to metformin.

REFERENCES:

- Nowakowski A. Epidemiologia cukrzycy. *Diabetologia praktyczna* 2002; 3 (4), pp: 181-185.
- Kawalec P, Kielar M, Pilc A. Koszty leczenia cukrzycy typu 1 i 2 w Polsce. *Diabetologia Praktyczna* 2006; 7 (5), pp: 287-294.
- Główny Urząd Statystyczny. Stan zdrowia ludności Polski w 2004 r. [http://www.stat.gov.pl/cps/rde/xbcr/gus/PUBL_stan_zdrowia_2004.pdf].
- Wild S, Roglic G, Green A, Sicree R, King H (May 2004). "Global prevalence of diabetes: estimates for the year 2000 and projections for 2030". *Diabetes Care* 27 (5): 1047-53.
- Clarke PM, Gray AM, Briggs A, Farmer AJ, Fenn P, Stevens RJ, Matthews DR, Stratton IM, Holman RR. A model to estimate the lifetime health outcomes of patients with Type 2 diabetes: The United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model (UKPDS no. 68). *Diabetologia*, 2004; 47, pp: 1747-1759.
- Eastman RC, Jaritt JC, Herman WH, Dasbach EJ, Zbrozek AS, Dong F, et al. Model of complications of NIDDM, model construction and assumptions. *Diabetes Care*, 1997; 20, pp: 725-34.
- Eastman RC, Jaritt JC, Herman WH, Dasbach EJ, Copley-Merriman C, Maier W, et al. Model of complications of NIDDM.II. Analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of normoglycaemia. *Diabetes Care*, 1997; 20, pp: 735-44.
- Clarke P, Gray A, Holman R. Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62). *Medical Decision Making* 2002; 22, pp: 340-349.
- Mathers C, Vos T, Stevenson Ch. The burden of disease and injury in Australia. AIHW cat. no. PHE 17. Canberra 1999: AIHW.
- Smith DG, Nguyen AB, Peak CN, Frech FH. Markov modeling analysis of health and economic outcomes of therapy with vasartan versus amlodipine in patients with type 2 diabetes and microalbuminuria. *Journal of Managed Care Pharmacy* 2004; 10 (1), pp: 26-32.
- Redekop WK, Koopmanschap MA, Stolk RP, Rutten GEHM, Wolfenbuttel BHR, Niessen LW. Health-related quality of life and treatment satisfaction in Dutch patients with type 2 diabetes. *Diabetes Care* 2002; 25 (3), pp: 458-463.
- Currie CJ, Morgan CL, Poole CD, Sharplin P, Lammert M, McEwan P. Multivariate models of health-related utility and the fear of hypoglycaemia in people with diabetes. *Current Medical Research and Opinion* 2006; 22 (8), pp: 1523-1534.

This analysis was sponsored by Novartis Poland Sp. z o.o.



Arcana Institute ul. St. Dąbka 8, 30-732 Cracow, Poland, tel./fax. +48 (0) 12 263 60 38, e-mail: kontakt@inar.pl www.inar.pl

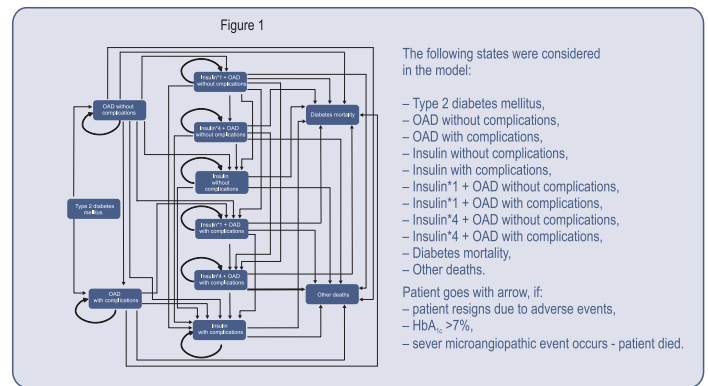


Table 1

Cost (per patient per year)	VILD + MET	GLIM + MET
Combined drug cost [PLN]	2 798.14	620.97
Insulin cost [PLN]	11 470	11 508
Cost of complications of type 2 diabetes mellitus treatment [PLN]	8 462	8 596
Additional costs [PLN]	23 396	23 715

1€ = 4.11 PLN, 24.08.2009

The influence of weight gain, hypoglycemic episodes, complications of type 2 diabetes mellitus and insulinotherapy on the quality of life were also estimated and were derived from Clarke 2002 [8], Mathers 1999 [9], Smith 2004 [10], Redekop 2002 [11], Currie 2006 [12].

Table 2

Total effect	VILD + MET	GLIM + MET
LYG	11.57552	11.57034
QALY	7.69512	7.64290