

Budget Impact of Adding one Dipeptidyl Peptidase-4 Inhibitor to Ministry of Health Jordan Tender List in the Treatment of Type II Diabetes Mellitus

Ibrahim Alabbadi^{1*}

¹ Associate Professor, MBA, PhD, Biopharmaceutics and Clinical Pharmacy Department, Faculty of Pharmacy, The University of Jordan.

ABSTRACT

Total health expenditure in Jordan accounted for 7.72% of the Jordanian GDP in 2011 in which about one third is spent on pharmaceuticals. Number of people with type2 diabetes is increasing in every country, in Jordan; the prevalence of diabetes in adult's ≥ 25 years of age is 17.1%, while an additional 7.8% of Jordanians have impaired glucose tolerance. The aim was to investigate the impact of adding one DPP-4 inhibitor as an oral hypoglycemic agent to the tender list of Jordanian MoH in the treatment of Type II DM. Quantities purchased by MoH in 2010 for oral hypoglycemic agents were used to calculate how many patients will be treated using these quantities. Annual cost of treating hypoglycaemia caused by oral hypoglycemics and their current acquisition cost were estimated. Costs of treating adverse effects were estimated based on MoH prices. Private pharmacy retail price for Vildagliptin was used to estimate budget impact of adding this DPP-4 inhibitor to the treatment options for DM patients in the public sector. It was concluded that budget impact of adding Vildagliptin to the tender list of MoH seems to have a very good potential of savings that is badly needed to treat more DM patients.

Keywords: Diabetes mellitus, budget impact, Jordan, vildagliptin, sulfonylureas.

1. INTRODUCTION

Jordan is a small lower- middle income developing country with limited natural resources. The Gross Domestic Product (GDP) is 20.5 billion Jordanian Dinars (JDs) and per capita of GDP is 3275.8 JDs (2011)⁽¹⁾. With an adult (>15 yrs) literacy rate of 93%, Jordan had a total unemployment rate of 12.2% in 2012⁽²⁾.

Total health expenditure (THE) accounted for 7.72% of the Jordanian GDP in 2011 (approximately 1,581 billion JDs) and 252.9 JDs per capita healthcare spending; just below one third of this spent is on pharmaceuticals (27.07%); a high percentage compared to those of other developed countries and is more in line

with countries in the Organisation for Economic Co-operation and Development (OECD)⁽³⁾. The Government of Jordan is committed to making quality health care services available and accessible to all citizens. The governance of the health care system in Jordan is vested in the Ministry of Health (MoH), in which governance within the MoH is highly centralized, and the main challenges facing the Ministry are improving efficiency, cost containment and quality of patient care. Because of the high percentage of spending on buying medicines, the pharmaceutical sector is considered a high priority to be looked at by the Jordanian MoH.

The country's health care system is divided between public and private institutions. In the public sector, the MoH operates 1,245 primary health-care centres and 27 hospitals, accounting for 37 % of all hospital beds in the country; the military's Royal Medical Services runs 11

* i.abbadi@ju.edu.jo, ibrahimalabbadi@yahoo.com

Received on 19/4/2015 and Accepted for Publication on 27/6/2015.

hospitals, providing 24% of all beds; and the Jordan University Hospital accounts for 3% of total beds in the country. The private sector provides 36 % of all hospital beds, distributed among 56 hospitals.

Being successful in dealing with communicable diseases and with its economic manifestations, the burden of disease in Jordan has shifted toward non-communicable diseases (NCD) e.g. cardiovascular diseases such as Diabetes Mellitus⁽⁴⁾. Diabetes mellitus (DM) is a common chronic disease caused by an absolute lack of insulin or relative lack of insulin as a result of impaired insulin secretion and action. In the long term, these contribute to the development of macro and micro-complications such as cardiovascular disease (CVD), retinopathy, nephropathy, and neuropathy⁽⁵⁾. In addition, DM negatively impacted the emotional well being by more than 45% with a high level of distress leading to depression in some cases⁽⁶⁾. The latter increases the need to improve self management and psychological support for DM patients in order to improve their quality of life throughout their living long years.

According to the International Diabetes Federation (IDF); 387 million people have diabetes in 2014 and by 2035 this will rise to 592 million worldwide. The number of people with type2 diabetes is increasing in every country, 77% of people with diabetes live in low- and middle-income countries and the greatest number of people with diabetes are between 40 and 59 years of age, 179 million people with diabetes are undiagnosed and Diabetes caused 4.9 million deaths in 2014⁽⁷⁾. In Jordan, the prevalence of diabetes in adult's ≥ 25 years of age is 17.1%, while an additional 7.8% of Jordanians have impaired glucose tolerance with no significant differences between women and men⁽⁸⁾.

The overall goal of diabetes management is to achieve and maintain controlled blood glucose and reduce the risk of long-term complications. However; this is associated with an increased risk of hypoglycaemia; a common event occurs in 24% to 60% of diabetic patient⁽⁹⁾. Hypoglycaemia is defined as abnormally low plasma glucose concentration which may expose the patients to potential harm; patients must be alerted to the risk of

hypoglycaemia when plasma glucose ≤ 70 mg/dl (≤ 3.9 mmol/L)⁽¹⁰⁾.

Hypoglycaemia is considered as a true medical emergency which requires immediate recognition and treatment to prevent organ and brain damage. It occurs suddenly and it's characterized by unpleasant physical and psychological symptoms such as shaking, sweating, drowsiness, nausea, poor motor coordination, mental confusion, negative mood, and unconsciousness⁽¹¹⁾. The symptoms of hypoglycaemia depend on the duration and the severity of hypoglycaemia and varied from autonomic activation to behavioural changes to altered cognitive function to seizures or coma. Repeated hypoglycaemic episodes lead to compromise physiologic and behavioural defences against future falling glucose concentration, causing a cycle of recurrent hypoglycaemia⁽¹²⁾.

Antihyperglycemic therapy used for the management of diabetes can be associated with hypoglycaemia, a condition that has a substantial clinical impact, causing distress to affected individuals and impairing their ability to perform everyday activities. Furthermore, untreated hypoglycaemia can cause a significant economic and personal burden, so the identification and prevention of hypoglycaemia can reduce diabetes burden by prevention of hypoglycaemia complications⁽¹²⁾.

The aggressiveness of therapy to achieve glycemic control is considered as most important risk factor for hypoglycaemia. Other risk factors include glucose-lowering medications, antecedent hypoglycaemia, alcohol, exercise and liver disease⁽¹³⁾. Over the time, symptoms of hypoglycaemia become less intense or even diminish altogether, resulting in hypoglycaemia unawareness in a significant proportion of diabetic patients, that is considered as important risk factor for severe hypoglycaemia⁽¹⁴⁾. On the other side, and because of all these, treating hypoglycemia resulted from those aggressive glycemic control including medications, is one of the costly interventions that increase the economic burden on the MoH pharmaceutical budget.

Data from clinical trials in which Dipeptidyl peptidase-4 (DPP-4) inhibitors were employed as monotherapy or added to antidiabetic treatment indicate

that the incretin-based therapies have very low risk for the development of hypoglycaemia⁽¹⁵⁾. The frequency of severe hypoglycemic events is the most important factor associated with fear of hypoglycemia; one of the obstacles to adherence to medications used to treat DM⁽¹⁶⁾. Both the frequency and the severity of hypoglycemia symptoms were associated with increase in worry of hypoglycemia and decreased quality of life among diabetic patients treated with a combination of metformin and sulfonylurea⁽¹⁷⁾.

To have an adequate glycemic control, there is a need not only for more effective therapeutic and educational approaches in management of diabetes, but also optimal allocation of resources by efficient use of scarce resources. The latter may include patient education regarding physical exercise and weight control, and decreasing the hypoglycemic fear of patients⁽¹⁸⁾.

The aim of this type of cost analysis was to investigate the impact of adding one DPP-4 inhibitor as an oral hypoglycemic agent to the tender list of Jordanian MoH in the treatment of Type II DM.

METHODOLOGY

Quantities purchased by MoH through its annual tender (2010) for oral hypoglycemic agents listed in the Jordanian National Drug Formulary (sulfonylureas: glimepiride 2 mg, glibenclamide 5 mg) were quantified - based on their winning prices- to how many patients will be treated using these quantities taking into consideration number of patients discontinue taking these medications compared to one DPP-4 inhibitor (Vildagliptin) due to side effects (hypoglycemia, weight gain) and adherence.

Annual cost of treatment failure for those patients, cost of treating hypoglycaemia caused by oral hypoglycemics mentioned above and the current acquisition cost of them were estimated.

Local endocrinologist expert opinion elicitation combined with literature data⁽¹²⁾ were used to determine all interventions required to treating mild, moderate and severe hypoglycemia. Costs of the latter were based on MoH prices in the public sector⁽¹⁹⁾. Acquisition cost in

the private sector (pharmacy retail price) for Vildagliptin was used to estimate budget impact of adding this DPP-4 inhibitor to the treatment options as an oral hypoglycemic for treating DM patients in the public sector (MoH).

RESULTS AND DISCUSSION

A- Ministry of Health Tender-2010 for Glimepiride 2mg = 4,000,000 tablets

Winning price: Glimepiride 2 mg = 0.35 JD/30 Tablet (0.01167 JD/tablet)

Total quantity: 133,333 pack of 30 tablets

Total price: 133,333 X 0.35 JD = 46,666 JDs (acquisition cost)

Average daily dose for one year treatment with Glimepiride is 4.5 mg (20)

i.e. 4,000,000 X 2 mg / 4.5 mg = 1,777,778 tablets per year

Number of patients treated by this amount annually is: 1,777,778 / 365 days = 4871 patients

Discontinuation rate of glimepiride over vildagliptin is 3%⁽²⁰⁾ i.e. 3% of 4871 patients will not continue taking glimepiride due to side effects = 3% X 4871 = 146 patients

B- Ministry of Health Tender-2010 for Glibenclamide 5 mg = 15,000,000 tablets

Winning price: Glibenclamide 5 mg = 3.796 JD/1000 Tablet (0.003796 JD/ tablet)

Total quantity: 15,000 pack of 1000 tablets

Total price: 15,000 X 3.796 JD = 56,940 JDs (acquisition cost)

Average daily dose for one year treatment with Glibenclamide is 10 mg (twice daily)

15,000,000 X 5 mg/ 10 mg = 7,500,000 tablets per year

Number of patients treated by this amount annually is: 7,500,000 / 365 = 20,548 patients

Extrapolating the same 3% discontinuation rate of Glimepiride above (although glibenclamide side effects are more) for glibenclamide will lead to that: 3% X 20,548 = 616 patients

- 146 patients and 616 patients (762 patients) can be ideally treated by Vildagliptin 50 mg twice daily (Jordanian National Drug Formulary listed item) with the following added benefits over all oral anti diabetics⁽²¹⁾:
 - No weight gain (80-90% of Type II DM patients are overweight) = weight gain is the leading cause of non compliance e.g. each 5 kg gained increase Coronary Heart Disease risk by 30%
 - Low risk of hypoglycaemia (same as metformin)
 - Increase adherence by 10% (this will decrease costs of treating Type II DM by 8.9%-28.9%) = each 10% increase of compliance will end up with 0.1 reduction in HBA₁C
 - No hypoglycaemic phobia (patient as well as physician fear of hypoglycaemia)
- 146 patients and 616 patients = 762 patients need 50 mg Vildagliptin twice daily for 365 days = Annual number of tablets of Vildagliptin 50 mg needed to treat those patients is:

762 X 365 days X 2 tablets = 556,260 tablets

C- Current costs:

1- Annual cost of treatment failure for 762 patients:

- 146 patients taking Glimepiride: 140 JDs (146 X 4.5 mg / 2 mg X 365 = 11,990 tablets; cost/tablet = 0.01167 JD, 11,990 X 0.01167 = 140 JDs)
- 616 patients takings Glibenclamide: 1707 JDs (616 X 10 mg / 5 mg X 365 = 449,680 tablets; cost/tablet = 0.003796 JD, 449,680 X 0.003796 JD = 1707 JDs)

2- Cost of treating hypoglycaemia due to sulfonyl urea:

- Incidence of hypoglycaemia for Glimepiride when compared to Vildagliptin respectively(20, 22).
- (16.2% versus 1.7% and 18.2% versus 2.3%) i.e. 14.5% and 15.9% (average = 15.2% more)
- Number of patients currently treated with sulfonyl urea per year are: 25,419 patients (4871 patients treated with Glimepiride and 20,548 patients treated with Glibenclamide)
- 3864 patients are estimated to have hypoglycaemia

(15.2% of 25,419) (21, 22) of which the difference in incidence of hypoglycaemia for Glimepiride when compared to Vildagliptin are as follows:

- i. Severe hypoglycaemia = 2 % i.e. 77patients
Estimated number of events per 52 weeks (1 year) = 10 to zero for Glimepiride when compared to Vildagliptin i.e. 10 folds; 10 X 77 = 770 events (for those 77 patients)
- ii. Moderate hypoglycaemia = 7.3 % i.e. 282 patients
Estimated number of events per 52 weeks (1 year) = 554 to 39 for Glimepiride when compared to Vildagliptin i.e. 14.2 folds; 14.2 X 282 = **4006 events** (for those 282 patients)
- iii. Mild hypoglycaemia = 9% i.e. 348 patients
- iv. Estimated number of events per 52 weeks (1 year) = 554 to 39 for Glimepiride when compared to Vildagliptin i.e. 14.2 folds; 14.2 X 348 = **4942 events** (for those 348 patients)
 - Treating hypoglycaemia⁽¹²⁾ and (local endocrinologist expert opinion elicitation):
 - i. Sever hypoglycaemia: admission immediately
 - 3-4 days in CCU/ICU = continuous infusion of 10% glucose plus corticosteroids
 - Lab tests: FBS every 2 hours for 12 hours then every 3-6 hours i.e. 34 times/3-4 days
 - C-peptide, Insulin level, Lever enzymes, Kidney function, CBC i.e. once/ each event
 - 1-2 days under observation in ward with insulin for one day to treat rebound hyperglycaemia
 - Follow up consultant visits after 2 weeks: FBS, Lever enzymes, Kidney function i.e. once / each event
 - Regular follow up every 3 months: HbA₁C (4 times / year)
 - FBS= 3-5 times per day (Fear of future hypoglycaemia (patient and physician hypoglycaemic phobia i.e. counteractive action to prevent hypoglycaemia at the expense of undesirable high glucose level) i.e. 4 X 360 days= 1440 measures/ year
 - For co morbidities: need consultations with: cardiologist, neurologist, nephrologist from 1-5 days i.e. average 3 days for 3 consultants = 9 consultations / year (assuming everything is fine; no complications such as Stroke, MI, Kidney Impairment,

- Retinopathy...etc)
- ii. Moderate hypoglycaemia: no admission, once monthly follow up
 - i.e. 12 consultant visits, 4 HbA₁C , 365 FBS tests (N.B. fear of hypoglycaemia will negatively affect quality of life; but indirect costs will not be included) per each event yearly
 - iii. Mild hypoglycaemia: no admission, once monthly follow up
 - i.e. 12 consultant visits, 4 HbA₁C, 365 FBS tests (N.B. fear of hypoglycaemia will negatively affect quality of life; but indirect costs will not be included) per each event yearly
- Costs of treating hypoglycaemia as per MoH: (main direct medical costs only e.g. disposables were excluded i.e. direct non medical costs and indirect costs were not included) N.B. monthly employees deductions for health insurance were excluded, also it was assumed that always MoH facilities' capacity are enough to receive hypoglycaemic cases⁽¹⁹⁾.
- (Physician visit =1.650 JDs; HbA₁C = 3 JDs; FBS = 0.5 JD = each strip without device; Lever enzymes = 8 JDs; Kidney function = 5.500 JDs; CBC =3 JDs; C-peptide = 8 JDs; Insulin level =7 JDs; Hospital stay for only eating and sleeping (first, 2nd and third class; average) = 11 + 6 + 3 / 3 = 6.660 JDs / day; CCU/ICU full day stay cost = 24 JDs)
- Cost of treating hypoglycaemia per 762 patients =
- 1. Mild and moderate hypoglycaemia:**
 - 12 consultant visits, 4 HbA₁C , 365 FBS tests = 12X1.650 JDs + 4X3 JDs + 365X0.5 JDs = 214.300 JDs per event
 - 4006 + 4942 = 8948 hypoglycaemic event per year for all treated patients with sulphonyl urea
 - 8948 X 214.300 = **1,917,556 JDs**
 - 2. Severe hypoglycaemia:**
 - 3-4 days stay (i.e. 3.5) in CCU/ICU + 1-2 days stay (i.e. 1.5) under observation in ward + 34 FBS/3-4 days stay + (C-peptide, Insulin level, Lever enzymes, Kidney function, CBC) once / each event + 1 consultant follow up visit / each event + HbA₁C (4 times / year) + FBS 1440 measures / year + for co-

morbidities 9 consultations/ year

- Cost per event treatment per year:
 $3.5 \times 24 \text{ JDs} + 1.5 \times 6.660 \text{ JDs} + (8+7+8+5.500+3) \text{ JDs} + 1.650 + 4 \times 3 \text{ JDs} + 1440 \times 0.5 \text{ JDs} + 9 \times 1.650 \text{ JDs} = 84 + 9.990 + 31.500 + 1.650 + 12 + 720 + 14.85 = 873.990 \text{ JDs}$
- Cost for 770 event = 770 X 873.990 JDs = **672,972.300 JDs**

1- Annual cost of treatment failure for 762 patients:

140 JDs + 1707 JDs = **1847 JDs**

2- Cost of treating hypoglycaemia side effect due to sulphonyl urea:

1,917,556 JDs + 672,972.300 JDs = **2,590,528.300 JDs**

1847 JDs + 2,590,528.300 = **2,592,375.300 JDs**

3-Total current acquisition cost of oral hypoglycaemics is:

46,666 JDs + 56,594 JDs = **103,260 JD**

Concluded results:

❖ **Current estimated direct medical costs in Jordanian Ministry of Health for treating type II DM with sulphonyl ureas:**

2,592,375.300 + 103,260 = 2,695,635.300 JDs

❖ **Additional budget needed to treat 3% (762 patients) by Vildagliptin 50 mg BID:**

556,260 tablets / year = 556,260 / 28 = 19,866 packs

Public price per pack in private pharmacies = 18.600

JDs

19,866 X 18.600 JDs = **369,516 JDs**

❖ **Estimated savings by treating 3% (762 patients) by purchasing Vildagliptin 50 mg from the private pharmacies is:**

2,695,635.300 - (103,260 + 369,516) = 2,222,859.300 JDs

CONCLUSION

Budget impact of adding Vildagliptin to the tender list of MoH seems to have a very good potential of savings that is badly needed to treat more DM patients

using the same current resources available. Furthermore, more adherence to medications, less exposure to adverse effects resulted from using current MoH tender listed oral

hypoglycemic agents and improving DM patients quality of life were important factors to be looked at in this regard.

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أثر إضافة أحد أدوية مثبطات أنزيم دايببتايل-4 لقائمة عطاء وزارة الصحة الأردنية لمعالجة السكري على الموازنة

إبراهيم العبادي¹

¹ قسم الصيدلة الحيوية والسريرية، كلية الصيدلة، الجامعة الأردنية، عمان، الأردن.

ملخص

بلغ حجم الاتفاق على الصحة في الأردن لعام 2011 ما نسبته 7.72% من الناتج الإجمالي المحلي ثلثها صرفت على الأدوية. عدد المصابين بمرض السكري من النوع الثاني في ازدياد حيث وصلت 17.1% ممن هم في عمر 25 سنة فأكثر في الأردن وحوالي 7.8% يعانون من مشاكل تحمل الجلوكوز. هدفت هذه الدراسة إلى بحث أثر إضافة أحد أدوية مثبطات أنزيم دايببتايل-4 لقائمة عطاء وزارة الصحة الأردنية لمعالجة السكري على الموازنة. تم احتساب عدد المرضى الذين تمت معالجتهم لدى وزارة الصحة الأردنية سنة 2010 من خلال حساب الكميات المشتراة من أدوية مخفضات السكري الفموية، تم تقدير كلفة علاج هبوط السكر الناتج عن استخدام هذه الأدوية سنويا اعتمادا على أسعار وزارة الصحة. تم تحديد سعر دواء فيلداقلابتين من سعر البيع للجمهور المحدد من قبل المؤسسة العامة للغذاء والدواء الأردنية. خلصت هذه الدراسة إلى أن إضافة أحد أدوية مثبطات أنزيم دايببتايل-4 (فيلداقلابتين) لقائمة عطاء وزارة الصحة الأردنية لمعالجة السكري من النوع الثاني سيوفر مجال جيد للتوفير على الموازنة مما يمكن من معالجة أعداد أكبر محتاجة من المرضى.

الكلمات الدالة: مرضى السكري، الأثر على الموازنة، الأردن.

تاريخ استلام البحث 2015/4/19 وتاريخ قبوله للنشر 2015/6/27.