INCIDENCE AND LONG-TERM COST OF ORAL STERoidal-RELATED ADVERSE EVENTS IN CHRONIC DISEASES IN POLAND

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INTRODUCTION

Oral drugs have long been a standard therapy for the treatment of chronic diseases mostly related to the respiratory, systemic, skeletal and skin systems. And the strategy for optimal dosing and administration of these medications is currently under debate and evolves, especially in the context of reducing the public payer health care expenditures. The use of oral steroids is associated with a number of side effects that increase patient morbidity and mortality.1, 2 Although the relationship between use of glucocorticoids (GC) and occurrence of adverse events (AE) is widely acknowledged, the estimation of risk of specific AE is still impression, especially in the long-term. The aim of the study was to evaluate the impact of using different doses of oral corticosteroids (GC) in the treatment of chronic diseases on the risk of clinically significant long-term adverse events such as hip fractures, cataracts and diabetes mellitus. Additionally, the objective of the project was to quantify the economic cost of associated-elicited side effects in long term follow up.

METHODOLOGY

In order to develop an economic model medical literature investigating the link of association between selected event (shown below table for different chronic diseases connected with respiratory, renal, and skeletal disorders) and the risk of selected adverse events (fractures, diabetes, cataracts, osteoporotic fracture, infections, steroids, hyper- tension, colitis, pneumonias, and tuberculosis) associated with the use of oral corticosteroids was examined. Selection of readers was based on full-text studies (article published in 2012). Systematic search on 12/11/2011 with the following terms: “oral steroid + (connection to endocrine or extracorporeal and period of use) + the risk of certain adverse event as well as over generated by those adverse events.”

Analysis of available clinical data indicated a significant association between the use of oral corticosteroids and the incidence and mortality of hip fractures and cataracta patients treated with GC versus non-GC. In addition, due to the community-associated indication of glucocorticoids use with the risk of diabetes and high cost of treatment, it was decided to include the AE of DM. The model was based on the data presented in the observational studies. Curtis (2003),1 Weisdorf (2001),2 and Jones 2006,3,4. In addition, the results published as a result of the study of Jones 2006,3,4 was used. The studies evaluated for modeling confirmed a statistically significant association between the long-term use of specific doses of oral corticosteroids in populations of patients with different chronic diseases, and the occurrence of certain adverse events.

Population: Adults ≥18 years with chronic diseases using GC. Intervention: Oral treatment with glucocorticoids (prednisone or its equivalent), low dose (≤2.5 mg/day, low GC) and high dose (>7.5 mg/day, high GC). Comparator: No use of glucocorticoids (non-GC). Results: Incidence of adverse events (hip fractures, cataracts, diabetes mellitus) number needed to be treated longer (NNT-ML). Costs: Quality-Adjusted Life Year, QALY, Life Years Gained, LYG.

RESULTS

Incidence of adverse events (Figure 2):

- The incidence of hip fractures increased from 2.7% to 3.6% (non-GC versus low GC – 3.9 fold increase, non-GC versus high GC – 7.1 fold increase).
- The incidence of cataract increased from 4.6% to 10.4% (non-GC versus high GC – 2.3 fold increase) to 10.4% (non-GC versus high GC – 2.3 fold increase).
- The incidence of diabetes mellitus increased from 12.3% to 17.3% (non-GC versus high GC – 4.6 fold increase).

For a lifetime horizon, 100,000 population, the number of avoided adverse cases (due to lower dose GC compared to high dose GC) of hip fracture was 3,890 to 4,720, cataract – 67,960, diabetes mellitus – 4,480 (Figure 3).

Costs and effects. The use of low dose GC is a cheaper strategy and achieved 1 additional quality-adjusted months per patient (Figure 4). Short-term administration of high dose GC (6-9 years) in the lifetime horizon phase allows to avoid approximately 3,890 hip fractures, 209,761 cases of cataracts, 6,280 cases of diabetes mellitus. Diabetes mellitus, hip fractures, and cataract causes 77.91 million PLN (4,27 millions PLN for 100,000 patients) (Figure 5)."