The number of patients with chronic kidney diseases (CKD) is increasing worldwide and current trends in the prevalence of end-stage renal disease (ESRD) indicate that the population of ESRD patients around the globe is exceed 2 million patients. This increase in ESRD patients is being driven by an aging population plus an increase in the incidence of diabetes and other diseases causing kidney damage. Besides being a major health problem, CKD represents a major economic problem around the globe because of the high cost of renal replacement therapy (dialysis and transplantation). For these reasons and because there is a shortage of kidneys for transplantation, new methods of preventing and treating CKD must be developed to reduce the need of renal replacement therapy and to improve the overall health of patients with CKD.

Keto acids are amino acids without nitrogen. The non-essential keto acids metabolized without urea production. The ketoadsorption supplementation of a low protein diet is a logical leap forward in CKD treatment. There are numerous evidences on the favorable nutritional effects of Ketosteril (ketosid-ammonico) treatment in dialysis patients. Better quality of life and overall survival are attainable through improved nutritional status, which is also proved in practice.

OBJECTIVES

It is increasingly recognized that conclusions drawn from classical clinical trials are not always a useful aid for decision-making. Assessing the value of a drug or technology requires an understanding of its impact on current management in a practical, real-life setting. Our aim was to evaluate the real-life cost-effectiveness of Ketosteril treatment in dialysis patients in comparison with CKD treatment without Ketosteril treatment.

METHODS

A cohort calculation was presented on the basis of a representative patient and valid database from the Hungarian National Health Insurance Fund and Administration (NHIFA). NHIFA database uniquely includes health care utilization data (pharmaceuticals, in- and outpatient care services, labs, diagnostics, medical aids, sickness benefit) of the total population of Hungary. Since 2004, all financed health care services are strictly validated and use the same database structure.

Our retrospective analysis contains data of January 2004-January 2010 for all dialyzed patients with chronic kidney disease (CKD) and N18-19 code in ICD-10. The study population was selected through the following inclusion criteria:

- Continuous haemodialysis treatment after second quarter of 2004.
- Patients with at least two health care services (inpatient or outpatient care services) on relevant ICD-10 code (N18-19), during the study period.
- Patients were excluded as follows:
  - transplantation during the whole study period.
  - death after starting haemodialysis in a five months period.

CART module of R program was used (Classification And Regression Trees) to gain survival curves for relevant patient population subgroups. The algorithm of CART is selecting under the potential covariates to perform patients subgroup with statistically different survival curves. The selection is recursive and hierarchical, which assured the clarification of the covariant association.

Significantly (p<0,05) different survival curves on real life data were integrated to a Microsoft Excel platform decision tree model where the health-economic analysis was performed. Costs and health outcomes were registered and compute monthly. The Hungarian yearly discount rate of 5% was used for both costs and outcomes. The time horizon was clarified on the basis of the national health system. Exchange rate was 300 HUF/EUR. Main outcome of the analysis was incremental cost of life years gained (LYG). The pharmaco-economic analysis was conducted from a payer perspective.

RESULTS

Primary 14 347 CKD patients were detected, but after selection criteria altogether 13 615 patients' data were enrolled, that included 1 008 patients with Ketosteril treatment with a mean follow up of 35 months.

In case of categorical covariates Fisher test was performed, while numerical covariates were analyzed with correlation (both Pearson and Spearman correlation coefficient were calculated).

Distributions of covariates with significant effect were measured in the modeling arms, to capture differences between the compared patient groups. As Figure 1 show, probability distribution was comparable by age groups, gender (44% vs 44% female with Ketosteril) and comorbidity between the two study population. Since these parameters showed a homogeneous distribution and have the same effect on both therapeutically arms, these effect were not involved into the modeling phase.

The survival analysis detected significant (p<0,05) benefit with Ketosteril treatment (Figure 2).