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ABSTRACTS

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ECONOMIC EVALUATION OF TYPE 2 DIABETES MELLITUS TREATMENT STRATEGIES: A COST CONSEQUENCE ANALYSIS OF SITAGLIPTIN VS CONVENTIONAL TREATMENT IN ITALIAN REGIONS

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Introduction: Diabetes mellitus is a chronic degenerative disease associated with a high risk of chronic complications and comorbidities, with a significant impact in terms of both epidemiologic and economic burden.

Objectives: A cost consequence analysis, aimed at assessing the economic impact of sitagliptin (SITA) compared with sulfonylurea (SU) for the treatment of type 2 diabetes mellitus, was developed from both the Italian Regional Health Service (RHS) and societal perspectives.

Methods: A cost consequence analysis was carried out with the aim to compare DPP4i and SU, as second line therapy in add-on to metformin, in terms of costs and related clinical events. With the aim to capture all the direct and indirect effects related to both compared alternative treatments, the model allows to choose across different time horizons (from 6 to 36 months). As the analysis can be performed from both RHS and societal perspectives, both direct and indirect costs could be included. The following costs have been considered: drug, automonitoring glycemic control, visits, main diabetes' complications, and costs related to the switch to insulin therapy. In order to provide a realistic overview of the burden related to both therapeutic strategies, also complications have been considered in the analysis. With reference to this, it is important to highlight that both SU and SITA show the same efficacy in controlling blood glucose but different incidences in terms of hypoglicemic events and cardiovascular (CV) events. In particular, both severe and non severe hypoglicemic events and the four main CV events (myocardial infarction, stroke, cardiovascular death and revascularization) have been included. Local data were used, wherever available. Epidemiologic data have been collected through national and international literature. Efficacy data have been collected through clinical trials and meta-analyses. Resource consumption was quantified by using data from literature and, when not available, through experts' opinions. Regarding costs, national tariffs have been taken into account and, when not available, costs have been collected from literature. Indirect costs have been quantified by considering working days/working hours lost due to diabetes' complications, collected through available literature. In particular, indirect costs have been obtained by multiplying the number of days/hours of lost productivity by daily/hour wage. Finally the analysis has been validated by a group of experts in this area.

Results: By performing the analysis from the italian RHS perspective and considering 3 years time horizon on a cohort of 100 diabetic subjects, SITA+metformin represents a sustainable alternative and in some Regions (e.g. Lombardy) a cost saving alternative. From the societal point of view, the analysis shows that SITA+metformin strategy is a cost saving alternative in almost all Regions. This is related to a significant lower productivity loss due to major cardiovascular events and to hypoglicaemic events.

A strength of the model is represented by the possibility to capture long-term effects related to both alternative strategies that, in turns, shows how SITA can be considered a valid alternative especially by considering all the avoided complications related to SITA adoption. Also the possibility to include durability effects, indirect costs and different kind of costs can be considered a strength of the analysis as it allows the model user to perform and tailor the analysis on the basis of his own needs.

Conclusions: On the basis of the economic evaluation developed it is possible to state that SITA represents sustainable alternative for the management of diabetes from both clinical and economic perspectives.

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Keywords: Economic burden; Type 2 Diabetes mellitus; Direct and indirect costs.

Disclosures

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Conflict of interests: The Authors declare that they have no conflict of interest related to the abstract.

COST-EFFECTIVENESS ANALYSIS OF OLODATEROL VERSUS FORMOTEROL IN THE TREATMENT OF PATIENTS WITH MODERATE TO VERY SEVERE (GOLD II-IV) CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN ITALY

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Introduction: the current international guidelines for the treatment of chronic obstructive pulmonary disease (COPD) recommend regular treatment with a long-acting anticholinergic drug or a long-acting ß-agonist for patients with moderate to very severe COPD.

Objective: to evaluate the cost-effectiveness of olodaterol once daily versus formoterol twice daily in patients with GOLD II-IV chronic obstructive pulmonary disease (COPD) in Italy.

Methods: a Markov decision model with a 3-month cycle and a lifetime horizon was adopted. There are a total of 10 health-states in the model, including death. The other nine states correspond to combinations of one of three COPD severity stages (moderate, severe, and very severe COPD) and one of three exacerbation severities (no exacerbation, non-severe exacerbation, and severe exacerbation). Severity was based on post-bronchodilator FEV1 and transitions were based on outcomes of 1222.13 and 1222.14 clinical trials. Utilities were derived from EQ-5D scores evaluated in 1222.13 and 1222.14 clinical trials. Italian costs were obtained from literature and local sources. Uncertainty was assessed by deterministic and probabilistic sensitivity analysis.

Results: The incremental cost-effectiveness ratio (ICER) of olodaterol was €5,657.83/QALY and €5,802.37/LY versus formoterol. Probability of olodaterol being cost-effective at €40,000 per QALY/LY gained was 70%. Deterministic and probabilistic sensitivity analysis confirmed the base case results.
Conclusions: At willingness to pay thresholds of €40,000 per QALY/LY gained, olodaterol is cost-effective versus formoterol in the treatment of patients with GOLD II-IV COPD in Italy.
Keywords: COPD, Cost-effectiveness analysis, Olodaterol, Formoterol.
Disclosures
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Conflict of interest: The author has no conflict of interest.

COST-EFFECTIVENESS OF PAZOPANIB VERSUS SUNITINIB AS FIRST-LINE TREATMENT FOR LOCALLY ADVANCED OR METASTATIC RENAL CELL CARCINOMA FROM THE ITALIAN NATIONAL HEALTH SERVICE PERSPECTIVE

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Introduction: Based on direct head to head comparisons, pazopanib demonstrated 1) to be non-inferior vs sunitinib in terms of Progression Free Survival (PFS) as a first line therapy in patients with advanced or metastatic Renal Cell Carcinoma (mRCC) and 2) to be significantly preferred by patients after being exposed to both pazopanib and sunitinib.
Objective: This study aims to evaluate the cost-effectiveness of pazopanib versus sunitinib as first-line treatment of patients with mRCC, adopting the Italian National Health Service perspective and based on Progression free survival (PFS), Overall survival (OS) and non-study medical resource utilization (MRU) data from COMPARZ, utilities data from PISCES, and published Italian cost estimates.
Methods: A partitioned-survival model based on survival and disease progression reported in COMPARZ trial was developed. In the base case, both empirically reported OS and investigator-assessed PFS from COMPARZ were used for both drugs. Utility values from PISCES were used for the progression free period. Post progression utility was estimated to be 0.5509 based on the mean EQ-5D utility value after termination of second-line therapy in the sunitinib Phase III trial Protocol A6181034). Direct medical costs included: 1) medications costs, 2) routine follow-up care costs, 3) terminal care costs, and 4) medical costs associated to MRU. For each treatment strategy, the model generated expected Progression Free Life Years (PFLYs), post progression life years (PPLYs), overall life years (LYs), Quality adjusted life years (QALYs), costs. Comparative economic value was expressed in terms of the incremental cost per QALY gained and Net Monetary Benefit (NMB) of pazopanib vs. sunitinib. Probabilistic and deterministic sensitivity analyses (PSA&DSA) were planned to assess the impact on results of methodological and parameter uncertainty.
Results: Pazopanib dominates sunitinib, as it is expected to be associated with higher QALYs and lower costs. When NMB was evaluated with WTP thresholds of €30,000 and €50,000, a benefit of €8,766 and €10,665 is associated with pazopanib vs sunitinib, respectively. The probability of pazopanib being cost-effective versus sunitinib is 99%, 98% or 92% at cost-effectiveness thresholds of €20,000, €30,000 or €50,000 per QALY, respectively. Cost and QALY differences were in favour of Pazopanib in all the planned DSA scenarios.
Conclusions: This study suggests that pazopanib represents a cost-effective intervention compared with sunitinib as first-line treatment of mRCC in Italy. In order to quantify the net benefit to the Italian National Health System, the developing of a budget impact model is warranted.
Keywords: Cost-effectiveness, partitioned-survival analysis, pazopanib, Metastatic Renal Cell Carcinoma, Italian National Health Service.
Disclosures
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Conflict of interest: None declaired.

COST-BENEFITS AND BUDGET IMPACT OF IVABRADINE IN THE TREATMENT OF HEART FAILURE

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Introduction: Heart failure (HF) is a clinical syndrome characterized by symptoms such as water retention, dyspnea and fatigue. The population suffering from this syndrome in industrialized countries is 23%, while in Italy the prevalence is equal to 1% - namely approximately 600,000 patients (AGENAS).The burden of HF costs to the National Health System is significant, representing up to 2% of the national health expenditure in western countries; with the most considerable portion inherent to hospital admissions.
Objective: The objective of this research was to assess the incremental ratio between cost-effectiveness and cost-benefits of Ivabradine on top of standard treatment, versus placebo on top of standard treatment in patients suffering from chronic heart failure. Analysis has been conducted on the basis of effectiveness demonstrated by Ivabradine during SHIFT randomized and controlled trials. Assessments have been conducted by adapting, according to the population and organization system in Italy, a previously established Markov model for the presentation to national regulatory bodies.
Methods: Demographical and clinical characteristics of the Italian population have been collected from the RCT SHIFT and from the IN -HF Registry (data referring to actual Italian practices). Costs have been inferred by the electronic computer systems of the National Health System. All analysis have adopted the NHS perspective.
Results: With reference to the lifetime temporal horizon, our basecase (RCT SHIFT) assessments have confirmed that the adoption of Ivabradine is socially acceptable with a cost per QALY equal to € 17,434.86. Probabilistic sensibility analysis demonstrates that Ivabradine on top of standard treatment is cost-effective, by adopting a threshold of € 30,000 in over 87% of cases and in over 93% of cases adopting a threshold of € 40,000.
Conclusions: Results obtained for the Italian population and in the organizational context of the Italian National Health System have confirmed, as already confirmed by NICE, the evidence of social acceptability of Ivabradine treatment.
Keywords: Budget impact, Cost-effectiveness, Heart failure.
Disclosures
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A COMPARISON OF EQ-5D HEALTH-RELATED UTILITIES USING ITALIAN, UK, AND US PREFERENCE WEIGHTS IN A SAMPLE OF CROHN'S DISEASE PATIENTS

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Introduction: Weights associated to EQ-5D-3L represent preferences for health states elicited from general population's samples. Weights have not yet been calculated for every country; until recently, Italy has adopted UK weights, as many other developed countries. However, empirical research shows that cross-country differences exist. Up to now, very few studies have compared the impact of different country-based preference weights on given patients populations.

Objective: This empirical study aims at investigating the impact of Italian weights in comparison with UK and US scores on health-related utilities calculation using a sample of Crohn's Disease (CD) patients.

Methods: The study is based on a survey on health-related quality of life (HRQoL) in patients (n=552) affected by active CD, conducted in Italy from 2012 to 2013. Methods include: descriptive statistics, Kendall's tau rank correlation coefficients, ordinary least-square regression (OLS).

Results: Utilities computed through the Italian algorithm (mean: 0.76; standard deviation [SD]: 0.20; median: 0.81) are generally higher than US (mean: 0.69; [SD]: 0.22; median: 0.77) and UK (mean: 0.57; [SD]: 0.32; median: 0.69) utilities. UK preference weights result in the highest number of negative values (i.e. health-related quality of life perceived worse than death). All three values distributions are left-skewed due to very low scores associated with the most serious health states. Regardless the tariff set considered, OLS results highlight that more severe disease (Harvey Bradshaw Index >16) reduces the mean conditional EQ-5D-3L index ($p<0.0001$). Kendall's rank correlation between EQ VAS score and EQ-5D-3L index is positive ($p<0.0001$), despite patients tend to value more their HRQoL when responding to EQ-5D-3L questions than on EQ VAS scale.

Conclusions: Results reveal remarkable differences among the three national tariff sets and especially when severe health states occur, suggesting the need for country-specific preference weights when evaluating utilities. More research is needed to quantify the impact of national tariffs on cost-effectiveness analyses.

Keywords: EQ-5D, preference weights, utility values, VAS, Crohn's Disease.

Disclosures

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A NEW DECISION MODEL FOR ECONOMIC EVALUATION OF NOVEL THERAPIES FOR HCV

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Introduction: The dramatic prevalence rates of HCV observed in Italy and the high prices that are expected to be required by the pharmaceutical industry for more and more effective but also costly drugs, raise some critical issues about how to regulate access to such drugs.

Objective: The objective of this study is to present a new decision model for the evaluation of novel therapies for HCV. It is intended to provide a tool for the decision-maker that seeks to address the main issues related to the introduction new treatments.

Methods: The model follows the Bayesian approach, using data from reference literature for staging the action of treatments depending on the level of fibrosis (F0, F1, F2, F3, F4). The model is designed to consider patients with all genotypes and allows to make comparisons between innovative and traditional therapies (dual, triple, IFN free, PI combinations, etc.), for both experienced and naïve patients. In addition, the model is used to simulate mixed cohorts of patients, representing a population with HCV with different levels of fibrosis and different genotypes. To show the potential of the model, we created some simple scenarios assuming different levels of SVR and pricing. Lower SVR results in faster disease progression and higher probability to develop advanced liver disease. The model considers a lifetime horizon with annual cycles. The analysis has been performed under the National Health Service point of view, including only direct medical costs. Costs and outcomes have been discounted at a 3% annual rate.

Results: Even assuming an SVR rate of 100%, the administration of new treatments for HCV subjects F1 / 2 has an incremental cost-effectiveness ratio not sustainable. In contrast, for the subjects F3 and F4, low incremental SVR rates and an incremental cost of the innovative therapy of € 40,000 would be cost-effective.

Conclusions: The added value of this model is its applicability to diverse assessment needs. In addition, the model offers insights on how the industry will have to develop strategies for entering the market and offer sustainable prices for decision-makers and at the same time remunerate the investment in research and development.

Keywords: Economic Evaluation, Cost-effectiveness analysis, Cost-utility analysis, Markov Model, liver disease.

Disclosures

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ECONOMIC ASSESSMENT OF ELTROMBOPAG IN THE TREATMENT OF THROMBOCYTOPENIA

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Introduction: Thrombocytopenia is one of the most common complications of HCV and one of the main obstacles to possible treatment with antiviral therapy. Around 15% of patients undergoing antiviral therapy are found to be cytopenic. This complication has major repercussions on the patient's health, as it can lead to the withdrawal of antiviral therapy and hence disease progression, culminating in decompensated cirrhosis and hepatocarcinoma. Thrombocytopenic HCV patients currently have no choice but to stop interferon therapy or reduce the dose, with a consequent risk of a diminished sustained viral response (SVR).

Objective: This study assesses the cost-effectiveness of eltrombopag in the treatment of HCV-related thrombocytopenia.

Methods: A Markov model was constructed on the basis of the clinical trials ENABLE 1 and ENABLE 2. Three alternatives were considered: 1) Scenario 1: treatment with eltrombopag in both the enabling phase and during AVT, as in the ENABLE trial design. 2) Scenario 2: no eltrombopag treatment and no AVT. 3) Scenario 3: no eltrombopag treatment and subsequent administration of a reduced dose of peg-IFN. Low SVR results in faster disease progression and poorer quality of life. The model has a lifetime horizon with annual cycles. Both costs and benefits have been discounted at a 3% rate. Since the study was conducted under the Italian NHS perspective, only direct medical costs were accounted for.

Results: Base case results demonstrate that Scenario 1 is associated with a cost per QALY of €30,020.94 in comparison with Scenario 2. The ICER reaches a value of €32,752.44 per QALY when scenario 1 is compared with scenario 3.

Conclusions: The use of eltrombopag in HCV patients with thrombocytopenia is cost effective as leads to a reduction in disease progression and thus a drop in the number of patients with advanced liver disease.

Keywords: Cost-effectiveness, Economic evaluation, Markov Model.

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