11SG-003

STUDY OF THE USE OF INTRAVENOUS IMMUNOGLOBULINS DURING THE FOURTH QUARTER OF 2018 AND ANALYSIS OF ITS OFF-LABEL USE

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Background and importance The use of intravenous immunoglobulins (IVIg) has increased as a result of their therapeutic usefulness in a great number of diseases. Despite this, IVIg label indications remain limited, so it is interesting to study their off-label use.

Aim and objectives To describe the use of IVIg in our hospital for 3 months and to determine if they have been used for labelled indications.

Material and methods This was a retrospective study (October–December 2018) and a descriptive analysis of the use of IVIg per patient and clinical indication. Information was collected from the hospital's information systems and the computer records of the Farmatools software.

Results Eighty-nine patients received IVIg during the study period, with an average age of 61 years at the end of the study (3 months–86.7 years); there were 40 (45%) men and 49 (55%) women. When IVIg were used as replacement therapy, the dosage used was 200–400 mg/kg every 3–5 weeks. In the remaining indications, the dose used per treatment cycle was 1–2 g/kg divided over 2–5 days. IVIg were used for labelled indications in 80% of patients (71/89) compared with 20% for off-label indications (18/89). Among the latter, the indications were: demyelinating neuropathies (6/18), myasthenia gravis (2/18), myopathies (2/18), encephalitis/encephalomyelitis (2/18), Morvan syndrome (1/18), syndrome paraneoplastic (1/18), refractory atopic dermatitis (1/18), paraneoplastic dermatomyositis (1/18), scleroderma (1/28) and anti-synthetase syndrome (1/18).

Conclusion and relevance The use of IVIg in unauthorised indications was frequent (20%), mainly in the field of neurology. This justifies the development of a protocol for the use of IVIg in this field for those indications with more scientific evidence and more common use: demyelinating neuropathies, myasthenia gravis and myopathies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

11SG-004

ECONOMIC COMPARISON OF THERAPEUTIC ALTERNATIVES FOR FIRSTLINE TREATMENT OF MULTIPLE MYELOMA

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Background and importance A combination of daratumumab, bortezomib, melphalan and prednisone with daratumumab for maintenance (DVMP-D) has been authorised as a firstline treatment for patients with newly diagnosed multiple myeloma who are ineligible for stem cell transplantation (NDMM-NoT). An economic comparison of different alternatives available was performed, according to their economic impact.

Aim and objectives To develop an economic comparison among the therapeutic alternatives in NDMM.

Material and methods A bibliographic research was conducted in MEDLINE and EMBASE databases to identify treatment schemes with daratumumab, lenalidomide, bortezomib and thalidomide, or their combinations, in NDMM. Only authorised treatments used in clinical practice were selected. Efficacy was assessed as progression free survival. Randomised clinical phase II–III trials, which compared selected therapeutic alternatives in patients with NDMM-NoT, were included. Articles in Spanish or English language were selected. Costs of the first year of treatment were calculated from a National Health System perspective, using notified laboratory sale prices and including taxes (4% VAT) and a 7.5% rebate (in accordance with the national Royal Decree Law 8/2010). Associated direct costs in the first year were added. Incremental costs of each therapeutic alternative with respect to the reference was quantified. DVMP-D was taken as the reference in the cost incremental study.

Results Results of the systematic review included 593 studies. Nine trials were selected which analysed seven drug combinations: DVMP-D; bortezomib+melphalan+prednisone (VMP); melphalan+prednisone+thalidomide with thalidomide for maintenance (MPT-T); lenalidomide+dexamethasone for maintenance (RD); lenalidomide+dexamethasone for 18 cycles (RD18); melphalan+thalidomide+prednisone (MTP); and bortezomib+lenalidomide+dexamethasone with lenalidomide+dexamethasone for maintenance (VRD-RD). Daratumumab+lenalidomide+dexamethasone with daratumumab for maintenance was excluded for non-use by the National Health System (combination not funded). A visit to outpatients was estimated at 167€, according to the bibliography. Treatment costs for the first year were: DVMP-D 184 214€; VMP 44 435€; MPT-T 44 435€; RD 81 520€; RD18 81 520€; MTP 77 209€; and VRD-RD 104 850€. Regarding incremental costs, the most expensive scheme was the reference treatment (DVMP-D), followed by VRD-RD (–79 364€). The cheapest combination was MPT-T (–164 094€), followed by VMP (–139 779€).

Conclusion and relevance There are seven treatments, including daratumumab, lenalidomide, bortezomib and thalidomide for NDMM-NoT. The most expensive schemes for the first year of treatment are DVMP-D and VRD-RD; and the cheapest combinations are MPT-T and VMP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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11SG-005

ABC-VEN CROSSTAB ANALYSIS: A DECISION MAKING SYSTEM FOR ANTICANCER MEDICINES

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Background and importance Health systems have limited resources, and these should be used responsibly to optimise outcomes for patients. The ABC (pareto analysis for expenditure) and VEN (health impact) methodology was developed by the WHO to help hospitals evaluate current spending.

Aim and objectives A decision making system was developed for inventory management of chemotherapy agents and medicines to treat their adverse reactions (CA-MtADR). As these medicines are expensive, we formulated an ABC-VEN matrix

as a combination of two analytical tools, to produce a budget optimising management system.

Material and methods Dispensing data for the first 6 months of 2019 from the haematology, oncology and chemotherapy departments were collected. ABC analysis was performed: class A accounted for 72% of total expenditure, class B for 23% and class C for 5%. The VEN tool was further extended to a score index (summarising the characteristics of the health impact of the medicines) grouped into three classes: class V for vital, class E for essential and class N for non-essential medicines. Crosstab ABC-VEN analysis resulted in three major categories: I (AV, BV, CV, AE), II (BE, CE) and III (AN, BN, CN).

Result Fifty-seven CA-MtADR were analysed. Expenditure for CA-MtADR was 40% of the total expenditure for medicines in the hospital. According to the ABC analysis, 7 medicines (12%) were class A, 12 medicines (21%) class B, and 38 (67%) class C. According to the VEN analysis, 9 medicines (16%) were characterised as V, 43 (75%) as E and 5 (9%) as N. According to the ABC-VEN crosstab analysis, category I (eg, daratumumab (ATC L01XC24)) included 16 medicines (28%), category II (eg, trastuzumab emtansine (ATC L01XC14)) 36 medicines (63%) and category III (eg, pantoprazole (ATC A02BC02)) 5 medicines (9%).

Conclusion and relevance ABC-VEN crosstab analysis revealed three categories of corresponding priority: CA-MtADR category I, including expensive and/or vital medicines which need patient oriented personalised stock management; CA-MtADR category II, medicines which should be monitored with special consideration to ensure availability (because they are essential); and CA-MtADR category III, medicines where stock is according to demand (due to low price). ABC, VEN and ABC-VEN analysis can assist in developing a robust approach to improve budgetary planning in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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1ISG-006 EFFECTIVENESS EVALUATION OF HIGH COST DRUGS FOR ADVANCED NON-SMALL-CELL LUNG CANCER: REAL WORLD EVIDENCE, COMPLIANCE WITH CLINICAL PRACTICE GUIDELINES AND ECONOMIC EVALUATION

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Background and importance Lung cancer has a poor prognosis and is the most common cause of cancer death. In Italy, lung cancer is the third most common cancer. Treatment decisions are based on the histology and molecular characteristics of the tumour. Treatment options for non-small-cell lung cancer (NSCLC) are targeted therapies (tyrosine kinase inhibitors (TKIs)), immunotherapy or chemotherapy.

Aim and objectives To analyse drug effectiveness for advanced NSCLC in our hospital, to assess compliance with clinical practice guidelines and to perform an economic evaluation.

Material and methods We identified all patients with advanced NSCLC treated with high cost drugs (pemetrexed, erlotinib, gefitinib, afatinib, osimertinib, crizotinib, pembrolizumab and nivolumab) from 1 May 2016 to 30 April 2018. Patients were stratified by age, gender, therapy, ECOG (Eastern

Cooperative Oncology Group) performance status (PS) and type of cancer treatment (targeted therapy, immunotherapy or the historical standard of care, pemetrexed). We assessed progression free survival (PFS) and overall survival (OS) with the Kaplan–Meier method. We assessed compliance with Italian clinical practice guidelines and we analysed drug costs.

Results We found 92 cases of NSCLC; 70% were men and mean age was 65 years. We found that 50% were treated with pemetrexed, 30% with immunotherapy and 20% with targeted therapy; 61% were firstline treatments. Median PFS was 4.3 months and median OS was 8.6 months. Targeted therapy was most likely to improve PFS (5.9 months), followed by pemetrexed (4.3 months) and immunotherapy (2.9 months). Targeted therapy was similarly best for OS outcome (15.3 months), followed by immunotherapy (11 months) and pemetrexed (8.6 months). After patient stratification, there was no statistically significant difference between age, gender or therapy groups. PS was an indicator of better prognosis: cases with a baseline PS score of 0 (75%) were associated with longer PFS (5.5 months) and OS (11 months). Compliance with clinical practice guidelines was high. Afatinib and gefitinib were the least expensive TKIs. Nivolumab was less expensive than pembrolizumab.

Conclusion and relevance TKIs for the management of NSCLC are cost effective. Afatinib is an important firstline option for EGFR mutation positive NSCLC. Gefitinib can be an effective secondline therapy. Pemetrexed can still be recommended for EGFR and ALK wild-type non-squamous advanced NSCLC. However, our analysis suggests a limited effectiveness of immunotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-007 NEW CANCER DRUG APPROVALS IN PORTUGAL

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Background and importance In Portugal, all new drugs, after EMA approval, undergo a national health technology assessment process to decide their reimbursement status, by the SNS (Portuguese National Health System).

Aim and objectives The objective of this study was characterisation of the drug approval processes for cancer drugs by the INFARMED (Portuguese Regulatory Agency).

Material and methods The 10 latest drugs approved for different types of cancer were analysed, considering their therapeutic indication, type of economic analysis performed and efficacy outcome.

Results This analysis was performed in October 2019. The 10 latest cancer drugs approved (midostaurin, olaparib, brentuximab vedotin, pomalidomide, durvalumab, venetoclax, ixazomib, alectinib, atezolizumab and cabozantinib) are for use in refractory disease (60%), firstline treatment of metastatic disease (20%) and maintenance therapy in patients who have not progressed after firstline therapy (20%). A cost utility analysis was made for seven drugs, cost efficacy for two drugs and a cost minimisation analysis for two drugs (one of the drugs had two types of analysis as there were two different groups of patients). The efficacy outcome considered was overall survival in 60% and progression free survival in 30%. One evaluation considered overall response. The average HR for the