Conclusion and relevance BM expenditure increased by more than 50% in the last five years, with MAb being mainly responsible. The biological active substances with the highest budgetary impact were medicines to treat immune mediated diseases. The incorporation of BS will lead to a reduction of 20% in BM costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 2: Selection, procurement and distribution

OFF-LABEL DRUGS: USE ANALYSIS AND PHARMACOEPIDEMIOLOGY IN A COVID CENTRE IN ROME

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Background and importance The coronavirus pandemic has involved the sudden management of innovative therapeutic opportunities to counter it. A drug’s off-label use has required a sudden supply and the production of legislation to settle such handling to target real data towards a shareable and objective data collection flow.

Aim and objectives The aim of the study was to analyse the supply process of off-label drugs and reference to the national legislation for each medicinal product, regarding consumption data and the number of COVID-19 patients treated in a COVID centre in Rome, with 200 COVID beds and 40 beds in two intensive care units.

Material and methods For the following products, the supply and handling data were analysed from 1 February 2020 to 31 July 2020: chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colecitast, raltegravir and tocilizumab. The AIFA’s reference regulations of these drugs were highlighted in the same period. Pharmacoepidemiological data were obtained.

Results The drug’s off-label request was first considered. After the AIFA’s decision to include in the 648/96 Law (GU 69 17.03.2020) chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colecitast, the UOC Pharmacy drafted a specific request form according to the 648/96 Law, to convey the supply and distribution of drugs to the departments through a reporting channel as the regulations required. 10 658 tablets of lopinavir/ritonavir were given to 250 patients, 660 tablets of darunavir/colecitast to 32 patients, 302 150 tablets of hydroxychloroquine to 350 patients and 330 tablets of chloroquine to 33 patients. Raltegravir tablets were obtained for compassionate use for one patient. Tocilizumab was introduced through an off-label company procedure. Later, the centre was included in the TOCVID-19 clinical trial (19 March 2020) and patients were moved to the clinical trial. During the off-label use period, 54 therapies were provided and 34 of these required a second dose. From an analysis of the epidemiological data, 80% of patients had at least one comorbidity and age over 75 years; 60% were men. Death occurred in 6% overall, with a 30% death rate for patients over 75 years, according to national data.

Conflict of interest No conflict of interest

POSITIONING OF DORAVIRINE IN THE PHARMACOTHERAPEUTIC GUIDE OF A THIRD LEVEL HOSPITAL

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Background and importance Recently, the EMA and AEMPS have approved the use of doravirine (DOR) a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class. At present, the therapeutic arsenal available in Spain presents various options within each class.

Aim and objectives To position DOR within the antiretroviral therapies (ART) already available in the hospital’s pharmacotherapeutic guidelines and assess its incorporation.

Material and methods A bibliographic search was conducted on DOR’s positioning in the main national and international guidelines with the following terms: HIV, adults and guidelines; GESIDA (Spain); DHHS (American) and EACS (European). Possible advantages with respect to the ART already available in hospital were analysed. In addition, an economic evaluation was conducted comparing with available ART and the potential patients who would benefit from its use. The official list price was used with the deduction described in the Royal Decree Law 8/2010 as well as 4% VAT.

Results Gesida guidelines (July 2020) recommended the combination DOR+FTC/TAF or DOR/3TC/TDF (not yet marketed in Spain) as an alternative to the preferred regimens (C-I), but never as the initial therapy. On the other hand, the DHHS guidelines (June 2020) recommended DOR as the initial regimen in certain clinical situations. EACS guidelines (2019 update) recommended it as an initial regimen in combination with two NRTIs or as DOR/3TC/TDF.

The main advantages of DOR are: efficacy in high viral loads (rilpivirine (RVP) is not effective), lower potential for drug interactions, lack of food restrictions, fewer adverse effects on the CNS compared with efavirenz (EFV) and a neutral lipid profile (avoiding dyslipidaemia induced by EFV or boosted protease inhibitors).

The number of patients undergoing treatment with NNRTIs in our hospital was 322 (n=1894 total active HIV positive...
Background and importance A greater benefit was suggested with early treatment with remdesivir against COVID-19. Aim and objectives To develop a systematic review and methodological interpretation of subgroup analyses according to timing of use of remdesivir in COVID-19.

Material and methods A bibliographic review in MEDLINE was conducted up to 10 October 2020. The ‘Clinical Queries/ Narrow’ tool was used with the search strategy: ((Therapy/ Narrow[filter]) AND (remdesivir AND COVID)). Randomised clinical trials (RCTs) with subset analysis about early and late use of remdesivir (≤10 vs >10 days from symptom onset, or ≤9 vs >9 days) were selected. The rest of the studies were excluded. All endpoints with subgroup analysis regarding timing of remdesivir use were assessed. Two methodologies were applied. The first considered statistical interaction among subsets, prespecification, biological plausibility and consistency of the subgroup analyses of similar RCTs. The second methodology was a validated tool with preliminary questions to discard subset analysis without minimal relevance, and a checklist. This checklist assigned a score related to a recommendation for applicability of subgroup analysis in clinical practice.

Results 20 results were found after review; 16 studies were excluded because they were not RCTs and 1 study had no results were found after review; 16 studies were excluded because they were not RCTs and 1 study had no.

Conflict of interest No conflict of interest

Abstracts

2SPD-031 SUBGROUP ANALYSIS ABOUT EFFICACY OF EARLY USE OF REMDESIVIR IN COVID-19
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Background and importance Multiple therapeutic alternatives are used in untreated metastatic squamous non-small cell lung cancer (umSNSCLC). Paclitaxel–carboplatin–pembrolizumab combination (PC-pembrolizumab) has recently been authorised for this indication.

Aim and objectives To assess the comparative efficacy among different therapeutic alternatives used in mSNSCLC through a network meta-analysis (NMA).

Material and methods A search was conducted on 19 February 2020 with the following inclusion criteria: phase II/III randomised clinical trials (RCT), including drugs used in umSNSCLC, and overall survival (OS) as the efficacy endpoint. Exclusion criteria: mSNSCLC population with EGFR or ALK mutations and RCTs without a comparator common to the evaluated alternatives. Pooled hazard ratios (HR) were calculated by Bayesian methods, through the combination of direct and indirect evidence by the NMA. The agreement of direct and indirect estimations was assessed by node splitting models to evaluate the consistency of NMA. Delta value, maximum acceptable difference as clinical criterion of non-inferiority, was set at 0.70 (and its inverse, 1.43), used to calculate the sample size in the PC-pembrolizumab trial.

Results Nine RCTs were selected. PC was the common comparator. The DIC value for the fixed effects model was more favourable. No statistically significant differences between direct and indirect evidence were found, and therefore NMA was consistent. The PC-pembrolizumab combination was considered as the reference (treatment with the greatest magnitude of effect). HR for OS were: 1.4 (95% CI 0.89 to 2.3) versus carboplatin–gemcitabine; 1.6 (1.2 to 2.1) versus PC; 1.5 (1.1 to 2.1) versus nab–PC-atezolizumab; 1.8 (1.3 to 2.5) versus PC–figitumumab; 1.4 (0.96 to 2.0) versus PC-motesanib; 1.3 (0.66 to 2.5) versus PC-nectumumab; 2.1 (0.86 to 5.0) versus PC-olaratumab; 2.9 (1.7 to 4.8) versus PC-sorafenib and 1.2 (0.82 to 1.7) versus pembrolizumab monotherapy. Carboplatin–gemcitabine, PC-motesanib, PC-nectumumab, PC-olaratumab and pembrolizumab did not present statistically