RESULTS:

In 2007, the use of eculizumab was approved by the United States Food and Drug Administration and the European Medicines Agency. In Brazil, despite the provision of eculizumab through judicial proceedings since 2009, the manufacturer of eculizumab only requested a licence for it in 2017, after several meetings with the government when the company agreed to provide the drug at approximately half the price of the imported product. The efficacy of eculizumab in PNH patients was assessed in one randomized, placebo controlled study, one single arm study, and one long-term extension study. The drug reduced hemolysis and the need for transfusion, although the studies had methodological problems. The efficacy of eculizumab in the treatment of aHUS was assessed in four prospective, controlled open-label studies, two long-term extension studies, and one retrospective study. Eculizumab normalized platelet counts and reduced the need for plasmapheresis, although the studies had no control group. Eculizumab was well tolerated, with no meningococcal infections occurring after patients were immunized.

CONCLUSIONS:

Some companies have no interest in licensing their products in Brazil because their provision by judicial proceedings is more lucrative. This situation promotes litigation and irrational prescription of drugs, and also obligates the Brazilian government to import expensive health products.

PD66 Indirect Comparison Of Treatments For Metastatic Melanoma

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INTRODUCTION:

Vemurafenib plus cobimetinib (VC) for the treatment of metastatic melanoma was requested to be included in the National Formulary in Uruguay. The standard of care for metastatic melanoma in Uruguay is dacarbazine. There is no published head-to-head trial assessing the effects of VC versus dacarbazine. The objective of this study was to perform an indirect comparison of the effects of dacarbazine, compared with VC, based on the results of trials that included both treatments versus the same comparator (vemurafenib alone).

METHODS:

We searched Pubmed and The Cochrane Library for trials comparing either VC or dacarbazine with vemurafenib. Trials were assessed in terms of risk of bias, similarity of interventions and inclusion and exclusion criteria, and comparability of characteristics of patients in the vemurafenib arm. We performed an indirect comparison using the Bucher method.

RESULTS:

From the literature search we retrieved two studies that met the inclusion criteria: a randomized clinical trial that assessed VC versus vemurafenib or placebo and another assessing dacarbazine versus vemurafenib. Both studies were similar in terms of methodological quality, inclusion and exclusion criteria, and comparability of the vemurafenib arms. However, the comparison of overall survival and progression-free survival curves for the vemurafenib arms were quite different between the two trials. At 9 months, overall survival was eighty-one percent and fifty-five percent and progression-free survival was thirty percent and fifteen percent, respectively. The indirect comparison provided the following hazard ratios: 0.24 (95% confidence interval [CI]: 0.14–0.48) for overall survival; 0.13 (95% CI: 0.09–0.19) for progression-free survival; and 0.15 (95% CI: 0.02–1.29) for grade 4 adverse events.

CONCLUSIONS:

Treatment with VC increased overall survival and progression-free survival, compared with dacarbazine. Severe adverse events were less frequent with the combined therapy. However, the differences in the vemurafenib survival curves increases doubts about the accuracy of the indirect estimators of overall survival and progression-free survival.

PD67 Strengthening And Accelerating Health Technology Assessments Through Artificial Intelligence

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