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Leveraging Clinical Data Warehouses to Measure Impact of Update Prescription Guidelines of Polyvalent Immunoglobulins in 2018 in France

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Abstract. In France and in other countries, we observed a significant growth in human polyvalent immunoglobulins (PvIg) usage. PvIg is manufactured from plasma collected from numeral donors, and its production is complex. Supply tensions have been observed for several years, and it is necessary to limit their consumption. Therefore, French Health Authority (FHA) provided guidelines in June 2018 to restrict their usage. This research aims to assess the guidelines' impact of the FHA on the use of PvIg. We analyzed data from Rennes University Hospital, where all PvIg prescriptions are reported electronically with quantity, rhythm, and indication. From the clinical data warehouses of RUH, we extracted comorbidities and lab results to evaluate the more complex guidelines. We globally noticed a reduction in the consumption of PvIg after the guidelines. Compliance with the recommended quantities and rhythms have also been observed. By combining two sources of data, we have been able to show an impact of FHA's guidelines on the consumption of PvIg.

Keywords. Retrospective study, Polyvalent Immunoglobulins, monitoring, clinical data warehouse

1. Introduction

Worldwide, there is a significant growth in PvIg usage. Therefore, supply tensions have emerged, for now, since several years [1]. In France because of blood product safety regulations, PvIg are submitted to a traceability procedure. The prescription and administration of the PvIg are therefore well controlled and monitored. However, this drug is frequently out of stock and subject to regular guideline usage to prioritize diseases and relevant clinical cases. In France, the FHA gave more restrictive new indications in June 2018. The second guideline update was performed in April 2019. In the context of monitoring the appropriate usage of PvIg consumption after these new guidelines, we conducted a retrospective study on PvIg in Rennes University Hospital (RUH). We assessed the impact of FHA guidelines at several levels. First, we measured consumption

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by patient-year, and then we evaluated the appropriateness of quantities and rhythms according to the guidelines.

2. Materials and Methods

At RUH, traceability procedure is conducted by pharmacists who fill a form for each PvIg prescription. For this study, we collected PVIg administrations for patients in RUH between 1 January 2013 and 31 December 2022. Patient identification, weight, PvIg dosage received, rhythms, and indication (pathology) were available through a database recording all filled PVIg prescription forms. We also used the clinical data warehouse of RUH to collect more data like comorbidities and lab results. We standardized the disease names and the received quantity of PvIg. Some guidelines require a threshold on a lab dosage or comorbidity such as kidney failure. We observed the evolution of the consumption of PvIg within the RUH at two levels; overall in the entire hospital and by ward (neurology, hematology, and internal medicine).

3. Results, Discussion and Conclusions

More than 1,500 unique patients received at least one dose of PvIg at RUH between 2013 and 2020. The number of prescribed doses per year declined after the publication of the guidelines in June 2018 from 2,465 to 2,276. For Hematology and internal medicine, we noticed a decrease in both the treated patients and the quantity of PvIg just before the first guidelines (probably because of out-of-stock). For neurology, the number of patients who have received PvIg is growing, but the quantity is stable. For all wards, the consumption is growing up since 2022. For a secondary criterion, we achieved cross databases (PVIg prescription database of pharmacists and clinical data warehouse of RHU). We found a better compliance to guidelines on this criterion after guidelines (78% of compliance before guidelines to 86% after guideline). The impact of guidelines on diseases with a small number of patients is complex to assess. Overall, the impact of guidelines on the drop in PvIg consumption is difficult to assess because of several other factors, such as out-of-stock periods and the COVID-19 pandemic. Similar study was recently performed in Catalonia (Spain) [2]. They observed that the mean consumption decrease between 2020 and 2021 but it is probably due to COVID-19 (not observed in our study). It could be interesting to expand the study to a multi-centric analysis by using clinical data warehouse in other hospitals to bring a better overview of pathologies with a small number of patients.

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