Background: LZD is approved for FDA label and Belgian Summary of Product Characteristics (SmPC) for the treatment of SSTI and pneumococci caused by Gram-positive organisms (mainly MSSA and VRE) only. No SmPC recommendations are given for infections also positive LDA for osteomyelitis and as an alternative for CNS infections and bacteremia (CCID 2012; 52; n=385). LDA is limited by adverse events, the incidence of which may vary according to the lengths and conditions of therapy. The aim of this was to describe LDA actual use and on-set of adverse events in real-life clinical practice.

Methods: Observational, retrospective study in 4 Belgian hospitals [about 4,000 beds] over 1 year (2016). Analysis of medical files (248 treatments) to collect information on (i) patient’s characteristics and treatment modalities, (ii) occurrence, causality, and severity of adverse drug reactions (ADR), and (iii) concomitant medications (increasing the risk of developing a serotonin syndrome [SS]).

Results: Only 18 % of prescriptions matched the indications approved in the US and in the Belgian SmPC, but 47% of those matched the indications approved in the US and in the Belgian SmPC, but 47% of those matched the indications approved in the US and in the Belgian SmPC, but 47% of those matched the indications approved in the US and in the Belgian SmPC. ADRs were observed in 18/44 cases for patients with in-label indications, 13/30 (43%) for patients with IDSA indications, and 30/127 (26%) for patients with other indications. Treatment > 10 days was the only significant risk factor for OPC (Kaplan-Meier; p<0.005 [Mann-Whitney]). 8 cases of CNS ADR were reported. Although 40% of Belgian label indications, 41/116 for patients with IDSA indications, and 30/127 for patients in FDA label) and was observed in 18/44 cases for patients with in-label indications, 13/30 (43%) for patients with IDSA indications, and 30/127 (26%) for patients with other indications. Treatment > 10 days was the only significant risk factor for OPC (Kaplan-Meier; p<0.005 [Mann-Whitney]). 8 cases of CNS ADR were reported. Although 40% of prescriptions were at least 1 drug, increasing ≤5 risk, ≤5 was actually observed in only 1 patient.

Conclusion: LDA is mainly used for off-label indications, some of which, however, are in the IDSA recommendations. The high incidence of ADR (41%) as well as the frequency of use of co-medications putting patients at risk of SS highlight the importance of follow-up for LZD-treated patients. A prospective study will be started to further identify potential risk factors.

INTRODUCTION & OBJECTIVES

The anti-Gram-positive antibiotic linezolid (LZD) has been introduced on the market in 2000 with limited indications. Due to its excellent bioavailability (favoring patient’s discharge) and activity against Gram-positive isolates resistant or less susceptible to first choice drugs (i.e., lactams, vancomycin, …), it is often used off-label. However, it can also lead to severe adverse drug reactions (ADR) such as hematological or neurological disorders, or a serotonin syndrome (SS) which associated with serotoninergic drugs.

The objectives of our study were to assess
- the real use of LZD in Belgian hospital centers,
- the nature, time of onset, and frequency of LZD-induced ADRs

RESULTS

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RESULTS

Analysis of medical files from patients treated with linezolid between January 2016 and December 2016 in 4 Belgian Hospitals (3 University hospitals; 1 general hospital).

Main collected information:
- key patient’s characteristics (age, sex, weight, renal function)
- treatment indications (in comparison with approval labels and IDSA guidelines)
- type and resistance pattern of the reported causative organism(s)
- adverse drug reaction data (noted against a predefined list based on Belgian SmPCs and FDA PI labels)
- Statistical analysis performed with SPSS version 25.

MAIN METHODS

Linezolid was mainly used off-label if considering the FDA and Belgian approval indications, but more often in-label according to IDSA guidelines.

Hematological (thrombocytopenia, anemia) and other ADRs were observed with a much larger frequency than indicated in the Belgian SmPC or the FDA label, which should encourage closer follow-up of patients treated with LZD.

Serotonin syndrome was uncommon (<1%) despite the high proportion of patients (40%) to whom a serotoninergic drug had been co-prescribed.

REFERENCES


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