Ganciclovir use evaluation in kidney transplantation

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Abstract

Objective: In this study, we evaluated certain aspects of the usage and administration of one lifesaving, high cost medication, i.e., Ganciclovir for the prevention and treatment of cytomegalovirus (CMV) infection in transplant patients.

Methods: This study was performed from 2013 to 2015 by conducting a medication use evaluation (MUE) program in the kidney transplantation departments of two tertiary care hospitals in Isfahan, Iran. The MUE criteria for the drug were developed by applying drug information references. In every category of data, the number (percent) of cases, in which drug therapy was in accordance with the predetermined criteria, was calculated.

Findings: During the study period, 67 cases were observed. The only documented drug interaction was the minor interaction of Ganciclovir with mycophenolate mofetil in 77% of the patients. In all patients, intravenous (IV) infusion was the route of administration, mainly in the peripheral veins. Four patients showed adverse drug reaction, which leads to Ganciclovir discontinuation. Ganciclovir was administered despite contraindication in 34.3% of the patients.

Conclusion: In this study, we faced a relatively unacceptable situation, in which Ganciclovir is handled somehow inappropriately. It seems necessary to develop an updated local guideline to approximate the administering pattern of such costly medications to standard protocols.

Keywords: Cytomegalovirus; Ganciclovir; kidney transplantation; medication use evaluation.

1. Introduction

Medication use evaluation (MUE) is a continuous and structural analysis of drugs usage, which is routinely authorized and managed by an interdisciplinary team.[1] This process involves a comprehensive review of practitioner prescribing, pharmacist dispensing, nurse administering, and patient use of medication.[2] By comparing the actual status of drug use to predetermined standards, MUE can detect inappropriate or unnecessary drug therapy. MUE findings may help health care systems to improve prescribing patterns and optimize the use of scarce resources.[3,4] Pharmacists as an integral participant of MUE programs can improve the quality of patients care by preventing unnecessary or inappropriate medication usage and adverse drug reactions.[5‑7] MUE programs should be planned to include the drugs considered to be problematic if not used correctly or the drugs prescribed to be used for specified diseases or special populations. Organ transplant recipients receive immunosuppressive regimens which put them at an increased risk for opportunistic infections such as cytomegalovirus

(CMV). Ganciclovir is the medication mostly used to prevent or treat CMV infection in this patient population.[8,9] No comprehensive study has yet been done to assess the usage pattern of this antiviral drug in the hospital wards. We designed this study as a MUE program to address certain aspects of Ganciclovir use, namely, adverse reactions, contraindications, drug interactions, and its administration by nurses.

2. Methods

This study was designed as a prospective cohort from 2013 to 2015 to characterize the usage pattern of Ganciclovir in concordance with the predefined assessment criteria by conducting a MUE program in the kidney transplantation departments of two tertiary care university-affiliated hospitals in Isfahan, Iran. Assessment criteria were developed to evaluate the appropriateness of Ganciclovir use by applying the Ganciclovir package insert and Lexicomp® drug information handbook. A pharmacist performed data collection in the wards by reviewing patients' medical documents and charts and laboratory findings, as well as observing the nurses' performance regarding drug storage, handling, and preparation for administration. The collected data were categorized and analyzed using Statistical Package for Social Sciences software, version 20.0, for Windows (SPSS, Chicago, IL, USA). In every category of data, the number (percent) of cases, in which drug therapy was in accordance with the predetermined criteria, was calculated.

3. Result

During the study period, 67 cases were observed. The only documented drug interaction was the minor interaction of Ganciclovir with mycophenolate mofetil in 77% of the patients, which is not a clinically important interaction. In Ganciclovir handling, nurses did not observe the precautions regarding hazardous agents [10] (wearing gloves, glasses, mouth mask, and using laminar air flow hood). According to Ganciclovir package insert,[11] after dissolving the dry substance, the solution can be stored at room temperature and can be used within 12 h; while the diluted infusion solution should be kept in refrigerator and should be used within 24 h. However, in these wards, after Ganciclovir powder reconstitution, the solution was stored in refrigerator for at least 24 h and further dilution with normal saline or dextrose water took place before administration. During a short time of study period (from June 2013 to October 2013) because of drug resources' shortage in the country and also considering the cost, nurses had to store reconstituted vials for 72 h; however, thereafter, owing to relatively better situation regarding drug supply, the storage time was reduced to 24 h. In all patients, IV infusion was the route of administration; however in three cases, Ganciclovir was infused within <1 h. As recommended in drug information references,[12] Ganciclovir should be infused only into the central veins with good blood flow, but our nurses' choice was mainly the peripheral veins. In most cases, the set of infusion was flushed with normal saline before drug administration, but in some cases, the set of infusion was flushed only if the patient needs to receive

another parenteral drug, using this set. While it is emphasized that Ganciclovir should be administered postdialysis, this rule was not followed in one case. From 67 patients, four patients showed adverse drug reaction (two cases of neutropenia and two cases of thrombocytopenia), which leads to Ganciclovir discontinuation. Ganciclovir was administered despite contraindication (hemoglobin <8 g/dL) in 34.3% of the patients.

4. Discuss

MUE studies can recognize inappropriate and/ or unnecessary high‑cost drug therapies by comparing the actual status of medication use with predetermined standards or guidelines. When problems are identified, interventions are designed and implemented to improve drug use, which mainly include conducting educational programs, provision of drug information, making change in hospital policies and procedures, or changes in the drug formulary.[13,14] Establishing the MUE process in hospitals is the key way to promote effectiveness and safety of drug therapy, while optimal medication therapy can lead to improved patient outcomes and minimized overall costs.[14] This study is the first MUE on Ganciclovir in kidney‑transplanted patients. The purpose was to study the pattern of utilization in our hospitals for this high‑cost medication. Ganciclovir is used in the transplantation centers of Iran since many years ago; however, by conducting this study, we faced a relatively unacceptable situation, in which the medication is handled somehow inappropriately by nursing staff. It seems necessary to develop and implement an updated local guideline to approximate the administering pattern of such important and highly used medications to standard protocols. Additional opportunities to improve the medication use may exist through health‑care staff

education. Pharmacists can ease this process by addressing areas which need improvement through conducting and re‑evaluating the MUE processes.[15].

5. References

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