Comparative Study Between Brand and Generic Imatinib Mesylate Using Molecular Genetic Analysison CML Libyan Patients

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INTRODUCTION

Chronic myeloid leukemia (CML) is a hematological malignancy characterized by the presence of the Philadelphia chromosome, resulting in the abnormal fusion protein BCR-ABL1. Imatinib, a tyrosine kinase inhibitor, has revolutionized the treatment of CML. However, the availability of generic versions of Imatinib raises concerns regarding their therapeutic equivalence to brand-name counterparts.

AIM

The ability of imatinib mesylate400mg to achieve the molecular genetics response through RT-PCR among the CML– chronic-phase patients compared with brand imatinib and to evaluate the molecular structures and chemical properties of the generic utilizing ultraviolet (UV) spectroscopy, Fourier transform infrared (FTIR), and fluorescence techniques.

DESIGN

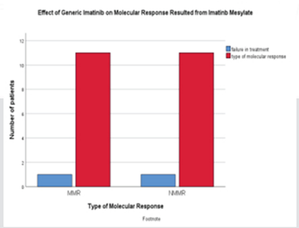
This retrospective study was conducted in Libya on CP CML patients registered at adult oncology outpatient department from January 2005 to December 2020.

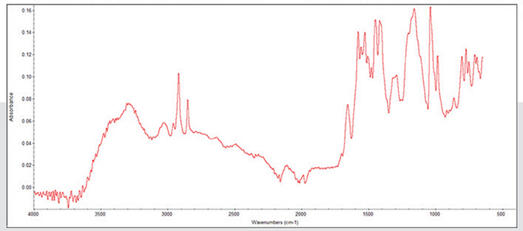
PATIENTS

Sixty-seven CML patients from Libya were enrolled in this comparative study. The median age was 41 (18–75) years; 34 were women (50.7%), 33 were men (49.3 %); median duration time of follow up, 70 months (12–180).Patients were divided into three groups: Group A received brand imatinib (n=28);Group B, generic imatinib (n=15);and Group C, both generic and brand imatinib (n=24).

RESULTS

Results of the RT-PCR analysis demonstrated no significant difference in the molecular response.In Group A(P>0.05) 12(50%) patients achievedmajor molecular remission when on brand; 1(8.33%) patient exhibited failure of treatment when switched to generic. The reduction in BCR-ABL1 transcript levels, indicative of treatment response, was comparable among all groups. Additionally, the physicochemical analysis of the Imatinib samples using UV spectroscopy, FTIR, and fluorescence techniques revealed no significant differences in their spectral patterns and fluorescence emission characteristics among the brand andgeneric. These findings indicate comparable molecular structures and chemical properties of generic and brand imatinib, regardless of the treatment regimen.





FTIR Spectra of Imatinib Mesylate capsules (Aqvida)

CONCLUSIONS

The therapeutic equivalence of generic imatinib reinforces its potential as a cost-effective alternative for CML treatment in resource-constrained settings like Libya.

ACKNOWLEDGEMENTS

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