



# SAFETY BETWEEN THE USE OF COMMERCIAL AND GENERIC IMATINIB: IS THE EXCIPIENT RELEVANT?

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## BACKGROUND



Imatinib (IM) is a tyrosin kinase inhibitor approved to treat chronic myeloid leukemia (CML) and others diseases. This drug can be administrated in commercial and generic formulations. Not all generic formulations are exactly designed as the commercial drug because not always the excipient is the same. In our hospital, we change imatinib from commercial to generic in June of 2016.

## PURPOSE



The aim of our study is to analyze if there are significant differences in terms of safety between the use of commercial and generic formulations of imatinib since one of June of 2016 to September of 2018 in our hospital and to compare if tolerance changes when the excipient is changed.

## MATERIAL AND METHODS



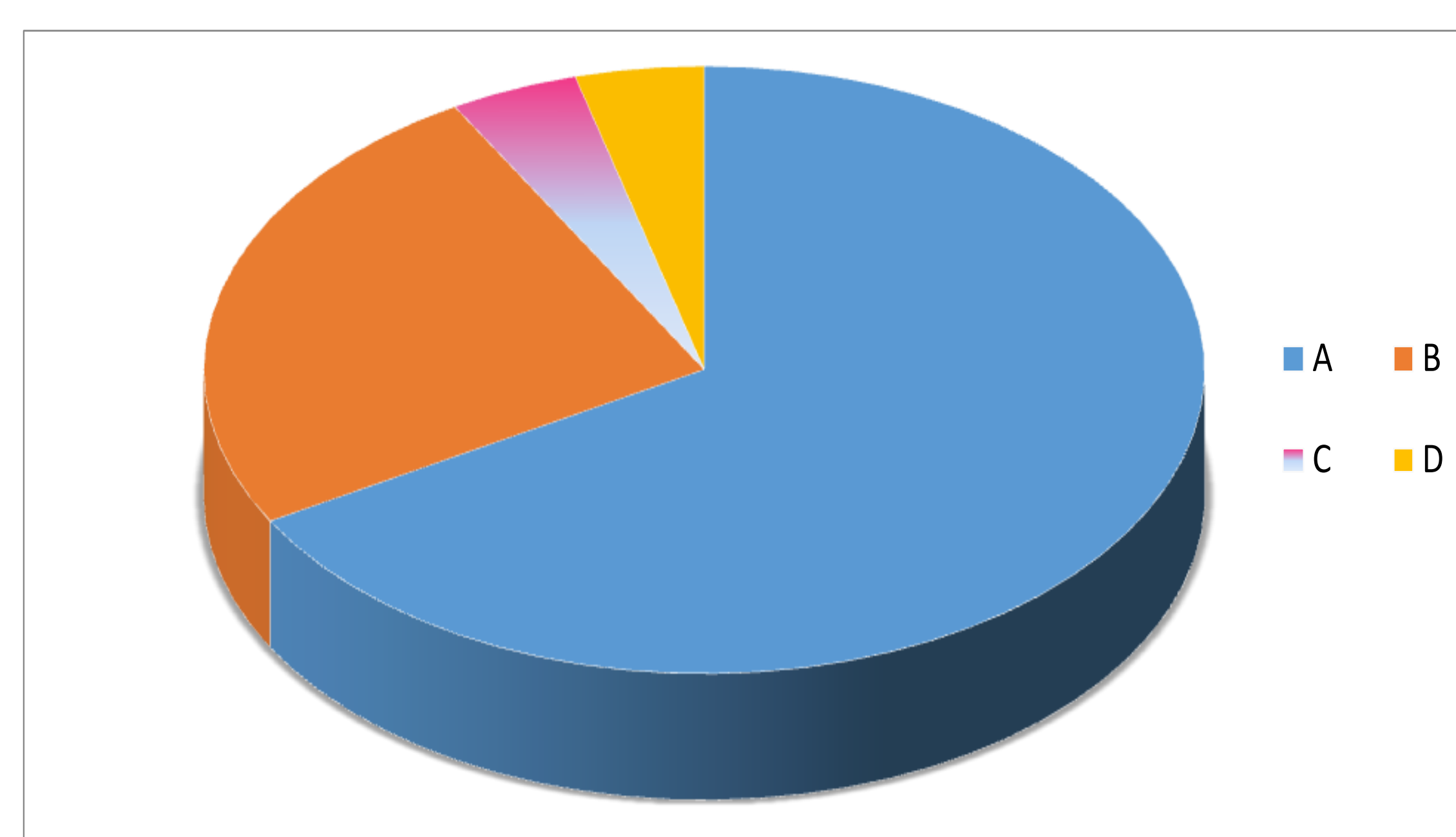
We performed in a second-level hospital a retrospective, observational and descriptive study to evaluate patients treated with commercial imatinib (CI) and generic imatinib (GI). With this purpose we analyzed the next variables: demographic data, diagnosis, changes between commercial and generic treatment, adverse events with both presentations and dose.

## RESULTS

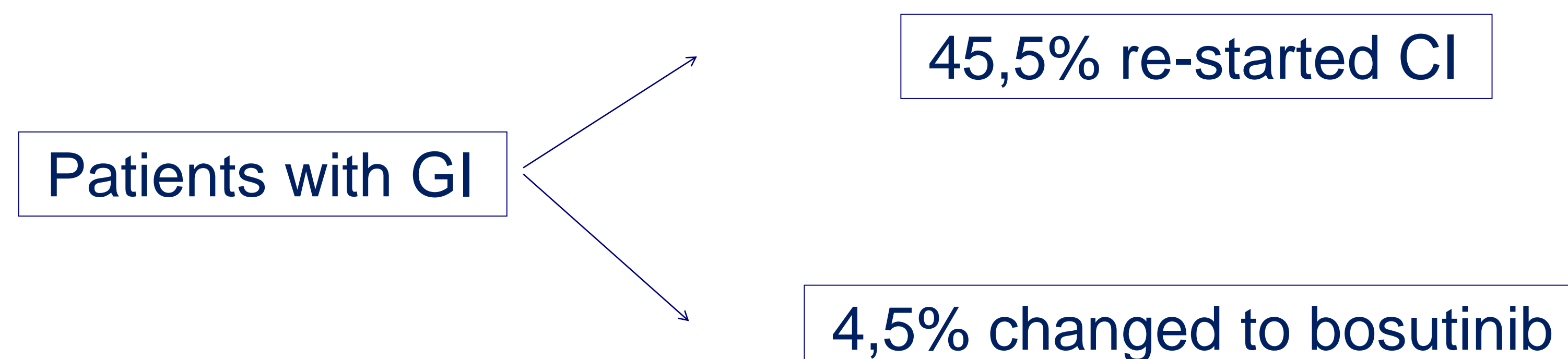
Total: 24 CML patients (58% men), average age  $67 \pm 9$  years.

### Treatment with IM

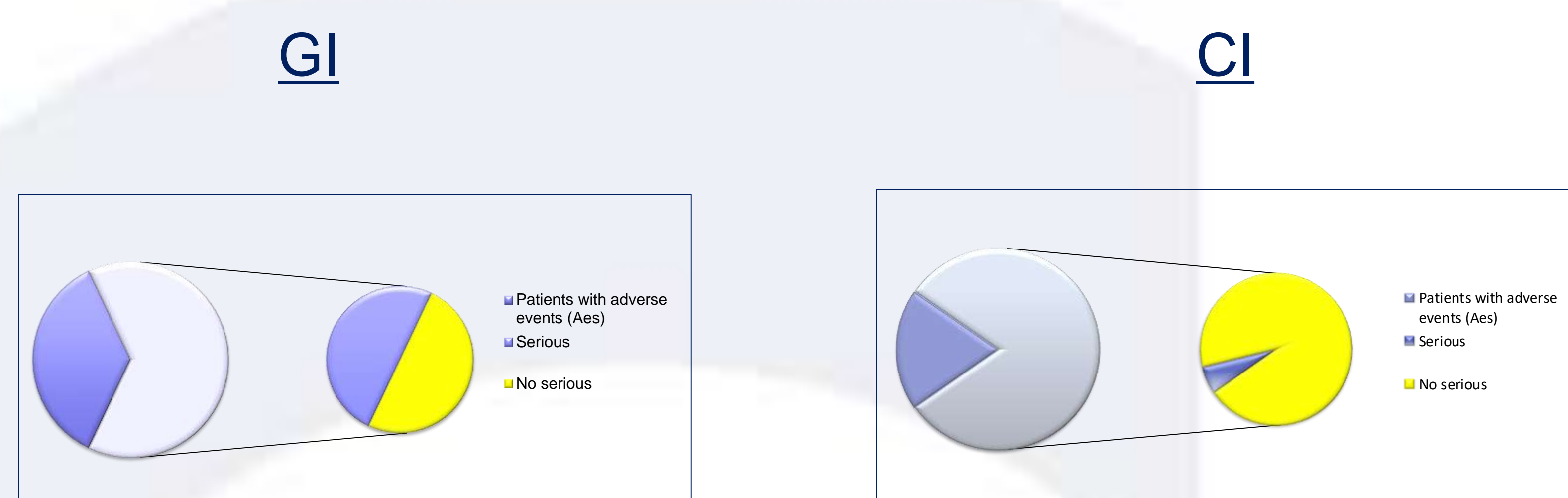
- A: Switched from CI to GI
- B: Started with GI
- C: Remained with CI
- D: Changed to nilotinib



### Change of treatment because adverse events (AEs)



### Adverse events (AEs)



### Differences with the excipients

- GI contained *hydroxypropylmethylcellulose*
- CI had *microcrystalline cellulose*

## CONCLUSIONS

Patients treated GI experienced more serious AEs than with CI. This difference could be explained because the difference in excipients between both presentations. In conclusion, when thinking about including new generic drugs in hospital guidelines, a comparison of excipients profile should be included in order to evaluate tolerance before its admission.



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