

# The impact of therapeutic drug monitoring during Biosimilar Infliximab Switch in Inflammatory Bowel Disease

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## Background

- ❖ Therapeutic Drug monitoring is an established strategy for managing patients with IBD on biologics
- ❖ Biosimilar switching of originator Infliximab is recommended by ECCO and BSG
- ❖ The role of Therapeutic Drug Monitoring during biosimilar Infliximab is not well studied

## Objectives

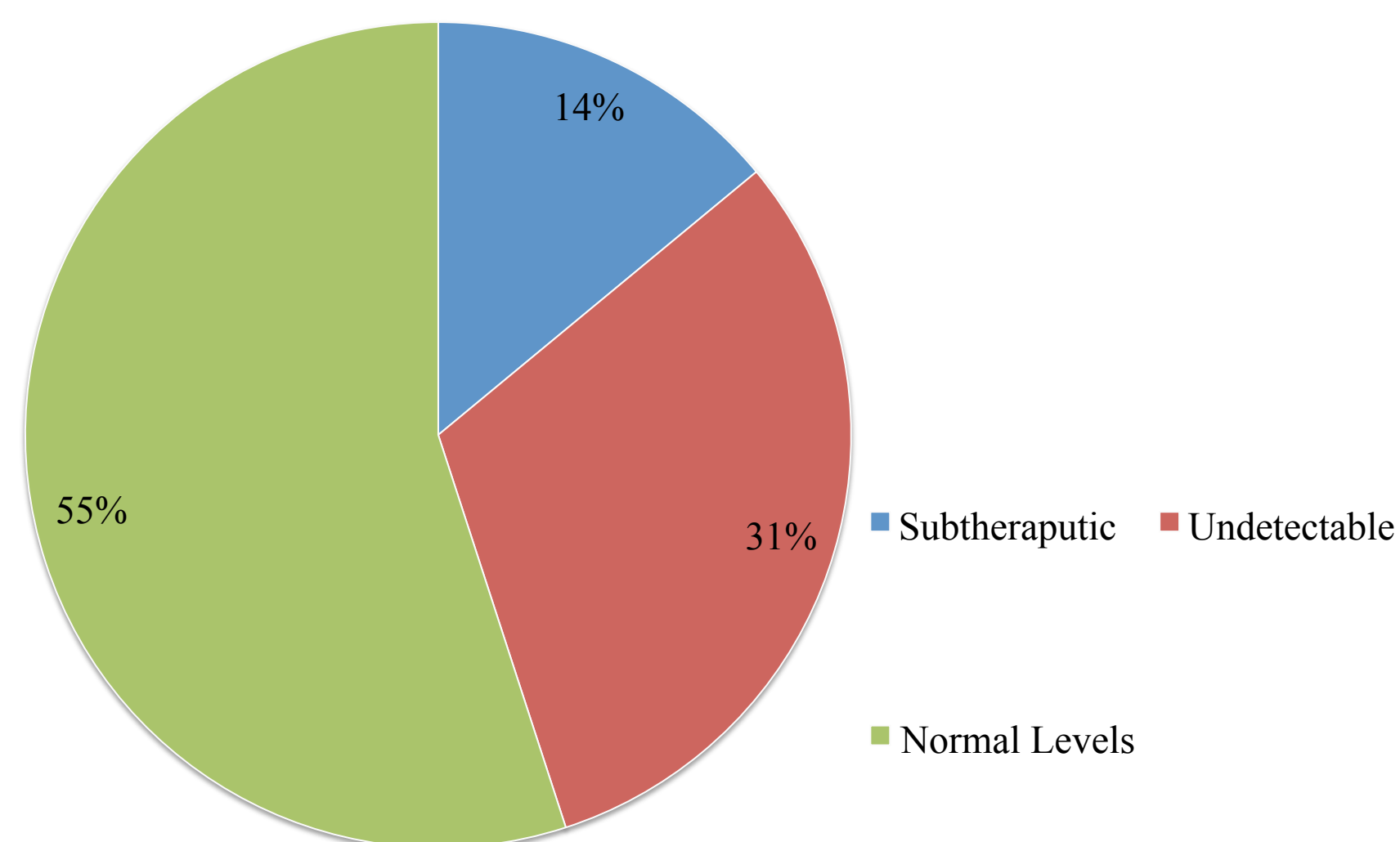
- ❖ To study the impact of TDM on Biosimilar infliximab switching by detecting the proportion of patients who have sub-therapeutic drug levels and/or anti-IFX antibodies before and after the switch
- ❖ Disease activity and its relation to Infliximab levels and use of other immune modulators such as Azathioprine, Methotrexate, 6 mercaptopurine etc

## Methods

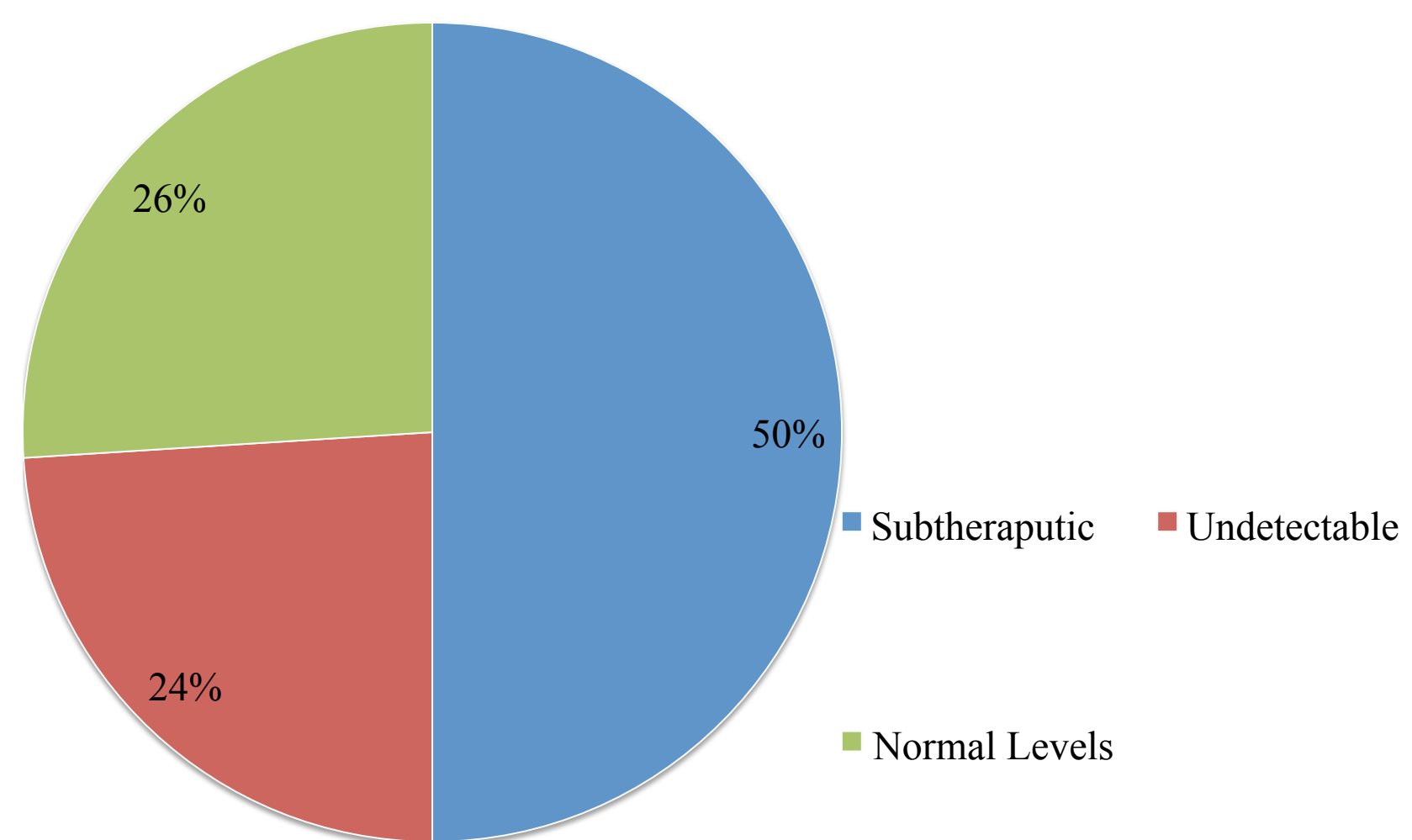
- ❖ Retrospective study of patients switched to Remsima in 2017 at two hospital sites, Darlington Memorial Hospital and Hull Royal Infirmary.
- ❖ 119 patients were included in the study
- ❖ Disease activity measured using Harvey Bradshaw Index/Simple Clinical colitis Activity Index/Faecal Calprotectin /Imaging
- ❖ Pre and post Infliximab and antibody levels recorded
- ❖ Concomitant use of immunomodulators noted.

## Results

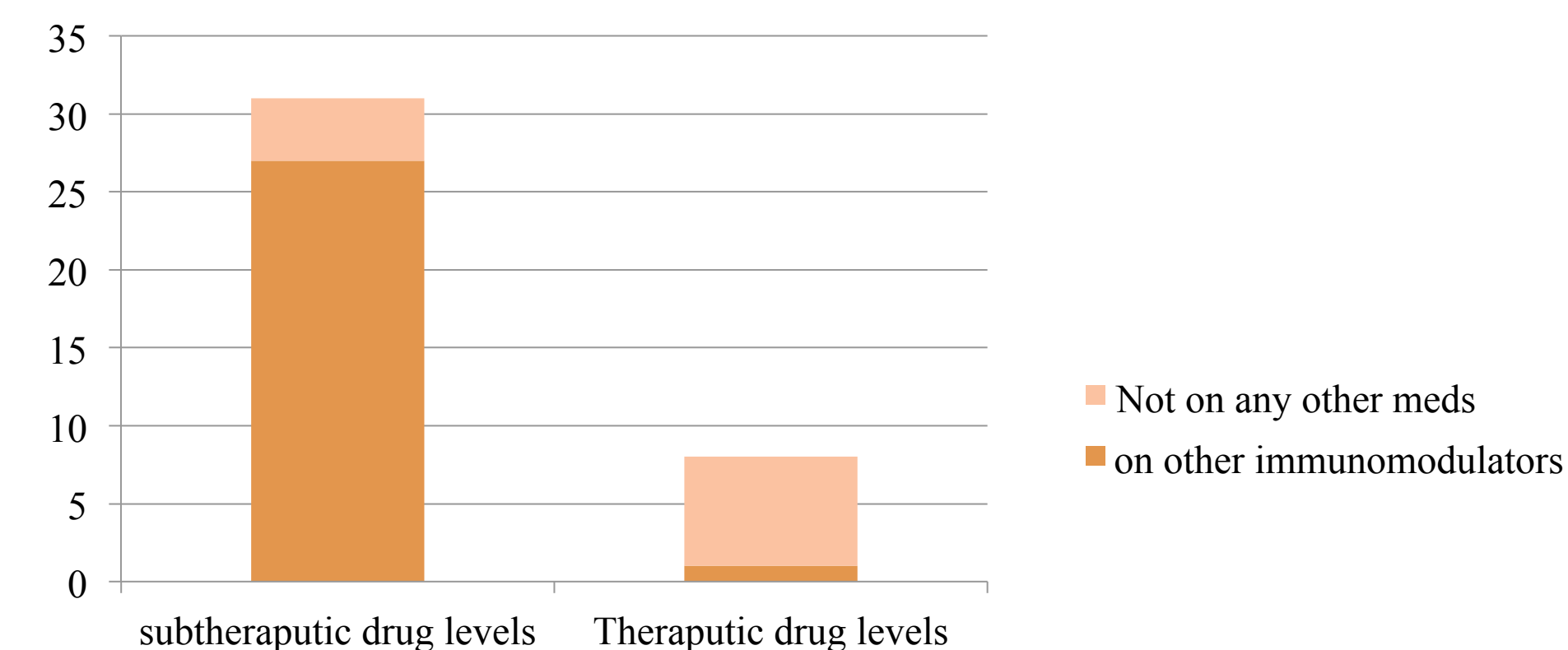
Pre switch Drug levels in patients with positive antibody (n=16)



Post switch Drug levels in same patients



Patients with Active disease (n=39)



	Subtherapeutic/undetectable IFX (n=86)	On other meds	Not on other meds
Active disease		27	4
In remission		40	15

## Results highlights

- ❖ Patients with positive antibodies (n=16) continued to be positive post switch
- ❖ Some patients (n=7) had on going disease activity despite adequate drug levels
- ❖ Some patients (n=40) were in remission in spite of low drug levels, likely effect of use of other immunomodulators.

## Conclusion

- Therapeutic drug and antibody monitoring before and 3 months after Biosimilar switch detects secondary loss of response in patients maintained on scheduled IFX and should be recommended over blanket switching. It also prevents unnecessary switching for some patients who are no longer responding the IFX or may merit a drug withdrawal.

## Useful links:

- <http://gut.bmj.com/content/64/10/1539>
- <https://www.ncbi.nlm.nih.gov/pubmed/25724455>

