Conclusion: In this nationwide analysis we show that almost 20% of patients require ongoing IBD medications following TC for UC. Younger age is associated with higher rate of subsequent medication use. Patient expectations need be adjusted to account for the potential ongoing requirement of long-term medication following TC.

DOP51

De-escalation of biological therapy in Inflammatory Bowel Disease patients following prior escalation

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Background: There are limited data available on de-escalation of biological therapy after prior escalation in inflammatory bowel disease (IBD) patients. The aim of this study was to assess the frequency and success rate of de-escalation of biological therapy in IBD patients after prior dose escalation and evaluate which measures are used prior to de-escalation.

Methods: This multicentre, prospective, cohort study enrolled IBD patients treated with infliximab (IFX), adalimumab (ADA) or vedolizumab (VEDO) in whom therapy was de-escalated at least once after prior biological escalation. Objective disease measures for de-escalation were defined as faecal calprotectin ≤ 200 µg/g and/or therapeutic or supratherapeutic trough levels and/or radiologic or endoscopic remission. Successful de-escalation was defined as remaining on the same or lower biological dose for ≥6 months after de-escalation.

Results: In total, 206 IFX users, 85 ADA users and 55 VEDO users underwent therapy escalation. Of these, 34 (17%) patients on IFX, 18 (21%) patients on ADA and 8 (15%) patients on VEDO had received at least one subsequent de-escalation. De-escalation was successful in 91% of IFX patients, 89% of ADA patients and 100% of VEDO patients. The probability of remaining on the de-escalated regimen or further de-escalation after 1 year was 85% for IFX, 62% for ADA and 100% for VEDO. De-escalation based on objective disease measures was performed in 67% of all de-escalations. Objective de-escalations were successful in 98% versus 80% of subjective de-escalations.

Conclusion: De-escalation after biological escalation is successful in the majority of patients. Objective markers of remission increase the likelihood of successful de-escalation.

DOP52

Safety of Inflammatory Bowel Disease drugs during pregnancy and breastfeeding: Mothers and babies' outcomes (DUMBO registry)

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Background: Prospective registries are necessary to evaluate the safety of inflammatory bowel disease (IBD) treatment during pregnancy and in children in the long term.

Aims: The overall aim of DUMBO registry is to know the risk of serious adverse events (SAEs) during pregnancy and in children up to 4 years of age exposed during pregnancy to drugs for IBD (mainly focused on biologics), compared to unexposed children. In this analysis we aim to evaluate the risk of SAEs during pregnancy and the predictive factors of it (mainly focused on IBD drugs).

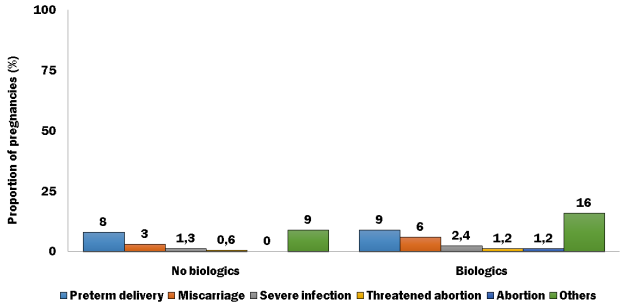
Methods: Prospective, observational and multicentre registry, which enrols pregnant women with IBD (Crohn's disease, ulcerative colitis, IBD-unclassified) over 5 years in 70 centres in Spain. The registry was kicked off in September 2019. SAE was defined based on "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting by European Medicines Agency". Study protocol is summarized in figure 1.

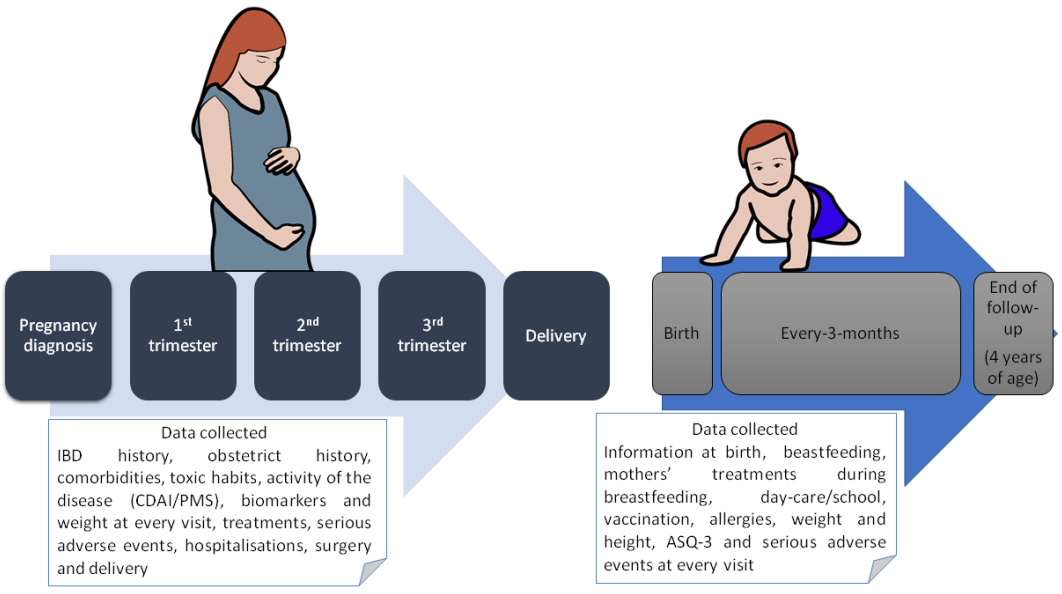
Results: 433 women have been included so far; 241 got pregnant at least 9 months before this interim analysis (table 1).

Table 1. Patients' characteristics

	%
Ulcerative colitis	41
Extensive colitis	35
Left-sided colitis	25
Crohn's disease	58
L1	49
L2	13
L3	38
B1	72
B2	13
B3	15
Perianal disease	25
Previous surgery	20
Former smokers	27
Comorbidities	28

Mean age was 34 years, and 17% of women had active disease at any time during pregnancy. 23% of pregnancies were exposed to immumodulators (thiopurines), 25% to biologics and 10% to combo therapy (biologics and immunomodulators). 85 pregnancies (35%) were exposed to biologics (60 anti-TNF, 17 ustekinumab, and 8 vedolizumab) either in combo or in monotherapy. There were 237 newborns (227 singleton and 5 pair of twins), 9 miscarriages and 1 abortion. 72% of patients had vaginal delivery and 28% C-sections (18% due to perianal CD or active disease). A total of 59 pregnancies (24.5%) reported at least one SAE: 32% in exposed to biologics and 20.5% in non-exposed group (p>0.05) (figure 2).





Crohn's disease activity index, CDAI; Partial Mayo Score, PMS

Data included in the CRF by the researchers of the study team
Data quality ensured by site monitoring

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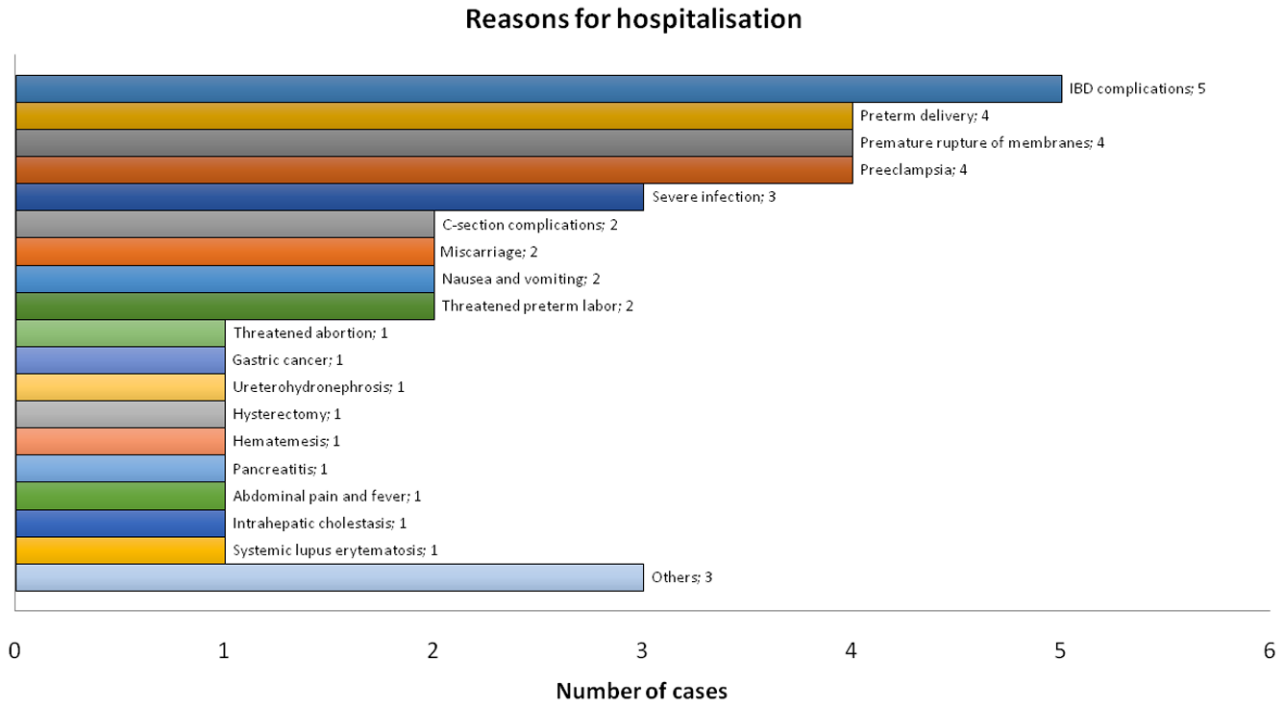

Four out of 17 pregnancies exposed to ustekinumab and 3 out of 8 exposed to vedolizumab had SAEs (non-related with the drug). In the multivariate analysis, adjusted by disease activity, in comparison with no immunosuppressive treatment, neither immunosuppressants [Odds ratio (OR)=1.1, 95% confidence interval (CI)=0.3–4.3] nor biologics in monotherapy or in combo (OR=0.8; 95%CI=0.2–3) were associated with higher risk of SAEs. 40 patients (17%) were hospitalised due to complications during pregnancy or delivery (figure 3).

Two patients underwent surgery during pregnancy due to IBD complications

Conclusion: IBD treatment (either immunomodulators or biologics) does not increase the risk of SAEs during pregnancy. Nevertheless, one-quarter of IBD women suffer SAEs during pregnancy and about 20% need hospitalisation, which should be taken into account when managing IBD during pregnancy.

DOP53

Pregnancy outcomes in the ozanimod clinical development program in relapsing multiple sclerosis, Ulcerative Colitis, and Crohn's Disease

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Background: Ozanimod, an oral sphingosine 1-phosphate (S1P) receptor modulator selectively targeting $S1P_1$ and $S1P_5$, has demonstrated efficacy in patients with relapsing multiple sclerosis (rMS) and ulcerative colitis (UC), and is being studied in Crohn's disease (CD). $S1P_{1-3}$ receptors are involved in vascular formation during embryogenesis. Within studies in the ozanimod clinical development program, female participants of childbearing potential were required to use effective contraception while receiving and up to 3 months after discontinuing ozanimod; treatment discontinuation was required if pregnancy was confirmed. Here we review pregnancy outcomes data with ozanimod use in rMS, UC, and CD.

Methods: All pregnancies, including participant and partner pregnancies, in the ozanimod clinical development program with an initial diagnosis prior to a cut-off date of September 30, 2020 were assessed for pregnancy outcomes.

Results: At cut-off, safety data on 4131 participants were available. A total of 83 pregnancies were reported in the safety database of participants treated with ozanimod or their partners (Table). All pregnancy exposures occurred during the first trimester. Of the 60 pregnancies in ozanimod clinical trials, 9 were reported in patients with UC, and 3 in patients with CD. Participants discontinued study medication promptly except for those who elected pregnancy termination and did not discontinue study medication. Among all pregnancies in the ozanimod clinical development program, the incidence of spontaneous abortion in clinical trial participants was 15%; the