De-escalation of combination drug therapy in inflammatory bowel disease patients

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BACKGROUND

- There are limited data on the use of multiple biologics or small molecule drugs in combination to treat patients with inflammatory bowel disease and much less in methods for successful de-escalation of combination therapy.

AIMS

- The aim of this study was to evaluate contributing factors to the decision to de-escalate, and successful de-escalation.

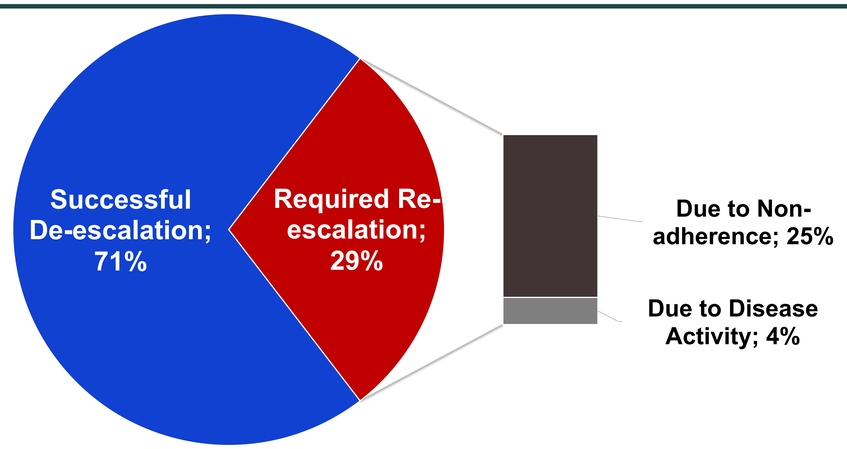
METHODS

- A retrospective cohort study was performed for IBD patients who were on combination (dual biologics or biologic + small molecule) therapy and underwent de-escalation.
- Data was collected at both the visit at which the decision to de-escalate was made and the next follow-up visit.
- Data collected included patient demographics, such as age, gender, BMI, albumin, CRP, ESR, and clinical scores.
- At the follow-up visit, patient compliance with the de-escalation plan, and the necessity to re-escalate therapy was evaluated.

RESULTS

Descriptive Overview of patient data with decision to de-escalate

	De-escalation Beginning		Follow-Up		p-value
	Number of patients	Average	Number of patients	Average	
Patient Age	25	37.38	-	-	-
Male	13	-	-	-	-
Female	12	-	-	-	-
BMI	23	23.5	-	-	-
Crohn's Disease	13	-	-	-	-
Ulcerative Colitis	11	-	-	-	-
Indeterminate Colitis	1	-	-	-	-
Disease Duration	25	15.24	-	-	-
HBI	11	3.59	11	3.72	ns
Mayo	11	2.09	9	0.78	ns
UCAI	7	3.26	5	0.4	ns
Albumin	20	4.11	17	4.11	ns
CRP	19	6.96	15	6.52	ns
ESR	19	14.94	15	9.6	ns
Biologic + Biologic	11	-	-	-	-
Biologic + SM	11	-	-	-	-
Biologic + Biologic + SM	3	-	-	-	-
Type of De-escalation					
Taper Biologic	11	-	-	-	-
Stop Biologic	8	-	-	-	-
Taper Small Molecule	7	-	-	-	-



RESULTS CONT.

- The decision to de-escalate was made in patients in clinical remission with CRP, ESR, and albumin within normal limits.
- For the 25 patients that underwent de-escalation, 24 had a follow up visit.
- Of these 24 patients, 71% successfully de-scalated therapy without disease recurrence.
- 7 (29%) of patients required a re-escalation of therapy due to non-adherence and disease activity
- Of the 6 non-adherent patients, 4 stopped their therapy due to insurance coverage and 2 incorrectly followed de-escalation instructions.
- Patient non-adherence with de-escalation was significantly associated with the necessity for re-escalation at follow up visit (p=0.019).
- The type of de-escalation (taper of biologic, stop biologics, or taper small-molecule therapy) was not significantly associated with the necessity for re-escalation, albumin, ESR, CRP, or clinical scores of disease activity.
- As expected, the difference in clinical scores and inflammatory markers between initial visit and follow-up was not significant; although, UCAI, Mayo score, and ESR trended towards significant decreases.

CONCLUSIONS

- **In our retrospective cohort study, patient adherence was the most important predictive factor for successful de-escalation from combination therapy.**
- **The type of agent (biologic / small molecule) de-escalated did not affect inflammatory levels at follow up.**
- **These findings suggest that patients on combination therapy can be carefully de-escalated with appropriate biomarkers showing remission.**