High rates of oral 5-aminosalicylic acid co-prescription with advanced therapy in patients with ulcerative colitis

Ziheng Calvin Xu[1], Marwan Al-Banaa[1], Ethan Tan[1], Bilqis Onibon[1], Shees Salman[1], Tim Levar[1], Rebecca Pearce[1], Mayur Garg[1,2], Soleiman Kashkooli[1], Robert Little[1]

1. Northern Health, Melbourne, Victoria, Australia
2. Department of Medicine, University of Melbourne, Victoria, Australia

Northern Health

INTRODUCTION

- 5-aminosalicylates (5-ASA) is the first-line treatment for inducing and maintaining remission in patients with mild to moderate ulcerative colitis (UC).
- The additive role of 5-ASA therapy after advanced therapy is initiated is minimal[1].
- The cost of 5-ASA therapy can be significant with annual per patient costs of up to $3469.

AIMS

- We aimed to quantify the co-prescription of oral 5-ASAs with advanced therapies in UC, evaluate associations with disease activity and estimate annual costs.

METHODS

- Retrospective observational study of all consecutive adult patients with UC receiving advanced therapy from a single tertiary IBD centre.
- Data collection included patient and disease characteristics, 5-ASA and advanced therapy type, dose and duration and objective disease activity (most recent intestinal ultrasound [IUS], faecal calprotectin [FCP] and endoscopy within 12 months).
- Biochemical remission was defined as FCP <150 µg/g.
- Sonographic remission was defined as normal bowel wall thickness without hyperaemia.
- Endoscopic remission was defined as Mayo endoscopic subscore of 0.
- Histological remission was defined as the absence of active neutrophilic infiltrates.

RESULTS

- 230 patients were included in the analysis.
- 42% female, median age 40 years, median disease duration 96 months.
- Concurrent oral 5-ASA therapy was used in 116 patients (50%) for a median duration of 42 months (IQR 11–59), including 19 overlapping months with the most recent advanced therapy.
- The majority (89%) remained on maximal induction doses and annual average costs were estimated at $3469.73 per patient.
- Almost 2/3rds of patients remaining on 5-ASAs were in biochemical and/or sonographic remission and 1/3rd were in endoscopic and histological remission.
- Rates of 5-ASA co-prescription varied by type of advanced therapy, being most common with Vedolizumab (31.9%), followed by intravenous Infliximab (21.6%) and Upadacitinib (14.7%).
- Combination oral 5-ASA and advanced therapy was associated with topical 5-ASA use (p = 0.002) and shorter duration on current advanced therapy (p = 0.03) compared to those on an advanced therapy alone.
- No significant differences in clinical, biochemical, endoscopic, or histologic disease activity were observed between patients receiving advanced therapy alone and those receiving advanced therapy plus 5-ASA (Table 1).

Characteristic	Advanced Therapy (n = 114)	Advanced therapy + 5-ASA (n = 116)	p value
Age, median (IQR)	40 (27–53)	39 (30–55)	0.20
Female	55 (48.2%)	41 (35.3%)	0.06
Disease duration (months)	72 (33–113)	66 (32–117)	0.58
Duration of current advanced therapy (months)	20 (11–42)	18 (8–30)	0.03
Advanced therapy type			
infliximab IV	16 (14.0%)	25 (21.6%)	0.168
infliximab SC	16 (14.0%)	5 (4.3%)	0.011
adalimumab	2 (1.7%)	0 (0%)	0.24
golimumab	1 (0.8%)	2 (1.7%)	>0.99
vedolizumab IV	38 (33.3%)	37 (31.9%)	>0.99
vedolizumab SC	8 (7.0%)	8 (6.9%)	>0.99
upadacitinib	17 (14.9%)	17 (14.7%)	>0.99
ustekinumab	12 (10.5%)	12 (10.3%)	>0.99
tofacitinib	3 (2.6%)	8 (6.9%)	0.21
ozanimod	0 (0%)	1 (0.8%)	>0.99
etrasimod	0 (0%)	1 (0.8%)	>0.99
infliximab + stelara	1 (0.8%)	0 (0%)	>0.99
Previous advanced therapy	61 (63.5%)	63 (54.3%)	0.99
Topical 5-ASA use	12 (10.5%)	31 (26.7%)	0.002
Clinical remission	97 (85.1%)	87 (75.0%)	0.06
FCP (µg/g)	48 (14–281)	70 (20–240)	0.63
FCP < 150 µg/g	76 (66.6 %)	79 (68.1%)	>0.99
IUS remission	19/24 (79.2%)	22/35 (62.9%)	0.25
Endoscopic remission	51 (44.7%)	38 (33.0%)	0.07
Histological remission	51 (44.7%)	41 (35.6%)	0.17

Table 1. Patient, disease and medication characteristics according to 5-ASA co-prescription with advanced therapies. Values presented as median (IQR) or number (%), unless specified.

CONCLUSIONS

- Co-prescription of 5-ASAs and advanced therapies is common despite high rates of objective remission.
- No significant differences in clinical, biochemical, endoscopic, or histologic disease activity were observed in patients remaining on 5-ASA therapy vs those on advanced therapy alone
- Identifying patients suitable for a trial of 5-ASA withdrawal may allow reductions in healthcare expenditure and improve adherence.

Reference

1. Singh, S., et al., *No benefit of continuing vs stopping 5-aminosalicylates in patients with ulcerative colitis escalated to anti-metabolite therapy.* Aliment Pharmacol Ther, 2020. 52(3): p. 481-491.