Abstract P34 Table 1

Category	Variables	TFV (n=142)	ETV (n=75)	p Value
Demographic	Age	41 (19–80)	42 (19–76)	NS
	Gender: M (%)	143 (67.5)	62 (80.5)	<0.05
	African-Caribbean (%)	100 (47.2)	43 (55.8)	NS
Clinical	Liver transplant (%)	9 (4.3)	0 (0)	NS
	Hepatocellular carcinoma (%)	14 (6.8)	0 (0)	0.014
	Bilirubin	11 (3–148)	12 (4–37)	NS
	AST	29 (12–215)	40 (20–328)	<0.001
	INR	1.05 (0.88–1.86)	1.05 (0.94–2.47)	NS
	Albumin	44 (24–52)	44 (29–50)	NS
VD and Bone markers	Baseline Vitamin D (g/l)	14.2 (0–49)	16.1 (6–50)	NS
	12 months Vitamin D (g/l)	14.5 (0–44.5)	13.6 (4.2–43.5)	NS
	Baseline Calcium mmol/l	2.24 (2.01–2.41)	2.25 (2.08–2.4)	NS
	12 months Calcium mmol/l	2.23 (2.08–2.35)	2.23 (2.10–2.37)	NS
	Baseline Phosphate mmol/l	0.99 (0.38–1.71)	0.91 (0.58–1.27)	0.011
	12 months Phosphate mmol/l	1.06 (0.43–1.43)	0.96 (0.55–1.43)	0.017
	Baseline ALP IU/l	72 (39–325)	70 (42–229)	NS
	12 months ALP IU/l	75 (42–769)	68 (36–168)	0.004

ETV. There were 212 patients (73%) treated with TDF and 79 (27%) treated with ETV. Median age was 42 years (19–80); 266 (72%) were Male. African-Caribbeans represented 49% and South East Asians represented 24%. There were 14 patients (5%) with hepatocellular carcinoma (HCC) and 9 (3.1) patients post liver transplantation. Median AST was 30 (12–328), Bilirubin 11 (3–148), INR 1.05 (0.88–2.47) and albumin 44 (24–73). Prevalence of VD deficiency (VD <22 μg/l) in patients who had VD checked at baseline (n=192) was 81.3%. Distribution of VD deficiency was not significantly different based on ethnicity (p=NS), however, VD deficiency was more prevalent among men (85% vs 72%, p=0.034). 70/212 (33%) of those treated with TDF had VD supplements compared to 4/79 (5.1%) of ETV group, p<0.001. These patients were excluded from paired comparisons of VD over 12 months after TDF or ETV exposure.

In TDF treated patients, median VD was 14.2 (0–49) at baseline and 14.7 (0–41) 12 months of therapy, p=NS. There was no significant difference in median Ca^{2+} (2.24 vs 2.23, p=NS), PO_4 (0.99 vs 1.04, p=NS), however, ALP significantly increased after 12 months of TFV treatment (71.5 vs 75, p<0.05). Patients treated with ETV monotherapy, median VD at baseline was 16.1 (6–50) and after 12 months of ETV treatment was 13.6 (4.2–43.5), p=NS. No significant difference was found between baseline and 12 months Ca^{2+} (2.25 vs 2.23), PO_4 (0.91 vs 0.96) or ALP (70 vs 68), p=NS for all comparisons. Abstract P34 table 1 demonstrate demographic, clinical and bone markers of TDF and ETV treated patients at baseline and after 12 months of therapy. TDF group had significantly lower male prevalance and AST, but a significantly increased proportion of patients with HCC, baseline and 12 months PO_4 and ALP at 12 months.

Conclusion VD deficiency is highly prevalent in this cohort of CHB patients and should be appropriately identified and treated. TDF and ETV treatment had no significant effect on VD levels after 12 months of treatment in this cohort. However, there was significant rise in PO_4 and ALP after 12 months of TDF treatment; which may infer indirect longer effects on bone metabolism.

P35 LONG-TERM REMISSION IS ACHIEVABLE IN AUTOIMMUNE HEPATITIS USING TACROLIMUS OR MYCOPHENOLATE MOFETIL AND RESULTS IN REGRESSION OF FIBROSIS

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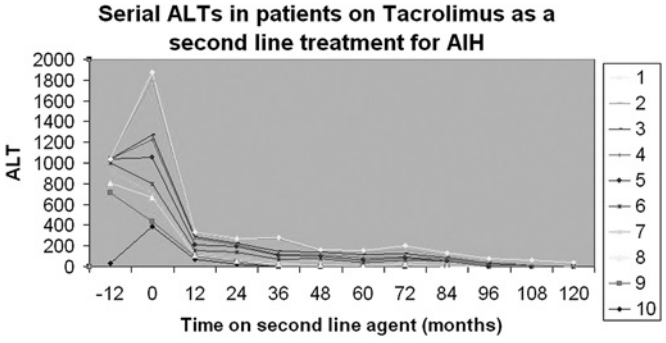
Introduction 10–20% of patients do not respond to conventional treatment of autoimmune hepatitis, or are intolerant of azathioprine. There is no established second line treatment. Experience with transplant immunosuppressive agents such as Tacrolimus (TAC) and mycophenolate mofetil (MMF) is limited to small numbers and short-term follow-up.

Aim To describe the progress of all patients who had failed conventional therapy and were treated with second line agents with at least 12-month follow-up.

Method An audit of patients identified who received second line agents for at least 12 months on maintenance dose <10 mg prednisolone. Patient records were reviewed and treatment endpoints based on aminotransferase changes defined as; Complete response (CR) - sustained normalisation for at least 12 months, partial response (PR) - improvement by >50% but not always normal over a 12-month period. Where applicable, interval histology was reviewed by a single pathologist to assess ISHAK fibrosis scores at the start and at least 18 months after commencing second line agents.

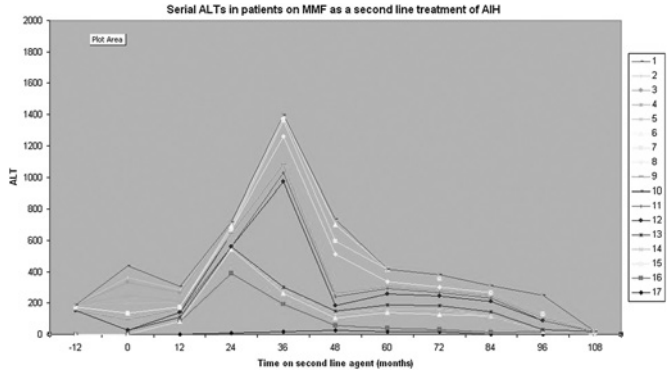
Results A total of 26 patients were identified. 9 were treated with TAC for a median 81 months (21–137), 16 with MMF for a median 81 months (30–114) and one on a combination of TAC and MMF. Median age is 56 (28–68) and 64 (40–79) respectively. The median dose of TAC is 3.5 mg/day (1–6) and MMF 1 g/day (1–2). All patients on TAC achieved CR. Two patients discontinued treatment; one renal impairment and one rationalising treatment after 27 months CR. 11/16 patients on MMF achieved CR, 5/16 achieved PR. Five patients no longer take MMF; two due to toxicity (recurrent chest infections at 60 months, GI disturbance at 78 months), one successfully withdrew treatment after 39 months CR, one switched to TAC as a treatment failure of MMF after 103 months and one was withdrawn after a diagnosis of larynx SCC. The combination patient achieved CR and has received 50 months dual treatment with confirmed histological remission. Four patients on TAC and five on MMF had interval biopsies. 3/4 patients on TAC (median 87 months) exhibited stable or reduced grades of fibrosis compared to 2/5 patients on MMF (median 101 months).

Conclusion Effective long-term maintenance of remission at 10 years is achievable on MMF and TAC in the absence of significant toxicity.



Abstract P35 Figure 1 Serial ALTs in patients on TAC as a second line treatment for AIH.

Achieving prolonged CR seems to confer disease control and can result in histological regression of fibrosis.



Abstract P35 Figure 2 Serial ALTs in patients on MMF as a second line treatment for AIH.

Abstract P35 Table 1 Summary of patients on second line treatment of AIH

Time on Treatment (months)	12	24	36	48	60	72	84	96	108	120
TAC results										
CR	8/10	6/10	3/6	3/6	3/6	5/6	3/5	3/3	2/2	1/1
PR	2/10	4/10	3/6	3/6	3/6	1/6	2/5	0/3	0/2	0/1
Never achieved CR	0									
MMF results										
CR	7/14	8/14	7/14	4/13	7/12	5/11	4/8	3/4	1/1	
PR	7/14	6/14	7/14	9/13	5/12	6/11	4/8	1/4	0/1	
Never achieved CR	3									

Abstract P35 Table 2 Comparative histology on second line treatment of AIH

TAC Pt	Ishak Fibrosis score Pre	Post	Change	Time between biopsies (months)
1	1	1	0	95
2	3	4	1	45
3	2	1	−1	43
4	3	1	−2	22

MMF Pt	Ishak Fibrosis score Pre	Post	Change	Time between biopsies (months)
1	1	1	0	41
2	5	6	1	22
3	4	0	−4	45
4	3	4	1	18
5	1	6	5	76

P36 MORBIDITY AND MORTALITY ASSOCIATED WITH VARICES IN PATIENTS WITH PRIMARY BILIARY CIRRHOSIS

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Introduction Several studies have shown that gastro-oesophageal varices (GOV) are relatively common in patients with PBC, and can occur in pre-cirrhotic and asymptomatic patients as well as in patients with advanced disease. An important practical problem faced by clinicians managing PBC patients with GOV is the approach to their long-term management especially, defining the appropriate timing for referral for liver transplantation.

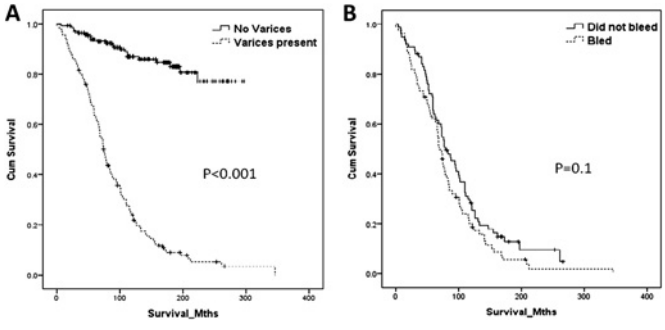
Aim To address the clinical impact of varices on morbidity and mortality in PBC in a large, long-term follow-up cohort of patients.

Method A retrospective study was designed to identify all PBC patients had had endoscopy (OGD) at the Freeman Hospital, Newcastle for any clinical indication. PBC patients with and without GOV at OGD were characterised by extensive review of their clinical records. Data obtained included survival and transplantation history. The log rank test was used to compare transplant free survival between groups.

Results 330 PBC patients (91.5% female, median age 64 yrs) were identified as ever having had an OGD at the Freeman Hospital. 159 [48% (95% CI 43% to 54%)] were found to have GOV. Subgroups with and without GOV were equivalent in terms of age, sex and time to endoscopy (Abstract P36 table 1). 39 (25%, 95% CI 18% to 32%) patients had GOV diagnosed at OGD performed at the time of their index bleed. In total, 83 (52%, 95% CI 44% to 60%) patients suffered 245 episodes of variceal bleeding during a median follow-up of 11 yrs (IQR 8). Of the 120 that did not present with a bleed 44 (37%, 95% CI 28% to 46%) bled a median of 1.5 yrs (IQR 3.75) after varices had been diagnosed In patients with varices that bled, there was no significant difference in the proportion that were on non-selective β blockers as compared with those that did not receive/tolerate these agents (48% vs 52%, p=0.75 Fisher's exact test). Unfortunately, data on the physiological adequacy of β blockade was not available. Importantly, 21 (13%, 95% CI 8% to 19%) PBC patients with varices had early stage (Scheuer Stage I, I-II, II) disease, and of these 3 (14%, 95% CI 3% to 36%) presented with a variceal bleed as the first presentation of their varices and a further 5 (24%, 95% CI 8% to 47%) bled during follow-up. Transplant free survival after diagnosis of PBC was significantly better in those without varices when compared to those with varices (p<0.001). There was no significant difference in survival in patients with varices that bled and those that did not (p=0.1) (Abstract P36 figure 1).

Abstract P36 Table 1 Baselines demographics of the PBC patients with and without varices

	Varices (N=159)	No varices (N=171)	p Value
Median age endoscopy (IQR)	64 yr (13)	64 yr (15)	0.394
Females (%)	90%	93%	0.173
Median time lag of OGD from PBC diagnosis (IQR)	4 yr (5)	5 yr (17)	0.952



Abstract P36 Figure 1 Kaplan–Meier curves comparing transplant free survival of PBC patients (A). with and without varices and (B). varices that bled vs varices that did not.

Conclusion The development of GOV heralds a poor prognostic outlook for patients with PBC. Bleeding from these GOV does not