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REAL-WORLD DATA FOR OBETICHOIC ACID TREATMENT IN WALES UTILISING A VIRTUAL MDT PANEL

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Obeticholic acid (OCA) is indicated in patients with primary biliary cholangitis (PBC) that have failed or are intolerant to therapeutic dose of ursodeoxycholic acid (UDCA). Optimal dosing of UDCA dependent on weight is essential before considering second-line treatment.

We present real-world data of our experience with OCA treatment in Wales between November 2017 – October 2020. A virtual MDT panel was set-up, compared with a spoke-hub model used elsewhere. Local consultants refer electronically to

Wales PBC pathway for 2nd line therapy with Obeticholic acid (OCA)

1. Ursodeoxy cholic acid (UDCA) is the first line treatment option for patients with PBC and all patients must have tried UDCA for **at least 12 months at a dose of 15 mg/Kg/day** before considering 2nd line therapy with Obeticholic Acid (OCA)(commercially available as OCALIVA).
2. OCA is indicated in the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in patients intolerant to UDCA (POISE study).
3. UDCA non-responders are defined using modified Toronto criteria after 12 months treatment with UDCA and confirmed if ALP > 1.67 x ULN.
4. Start treatment by adding Ocaliva 5 mg OD to existing treatment with UDCA. Assess biochemical response at 6 months. If response criteria met (ALP < 1.67 ULN and Bilirubin normalised) then continue on 5 mg OD for a total of 12 months. If response maintained then continue long-term (data not available on long-term outcome).
5. If biochemical response not achieved at 6 months, then the dose can be increased to 10 mg OD depending upon tolerability. Re-assess biochemical response at 12 months after initiation of OCA. If response criteria met, then continue long-term. Stop OCA if non-responder.
6. Patients with advanced liver disease:

Patients who have evidence of advanced disease (raised bilirubin > 50 and/or UKELD score > 48 or decompensated liver disease) should be considered for Liver transplant assessment in the absence of any obvious contra-indications. There is no data for using OCA in such patients.

In selected cases with Child's Pugh-B disease, OCA may be started at a reduced dose of 5 mg once weekly with very close monitoring of patients liver function and tolerability. Titrate to 5 mg twice weekly after 3 months depending upon response and tolerability. There is no role for using OCA in CP-C disease.

Adverse events:

- Approximately 5 – 10% of patients may discontinue treatment with OCA due to severe pruritus. Patients should be treated for pruritus in conventional manner (cholestyramine, Rifampicin etc.).
- LDL levels may rise transiently after OCA therapy and usually return to baseline in 3 – 6 months. Monitor lipid profile while on treatment.

Please complete the attached form and e-mail to: brijesh.srivastava@wales.nhs.uk

1. Patient details

Name:	Gender
DOB:	Date of PBC diagnosis:
Age at diagnosis of PBC:	Hospital:
Weight (Kg) =	Consultant:

2. Diagnosis of PBC confirmed: Yes ☐ No ☐

	Positive	negative
Anti-mitochondrial antibody (> 1:40 titre)	☐	☐
PBC specific ANA (e.g. Gp210; Sp100)	☐	☐
Smooth muscle antibody	☐	☐
Liver biopsy (if done) consistent with PBC	☐	☐

3. UDCA treatment

Is the patient on UDCA	Yes ☐	No ☐
If Yes, total dose = mg/day		
Total duration of UDCA treatment = months; years		
Is the patient intolerant to UDCA	Yes ☐	No ☐
If Yes, please give details:		

4. Biochemical response to UDCA after 12 months of therapy (modified Toronto criterion):

	Yes	No
Is ALP > 1.67 x ULN	☐	☐
Is Bilirubin < 50µmol/L	☐	☐
If yes to both, then patient may be suitable for treatment with OCA		

5. Pruritus

Is pruritus present	Yes ☐	No ☐
If Yes, grade severity: Mild ☐ Moderate ☐ Severe ☐		
Current treatment for pruritus =		

6. Stage of Liver disease

Fibroscan done	Yes ☐	No ☐
If Yes, fibroscan date: ; score = kPa		
Clinical evidence of cirrhosis/portal HTN	Yes ☐	No ☐
If cirrhosis present, specify if: Child's Pugh score = A B C		

7. Any significant co-morbidities or malignancy:

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8. Any other clinical details or comments:

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9. Biochemistry results –

Table 1. Please provide two most recent blood test results

Date	ALP	Bilirubin	ALT	Platelet	Albumin	IgG/IgM

Please provide reference range for ALP =

Virtual Panel MDT Outcome

10. Patient suitable to start OCA therapy: Yes ☐ No ☐

Comments (If no, specify reason):

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11. Assessing biochemical response to OCA after 6 and 12 months of therapy.

Date OCA treatment started:

Table 2. Blood results after 6 months and 12 months of OCA therapy.

Rx duration	Date	ALP	Bili	ALT	Platelet	Albumin	IgG/IgM
6 month							
12 month							

Is ALP < 1.67 ULN and Bilirubin normal:		Yes ☐	No ☐
CONTINUE OCA ☐		STOP OCA ☐	

Comments:

Abstract P089 Figure 1

the MDT panel which consists of a hepatologist from each of the six health boards in Wales. Treatment is initiated and monitored by the referring clinician. Modified Toronto criteria (ALP <1.67 x upper limit of normal (ULN)) is used to define biochemical response to OCA.

Out of 70 referrals received, 56 were approved for OCA use. Median age at the time of referral was 59 and 89% were females (n = 50). 48 (86%) were on optimal UDCA dose, while 8 (14%) were intolerant to UDCA. Median ALP prior to commencing OCA was 405 (211–817). 19/56 patients had cirrhosis (18 Child-Pugh A and 1 Child-Pugh B). 27 patients referred had documented pruritus, two of whom had severe pruritus. In those with severe pruritus low dose OCA

was started in one, and one did not commence OCA. The average time from approval to commencing OCA was 3 months. Patients with pruritus received standard pruritus treatment prior to commencing OCA.

Complete follow-up data after 12 months of OCA treatment was available for 33/56 patients. 12/33 (36%) patients achieved biochemical response. At 12 months, median ALP in the OCA responsive group was 165 (104–249), and median ALP in the OCA non-responsive group was 398 (218–887). This compares with the POISE trial where 46% met Toronto response criteria.¹

Use of second-line treatment with OCA is consistent and accessible across Wales, facilitated by our virtual MDT set-up,

Abstract P089 Figure 2 Final prototype liver model (1:1.3 scale) with embedded vasculature and tumour (above) and endoscopic view of right hepatic vein inside model (inset)

and was not adversely impacted by the COVID-19 pandemic. Patients do not need to travel to central hubs, and can remain under the care of their local hepatologist maintaining continuity of care and also promoting their involvement in decision making process. However, monitoring of 6- and 12-month response after starting OCA can be challenging as it is reliant on receiving follow-up data from the referring clinician. OCA dose must be adjusted based on the stage of liver disease and presence of pruritus.

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ASSESSING DOCUMENTATION OF ASCITIC PARACENTESIS IN LANCASHIRE TEACHING HOSPITALS NHS TRUST

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Ascites is a common presentation of decompensated liver cirrhosis and is associated with 50% mortality over 2 years.¹ Although complication rates of paracentesis are low (1.6%) and usually mild, significant complications including bleeding and death can ensue.²

The aim of the study was to measure the Lancashire Teaching hospitals NHS Trust's compliance for paracentesis documentation using the British Society of Gastroenterology and British Association of study of liver disease's paracentesis safety toolkit.³ The study involved retrospectively collected data from patients between January and April of 2020. A total of 13 patients were identified in keeping the inclusion criteria (known liver cirrhosis patients admitted with large volume ascites).

We found poor documentation practices involving procedure in the person performing procedure (84%), consent (53%), pre-procedure weight (15%), the plan for the amount of human albumin solution to be given (61%) and total given (38%), platelet count documentation (84%), recorded time of insertion (85%), color of the fluid drained (53%), and plan on when to remove the drain (61%). The audit also noted poor documentation post procedure including recorded time of removal (38%), total ascites drained (46%), and patient's weight recorded after removal (0%).

An updated version of the BSG toolkit was designed (divided into 2 main forms; 1 for insertion and the other for removal of drain), which will be implemented on the wards as well as the local trust's online system to aid documentation on the acute medical wards and emergency department. Furthermore, teaching sessions will be implemented to the medical and nursing staff rotations. Moreover, there is a plan to liaise with the education team to add a learning module on the induction for medical and nursing rotations.

This audit found poor documentation practices on a commonly performed procedure on the wards especially in patients with decompensated liver cirrhosis. The purpose of this audit was to highlight this and to point out that a unified documentation including all parameters should be present. This aids the clinicians in making decisions regarding patient care, enhances patients' safety and prevents important information from being missed. In addition, this could potentially save time especially on ward rounds.

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A COORDINATED NATIONAL RESPONSE MAINTAINED A SAFE AND EFFECTIVE UK LIVER TRANSPLANT PROGRAM DURING THE FIRST YEAR OF THE COVID-19 PANDEMIC

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Background UK healthcare provision has been severely affected by the COVID-19 pandemic, with specific challenges in liver transplantation (LT). Here, we describe the co-ordinated response to, and impact of, the first year of COVID, across all 7 adult and 3 paediatric UK LT centres.

Methods A series of national policy changes affecting the LT process were agreed. A 'high-urgent' (HU) category was established, prioritising for LT those with UKELD >60, HCC reaching transplant criteria, and others likely to die within 90 days. Donor age restrictions and changes to offering were phased throughout the year. These changes were flexed in response to the 'first wave' (implemented: March–July 2020) and 'second wave' (implemented: Jan–April 2021). During the second wave, organ and patient 'back-up' arrangements were introduced, selected centres were designated 'protected' by