BASL ArLD SIG meeting minutes

09 July 2020

The SIG met virtually on 9/7/20 with 47 attendees, chaired by Dr Ashwin Dhanda.

1. Alcoholic hepatitis – update on current and future research activity (Nikhil Vergis)

Dr Vergis provided an update on current studies. The ISAIAH trial (canakinumab v placebo) had a dip in recruitment activity in March and April due to COVID but there has been a significant rebound in June with strong recruitment. The MICAH trial is still in set up. Currently only Torbay has a green light to proceed but several other sites are close to opening.

Following the results of a small phase 2A study of the compound DUR-928 in 18 patients with moderate and severe AH, the sponsor (DURECT) is likely to open a larger phase 2B study in the UK in the near future.

Dr Vergis is leading a NIHR fellowship application which includes a trial platform for AH (multi-arm multi-stage [MAMS] design). This efficient trial design has the advantage of being adaptive with arms added or removed as needed. The sample size required is lower than traditional designs. The budget is tight and requires the use of historic controls from the STOPAH trial. The plan is to develop the proposal to test pioglitazone and metformin initially. The trial platform would be funded for 3 years. Subsequent modifications to the study will require separate funding.

Action: A working group is to be established to develop a NIHR proposal to add to this trial platform

2. Minimum unit pricing in Scotland (Ewan Forrest)

Prof Forrest provided a verbal update of the early effects of minimum unit pricing in Scotland since it was introduced just over two years ago. Initial data suggested a reduction in alcohol-related hospital admissions and liver-related deaths. However, the effects of COVID and lockdown seem to have reversed this effect in recent months. This may have an impact on the policy which has a sunset clause and will be reassessed for its benefit in the near future.

3. ArLD and COVID (Ashwin Dhanda)

This led to a discussion around the effect of lockdown on ArLD patients. Dr Dhanda presented some data from two UK surveys of alcohol consumption during lockdown. Both showed that more people reduced rather than increased alcohol consumption during the lockdown period. However, retail sales data show an increase in alcohol sales in supermarkets (up by 67%) and off-licences (up by 31%). The effect of lockdown on alcohol consumption is likely to be unequal across the population. Pre-existing high risk drinkers may be most affected. Additionally, it was noted that community alcohol services have been scaled back and detox units shut.

Anecdotally, there have been a greater number of hospital admissions with ArLD and these have been more severe with more complications such as variceal bleeding and alcoholic hepatitis. This phenomenon appears to have been observed at most centres around the country. Data has already been gathered locally in several centres but it was agreed that a SIG-wide approach would help

define the problem nationally. HES data would be useful but is unlikely to be granular enough to answer our question in full.

Action: A working group will be put together to coordinate data collection from centres around the UK.

4. WALDO and ALLHEAL (Richard Parker)

Dr Parker updated us on the progress of two observational studies that are open to new investigators. WALDO is a retrospective study of biopsy proven ArLD with data collection on outcome and mortality. Currently 472 patients have been recruited with a median follow-up of 3.2 years. ALLHEAL is a prospective study of any liver disease that permits access to participants' records in the future. An application for NIHR portfolio adoption is in progress which will be helpful to support other sites to recruit. Any contributor to these studies would have access to the dataset and can lead on research outputs that result from it. Interested collaborators should contact Dr Parker directly.

5. Access to transplantation – results of a regional audit (Anju Phoolchand)

Dr Phoolchand, an ST5 undertaking her NTN year in Plymouth/King's undertook a regional audit and presented her results to the group. The objective was to determine whether patients with ArLD cirrhosis are being considered for transplantation. A regional spot audit of all inpatients in the south west was conducted. Patients had advanced liver disease but almost half were abstinent from alcohol at presentation. Few patients had a documented discussion or decision regarding suitability for transplant. Full results are due to be presented at BSG 2021 in February.

The group commented that this would be a good SpR network project. Data should be collected on outpatients too as this is where these discussions often take place. We should also ask patients whether transplant has been considered. Dr Allison commented that he is leading work with NCEPOD to collect information on access to transplantation at a national level. There is an opportunity to dovetail this with more specific data.

Action: AD to coordinate with Mike Allison regarding national audit

6. Transplantation for severe alcoholic hepatitis (Mike Allison)

Dr Allison provided an update. There is currently a service evaluation of transplantation for patients with Acute on Chronic Liver Failure but alcoholic hepatitis is specifically excluded. The next step is to document which patients are discussed with and turned down by the transplant centres to identify any specific groups with a lack of access to transplantation. Basic prospective anonymised information will be collected by transplant centres on all patients discussed. This may be helped by several centres introducing electronic records of all referrals. However, it was noted that this would not identify patients not formally referred.

7. Patient involvement (Ashwin Dhanda)

Dr Dhanda led a group discussion about patient involvement in the SIG. It is noted that patients with ArLD are under-represented in liver patient groups despite ArLD being the most common cause of liver disease in the UK. Contribution to the SIG would be invaluable to provide a patient perspective and help guide the SIG's future activities. Many clinicians have a small number of patients who are engaged with clinical and research development and contribute as patient representatives. With the patient's permission, a pool of patient representatives known to SIG members could be drawn together and included in SIG activities.

It was commented that terms of reference are required so patients are aware of what is expected from the role. Resource for such a PPI group would also be needed. Furthermore, training of representatives would be helpful.

Action: AD to develop terms of reference and investigate training opportunities. SIG members will then be asked to contact and gain permission from potential representatives to share their details with the SIG.

8. Development of a ArLD patient care pathway (Lynn Owens)

At the last SIG meeting it was noted that several guidelines for the management of ArLD have been recently published and there was no appetite to generate more. However, there is a gap around holistic care of this patient group. We revisited this idea and feel that a document can be developed to guide the optimal care pathway for ArLD patients. This would include a multidisciplinary 'wrap-around' approach with input from all health professionals ranging from addiction services to community care. Lynn Owens has kindly agreed to coordinate a working group to take this forward.

Action: Interested SIG members will be invited to join a working group

9. Any other business

Mike Allison – would like to amend the ICD-10 codes for liver disease which have led to poor quality coding of activity. The SIG is supportive of rationalising the coding system.