

# **BASL Portal Hypertension SIG Steering Committee Inaugural Meeting (Teleconference)**

## **Minutes**

Wednesday 7<sup>th</sup> November 2018

16:00 – 17:00

Participants:

D Tripathi (DT, Chair), Jonathan Fallowfield (JF), Peter Hayes (PH), Jo Leithead (JL), Raj Mookerjee (RM), David Patch (DP), Vikram Sharma (VS), Adrian Stanley (AS), Emmanouil Tsochatzis (ET)

### 1. Introductions and apologies

No apologies with 100% participation! DT introduced the concept of the portal hypertension SIG. He was appointed by the BASL committee to lead the SIG for the first year. DT thanked all members of the steering committee for their participation.

### 2. BASL SIG terms of reference (attached)

The ToR were discussed. Key points:

- a. SIGs are open to all members, even those that are not members of BASL. Patients and lay public can also be members – this is encouraged by BASL. BASL hope that this will boost BASL membership.
- b. Admin support will be provided by BASL appointed administrator (Samantha Jones)
- c. Close links with CRNs and BSG. SIG lead expected to attend and report at the BASL-BSG Research Development Group meetings. The SIG is expected to support studies and grants submitted by individual members of the SIG after approval by SIG members.
- d. Links with industry are encouraged where appropriate.
- e. Publications are encouraged, although a current limitation is that BASL does not yet have a journal. It is expected BASL may collaborate with other societies in publications.
- f. SIGs will be approached to respond on behalf of BASL to national bodies such as NICE and HTA e.g. consultation for guidelines or NICE TAs.
- g. All agreed on the inclusive nature of the SIGs, and the importance of encouraging those that will play an active role and promote the activities of the SIG/BASL.

### 3. Research agenda

#### a. Clinical trials

- i. CALIBRE (Carvedilol versus variceal band ligation in primary prevention of variceal bleeding in liver cirrhosis).  
<https://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/portfolio-v/CALIBRE/CALIBRE.aspx>  
CI: D Tripathi  
Funding: NIHR HTA

CALIBRE is now open to recruitment and SIVs are well under way. There is an investigators meeting will take place in Birmingham on 6/12/18. More details:

<https://www.eventbrite.co.uk/e/calibre-investigators-meeting-tickets-51290279607?ref=>

DT encouraged all to support CALIBRE recruitment and send representation to the investigators' meeting.

- ii. HTA 17/32 variceal bleeding in patients with small oesophageal varices in cirrhosis. BOPPP <https://www.bsg.org.uk/resource/uk-wide-multi-centre-study-boppp-trial.html>  
CI: V Patel  
Funding: NIHR HTA

BOPPP is at set up stage. The protocol is being written. The proposed bleed rate of 15% at 3 years for patients with small varices and absence of red signs was felt to be higher than in the literature. All agreed on the need to support this trial which is complementary to CALIBRE. DT is in regular contact with the CI of BOPPP.

- iii. Early TIPSS trial  
CI: P Hayes

PH informed the group that recruitment completed in January 2018 with 65 patients recruited. He emphasised the logistical challenges with regards to prioritising an intensive care unit bed for patients who were stable after a variceal bleed. Data is being analysed and it is expected that the results will be submitted to ILC 2019 as a late breaking abstract.

There was discussion about whether there would be much of an appetite for a multicentre RCT given the logistical limitations.

- iv. Vascular liver disease: MASCOT - D Tripathi/ D Patch. Budd Chiari. INCPH. Collaborations with VALDIG.

DT mentioned the MASCOT study which is an observational study of patients who have myeloproliferative neoplasm with or without splanchnic vein thrombosis. It is a collaboration of haematology and hepatology at RFH and QEHB. Liver related outcomes include extension of thrombosis, variceal progression and decompensation. Recruitment is complete. Follow up underway.

DT & DP are members of VALDIG and actively involved with projects. Collaborations with VALDIG were encouraged by the group.

- v. Statins – E Tsochatzis.

ET informed the group that following previous discussions, there is at present insufficient data for NIHR HTA to fund a phase III clinical trial. He has been advised to seek funding from EME with a mechanistic primary end point. The proposal is for a study of 100 patients with 1 year follow up looking at effects on HVPG and non-invasive markers. The data from the study would be the basis to apply for funding for a Phase III study in compensated cirrhosis. ET will circulate a synopsis for discussion at the next meeting.

RM also mentioned the LiverHope Study (NCT03150459) which is a double blind placebo controlled RCT to evaluate Simvastatin Plus Rifaximin in Decompensated Cirrhosis. The aim is to recruit over 200 patients by autumn

2019. RM is the local PI and UCL are one of the Grant holders of a £6m EU grant. RM will keep the group updated. RM pointed out a recent study from Kolkata <https://doi.org/10.1097/MEG.0000000000001006> showing similar data to the previous Spanish study with added effects of statin over NSBB in reduction of HVPG. ET pointed out the short follow up of this study.

- b. Translational/mechanistic studies
  - i. CALIBRE sub studies
    - RM and DT are putting together an EME grant for biobanking of samples from a subgroup of patients (n=500) in the CALIBRE trial focusing on the effects of carvedilol on inflammation, immune response (PBMC), and oxidative stress.
  - ii. MRI
    - 1. B-SMART
      - There have been some technical issues and recruitment has been slow.
    - 2. MAPLE
      - DT will contact the lead site for more details of recruitment. It is believed that recruitment has again been slow.
  - iii. Relaxin (JF/PH)
    - Phase I and II studies have been published showing promising results on haemodynamic effects. A Phase RCT (NCT02669875) was unfortunately stopped prematurely as Novartis have stopped making Serelaxin. It is likely other pharmaceutical companies will make the drug or similar but at present the trial is on hold. JF also mentioned grants held for investigating biomarkers of AKI.
  - iv. HVPG-blood flow comparator study (RM/UCL)
    - This is an extension of the MRI protocol.
- 4. Clinical guidelines
  - a. TIPSS (BSG) – D Patch/ D Tripathi
  - b. Ascites (BSG) – G Aithal

Both these guidelines are being put together by the respective GDGs. It is hoped that BASL SIGs will be involved with future guidelines. An option is to consider ratification of the BSG guidelines by BASL but this will need further discussion perhaps at the Annual Meeting.
- 5. Databases
  - There was general agreement that these should be considered in the future. They would need to be specific groups of patients. It would be important to adhere to GDPR.
- 6. BASL Portal Hypertension SIG annual meeting
  - All agreed that this should be in spring/summer 2019. DT will circulate a proposed programme prior to next SIG steering committee meeting but is welcome to suggestions.
- 7. SIG membership drive
  - DT encouraged membership of the SIG through the BASL website. All steering committee members were encouraged to spread the word.
- 8. Next SIG Steering Committee meeting to be decided but will be in Jan/Feb 2019. DT will send a Doodle poll.