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Retrospective Cohort Study

Survival outcomes and predictors of mortality, re-bleeding and complications for acute severe variceal bleeding requiring balloon tamponade

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Answers to Reviewers:

We would like to sincerely thank both the reviewers for their time and valuable suggestions. Please find the responses below.

Reviewer #1

2. There was significant variability in inflation volumes of balloons with insufficient inflation of gastric balloon in 20% and insufficient inflation of oesophageal balloon in 45% which may affect primary haemostasis rate

• Note that migration of the SBT was not 20% due to underfilling (the underfilling of the gastric balloon was 20%, only 3 patients had documented SBT migration)

a) Training for gastroenterologists

- Although a high primary haemostasis rate was achieved despite suboptimal utilisation of SBT insertion, we believe that this further enforces training for gastroenterologists as important
- Optimal insertion technique and adequate volume inflation may produce even higher primary haemostasis rates (in this condition where failure to achieve primary haemostasis inevitably results in death)

- Avoidance of underfilling may also result in less SBT migration upwards into the oesophagus and reduce the chance of complications such as oesophageal perforation
- A statement regarding this has been inserted in the discussion section
- b) Reason for failure of primary haemostasis (n=7)
- The SBT technique is known not to be 100% effective and in some patients varices will bleed despite tamponade. Also, there may be concurrent bleeding from other varices not tamponaded (eg. gastric varices) where this may be difficult to appreciate with poor views obscured by high volume bleeding
- There were 7 patients who did not achieve primary haemostasis with documented clinical evidence of active variceal bleeding despite inflation of the SBT all these patients continued to rapidly deteriorate with worsening haemodynamic instability and vasopressor/inotrope requirements until death within hours which strongly suggests the cause of death was uncontrolled bleeding
- Only 1 of 7 patients had an insufficiently inflated gastric balloon (documented 100 ml) but all other 6 patients had likely adequately inflated gastric balloons at 250-400 ml so the failure of primary haemostasis is unlikely to be purely due to suboptimal inflation
- Only 2 patients had documented inflation of the oesophageal balloon at the same time
- This information has also now been inserted in the discussion section
- c) Limitation of study
- While not all patients with SBT inserted had optimal inflation of the balloons, the information regarding volume of balloon inflation and duration of inflation is not provided in other studies for comparison and reflects real world practice eg. high stress environment, unfamiliar procedure, variable experiences with specialists
- So while this is a limitation of the study to determine the "best attainable" primary haemostasis rate using SBT, this wasn't really the objective of the study but a statement regarding this limitation has been inserted in the discussion section as well

3. The references have been checked and amended, apologies

Reviewer #2

- The p values of the survival curve analyses have been inserted in Figures 2-4 (that depict survival curves for MELD >19, HCC and re-bleeding)
- The editing errors have been checked and amended