

Introduction Transfusion thresholds for upper gastrointestinal bleeding (UGIB) are controversial. Observational studies suggest associations between liberal red blood cell (RBC) transfusion and adverse outcome, and a recent trial reported increased mortality following liberal transfusion.

Methods Pragmatic cluster randomised trial to evaluate the feasibility and safety of implementing a restrictive (transfusion when haemoglobin (Hb) <8g dL) versus liberal (transfusion when Hb <10 g/dL) RBC transfusion policy for UGIB. Hospitals were randomised to a policy which was implemented through a multi-faceted educational intervention targeting all staff caring for patients with UGIB. All adult patients were eligible to participate, regardless of co-morbidity; the only exclusion criterion was exsanguinating haemorrhage. Feasibility and exploratory clinical outcomes were recorded up to day 28.

Results 936 patients were enrolled in 6 hospitals. The consent rate for follow up was higher in the liberal arm (62% vs. 55%; $P = 0.04$). There were some baseline imbalances, however the Rockall and Blatchford scores were identical between arms as was the prevalence of ischaemic heart disease (IHD) (14% liberal arm vs. 15% restrictive arm). Protocol adherence was 96% in the restrictive arm vs. 83% in the liberal arm. In patients with a Hb <12 g/dL, the Hb at discharge was 10.7 g/dL (sd 1.2) in the liberal arm vs. 10.1 g/dL (sd 1.3) in the restrictive arm ($P = 0.05$). In the restrictive arm there was a 13% absolute reduction in the proportion of patients receiving RBCs (95% CI for difference in% -35 to 11, $P = 0.23$) with a mean of 0.8 fewer RBC units transfused (95% CI: -1.9 to 0.3, $P = 0.12$). Clinical outcomes were better in the restrictive arm, although differences were not statistically significant (28-day mortality, 7% liberal vs. 5% restrictive, adjusted difference in% = -1.3, 95% CI: -8.0 to 5.5, $P = 0.63$; further bleeding, 9 vs. 5%, $P = 0.29$; serious adverse events, 22% vs. 18%, $P = 0.48$). In the subgroup with IHD, there was a large observed difference for mortality (12% restrictive arm ($n = 6$) vs. 3% liberal arm ($n = 2$); interaction $P = 0.11$).

Conclusion The protocol was feasible and generated clinically important differences in the level of anaemia and RBC exposure. There was a consistent trend towards fewer complications in the restrictive arm, apart from the increased mortality observed in patients with IHD, which could in part be explained by imbalances in baseline risk. A large trial is required to clarify the risk-benefit balance before advocating restrictive RBC transfusion for all patients with UGIB.

Disclosure of Interest None Declared.

PTU-185 UPDATE ON THE HALT-IT TRIAL PROGRESS: TRANEXAMIC ACID FOR THE TREATMENT OF GASTROINTESTINAL HAEMORRHAGE – AN INTERNATIONAL, RANDOMISED, DOUBLE BLIND PLACEBO CONTROLLED TRIAL

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10.1136/gutjnl-2014-307263.259

Introduction Gastrointestinal (GI) bleeding is a common medical emergency and an important cause of morbidity and mortality in

high, middle and low income countries. Despite advances in resuscitative, pharmacological and endoscopic therapy, re-bleeding occurs in 10% of patients with non-variceal bleeding and up to 25% of those with variceal bleeding and is an important predictor of death. Excessive fibrinolysis may play an important role both in the failure to control initial bleeding and in the precipitation of re-bleeding through premature breakdown of blood clots at sites of vascular injury. This raises the possibility that an antifibrinolytic drug administered following GI bleeding could limit severity of bleeding and transfusion requirements.

Methods HALT-IT has been designed as a large, pragmatic randomised controlled trial which aims to quantify the efficacy and safety of tranexamic acid (TXA) in adults with significant acute upper or lower gastrointestinal bleeding. The trial will determine the effect of early administration of TXA on mortality, morbidity, blood transfusion, surgical intervention and health status in patients with GI bleeding. The primary outcome is death in hospital within 28 days of randomisation. Secondary outcomes include re-bleeding, need for surgery or radiological intervention, blood product transfusion and thromboembolic events.

Results UK recruitment began in August 2013. By January 2014, a total of 507 patients were randomised across 26 actively recruiting sites, averaging a recruitment rate of 20 patients per week. Centralised and statistical data monitoring ensures trial participants meet inclusion criteria and allows real time monitoring of event rates for the primary and secondary outcomes. The results will be presented by intention to treat and a pre-specified subgroup analysis will also determine the treatment effect in patients with liver cirrhosis and variceal bleeding.

Conclusion HALT-IT aims to recruit 8000 participants in hospitals worldwide and recruitment is ahead of schedule based upon a strong performance in the UK. The success of the trial to date has been dependent upon multi-disciplinary and societal engagement as well as infrastructural support provided by NIHR research networks. The results will add to our expanding knowledge about the role of tranexamic acid as an agent for patients with significant bleeding. It is anticipated that the full trial results will be available in 2017.

Disclosure of Interest None Declared.

PTU-186 THE "SPEEDBOAT-RS2": A NEW MULTI-MODALITY ENDOSCOPIC DEVICE FOR GASTRIC AND OESOPHAGEAL SUBMUCOSAL DISSECTION AND TUNNELLING

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10.1136/gutjnl-2014-307263.260

Introduction Gastric and oesophageal mucosal lesions are optimally removed en-bloc for accurate histology and complete resection. We describe, a simple to use, multi-modality endoscopic device ("Speedboat-RS2") for en-bloc gastric/oesophageal mucosal resection and for oesophageal submucosal tunnelling.

Methods The 'Speedboat-RS2' cuts in forward, lateral and oblique planes using bipolar radio frequency (RF) cutting, provides haemostasis with microwave coagulation and incorporates a retractable needle for submucosal injection and tissue irrigation. The instrument blade has an insulated 'hull' to prevent thermal injury to the muscularis propria and the device catheter is partially torque stable allowing rotation and orientation of the hull