100

Multi-Center Randomized Trial Comparing the 19G and 25G Needles for EUS-Guided FNA of Large Solid Pancreatic Mass Lesions

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Background: Retrospective studies suggest that given the increased necrosis in large solid pancreatic mass lesions, more passes are required at EUS-FNA for establishing onsite diagnostic adequacy. The hypothesis of this study is that a larger gauge needle will procure more tissue than a smaller gauge needle and therefore will establish the diagnosis with fewer FNA passes. Aim: To compare 19 and 25G needles for EUS-FNA of large solid pancreatic mass lesions. Methods: In this multi-center trial, patients with solid pancreatic mass lesions 35mm or greater in size were randomized to undergo EUS-FNA using 19 or 25G needle. FNA maneuvers were performed using the fanning technique and without the use of suction. A pathologist blinded to randomization sequence evaluated specimens onsite for diagnostic adequacy. Main outcome measures: Compare the median number of passes needed to establish onsite diagnostic adequacy, specimen quality (bloodiness graded as mild if <33%, moderate if 34-66%, severe if >67%) and complications between 19 and 25G needles. Sample size was estimated based on detecting a difference of one pass required to establish onsite diagnostic adequacy, using standard deviation of 1 for 19G and 1.9 for 25G needle (power 80%, $\alpha=0.05$). Results: Of 80 randomized patients (19G=40; 25G=40) there was no significant difference in patient or disease characteristics between the cohorts (Table). Except for specimen bloodiness that was significantly greater in the 19G cohort, there was no difference in the median number of passes required to establish onsite diagnostic adequacy, final diagnosis, technical failures (none) or complications (none) between the two cohorts. Conclusion: 19G needle has no advantage over a 25G needle for establishing onsite diagnostic adequacy when performing EUS-FNA of large solid pancreatic mass lesions.

	19G Needle (N=40)	25G Needle (N=40)	P
Median age (IQR): years	72.5 (62.5-77)	69.5 (61-76)	0.547
Male gender: n (%)	28 (70)	22 (55)	0.166
Median size (IQR): mm	40 (36.5-50)	40 (35-50)	0.981
Head/Uncinate Mass: n (%) Body/Tail Mass: n(%)	28 (70) 12 (30)	28 (70) 12 (30)	0.999
Vascular Invasion: n (%)	26 (65)	32 (80)	0.133
Onsite diagnostic adequacy: n (%)	39 (97.5)	40 (100)	0.999
Median passes to diagnosis (IQR): n	1 (1-1)	1 (1-1)	0.147
Moderate-Severe Bloodiness: n (%)	28 (70)	15 (37.5)	0.004
Needle cross-over: n (%)	1 (2.5)	0	0.999
Neoplastic: n (%) Chronic pancreatitis: n (%)	36 (90) 4 (10)	39 (97.5) 1 (2.5)	0.300

155

Risk Stratification in Acute Upper Gastrointestinal Bleeding: AIMS65 Is Superior to Glasgow-Blatchford and Rockall Scoring Systems in Predicting Inpatient Mortality

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The American College of Gastroenterology recommends early risk stratification in patients presenting with upper gastrointestinal bleeding (UGIB). Multiple algorithms predicting outcomes in UGIB have been developed, the most widely used of which are the Glasgow-Blatchford (GBS) and Rockall scores. AIMS65 is a novel risk stratification score recently validated to predict inpatient mortality, although its predictive accuracy has not been compared with both GBS and Rockall scores. AIMS65 assigns 1 point for: albumin level <3g/dL, INR >1.5, altered mental status, systolic blood pressure <90mmHg and age older than 65 years. Compared with existing scores, AIMS65 has the advantage of not being weighted and can be calculated with pathology values routinely obtainable in the emergency department. Aims: To validate AIMS65 as a predictor of inpatient mortality in patients presenting with UGIB and to compare AIMS65 with established GBS and pre-endoscopy Rockall scores. Methods: ICD-10 codes were used to identify patients presenting with UGIB requiring endoscopy to the Austin Hospital, a tertiary referral centre, over a 42-month period from 2010 to 2013. Patients were excluded if data required for calculation of risk scores were incomplete or if medical records revealed an alternative diagnosis. All patients were risk stratified using AIMS65, GBS and Rockall scores. Primary outcome was inpatient mortality. Secondary outcomes were: a composite endpoint of inpatient mortality, in-hospital rebleeding, and endoscopic, radiologic, or surgical intervention; blood transfusion requirement; intensive care unit (ICU) admission; rebleeding; and hospital length of stay. The area under the receiver-operating characteristic curve (AUROC) was calculated for each score. Results: 424 patients were included in the study. Median age was 71 years (range 15-93) and 66% were male. 293 (69%) patients presented on antiplatelet or anticoagulant therapy (154 (36%) aspirin, 48 (11%) clopidogrel and 90 (21%) warfarin or heparin); 209 (49%) presented on a proton pump inhibitor. Mortality was 4.3% and 17% achieved the composite endpoint. AIMS65 was superior to both GBS (AUROC 0.80 vs. 0.76, p<0.027) and Rockall (0.74, p=0.001) in predicting inpatient mortality and need for ICU admission (AUROC 0.74 vs. 0.70, p=0.005; and 0.61, p<0.001). GBS was superior to AIMS65 (AUROC 0.89 vs. 0.71 p<0.001) and Rockall (0.66, p<0.001) at predicting blood transfusion. AIMS65 and GBS were equivalent and both superior to Rockall in predicting the clinical composite endpoint (AUROC 0.62 vs 0.62, p=NS; and 0.55, p<0.001). Conclusion: AIMS65 is a simple risk stratification score for UGIB with superior accuracy to GBS and pre-endoscopy Rockall scores in predicting in-hospital mortality and need for ICU. If these results are confirmed in a prospective trial, AIMS65 should become the new standard of care.

156

Blood Transfusion in Acute Gastrointestinal Bleeding

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Background: Blood transfusion is a prominent element in clinical management of gastrointestinal (GI) bleeding. Packed red blood cell (PRBC) transfusion has been associated with adverse outcomes in a number of disease settings (burns, surgery). In GI bleeding, assessment of the need for PRBC transfusion has been confounded by the severity of illness and comorbidity that might have led to transfusion. Thus, we hypothesized that PRBC transfusion in GI bleeding is harmful even after adjusting for these conditions. Methods: 2733 patients presenting with acute GI bleeding were identified at 2 tertiary referral centers between 7/1/2006-12/31/2012. >100 clinical variables were collected. The severity of illness on admission was assessed using the sequential organ failure assessment (SOFA) scoring system. Outcomes including rebleeding, surgery, angiography, and death were assessed. Logistic regression analysis was performed by including 34 clinical variables in a model to determine their relationship with 30 day mortality. Results: 1918 patients were included. The mean age was 54, including 36% females. The mean hematocrits were 33% and 25% in the no transfusion and transfusion groups, respectively. The most common endoscopic lesions were ulcer disease and diverticulosis, in the upper and lower GI tracts, respectively (Table). Most patients received 2 units of PRBCs, regardless of SOFA score or cardiovascular status. Patients with a hematocrit < 21% represented a minority of patients in all SOFA score categories. There was a weak correlation between SOFA score and hematocrit (r=0.31). 30 day mortality was 7.1%, including 2.6% in those without transfusion, and 10.5% in those with PRBC transfusion, P<0.001). The mortality of those receiving a blood transfusion rose sharply in proportion to increasing admission SOFA scores (Figure 1). Patients not receiving a transfusion had a low mortality even at high SOFA scores. A history of cirrhosis, cancer, blood transfusion, elevated INR, elevated serum creatinine, elevated serum bilirubin, SOFA score, cerebrovascular accident, myocardial infarction, ICU admission, mechanical ventilation, use of vasopressors and surgery during hospitalization were independently associated with increased 30-day mortality. On multivariate logistic regression, after adjusting for SOFA score, PRBC transfusion was found to be associated with increased mortality OR 2.87 (1.68-4.90). Conclusions: In this large cohort including patients with acute GI bleeding, PRBC transfusion was associated with increased 30-day mortality, even after adjustment for potential confounders. The degree of anemia on admission did not correlate well with the severity of illness as measured by SOFA score, and thus is a poor transfusion trigger. The data suggest that re-defined transfusion practices may improve patient outcomes in gastrointestinal bleeding.

Clinical Features

	No blood transfusion (n = 840) (95% CIs)	Received Blood Transfusion (n=1078) (95% CIs)
Demographics		
Mean Age (years)	52 (51-53)	56 (55-57)
Female	35% (32-38)	37% (34-40)
Admission Clinical Data		
Systolic Blood Pressure (mean, mmHg)	130 (128-131)	119 (118-121)
Pulse (bpm)	91 (89-94)	95 (94-97)
SOFA (Mean - max @ 24 hrs)	1.5 (1.3-1.6)	2.4 (2.3-2.6)
ICU Admission	10%	36%
Use of pressors	2%	5%
Upper GI Tract Lesions		
Gastric/duodenal Ulcer	18%	29%
Gastroesophageal Varices	15%	21%