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Andexanet alfa use for reversal of factor Xa inhibitors

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OBJECTIVE: Andexanet alfa, a recombinant modified human factor Xa, was approved by FDA in May 2018 for the reversal of life-threatening or uncontrolled bleeding due to apixaban and rivaroxaban administration. The purpose of this review was to evaluate safety and efficacy, adherence to health system restriction criteria and approval process, and identification of barriers to timely administration.

METHODS: Electronic medical records of patients who received andexanet alfa between June 1st, 2018 and September 1st, 2020 were reviewed. Efficacy analysis was completed using modified criteria adapted from the ANNEXA-4 study, demonstrating hemostasis by 12 hours. Patients with multiple foci of intracranial bleeding were excluded from the efficacy analysis and patients who were admitted for less than 72 hours were excluded from the safety analysis.

RESULTS: During the study period, 35 patients received andexanet alfa. Among patients who received andexanet alfa for intracranial hemorrhage, 67% achieved good or excellent hemostasis. The mean length of hospitalization was 9 days and mean ICU stay was 5 days. No thromboembolic events were noted, and 7 patients died within 30 days. 74% of andexanet alfa orders adhere to restriction criteria and approval process. The median time from recognition of intracranial hemorrhage, defined as the time the CT head was read to the initiation of the reversal agent, was 110 minutes.

CONCLUSION: The use of andexanet alfa for intracranial hemorrhage in our health system achieved lower rates of good or excellent hemostasis compared to that in the intracranial hemorrhage subgroup from the ANNEXA-4 study. The majority of andexanet alfa use adhered to the restriction criteria and approval process; however, the approval process can be streamlined further to ensure timely administration of this agent for life-threatening bleeds.

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Development of a health system interdisciplinary pain care conference

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PURPOSE: The Johns Hopkins Medicine Opioid Stewardship Clinical Community (OSCC) identified the need for an interdisciplinary complex pain care conference including pain management and addiction services personnel, clinical pharmacists, and additional stakeholders. The objective of this project is to strategically develop the framework and resource plan needed to establish a sustainable conference through evaluating feasibility of partnership, developing didactic objectives and curriculum, and creating evaluation methods for conference improvement. This conference will foster discussion surrounding treatment of complex pain patients within The Johns Hopkins Health System (JHHS) and create an open exchange of best practices and evidence-based treatment guidance using clinical case-based examples.

SUMMARY: A small workgroup convened to develop a Strength, Weakness, Opportunity, and Threat analysis to evaluate a partnership with Project Extension for Community Healthcare Outcomes (ECHO)® versus developing conference infrastructure internally. Existing Project ECHO® forums were observed, and a feasibility assessment regarding longitudinal conference coordination expenses was written. With stakeholder collaboration, an agenda, conference effectiveness evaluation metrics, and curriculum topics will be developed. Emphasis was placed on establishing sustainable coordination for the quarterly interdisciplinary conference including meeting coordination, curriculum and case development, and strategies to promote conference attendance.

CONCLUSION: Developing a sustainable interdisciplinary complex pain care conference will allow for collaborative treatment of complex patients. This conference requires resources in the form of 10% effort of FTE coordinator support regardless of the final decision determining conference infrastructure. Next steps include finalizing quarterly participant evaluation, attendance list for conference implementation, sustainability planning, and surveying key stakeholders for input on didactic curriculum.

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Evaluation of adherence to the adult acid suppression clinical practice guidelines

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BACKGROUND: Acid suppression therapy (AST) reduces the risk of gastrointestinal bleeding (GIB). Proton pump inhibitors (PPIs) are recommended for high-risk patients for stress ulcer prophylaxis (SUP). AST may be associated with Clostridioides difficile infection (CDI) and pneumonia. Appropriate AST per clinical practice guidelines needs to be evaluated.

METHODS: This is a retrospective chart review study at MedStar Harbor Hospital (MHH). 100 patients from November 2019 to April 2020 were included. Inclusion criteria are adults ≥ 18 years old, ≥ 48 hours hospitalization, coagulopathy (platelets < 50,000 mm3 or INR > 1.5), mechanical ventilation > 48 hours, or dual antiplatelet therapy (DAPT). Exclusion criteria are contraindication to histamine 2-receptor antagonists (H2RAs) or PPIs, chronic AST, warfarin therapy, active upper GIB. The primary outcome is adherence to AST clinical practice guidelines. The secondary outcomes are subgroup analysis per indication, prescribing pattern, inappropriate AST at discharge, incidence of upper GIB, mortality, CDI, and pneumonia. Data analysis was performed using descriptive statistics, Fisher's exact test, and odds ratio.

RESULTS: AST was started in 46% of indicated patients. Subgroup analysis per indication (Table 1) showed an adherence rate of 91.3% (OR= 21.84; 95% CI, 4.74 to 100.54, P= 0.0001) in mechanical ventilation > 48 hours. Famotidine accounted for 87% of AST. 22.2% of patients were discharged from hospital on inappropriate AST. The incidence of upper GIB, mortality, CDI, and pneumonia were not statistically significant.

CONCLUSION: Pharmacists and other healthcare providers can play an important role in appropriate AST initiation and continuation aligned with evidence-based recommendations.

Criteria	AST Initiation n (%)	Odds Ratio (95% CI)	p-value
Platelets < 50,000 mm3 (n= 18)	6 (33.33)	0.52 (0.18 – 1.5)	0.24
INR > 1.5 (n = 36)	10 (27.78)	0.30 (0.12 – 0.72)	0.007
Mechanical ventilation > 48h (n= 23)	21 (91.30)	21.84 (4.74 – 100.54)	0.0001
DAPT (n=23)	9 (39.13)	0.70 (0.27 – 1.80)	0.45

Table 1: Subgroup analysis per AST indications

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Risk of hypoglycemia in non-Intensive Care Unit patients following intravenous regular insulin administration for hyperkalemia in a community hospital

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PURPOSE: At Suburban Hospital – Johns Hopkins Medicine, regular insulin administered intravenously is often utilized in the management of hyperkalemia. Following insulin administration, hypoglycemia is a possible risk that can lead to unfavorable complications including increased hospital length of stay, cognitive dysfunction and seizures. Because of the various risks associated with hypoglycemia, this study aimed to analyze the incidence of hypoglycemia in hyperkalemic patients treated with IV regular insulin at Suburban Hospital—Johns Hopkins Medicine.

METHODS: This was a retrospective cohort study performed through electronic chart review. Patients treated with at least one dose of IV regular insulin for hyperkalemia defined as a serum potassium level >5.1meq/L between January 2018 to December 2019 were included. ICU patients were excluded from this review as well as pediatric and pregnant patients. The primary outcome was hypoglycemia with blood glucose <70 mg/dL requiring treatment. Secondary outcomes compared the incidence of hypoglycemia in diabetic and non-diabetic patients as well as the length of hospital stay.

RESULTS: Hypoglycemia occurred in 22 patients (20.3%) while hypoglycemia did not occur in 86 patients (79.6%). In diabetic patients 26.2% developed hypoglycemia while in the non-diabetic population, 12.8% developed hyperglycemia.

CONCLUSION: Hypoglycemia in non -ICU patients in Suburban Hospital was not substantial. Highest incidence of hypoglycemia was in diabetic patients and patients with diminished renal function. The results of this study can be utilized to create a hyperkalemia order set that reduces the risk of hypoglycemia in the most vulnerable populations.

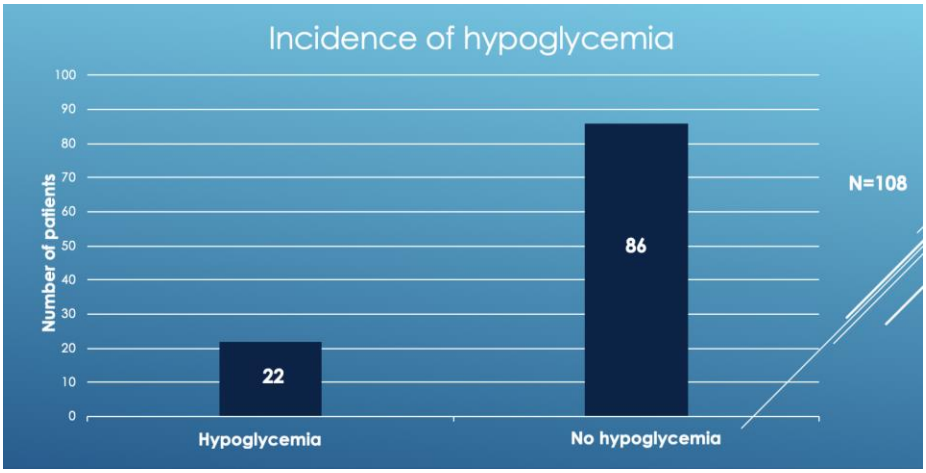

Table A: Incidence of hypoglycemia

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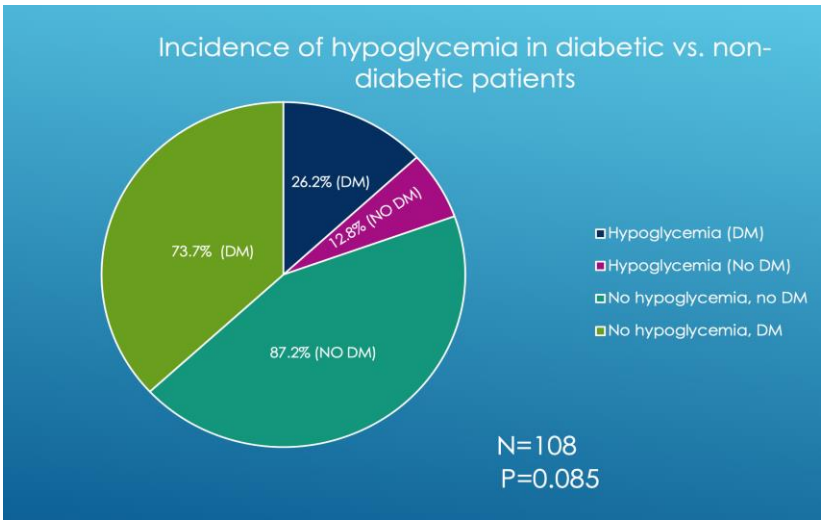

Table B: Incidence of hypoglycemia broken down by diabetic status

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Evaluating the treatment of acute delirium through a nurse-driven pain, agitation, and delirium protocol within an intensive care unit (ICU) at a community hospital

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PURPOSE: Delirium is a potential complication in the ICU that can have a detrimental effect on morbidity and mortality. The Pain, Agitation, and Delirium (PAD) protocol for mechanically ventilated patients addresses delirium while excluding non-mechanically ventilated patients at a community hospital. This study evaluated the incidence and treatment of delirium in all ICU patients at a community hospital.

METHODS: A retrospective chart review of adult patients admitted into the ICU with delirium (N=69) from March 2020 until March 2021 determined if a nurse-driven PAD protocol impacted delirium resolution through pharmacologic management. Primary outcomes measured the occurrence of delirium in critically ill patients. Secondary outcomes evaluated pharmacologic treatment of delirium in the ICU and its impact on ICU and hospital lengths of stay.

RESULTS: The rate of delirium occurrence was 36% in all patients identified over the course of one year. Benzodiazepines and antipsychotics did not have a significant effect on delirium resolution (P=0.438 and P=0.7819 respectively) while weaning sedation did have a significant impact on delirium resolution in hypoactive delirium (P=0.046). Patients who did not experience delirium resolution had longer lengths of ICU and hospital stay and significantly had longer days on mechanical ventilation.

CONCLUSIONS: While benzodiazepines and antipsychotics did not significantly impact delirium resolution for hyperactive and mixed presentations of delirium, weaning sedation was shown to have a significant impact on hypoactive delirium. Since 23% of patients with ICU delirium were not mechanically ventilated, this study emphasizes the need for a more inclusive PAD protocol.

Median Age (range)	
70 years (19 -91 years)	
Patient Characteristics	**Total Patients**
Male, n (%)	42 (61%)
Female, n (%)	27 (39%)
Use of mechanical ventilation, n (%)	53 (77%)
Psychiatric history, n (%)	17 (25%)

Table 1: Baseline characteristics

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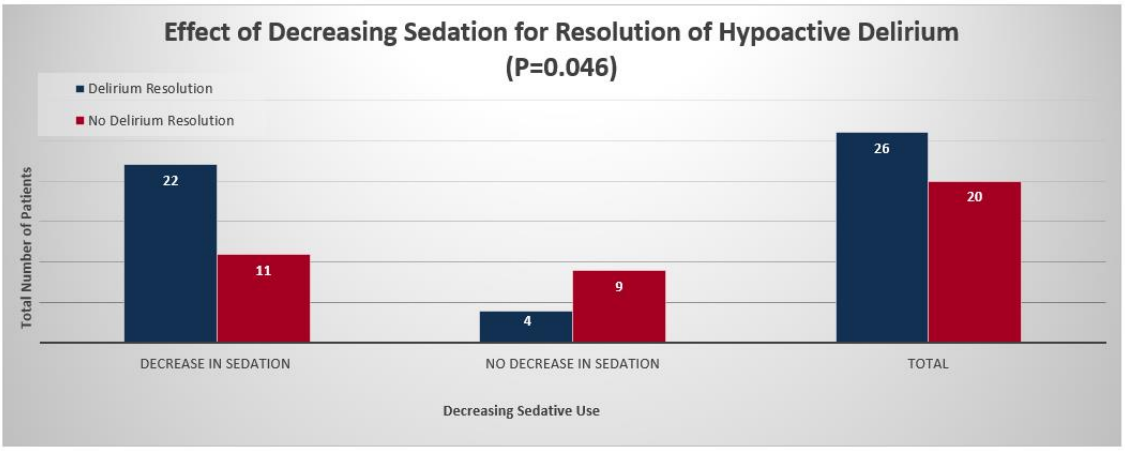

Table 2: Results

Benzodiazepines and antipsychotics did not have a significant effect on delirium resolution (P=0.438 and P=0.7819 respectively) while sedation weaning had a significant impact on delirium resolution in patients with hypoactive delirium (P=0.046)

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Safety and Efficacy of a Pharmacy-Driven Vancomycin Dosing Protocol in a Community Hospital

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BACKGROUND: The vancomycin dosing protocol at Howard County General Hospital (HCGH) was updated in 2020 to reflect current guideline evidence, including AUC/MIC-guided dosing for patients with severe *Staphylococcus aureus* infections.

OBJECTIVES: The primary efficacy outcome for this quality improvement project was to compare the percentage of vancomycin troughs within therapeutic range (9.5-20.4 mcg/mL) prior to and following protocol revision. The primary safety outcome was to compare the incidence of acute kidney injury (AKI), defined as an increase in SCr by >0.3 mg/mL or by 50% over 48 hours, between the two groups.

METHODS: This retrospective chart review included patients 18 years or older who received intravenous vancomycin therapy with at least one trough level measured during admission at HCGH between June 2019 and April 2021. Patients receiving vancomycin for surgical prophylaxis and patients with impaired renal function were excluded.

RESULTS: A total of 449 patients were included in the analysis (N=200 prior to revision; N=201 following revision; N=48 AUC/MIC subgroup). There was a similar percentage of therapeutic vancomycin troughs (58.7% vs 57%, p=0.7620) and incidence of AKI (12.5% vs 17.9%, p=0.1641) prior to and following protocol revision. A subgroup of patients dosed utilizing an AUC/MIC-guided strategy demonstrated a slightly decreased incidence of AKI compared to other patients following the protocol revision (8.3% vs 17.9%, p=0.1266). Vancomycin levels for this subgroup were categorized utilizing both a trough-guided and AUC/MIC approach, with a trend towards more drug levels categorized as therapeutic when utilizing a target AUC/MIC of 400-600 mcg*hr/mL compared to a target trough of 15-20 mcg/mL (31% vs 17%, p=0.1505) (Table 1).

CONCLUSIONS: There were no statistically significant differences in the primary efficacy and safety outcomes prior to and following protocol revision. An AUC/MIC-guided dosing strategy demonstrated a trend toward decreased vancomycin exposure and lower incidence of AKI.

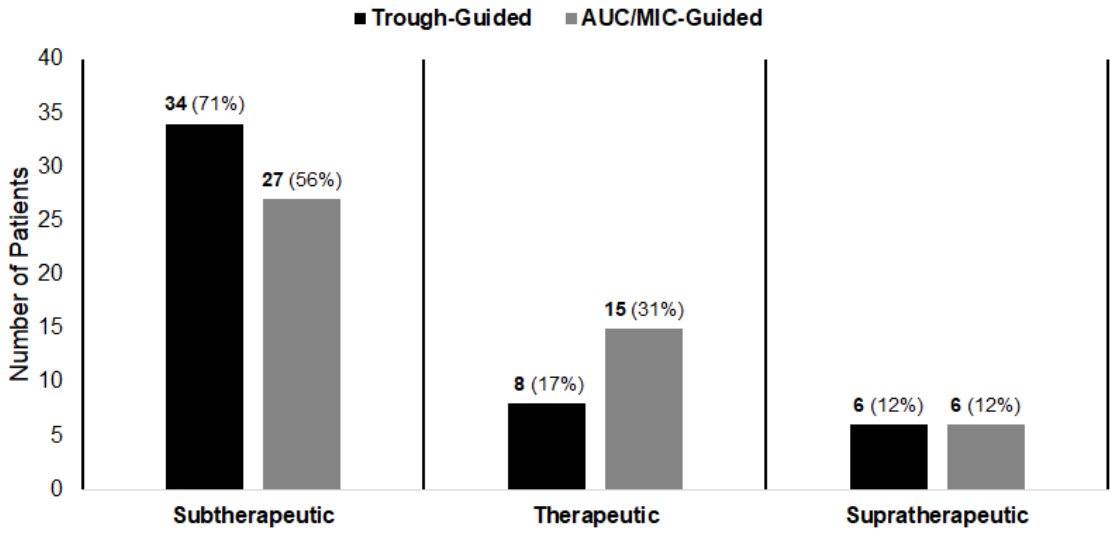

Figure 1: Vancomycin Level Categorization: Trough-Guided vs AUC/MIC-Guided Dosing
Percentage of subtherapeutic (<14.5 mcg/mL), therapeutic (14.6-20.4 mcg/mL), and supratherapeutic (>20.4 mcg/mL) troughs, utilizing trough-guided versus AUC/MIC-guided (400-600 mcg*hr/mL) strategies.