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Peptic Ulcer With Adherent Clot—Treat It or Leave It: A Systematic Review and Metanalysis of Randomized Trials

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[0658] Table 1. First endoscopic procedure EGD vs PE in LVAD related GI bleeding.

	EGD	PE	p-val
N	48	64	
Diagnostic Yield First Endoscopy, n (%)	29 (60.42)	39 (60.94)	0.96
Therapeutic Yield First Endoscopy, n (%)	20 (41.67)	35 (54.69)	0.15
30 Day Readmission due to GIB, n (%)	13 (27.08)	14 (21.88)	0.52
90 Day Readmission due to GIB, n (%)	20 (41.67)	18 (28.13)	0.13

Results: 67 patients with 204 GIB admissions while on LVAD support were included. Mean age was 66.7 ± 10.48 years, 76% were male and 78% Caucasian. GIB sources were most frequently encountered in the stomach and proximal small bowel (Figure 1A). Angiodysplasias represented the most common etiology of GIB (Figure 1B). Out of the 204 admissions, 112 patients underwent either EGD or PE as the initial endoscopic modality. 94 (83.9%) of these patients presented with melena. Compared to EGD, PE did not result in increased diagnostic (60.42% vs. 60.94%, p=0.96) or therapeutic yield (41.67% vs. 54.69%, p=0.15). When comparing diagnostic and therapeutic yields of any initial combination of endoscopic procedures that included PE (n=98) with procedures that did not include PE (n=106), still no statistically significant difference could be found (63.27% vs. 61.32%, p=0.8; 44.9% vs. 39.6%, p=0.68).

Conclusion: Despite previous studies suggesting a role of PE as initial modality in identifying and treating culprit lesions in LVAD associated GIB, our data supports that an initial approach with EGD results in similar diagnostic and therapeutic yields as most lesions are within reach with a standard endoscope. Choosing this approach did not significantly impact the 30- and 90-day readmission rates due to GIB.

S659 Presidential Poster Award

Peptic Ulcer With Adherent Clot—Treat It or Leave It: A Systematic Review and Meta-analysis of Randomized Trials

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Introduction: Peptic ulcer diseases (PUD) remain the most common cause of hospitalized upper GI bleeding patients (30%-60%). Upper endoscopy is needed for diagnosis, stratification, and endoscopic hemostatic therapy of these ulcers depending on the presence of stigmata of increased risk of rebleeding. PUDs with adherent clot (Forrest classification IIb) are at 20-30% risk of rebleeding with a 7% mortality rate. Recent ACG guidelines could not reach a recommendation for or against endoscopic interventions for ulcers with adherent clot resistant to vigorous irrigation. This systematic review and meta-analysis aims to analyze the randomized studies for the treatment of PUD with adherent clot.

Methods: The OVID/Medline and Google Scholar databases were screened through June 2021 for randomized studies reporting outcomes (rebleeding and mortality rates) in patients with adherent clot undergoing either endoscopic or medical intervention. Random effects models were used for the meta-analysis. I² statistics were used to interpret heterogeneity, with I²>75% indicating substantial

[0659] Table 1. Baseline Characteristics of Included Studies.

Author	Year	Country/Region	Adherent clot (n)	Endoscopic treatment(n)	Medical treatment (n)	Type of Endoscopic intervention
Jensen	2002	USA	32	15	17	epinephrine injection, shaving down the clot with cold guillotine, and bipolar coagulation
Bleau	2002	USA	56	21	35	Epinephrine injection and mechanical removal of the clot
Jung	2002	Korea	19	10	9	ethanol injection therapy.
Bini	2003	USA	244	138	106	epinephrine injection, treatment of underlying stigmata with a polypectomy snare or electrocoagulation
Sung	2003	Hong Kong	39	15	24	epinephrine injection followed by thermocoagulation.
Otordano	2004	Italy	156	78	78	Epinephrine injection followed by thermocoagulation using heater probe
Kim	2007	Korea	86	42	44	Endoscopic hemoclipping
Telwani	2017	USA	81	40	41	Epinephrine injection; multipolar electrocoagulation

Figure 1A

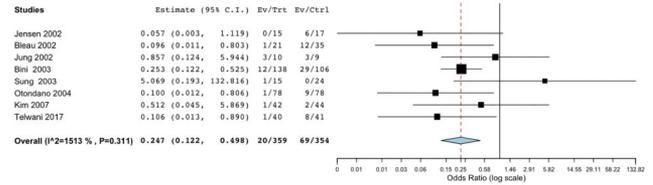
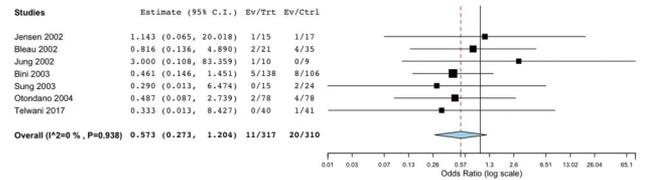


Figure 1B



[0659] Figure 1. Forest plots of re-bleeding (A) and mortality (B) rates between endoscopic and medical treatment groups.

inter-study variation. A sensitivity analysis was performed using the leave one out method. A p-value < 0.05 was considered statistically significant.

Results: Initial database search yielded 1568 articles, of which 8 randomized studies were finally included (Table 1). The total sample size consisted of 713 patients with adherent clot; of which 359 underwent endoscopic intervention while 354 were treated with medical therapy alone (proton pump inhibitors). Meta-analysis of re-bleeding and mortality rates between endoscopic and medical treatment groups revealed a decreased risk of rebleeding with endoscopic intervention (OR 0.247, 95%CI: 0.122-0.498, P=< 0.001) (Figure 1A). Mortality rates (OR 0.573, 95% CI: 0.273-1.204, P=0.151) (Figure 1B), and rates of surgery did not differ significantly between the two cohorts (OR 1.177, 95%CI: 0.598-2.317, P=0.638). However, there was heterogeneity in the type of endoscopic interventions used.

Conclusion: The results of our meta-analysis show that endoscopic interventions could benefit patients presenting to the hospital with UGIB due to PUD with adherent clot by decreasing risk of rebleeding. However, there was no effect of endoscopic therapy on mortality. Further, high-quality randomized controlled studies are needed to guide the endoscopists about managing PUD with adherent clot.

S660

Cost Effectiveness of Andexanet Alfa for Major Gastrointestinal Bleeding Associated With Factor Xa Inhibitors

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Introduction: Oral Factor Xa (FXa) inhibitors are used to prevent and treat thrombotic events but may exacerbate acute major bleeding. Andexanet alfa (andexanet), a modified recombinant inactive form of human FXa, is a novel specific antidote to reverse FXa inhibitor effects. This study calculated the cost effectiveness of using andexanet to reverse anticoagulation in FXa inhibitor-associated gastrointestinal bleeding (GIB) from a US payer and societal perspective.

Methods: A decision tree with a two-state Markov model over a lifetime horizon was used to compare andexanet to prothrombin complex concentrate (PCC). The model consisted of two linked modules: an acute phase of 30 days from admission with GIB and a long-term lifetime survival phase. Patients in the acute phase were assigned a probability of 30-day mortality from available data which determined their entry into the long-term phase. Hospitalization costs were modeled by assigning probabilities based on re-bleed risk and subsequent interventions (endoscopic therapy, angiographic embolization, and surgery). Utilities were calculated by assuming all patients were at increased risk of death due to GIB; long-term survival and morbidity were assumed to be similar for the reversal strategies since long-term comparative data were not available. Discounting was applied to outcome and costs. The societal perspective included indirect costs encompassing caregiver support and productivity losses. New technology add-on payments (NTAP), applied by Centers for Medicare and Medicaid Services to new and transformative technologies to provide support beyond standard diagnosis related group payments, were included as an offset against andexanet pharmacy costs.

Results: In comparison to PCC, andexanet incremental total costs (including drug, hospitalization, and long-term) were \$5,301 (payer) and \$3,486 (societal); incremental quality-adjusted life-years (QALYs) for both perspectives were 0.53. This resulted in incremental cost-effectiveness ratios (ICERs) of \$9,946/QALY (payer) and \$6,540/QALY (societal). Findings were robust to probabilistic and deterministic sensitivity analysis, with the most influential parameters being drug costs, mortality rates, and age.

Conclusion: Our analysis suggests that compared to PCC, andexanet can be considered cost effective in the treatment of FXa inhibitor related major GIB at a willingness to pay threshold of \$50,000/QALY gained from both US payer and societal perspectives.