

Clopidogrel bisulfate and the risk of bleeding after endoscopic sphincterotomy

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Introduction

Guidelines from several professional societies suggest “holding” antiplatelet agents in advance of high-risk procedures. Previous studies suggested that antiplatelet agents did not significantly increase the risk of clinically-important bleeding events following endoscopic sphincterotomy (ES). Given the scant evidence in support of these contentions, our primary aim was to determine if the risk of post-sphincterotomy bleeding was increased in patients taking clopidogrel bisulfate.

Methods

We conducted a retrospective cohort study. Data were collected (2016-2020) on adult patients who underwent Endoscopic sphincterotomy (n=13,796). From the total patient population, 89 were excluded due to protected admission/discharge. Of the remaining 13,707 patients in the study, 2,837 patients were taking clopidogrel bisulfate and 10,870 were not taking Clopidogrel. We employed logistic regression, bleeding event was defined as a hemoglobin drop (>3 g/dL), and/or a required transfusion, as our primary dependent variable. clopidogrel was the main predictor variable and acuity variables and selected co-morbidities were co-variates.

Results

Clopidogrel was not a significant predictor of bleeding events (Odds ratio, 0.70; 95% CI 0.44-1.16, NS). Bleeding events were also not significantly related to age (P = 0.31) or emergency department admission (p = 0.70). However, year admitted, length of stay, emergency ES vs scheduled ES, chronic pulmonary disease, hypothyroidism, and obesity were significantly (P < 0.05) related to bleeding events.

Discussion

Bleeding occurred after ES in 0.87% of patients in the control group and 0.99% of those taking Clopidogrel. clopidogrel was not significantly related to bleeding risk in our population. The bleeding rates in Clopidogrel group and control group were less than 1%. several covariates were significantly related to an increased risk of bleeding such as emergent ERCP, and patients with chronic pulmonary disease, hypothyroidism, hypertension, or obesity. Our study has limitations, all patients in our data set were in our hospitals network, increasing the risk of selection bias. we also did not analyze the indications for endoscopic sphincterotomy. Despite that, we had a large sample size and an extended data gathering period (2016-2020) which likely counteracted some of the above concerns. In conclusion, peri-procedural or post-procedural use of clopidogrel bisulfate was not associated with a significant risk of bleeding events following endoscopic sphincterotomy.

Figure 1. Patient counts, exclusions, and groupings for the 13,796 patients in the initial data extraction

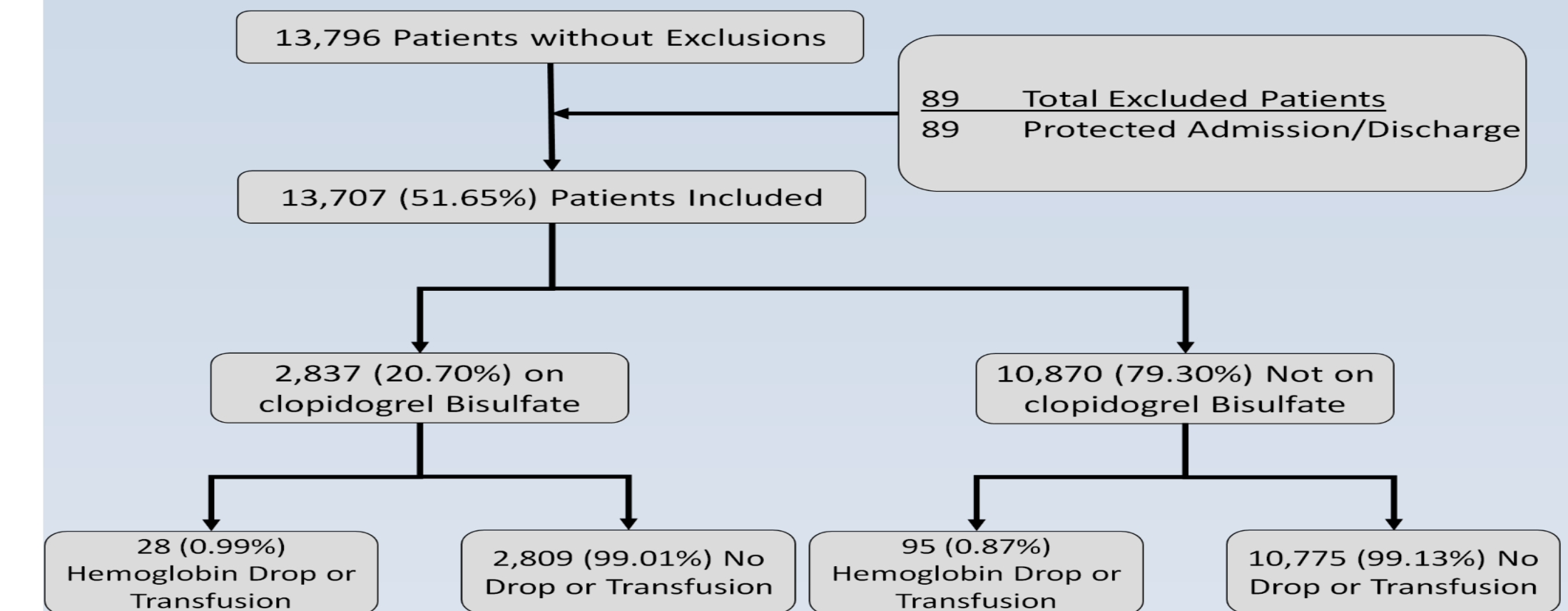


Table 6. Outcome Measures

	clopidogrel Bisulfate Used (N=2,837)	clopidogrel Bisulfate Not Used (N=10,870)	All Patients (N=13,707)
Hemoglobin Drop <3 and/or Transfusion	28 (0.99%)	95 (0.87%)	123 (0.90%)
Hemoglobin Drop <3	24 (0.85%)	75 (0.69%)	99 (0.72%)
Required Transfusion	7 (0.25%)	21 (0.19%)	28 (0.20%)
Required Readmission Transfusion	3 (0.11%)	18 (0.17%)	21 (0.15%)
Detailed Surgery Documented	580 (20.44%)	2,190 (20.15%)	2,770 (20.21%)