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PREVALENCE OF HIGH BLEEDING RISK PATIENTS IN INDIA: A NATIONWIDE DATABASE ANALYSIS

Internal Medicine

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ABSTRACT

Introduction: Aggressive antithrombotic therapy is essential for patients with a prior thrombotic event; however, its use is tempered by the heightened risk of bleeding, which contributes significantly to morbidity, mortality, and healthcare resource utilization. Existing bleeding-risk stratification tools predominantly focus on post-procedural patients or those already receiving antithrombotic therapy. We applied these predictors to estimate the prevalence of high-bleeding-risk (HBR) individuals in the general Indian population. **Methods:** We conducted a retrospective observational study of adults (18–85 years) attending outpatient clinics with complete medical records, including demographics, diagnoses, medication history, and laboratory results. Data on the prescription of gastroprotective agents were captured in an electronic case-report form (eCRF) and anonymized for analysis. **Results:** Records from 3,789 patients were screened; 1,811 met all eligibility criteria. Among these, 300 were aged ≥65 years, 370 had hypertension, 301 liver disease, 133 chronic kidney disease, 1,000 a history of smoking, 53 consumed alcohol, 4 a prior stroke, and 137 had a documented bleeding episode. Overall, 1,706 patients (94.2%) received at least one antacid; 1,668 were prescribed pantoprazole, either alone (n = 1,000) or combined with another agent (n = 668). Proton-pump inhibitors (PPIs) were co-prescribed with a prokinetic drug in 597 patients—predominantly domperidone (n = 528), followed by levosulpiride (n = 36) and itopride (n = 33). Forty-eight patients received an additional antacid alongside the PPI/prokinetic combination. **Discussion:** Using the HAS-BLED score, 82% (1485/1811) patients had ≥1 increased risk for bleeding (hypertension, impaired hepatic or renal function, prior stroke or bleeding, labile INR, age ≥65 years, or drug/alcohol use). Pantoprazole accounted for 97.7% of all PPI prescriptions. Our findings highlight the substantial prevalence of HBR features in general Indian population and the predominant use of pantoprazole-based gastroprotection in routine clinical practice.

KEYWORDS

HBR, Pantoprazole, Proton-pump inhibitor, prokinetic, antacid.

INTRODUCTION

Antiplatelet therapy is central to secondary prevention after spontaneous thrombotic events. Nevertheless, a heightened bleeding risk frequently limits the intensity and duration of such therapy.[1] Major bleeding not only offsets the benefits of antithrombotic treatment but also increases morbidity, mortality, and healthcare resource use.[2] Balancing thrombotic and haemorrhagic risks therefore demands an individualized assessment that integrates patient characteristics, comorbidities, concomitant medications, procedural hazards, and validated bleeding-risk scores. The expanding array of antithrombotic agents—including novel oral anticoagulants (NOACs), antiplatelet drugs, and combination regimens—further complicates clinical decision-making.[3]

Long-term antiplatelet or anticoagulant therapy is common in conditions such as acute coronary syndrome, where lifelong aspirin or dual antiplatelet therapy is recommended.[4] Chronic aspirin use is associated with gastritis and can progress to peptic-ulcer disease. Acidic agents such as aspirin and other NSAIDs undergo 'ion trapping' within gastric mucosal cells, prolonging cellular exposure and resulting in mucosal injury that may culminate in ulceration.[5,6] Complications of peptic ulcers include pain, bleeding, and perforation.[7,8] Consequently, patients on prolonged antiplatelet or NSAID therapy often receive gastroprotective agents, and accurate bleeding-risk prediction becomes pivotal.

Current bleeding-risk tools—including HAS-BLED and the Academic Research Consortium-High Bleeding Risk (ARC-HBR) criteria—were largely developed for patients undergoing procedures or already on antithrombotic therapy. We sought to apply these predictors to a broad outpatient cohort to determine the prevalence of high-bleeding-risk patients in the general Indian population and to examine real-world gastroprotective prescribing patterns.

METHODS

Study Design And Data Sources

We performed a retrospective observational study using nationwide electronic health records (EHRs) and administrative databases encompassing hospital discharges, outpatient visits, medication dispensations, laboratory results, and demographic data. These sources provided a representative sample across diverse Indian regions and healthcare settings.

Eligibility Criteria

Adults aged 18–85 years with complete medical records were included. Exclusion criteria were incomplete records; inherited bleeding disorders (e.g., hemophilia, von Willebrand disease); active malignancy or current cancer treatment; and any major surgery or significant trauma within the preceding three months.

Data Collection

Demographic data, clinical diagnoses, bleeding-risk factors (prior bleeding, comorbidities), antithrombotic therapy, and prescriptions for gastroprotective agents (PPIs or histamine-2 receptor antagonists [H2RAs]) were extracted. Authorized staff entered all variables into a secure eCRF. Data were de-identified before analysis, and the electronic data-capture system incorporated automatic validity checks and audit trails.

RESULTS

Patient Demographics

Out of a total of 3,789 patient records screened, 1,811 met the inclusion criteria and were included in the final analysis. The cohort comprised 1,338 male and 473 female patients. A total of 1,978 patients were excluded primarily due to incomplete demographic data, age outside the eligible range of 18 to 85 years, or the presence of confounding conditions such as a history of injury, surgical interventions, or genetic bleeding disorders. Notably, none of the included patients were undergoing chemotherapy at the time of data collection.

Bleeding Risk Factors

A wide range of bleeding risk factors were identified among the included patients. Hypertension was present in 370 patients; of these, 203 individuals exhibited systolic blood pressure readings of ≥140 mm Hg, while the remaining 167 patients were on antihypertensive therapy and considered to be adequately controlled. Chronic kidney disease (CKD) was documented in 133 patients, among whom 70 also had one or more additional risk factors for bleeding such as a history of

smoking, prior bleeding episodes, liver disease, ongoing antiplatelet therapy, anaemia, or thrombocytopenia. Smoking was the most prevalent risk factor, reported by 1,000 patients, whereas alcohol consumption was relatively rare, reported in only 53 patients. Liver disease was observed in 301 patients, with 183 of these individuals presenting with coexisting risk factors that could potentiate bleeding risk. A prior history of stroke was noted in 4 patients, all of whom also had additional bleeding risk factors. Documented episodes of active or prior bleeding were found in 137 patients, with the majority of cases involving upper gastrointestinal (GI) bleeding, primarily manifesting as melena or hematemesis. In terms of age-related risk, 300 patients were aged 65 years or older, placing them at elevated risk due to age alone (figure 1).

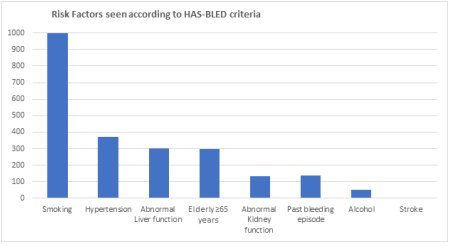

Figure 1: Bleeding Risk Factors

Use of Gastroprotective Therapy

Among the 1,811 patients evaluated, a substantial majority—1,706 patients (94.2%)—received at least one form of gastroprotective antacid therapy. Pantoprazole emerged as the predominant agent, prescribed in 1,668 cases. Of these, pantoprazole was administered as monotherapy in 1,000 patients, while the remaining 668 received it as part of a combination regimen. Notably, 597 patients in the combination group were co-prescribed a prokinetic agent along with pantoprazole. Among the 38 patients who received antacid therapy not containing pantoprazole, the prescribed alternatives included esomeprazole, rabeprazole, levosulpiride, ranitidine, and a combination of aluminium hydroxide, dimethicone, and milk of magnesia.

Co-prescription Of Prokinetic Agents

Prokinetic agents were frequently used in combination with proton pump inhibitors (PPIs). Domperidone was the most commonly prescribed prokinetic, co-administered with PPIs in 528 patients. Levosulpiride and itopride were used in 36 and 33 patients, respectively. In addition, 48 patients received a second antacid alongside their PPI-prokinetic regimen. These additional agents included alginate-based preparations (n=4), sucralfate (n= 12), a fixed-dose combination of pantoprazole with magaldrate and simethicone (n=30), oxetacaine (n=1), and an extra dose of rabeprazole 20 mg (n=1)

DISCUSSION

Our nationwide analysis provides new insight into bleeding-risk burden and gastroprotective prescribing in routine Indian outpatient practice. Using the HAS-BLED algorithm, 82% of adults harbored at least one bleeding-risk factor—a figure markedly higher than the 27–39 % high-risk prevalence reported in post-percutaneous-coronary-intervention cohorts in Europe and North America[9,10] and higher than the 31.9% five-year major-bleed incidence observed in a Japanese validation registry of the Academic Research Consortium (ARC) criteria.[11] This discrepancy reflects our broader, non-procedural population and underscores how comorbidities accumulate outside specialist cardiovascular settings.

The distribution of individual risk factors further contextualizes this burden. Smoking topped the list (55.2 %), consistent with data from the 2016–2017 Global Adult Tobacco Survey showing that 29 % of Indian adults consume tobacco in some form.[12] Because tobacco use is modifiable, its prominence highlights an actionable pathway for mitigating both thrombotic and haemorrhagic complications. Chronic kidney disease (7.3%) and chronic liver disease (16.6%) also emerged as stand-alone drivers of bleeding risk; their isolation in some patients aligns with earlier Indian registry work demonstrating disproportionate renal and hepatic comorbidity among high-risk atrial-fibrillation populations.[13]

Upper-gastrointestinal (GI) bleeding accounted for the majority of documented haemorrhagic events, reinforcing guideline recommendations for proton-pump-inhibitor (PPI) prophylaxis in antithrombotic recipients. Concordantly, 94.2 % of our cohort received at least one antacid, and pantoprazole dominated prescriptions (97.7% of PPI use). This mirrors earlier single-center and multi-center Indian audits where pantoprazole represented 68–90 % of inpatient PPI orders.[14] Pantoprazole's favourable safety profile, cost, and broad formulary availability likely explain this preference.

Fixed-dose combinations pairing pantoprazole with prokinetics were frequent, and domperidone comprised 88% of prokinetic use—closely echoing a 90% domperidone-pantoprazole combination rate in a recent Indian pharmacovigilance study.[15] While these regimens may improve dyspeptic symptoms, prescribers should remain cognizant of domperidone's QT-prolonging potential, particularly in elderly patients already flagged as high bleeding risk.

Our findings support routine, structured bleeding-risk assessment—even in primary-care settings—so that gastroprotection and antithrombotic strategies can be individualized. Given that modifiable factors (smoking, uncontrolled hypertension, alcohol) predominate, lifestyle interventions may meaningfully reduce overall HBR prevalence. Prospective studies should now determine whether the high PPI uptake observed here translates into reduced GI haemorrhage and mortality, and whether deprescribing efforts in low-risk patients can safely curb acid-suppressive therapy.

Key strengths of the study include the large, geographically diverse dataset and the application of validated risk scores. Limitations stem from the retrospective design, missing laboratory parameters that precluded full ARC-HBR scoring, and lack of longitudinal outcome data. Moreover, medication appropriateness (indication, dose, duration) could not be adjudicated.

In summary, bleeding-risk factors are ubiquitous among Indian outpatients, and clinicians overwhelmingly favor pantoprazole-based gastroprotection—often in combination with domperidone. Integrating systematic risk stratification with rational PPI stewardship could optimize both safety and resource utilization in this high-burden context.

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