Rate of Bleeding-Related Episodes (BREs) in Elderly Patients with Primary Immune Thrombocytopenia (ITP): A Population-Based Retrospective Cohort Study Using Medicare 20% Sample Data

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Background

- ITP is a rare disorder characterized by
  - Low platelet counts
  - Increased bleeding tendency
- Elderly ITP patients may have an increased bleeding risk
- Bleeding risk identified in clinical trials may not reflect “real world” rates of bleeding due to:
  - Select nature of patients participating in clinical trials
  - The assigned treatments
  - More frequent use of rescue medications
Objectives

- To estimate the real-world rate of “bleeding related episodes” (BRE) in elderly patients newly diagnosed with ITP

- To describe the setting of BRE management in elderly ITP patients
Methods

- Data source: Medicare 20% sample (2007-2012)
- Patient eligibility
  - Elderly (ages 67+) Medicare fee-for-service (FFS) enrollees diagnosed with primary ITP (287.31) between 1/1/2009 and 9/30/2012
  - No preexisting thrombocytopenia at index date, defined as date of the first ITP code or a thrombocytopenia code within 12 months before the first ITP code
  - No other medical conditions known to cause thrombocytopenia during baseline period
- Baseline: 12-month period before index date
- Follow-up: from index date to the earliest of death, disenrollment from Medicare FFS coverage, or 12/31/2012
Methods (cont’d)

- **BRE definition**
  - ≥1 bleeding event (of any severity) and/or use of rescue or emergency therapies for ITP (IVIg, anti-D, IV steroids, or platelet transfusions)
  - Claims with relevant codes with dates of service separated by ≤3 days were considered a single BRE

- **BRE type:**
  - Bleeding event only
  - Therapy use only
  - Both bleeding event and therapy use

- **Setting of BREs:** inpatient vs. outpatient

- **BRE rate calculated** as sum of BREs divided by time at risk
Results: Patient Characteristics

Age at index date, years

- 66-69: 21.6%
- 70-74: 20.2%
- 75-79: 9.3%
- 80+: 48.9%

Race

- Caucasian: 87.0%
- African-American: 6.1%
- Other: 7.0%

Level of comorbidity*

- Low (score 0): 40.5%
- Medium (score 1-2): 35.5%
- High (score ≥3): 24.0%

N = 3007 patients
Mean (SD) age: 79.6 (7.5) years
Sex: 55% female

*Level of comorbidity defined by Charlson Comorbidity Index.
Results: Rate of BREs, overall and by type

- Mean (SD) follow-up time: 2.1 (1.2) years
- 2202 patients (73%) had ≥1 BRE.
- 9096 BREs
  - Bleeding only: 46.3%
  - Therapy only: 47.6%
  - Bleeding & therapy: 6.1%
- Common types of bleeding: GI bleedings, hematuria, epistaxis, & ecchymoses
- Intracranial hemorrhage: 151 patients (5.0%)
Results: Rate of BREs by follow-up interval, overall and by type

- **0-<3 (n=3007)***
  - All BREs: 35.0
  - Bleeding only: 15.0
  - Therapy only: 10.0
  - Both: 5.0

- **3-12 (n=2680)***
  - All BREs: 20.0
  - Bleeding only: 5.0
  - Therapy only: 5.0
  - Both: 2.0

- **>12 (n=1940)***
  - All BREs: 10.0
  - Bleeding only: 3.0
  - Therapy only: 3.0
  - Both: 1.0
Results: Setting of BREs (inpatient vs. outpatient), overall and by type

- All BREs (n=9096)
  - Bleeding only (n=4208)
  - Therapy only (n=4333)
  - Bleeding & therapy (n=555)

- Percentage of patients in each setting:
  - All BREs: 78.5% IP & OP, 17.1% IP only, 4.4% OP only
  - Bleeding only: 76.6% IP & OP, 18.6% IP only, 4.8% OP only
  - Therapy only: 87.5% IP & OP, 12.0% OP only
  - Bleeding & therapy: 31.9% IP & OP, 45.8% IP only, 22.3% OP only
Strengths and Limitations

**Strengths**
- Large population-based study
- Real-world rate of BREs
- Generalizable to elderly ITP patients

**Limitations**
- Clinical data not available in the claims data
- Therapies and transfusions occurring in the inpatient setting (identified through ICD-9 procedure code) may have been undercounted.
- Incident ITP patients identified based on the presence of and time between diagnosis codes for ITP. This may not reflect the actual incident ITP population.
Conclusions

- Overall, elderly Medicare patients newly diagnosed with ITP experienced nearly two BREs per patient-year.
- The rate of BRE was highest within the first 3 months of follow-up and greatly decreased thereafter.
- Most ITP patients experienced at least one BRE, and nearly half of all BREs were defined by therapy use alone.
- The majority of BREs were managed in an outpatient setting.
Conclusions (cont’d)

- The estimates of real-world BRE rates in elderly patients newly diagnosed with primary ITP highlight the importance of examining both bleeding and rescue therapy use in the assessment of disease burden.
THANK YOU