



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

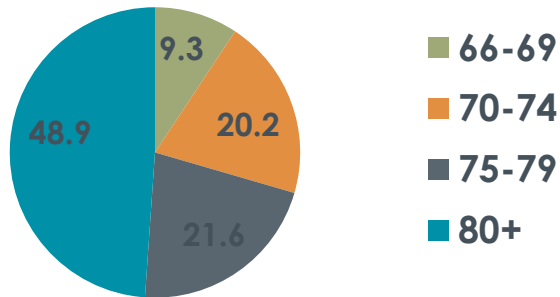
- Data source: Medicare 20% sample (2007-2012)
- Patient eligibility
 - Elderly (ages 67+) Medicare fee-for-service (FFS) enrollees diagnosed with primary ITP (287.31) between 1/1/2009 and 9/30/2012
 - No preexisting thrombocytopenia at index date, defined as date of the first ITP code or a thrombocytopenia 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

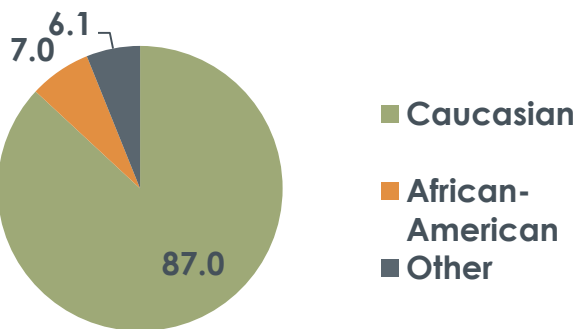


N=3007 patients

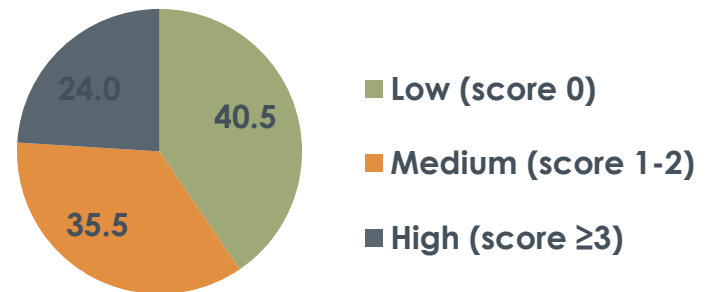
Mean (SD) age: 79.6 (7.5) years

Sex: 55% female

Race



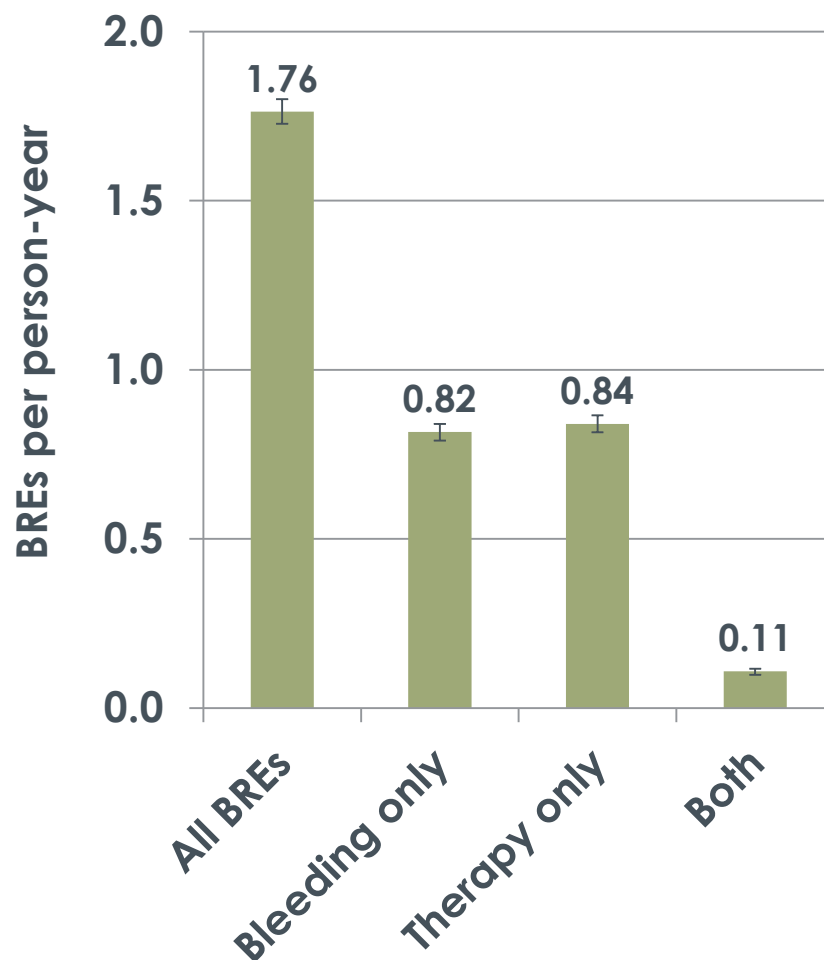
Level of comorbidity*



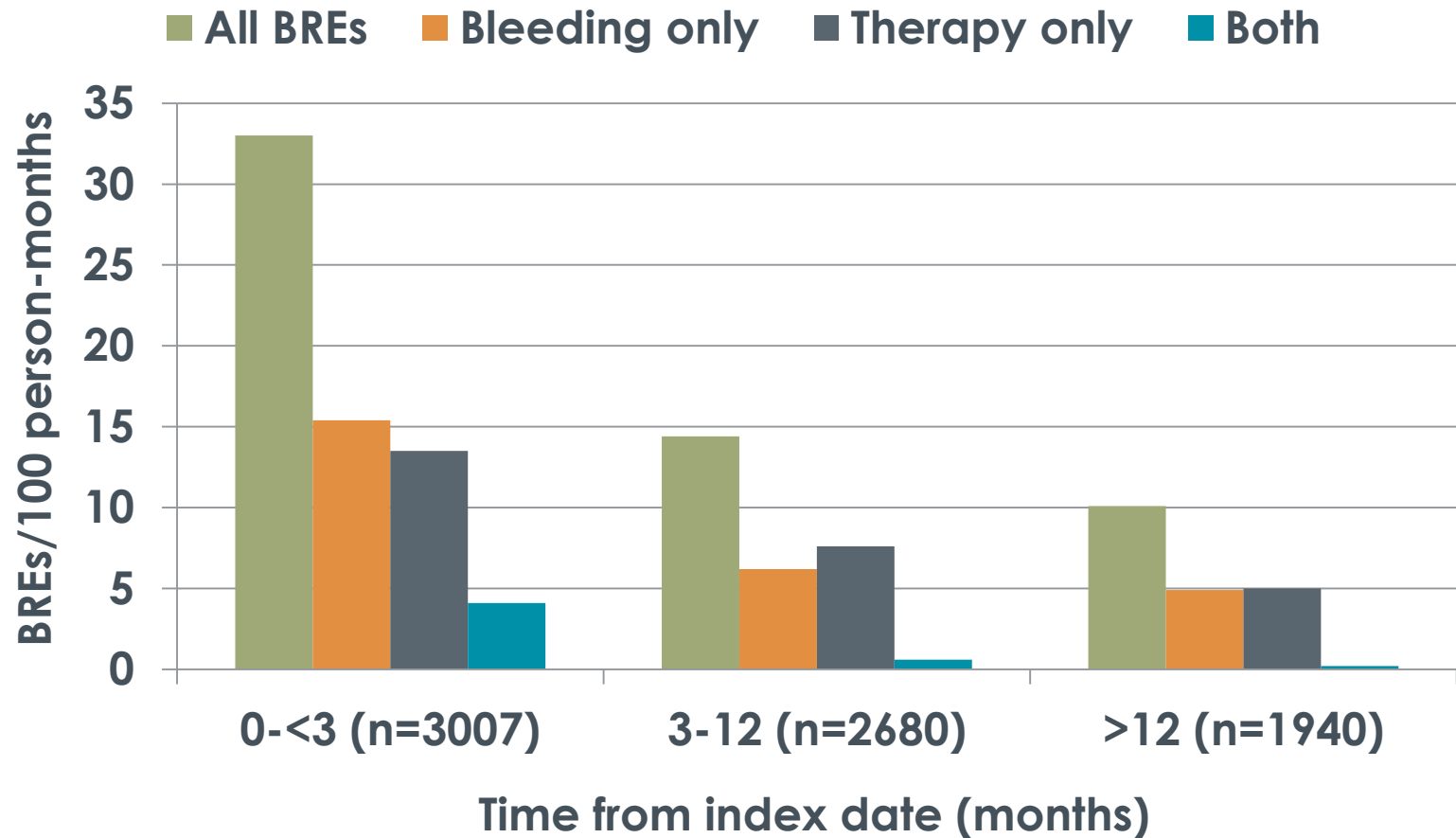
*Level of comorbidity defined by Charlson Comorbidity Index.

Results: Rate of BREs, overall and by type

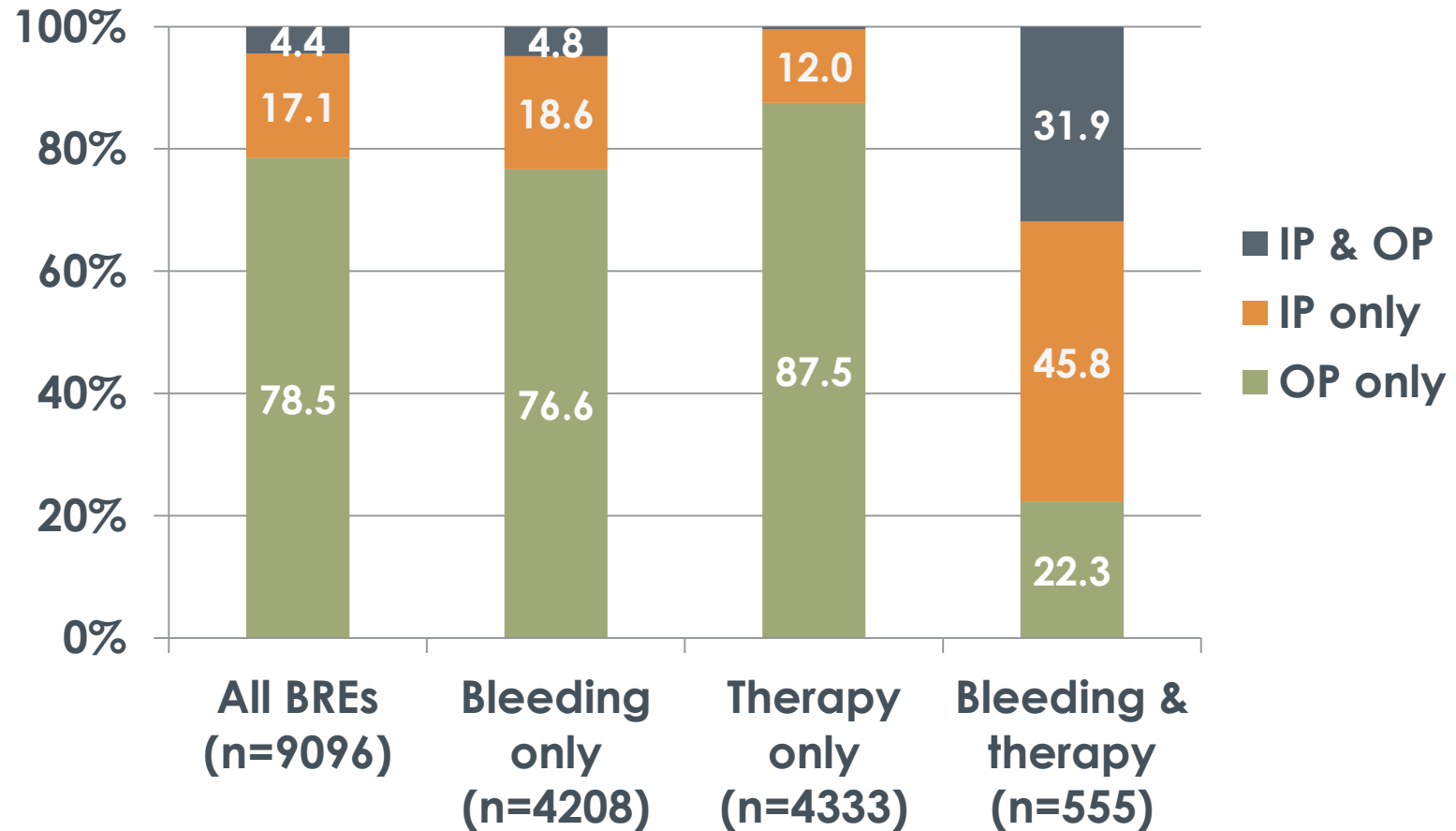
- Mean (SD) follow-up time: 2.1 (1.2) years
- 2202 patients (73%) had ≥ 1 BRE.
- 9096 BREs
 - Bleeding only:46.3%
 - Therapy only:47.6%
 - Bleeding & therapy:6.1%
- Common types of bleeding: GI bleedings, hematuria, epistaxis, & ecchymoses
- Intracranial hemorrhage: 151 patients (5.0%)



Results: Rate of BREs by follow-up interval, overall and by type



Results: Setting of BREs (inpatient vs. outpatient), overall and by type



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