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2020

Impact of Extended Interval INR Testing During the COVID-19 Pandemic

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Recommended Citation

Holder, Jordan PharmD; Noureldin, Maryam PharmD, BCPS,BCACP; and Verma, Priya PharmD, "Impact of Extended Interval INR Testing During the COVID-19 Pandemic" (2020). *Pharmacy*. 34.

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BACKGROUND

- Warfarin is an oral anticoagulant that requires regular monitoring of the international normalized ratio (INR).
- Warfarin is used in the treatment and prevention of venous thrombosis, pulmonary embolism and thromboembolic complications of atrial fibrillation and valve replacements, among other disease states.¹
- Time in therapeutic range (TTR) represents the percentage of time in which the INR remains within target range across time.
- TTR in a controlled environment is usually 55-65%, with 65% or greater being ideal for efficacy and safety standards.^{3,4,5}
- The COVID 19 global pandemic prompted recommendations from the Centers of Disease Control and Prevention (CDC) for the general public to practice social distancing to limit exposure of SARS COV-2. This is especially for those at higher risk for COVID-related complications.^{5,6}
- Due to the nature of indications for warfarin therapy, most warfarin patients are high-risk for COVID-related complications. Parkview Health took a multi-pronged approach to limit exposure. Strategies included: switching patients to alternative anticoagulation therapy, utilizing a patient self-testing (PST) program, using a drive-thru testing service, and instituting an extended interval INR monitoring protocol. (Figure 1)

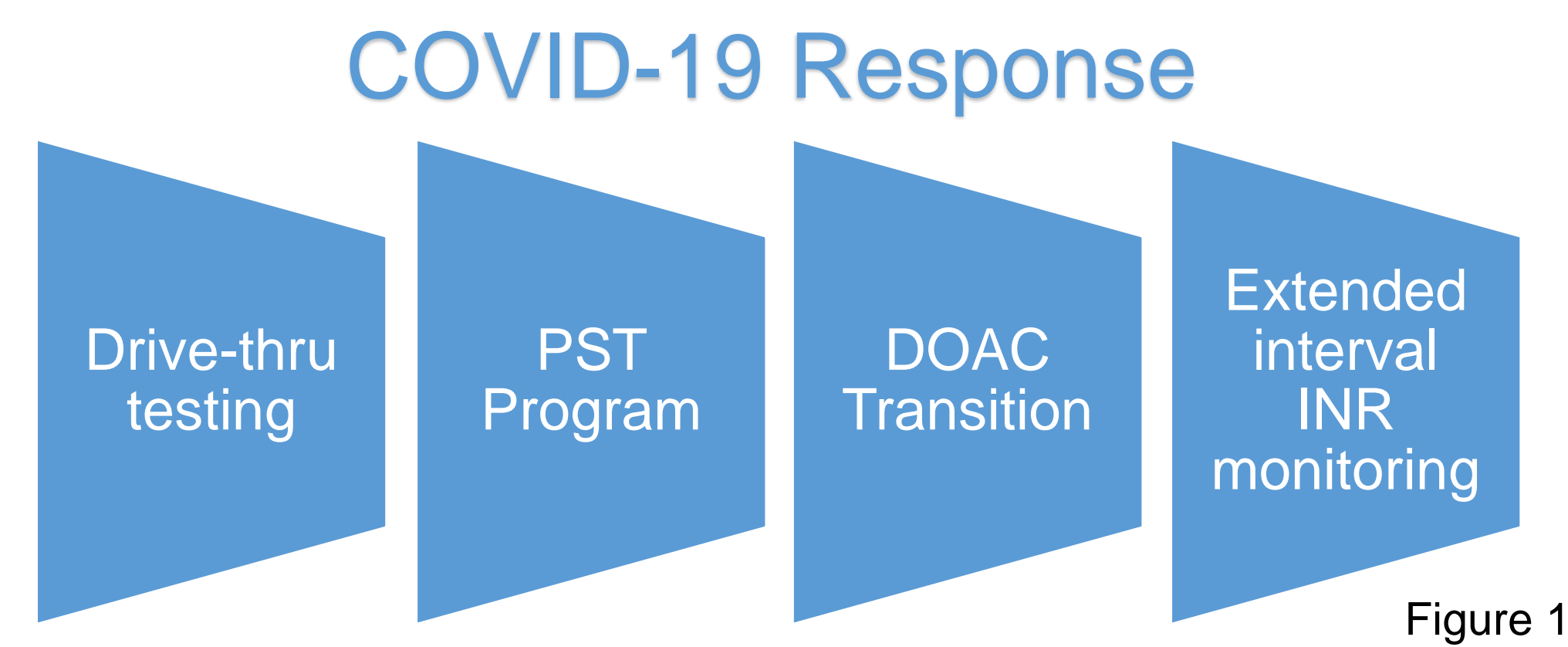


Figure 1

OBJECTIVES

- To determine if extended INR interval monitoring during the COVID-19 pandemic would significantly impact TTR or be associated with emergency department (ED) visits and hospitalizations with bleeding or clotting events.

METHODS

- This IRB-exempt study was a retrospective chart review of anticoagulation visits conducted from March 1st, 2020 to October 1st 2020.
- Patients had to meet prespecified criteria for extension. (Figure 2)
- All encounters reviewed were documented by the pharmacist and included a prespecified phrase to notify the team of the extended interval monitoring.
- Outcomes included: TTR at baseline in comparison to TTR at end of extension, bleeding or clotting events that require hospitalization or ED visit(s), and any minor bleeding events that required medical attention.
- Inclusion criteria: extended appropriately within the study time period and have at least one visit after initial extension.
- Exclusion criteria: Patients with inappropriate extension or no follow-up visit in the study timeframe after initial extension.
- A student t-test and descriptive statistics were used for data analysis.

| 8 Week Extension | 12 Week Extension |
|--|--|
| TTR ≥65%, 3 consecutive INRs in range, on warfarin for at least 3 months | TTR ≥65%, 4 consecutive INRs in range, on warfarin for at least 3 months |

Figure 2

RESULTS

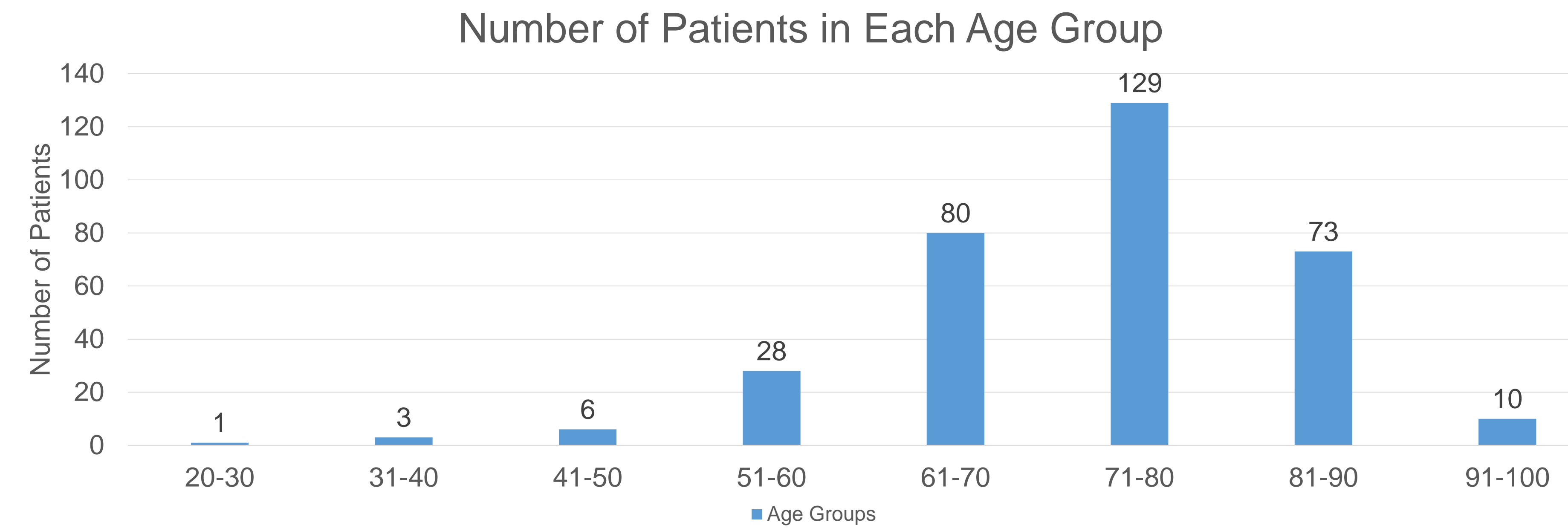


Figure 3

TTRs at the End of Study Period

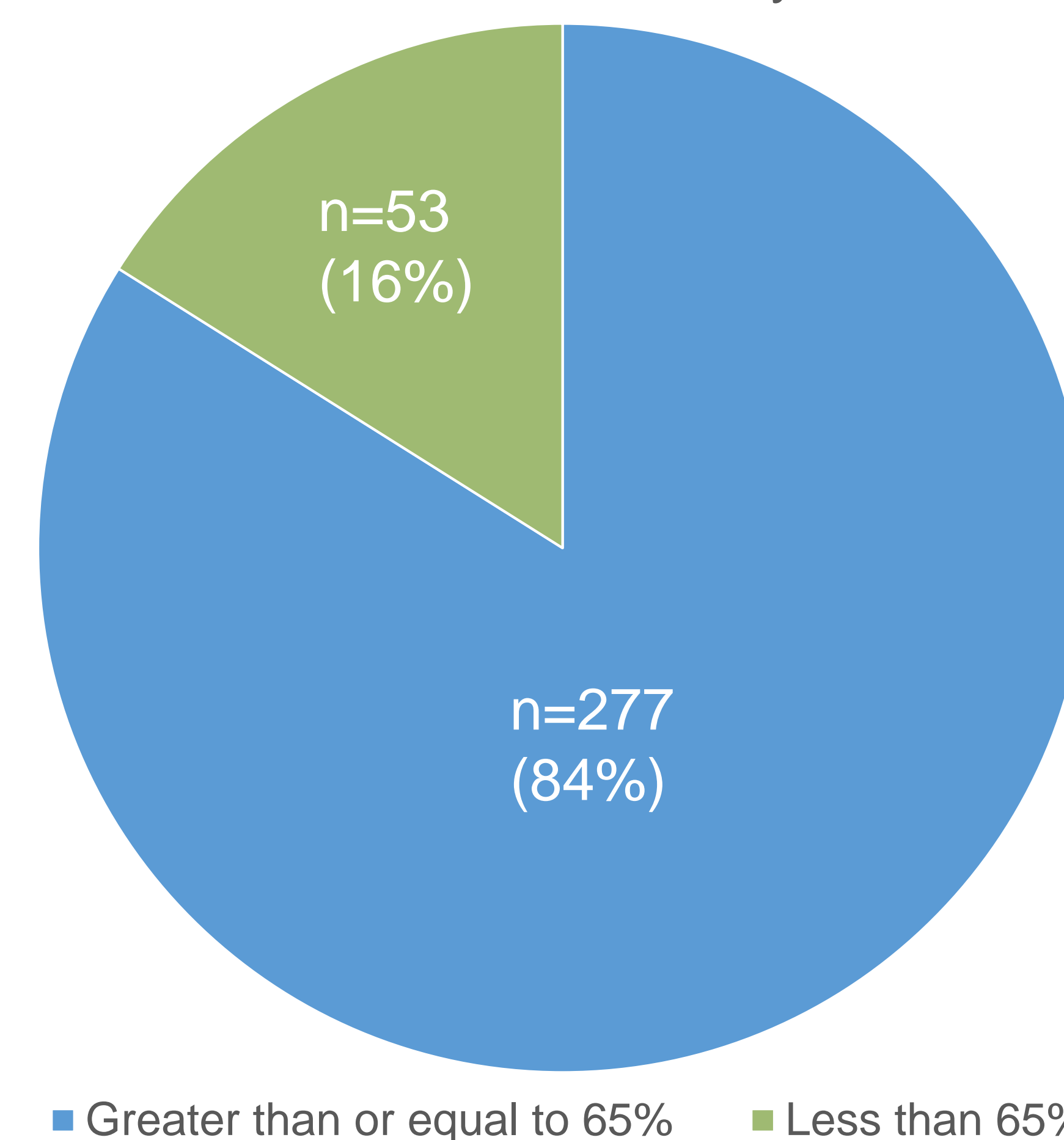


Figure 4

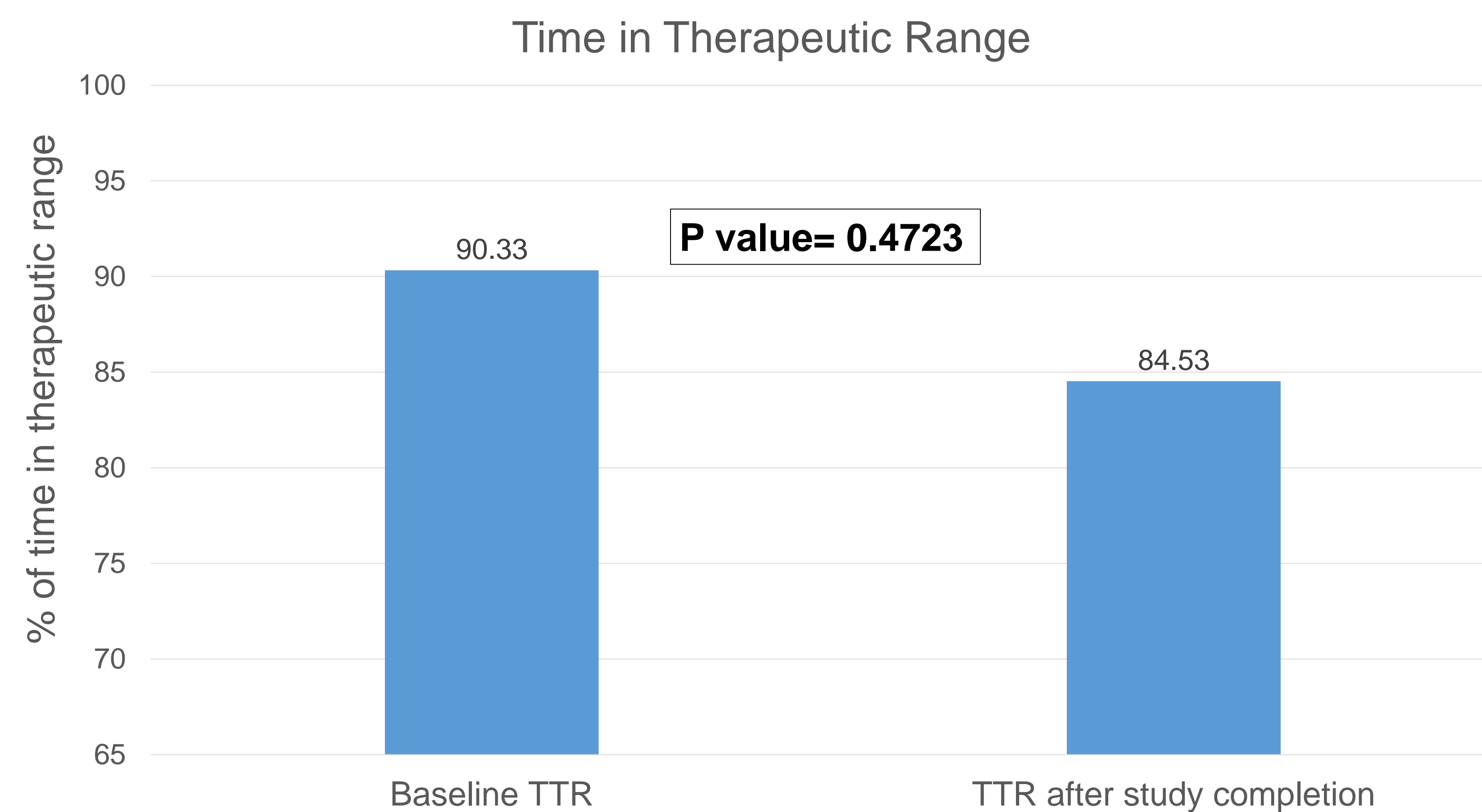


Figure 5

- A total of 330 patients met inclusion criteria.
 - 128 patients were female, 202 were male
 - Majority of patients had a diagnosis of atrial fibrillation, a goal INR range of 2.0-3.0, and were aged 61-90. (Figure 3, 6, and 7)
- During the study time period there were 4/2882 (0.14%) INRs ≥6 over seven months
- There was one bleeding event requiring an office visit, five bleeding events requiring either an ED visit or hospitalization, and two hospital visits for clotting events. Overall, 6/330 (1.82%) of patients experienced at least one bleeding event
 - One bleeding event requiring hospitalization had a subtherapeutic INR at the visit prior to the event, all other INRs were therapeutic at the visit prior to event
- 16/330 (<5%) of patients were not extended after initial extension.

| Indication for Warfarin Use | # of Patients |
|-----------------------------|---------------|
| Atrial fibrillation | 202 |
| PE | 37 |
| DVT | 32 |
| Mechanical Heart Valve | 30 |
| Other thrombus | 7 |
| Genetic Condition | 6 |
| Other | 16 |

Figure 6

| Goal INR Range | # of Patients |
|----------------|---------------|
| 1.5-2.0 | 3 |
| 1.5-2.5 | 2 |
| 1.8-2.5 | 1 |
| 2.0-3.0 | 314 |
| 2.5-3.5 | 10 |

Figure 7

DISCUSSION & CONCLUSIONS

- There was a slight reduction in TTR from baseline extension. However, this was not a statistically significant decrease from baseline.
- Majority of the patients continued to have a TTR ≥65% indicating continued efficacy of warfarin management-There were seven bleeding events and two clotting events attributable to six unique patients. Bleeding events were not correlated with INRs ≥6.0.
- The majority of patients at the clinic are considered high-risk for COVID-related complications, and this study showed risk of adverse events is low with extended INR interval monitoring.

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Disclosure

The authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
Holder J: Nothing to disclose | Noureldin M: Nothing to disclose | Verma P: Nothing to disclose |