

ORIGINAL ARTICLE

Evaluation of Bivalirudin in Percutaneous Coronary InterventionLia Vitale¹, Alexandria Stringberg², Namrita Trivedi²¹ University of Missouri – Kansas City, MO School of Pharmacy² Pharmacy, University of Missouri Health Care, Columbia, MO

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Abstract: The aim of this study was to analyze the appropriateness of bivalirudin utilization indicated for percutaneous coronary interventions (PCI). A total of 218 patients who were admitted to University of Missouri Health Care that underwent a PCI were included in this retrospective study. Analysis was conducted for appropriate utilization of bivalirudin in patients with a history of heparin induced thrombocytopenia (HIT) over unfractionalized heparin. Bivalirudin use was found to be inappropriate in 170 of the 218 patients evaluated (78%). By using, none experienced minimal bleeding, 15 experienced minor bleeding, three experienced major bleeding per the thrombolysis in myocardial infarction (TIMI) bleeding criteria, and none died as a result of bleeding complications.

Keywords: Bivalirudin, heparin, safety, percutaneous coronary intervention, utilization

INTRODUCTION

Percutaneous coronary intervention (PCI) is an invasive procedure to treat narrowing of the coronary arteries that is associated with coronary artery disease. Anticoagulants and antiplatelet medications are utilized during PCI [1]. Historically, heparin is the most commonly used blood thinner in acute coronary syndromes (ACS). Bivalirudin is a direct thrombin inhibitor with the potential for less pharmacologic and pharmacokinetic variability when compared to heparin [2]. Indirect inhibitors have a greater chance of becoming reversible, decreased anticoagulant effect, compared to that of direct inhibitors, meaning that heparin is a less stable medication with a variable half-

life [3]. The dosing of heparin is potentially more variable due to the risk of reversible activity, excretion rate, and other individual issues such as age and obesity [2]. Bivalirudin is indicated for patients who have a history of heparin-induced thrombocytopenia (HIT) and should not be administered in combination with a glycoprotein IIb/IIIa inhibitor due to an increased risk of bleeding [5]. Certain medications need to be administered with/before bivalirudin, including P2Y12 inhibitors and aspirin [6]. Due to the increased use of bivalirudin at University of Missouri Health Care, a medication use evaluation was conducted to evaluate the utilization and safety. A potential cost analysis of bivalirudin was performed.

METHODS

This is a retrospective chart review that included adult patients who received bivalirudin during a PCI at University of Missouri Health Care between January 1, 2017 and December 31, 2017. All patients over the age of 18 who received bivalirudin were included. The primary outcome was to assess the appropriate use of bivalirudin use in PCI. Bivalirudin was deemed appropriate if the patient had a previous history of HIT and did not also receive a glycoprotein IIb/IIIa inhibitor. Medications evaluated for administration before PCI included aspirin loading doses, abciximab or eptifibatid, and/or clopidogrel, prasugrel, or ticagrelor. Secondary outcomes included a cost evaluation, safety considerations based on incidences of bleeding classified by the TIMI bleeding criteria [7], and 30-day all-cause mortality. Patient characteristics were charted to evaluate patient risk factors for coronary events. A majority of patients were at intermediate to high risk for an event.

From January 1, 2017 to December 31, 2017 a total of that received bivalirudin. Of these patients, there were no prior incidences of HIT. A total of 170 patients may have been switched from heparin to bivalirudin in cath lab, three that received a glycoprotein IIb/IIIa inhibitor with bivalirudin, and 15 who received all three medications either before, during, or after a procedure. The safety evaluation found that none of the patients experienced minimal bleeding, 6.9% (n=15) of patients had minor bleeding, and 1.4% (n=3) had major bleeding according to TIMI bleeding criteria. In addition, there were five deaths within 30 days of PCI, but all were unrelated to bleeding complications. Causes of death included ascending cholangitis, two cardiac arrests, and two cardiogenic shocks. The following information can be found below: patient characteristics (Table 1), indications for PCI (Figure 1), and safety outcomes (Table 2).

RESULTS

Table 1. Baseline characteristics, history of HIT, and P2Y12 received of patients included in the study

Patient Characteristics n=218	n (%)
Age (years)	63_± 12.29
Weight (kg)	93_± 25.68
Race – white	198 (90.8)
CrCl (mL/min)	
≥ 30	212 (97.2)
< 30	6 (2.8)
Comorbidities	
Hypertension	168 (77.0)
Hyperlipidemia	121 (55.5)
Diabetes	94 (43.1)
CKD	10 (4.6)
Tobacco use	75 (34.4)
CAD	110 (50.5)

CABG	27 (12.4)
Prior PCI	80 (36.7)
HIT	0 (0)
P2Y12	
Clopidogrel	172 (78.9)
Prasugrel	5 (2.3)
Ticagrelor	41 (18.8)

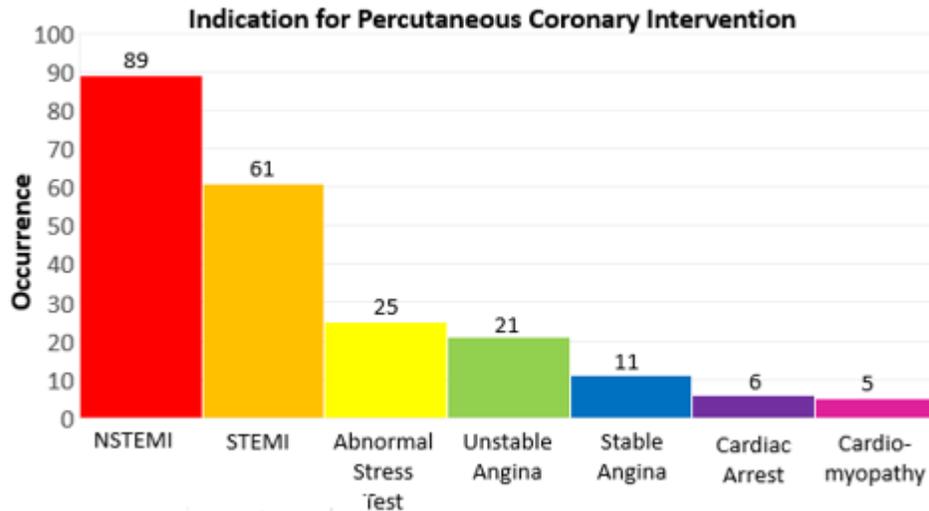


Figure 1. Patient Indications for Percutaneous Coronary Intervention

Table 2. Safety Outcomes

Outcome	N=218
TIMI Bleeding	
Minimal	0
Minor	15
Major	3
Mortality	5

DISCUSSION

There could have been a potential cost savings of \$27,696.00 if 170 patients had received heparin instead of bivalirudin within the catheterization lab. Potential cost savings was predicted by the cost of one bag of heparin multiplied by 170 patients subtracted

from the cost of one vial of bivalirudin multiplied by 170 patients. Of the patients that received bivalirudin, most did not have bleeding complications, i.e. only 15 (6.9%) of patients experienced minor bleeding and three (1.4%) experienced major bleeding, according to TIMI bleeding criteria. There were no deaths were related to major

bleeding complications, but five deaths did occur within 30 days of PCI.

CONCLUSION

Inpatient diabetes consultation improves post discharge glycemic control at 3 months, health care access and confidence with treating hypoglycemia. Unfortunately we could not detect a difference in frequency of hypoglycemia and glycemic control at 6 and 12 months after discharge despite increased health care access. A more structured approach with several follow up visits by diabetes specialists and educators are needed after discharge to sustain the significant improvements implemented during hospitalization.

Notes:

Author Contributions: Namrita Trivedi and Alexandria Stringberg conceived of the presented idea. Lia Vitale carried out the research, analysis of the results, and writing of the manuscript. Namrita Trivedi and Alexandria Stringberg acted as preceptors to Lia and assisted in the implementation of the research and analysis.

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References

1. American College of Cardiology. (2018). Choosing the Best Anticoagulation Strategy For Primary Percutaneous Intervention: Bivalirudin vs. Heparin - American College of Cardiology. [online] [Accessed 20 Jun. 2018].
2. Bivalirudin versus Heparin Monotherapy in Myocardial Infarction. (2018). *New England Journal of Medicine*, 378(3), pp.298-301.
3. <http://www.micromedexsolutions.com.proxy.library.umkc.edu/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch#> [Accessed 16 Jun. 2018]
4. https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6463#cpg [Accessed 20 Jun. 2018].
5. Lee, C. and Ansell, J. (2011). Direct thrombin inhibitors. *British Journal of Clinical Pharmacology*, 72(4), pp.581-592. Andreou, C., Maniotis, C. and Koutouzis, M. (2017). The Rise and Fall of Anticoagulation with Bivalirudin During Percutaneous Coronary Interventions: A Review Article. *Cardiology and Therapy*, 6(1), pp.1-12.
6. Levine, G., Bates, E., Blankenship, J., Bailey, S., Bittl, J., Cercek, B., Chambers, C., Ellis, S., Guyton, R., Hollenberg, S., Khot, U., Lange, R., Mauri, L., Mehran, R., Moussa, I., Mukherjee, D., Nallamothu, B. and Ting, H. (2011). 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation*, 124(23), pp.2574-2609.
7. Mehran, R., Rao, S., Bhatt, D., Gibson, C., Caixeta, A., Eikelboom, J., Kaul, S., Wiviott, S., Menon, V., Nikolsky, E., Serebruany, V., Valgimigli, M., Vranckx, P., Taggart, D., Sabik, J., Cutlip, D., Krucoff, M., Ohman, E., Steg, P. and White, H. (2011). Standardized Bleeding Definitions for Cardiovascular Clinical Trials: A Consensus Report From the Bleeding Academic Research Consortium. *Circulation*, 123(23), pp.2736-2747.