CODEN [USA]: IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

http://doi.org/10.5281/zenodo.1301256

Available online at: http://www.iajps.com Research Article

A CROSS-SECTIONAL RESEARCH ON PCI (PERCUTANEOUS CORONARY INTERVENTION, BLEEDING SITE & ASSOCIATED RISK FACTORS IN CONTEXT TO MAJOR & MINOR BLEEDING & BLEEDING DEFINITIONS

[1]Dr. Hira Shahzad, [2]Dr. Salman Falak, [3] Dr. Tooba Jalees

[1]Women Medical Officer DHQ Narowal

[2]Medical Officer BHU Ghanian Ghazi Safdarabad

[3]Mayo Hospital Lahore

Abstract:

Objectives: *This research aimed to find out the risk factors and bleeding association in the patients experiencing PCI (Percutaneous Coronary Intervention).*

Methodology: *We included 500 consecutive cases in our cross-sectional research who experienced PCI at Allied Hospital, Faisalabad (October, 2016 to December, 2017). We defined bleeding in per the criteria of "REPLACE – 2".*

Results: *Male to female proportion in our research was respectively 82 and 418 with respective percentage of 16.4% & 83.6% with a dominance of male over female. The factor of mean age was observed as (53.4 ± 9.6) years. Total complicated cases of bleeding were 31 (6.2%); further division was as that major and minor bleed cases were respectively 4 (0.8%) and 27 (5.6%). One death case was also reported because of (retroperitoneal) major bleeding. Female to male frequency of bleeding complication was respectively 8.5% & 5.7% with a significant P-value of (0.24). Majority of the cases were dealt with radial route (88.6%). Diabetic cases were involved in the risk because of the post-interventional bleeding (Odds Ratio as 6.4; P-value < 0.0001), hypertension (Odds Ratio: 13.2; P-value < 0.0001), smoking (Odds Ratio: 8.31; P-value < 0.0001) and BMI more than 40 (Odds Ratio: 6.8; P-value < 0.002), streptokinase use (Odds Ratio : 3.1; P-value < 0.0005), femoral approach (Odds Ratio : 4.2; P-value < 0.02), anemia (Odds Ratio : 44.8 ; P-value < 0.0001) and ACT ≥ 350 (Odds Ratio : 3.73 ; P-value < 0.0005). Procedure duration in females was (≥60) minutes with the use of IIIa inhibitors/ Glycoproteins IIb (GPI) in the above fifty years cases there was no relation of post-interventional bleeding.*

Conclusion: *There is a rare occurrence of the major bleeding related complications in the course of PCI which is one of the vital reason behind the mortality and morbidity proportions.*

Key Words: *Bleeding, Percutaneous Coronary Intervention (PCI), Post-Operative, BMI and Site.*

Corresponding author:

Dr. Hira Shahzad,

Women Medical Officer,

DHQ Narowal

QR code

Please cite this article in press Hira Shahzad et al., ***A Cross-Sectional Research On PCI (Percutaneous Coronary Intervention, Bleeding Site & Associated Risk Factors In Context To Major & Minor Bleeding & Bleeding Definitions,*** *Indo Am. J. P. Sci, 2018; 05(06).*

INTRODUCTION:

Repeatedly observed non-cardiac complication is bleeding after PCI [1]. With the application of novel anti-platelets, anti-coagulants and glycoprotein IIb/IIIa inhibitors have reduced the incidence of ischemic complications but bleeding risk is still at large [2 – 4]. These complications result in the shape of increased hospital stay and cost, dissatisfaction of patient's mortality and morbidity [4 – 7].

There is a strong association of stroke, myocardial infarction and repeat procedures of revascularization after PCI [1, 8]. Bleeding may vary in the range of 1.4 – 12.8 percent after PCI [9, 10]. Adverse outcomes are associated with non-accessible bleeding sites [1, 7, 8, 11]. Blood transfusion is mandatory in five percent of the PCI patients which also increases mortality [10].

Older age, female gender, anemia, BMI, renal insufficiency, diabetes mellitus, hypertension, smoking etc. are among the contributing factors [1, 2, 6, 8, 12 – 14]. Other associated factors include ST-elevation myocardial infarction, emergency procedure, cardiogenic shock, femoral artery access, intervention duration, intra-aortic balloon pump use and larger sheath diameter [1, 2, 4, 10, 13, 15].

Bleeding episodes have been reduced from radial artery access, weight adjusted heparin vascular closure devices and direct thrombin inhibitor [3, 4, 5, 7, 15 – 18]. This research aimed to find out the risk factors and bleeding association in the patients experiencing PCI (Percutaneous Coronary Intervention).

METHODOLOGY:

We included 500 consecutive cases in our cross-sectional research who experienced PCI at Allied Hospital, Faisalabad (October, 2016 to December, 2017). We defined bleeding in per the criteria of "REPLACE – 2". The cases were of stable angina and ACS (Acute Coronary Syndromes). We did not include all the patients with previous diagnosis of bleeding diathesis and systemic bleeding, elevated creatinine and urea.

Major bleeding was referred to intraocular, intracranial, retroperitoneal or a clinical overt bleeding with hemoglobin drop (3 g/dl) or (4 g/dl) or two units blood transfusion (RBC). Clinical overt bleeding was not comparable with the mentioned criteria. Data of the patients was collected after informed consent. We documented bleeding site, bleeding events, hemodynamic status, hemoglobin level drop, blood transfusion frequency, outcomes and hospital stay duration.

Two hours prior to PCI every patient was managed with Aspirin (300 mg) and Clopidogrel (600 mg) with six french arterial sheath. Unfractionated heparin was given before intervention intravenous bolus (50 – 100 units/kg) to activate the clotting in the time period of (200 sec – 250 sec with GPI) and ACT of (300 sec – 350 sec without GPI).

Femoral or radial arterial access route, drug or bara metal eluting stent use and abciximab/ eptifibatide/tirofiban GPI use was decided by the physician. The removal of arterial sheath was made after the procedure (ACT < 180 sec). A 24 hours monitoring was carried out, longer stay was prescribed in case of bleeding. Patients were discharged with an advice of reporting of any post procedure bleeding.

Data was analyzed on SPSS and presented in mean, percentage and ±SD. Chi square was also applied for data comparison (P-value ≤ 0.05).

RESULTS:

Male to female proportion in our research was respectively 82 and 418 with respective percentage of 16.4% & 83.6% with a dominance of male over female. The factor of mean age was observed as (53.4 ± 9.6) years. Total complicated cases of bleeding were 31 (6.2%); further division was as that major and minor bleed cases were respectively 4 (0.8%) and 27 (5.6%). One death case was also reported because of (retroperitoneal) major bleeding. Female to male frequency of bleeding complication was respectively 8.5% & 5.7% with a significant P-value of (0.24). Outcomes about bleeding site and associated risk factors have been shown in Table I and II with respective figures.

Table – I: Sites of Bleeding

Type / Site	Number (31)	Percentage
Bruises (Arm, Shoulder, Back)	4	12.9
Epistaxis	1	3.2
G.I. Bleed	2	6.5
Gums	8	25.8
Hematoma (Arm)	7	22.6
Hematoma (Thigh)	7	22.6
Retroperitoneal	2	6.4

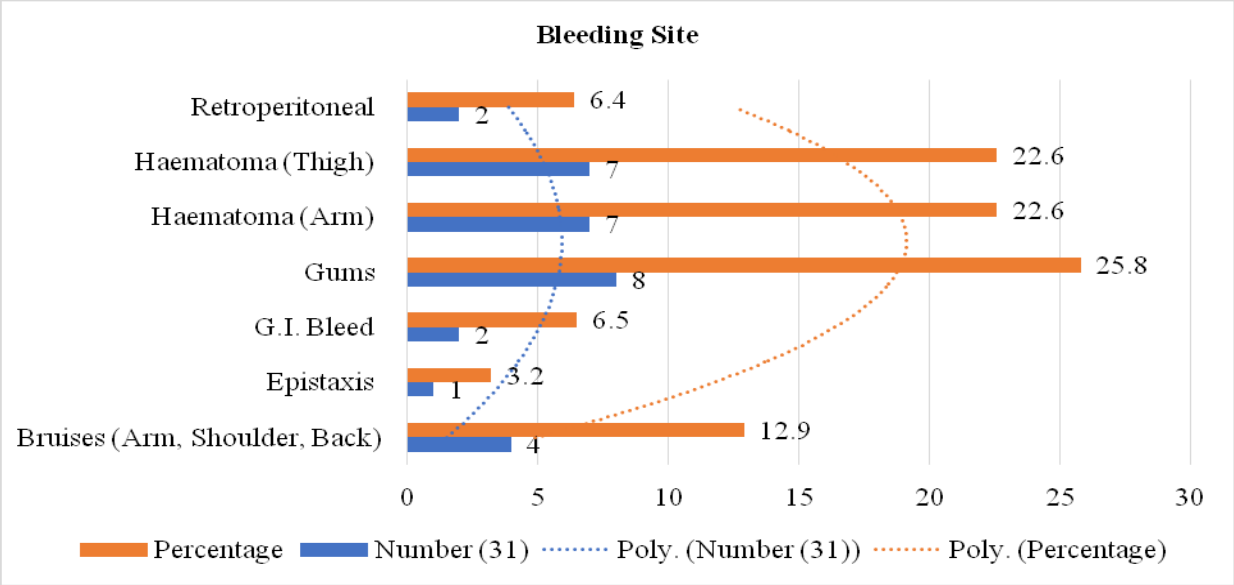
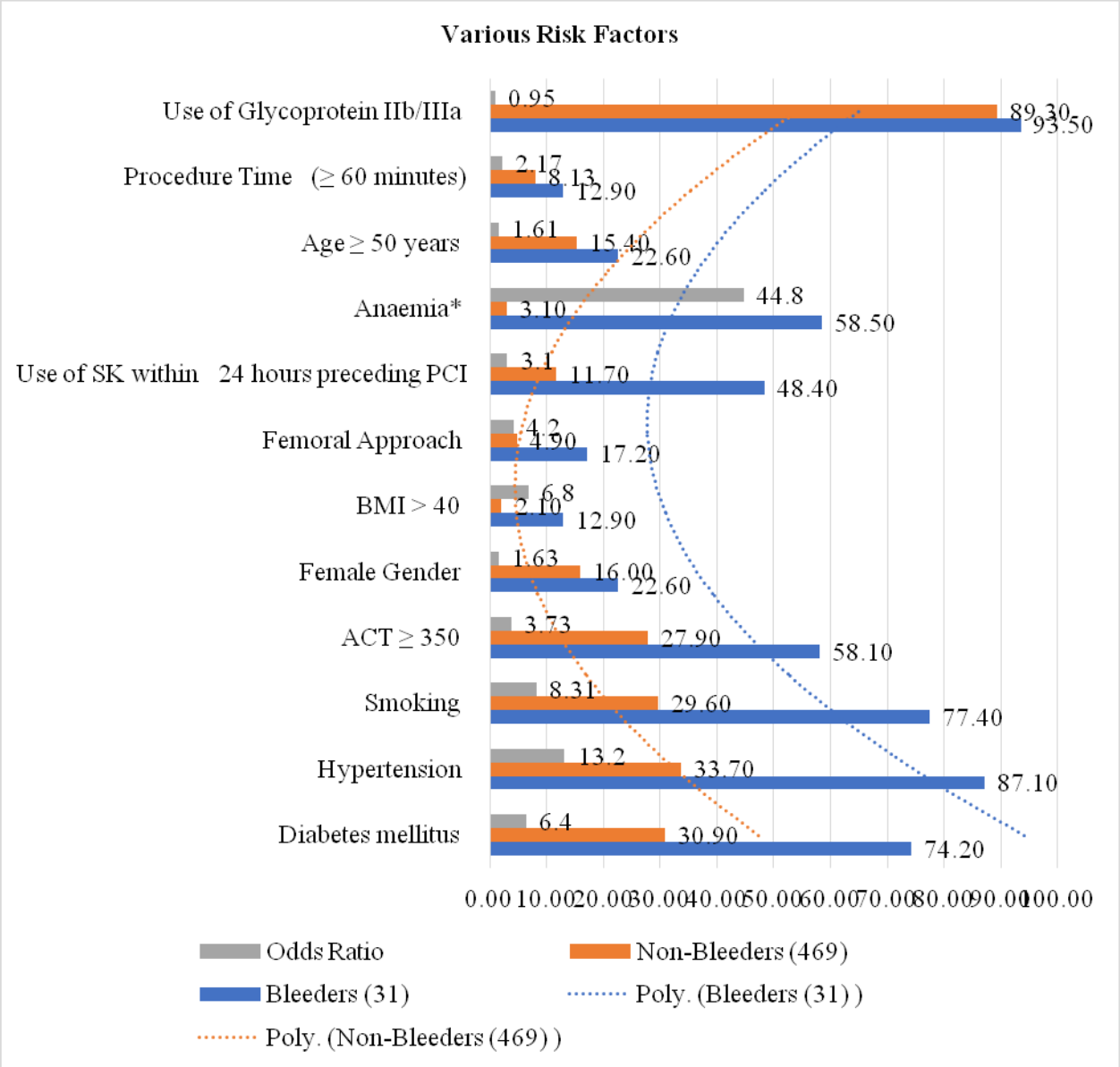


Table – II: Association of various Risk Factors with post-PCI bleeding

Risk Factor	Bleeders (31)	Non-Bleeders (469)	Odds Ratio	95% CI	Significance of Difference
Diabetes mellitus	74.20	30.90	6.4	2.8 – 14.7	P < 0.0001
Hypertension	87.10	33.70	13.2	4.5 – 38.5	P < 0.0001
Smoking	77.40	29.60	8.31	13.5 – 19.7	P < 0.0001
ACT ≥ 350	58.10	27.90	3.73	1.78 – 7.83	P < 0.0005
Female Gender	22.60	16.00	1.63	0.7 – 3.9	P = 0.28
BMI > 40	12.90	2.10	6.8	2.0 – 23.1	P < 0.002
Femoral Approach	17.20	4.90	4.2	1.9 – 9.4	P < 0.02
Use of SK within 24 hours preceding PCI	48.40	11.70	3.1	1.2 – 7.9	P < 0.0005
Anemia	58.50	3.10	44.8	19.9 – 100.9	P < 0.0001
Age ≥ 50 years	22.60	15.40	1.61	0.67 – 3.87	P = 0.25
Procedure Time (≥ 60 minutes)	12.90	8.13	2.17	0.71 – 6.6	P = 0.17
Use of Glycoprotein IIb/IIIa	93.50	89.30	0.95	0.57-1.61	P = 0.86



DISCUSSION:

Outcomes about rare major bleeding and post-PCI bleeding were observed as 0.8% and 6.2%. Various patients and therapies had various bleeding proportions with a bleeding reduction trend [2, 3, 5, 12, 17, 19]. REPLACE – 2 trials had less bleeding in the perspective of novel PCI [3, 12]. Two authors reported major bleeding in the trials of "STEEPLE" as 6.5% & 5.4% [6, 11]. TIMI trial was used by Kinnard while major and minor bleeding was 5.4% and 12.7% [10]. Universal definition of bleeding requires a consensus as numerous trials are under consideration and six grades were introduced from grade Zero – Six that is no bleeding to severe bleeding [9, 19]. We observed less incidence of bleeding in comparison to the previously observed research studies, radial route was observed in abundance in (88.6%). Radial route is preferred because of reduced complications, patients' preference, early ambulation and convenience. RIVAL (radial versus femoral) access trial also reduced bleeding (64%) with a complication rate of 1.4% in the vascular site [17]. Radial access is less common in USA [20].

Our mean age can be compared with previous research population trend (53.4 ± 9.6) years [21]. Higher bleeding was observed in West because of frequent employment of high risk cases and trans-femoral route. Bleeding site and risk factors can also be compared with the previous local research studies as shown in both the tables [16, 22].

Obese and overweight cases were included in our population of PCI as mean BMI was (28.7 ± 5.1) with frequent vascular access hematomas (high in females, 57.14%), which is also comparable with other research outcomes [12, 18].

Development of femoral access was observed in two cases and one female sixty-year-old patient died (diabetic, hypertensive, BMI = 28.9 and additional groin hematoma with retroperitoneal hematoma, seventy minutes interventional duration, double bolus infusion and eptifibatide, ACT = 290) expired in the twenty-four hours.

According to the report of BMC-2 association of bivalirudin was observed with low risk factors [15]. Major gastrointestinal bleeding was observed in 2 cases (0.4%, both genders > 65 Years), patients showed a history of hypertension, baseline anemia and diabetes. There are also reports of gastrointestinal bleeding as (21% & 3.5%) in previous studies with diabetes, older age, baseline anemia and smoking as markers [8, 11, 13].

Higher bleeding was associated with diabetes, smoking, hypertension and baseline anemia [2, 4, 6, 8, 13]. Higher bleeding was also linked with the anemic patients and ACT (≥ 350 seconds). Brenner observed a linear increase in bleeding risk as ACT (365 seconds) (P-value = 0.01) [14]. Independent association of elevated unfractionated heparin weight was observed with increased bleeding [14].

Significant association was found between bleeding events and 24-hours of thrombolysis with streptokinase PCI. According to NORDISTEMI research twelve hourly (thrombolysis) GUSTO severe bleeding was observed in (1.9%) cases [23]. Literature has also revealed association of bleeding with advanced age, prolonged interventional duration, Glycoprotein IIb/IIIa (GPI) use and female gender [1 – 4, 6, 10, 12, 15].

Blood transfusion was made in 4 cases (0.8%); whereas, Kinnard reported (5.4%) cases. Blood transfusion dead cases were (10.6%, major bleeding) in comparison to the (5.1%, major bleeding without blood transfusion) with one unit one-year mortality rate [10].

CONCLUSION:

There is a rare occurrence of the major bleeding related complications in the course of PCI which is one of the vital reason behind the mortality and morbidity proportions.

REFERENCES:

1. Mehran R, Rao SV, Bhatt DL, Gibson CM, Caixeta A, Eikelboom J, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. Circulation 2011; 123:2736-2747.
2. Rao SV, Ou FS, Wang TY, Roe MT, Brindis RG, Rumsfeld JS, et al. Trends in the prevalence and outcomes of radial and femoral approaches to percutaneous coronary intervention. A report from the National Cardiovascular Data Registry. J Am Coll Cardiol Intv 2008; 1:379-386.
3. Hameed S, Tawwab S, Shahbaz A, Sami W, Sherwani M, Azhar M. Cardiac mortality trends in the emergency department of a tertiary care cardiac centre. Pak J Med Sci 2007; 23:825-31.
4. Shaikh AH, Siddiqui MS, Hanif B, Malik F, Hasan K, Adhi F. Outcomes of primary Percutaneous Coronary Intervention (PCI) in a tertiary care cardiac centre. J Pak Med Assoc 2009; 59:426-433.
5. Bohmer E, Hoffmann P, Abdelnoor M, Arnesen H, Sigrun H. Efficacy and safety of immediate angioplasty versus ischemia-guided management after thrombolysis in acute myocardial infarction in areas with very long transfer distances: Results of the NORDISTEMI (Norwegian study on District treatment of ST-Elevation Myocardial Infarction). J Am Coll Cardiol 2010; 55:102-110.
6. Kim Y, Lee JY, Ahn JM, Song H, Kim WJ, Yun SC, et al. Impact of bleeding on subsequent early and late mortality after drug-eluting stent implantation. J Am Coll Cardiol Intv 2011; 4:423-431.
7. Verheugt FW, Steinhubl SR, Hamon M, Darius H, Steg PG, Valgimigli M, et al. Incidence, prognostic impact, and influence of antithrombotic therapy on access and nonaccess site bleeding in percutaneous coronary intervention. JACC Cardiovasc Interv 2011;4(2):191-7.
8. Nikolsky E, Stone GW, Kirtane AJ, Dangas GD, Lansky AJ, McLaurin B, et al. Gastrointestinal bleeding in patients with acute coronary syndromes: Incidence, predictors, and clinical implications. Analysis from the ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) Trial. J Am Coll Cardiol 2009; 54:1293-1302.
9. Rao SV, Grady K, Pieper KS, Granger CB, Newby LK, Mahaffey K, et al. A comparison of the clinical impact of bleeding measured by two different classifications among patients with acute coronary syndromes. J Am Coll Cardiol 2006; 47:809–816.

10. Kinnaird TD, Stabile E, Mintz GS, Lee CW, Canos DA, Gevorkian N, et al. Incidence, predictors, and prognostic implications of bleeding and blood transfusion following percutaneous coronary interventions. Am J Cardiol 2003; 92:930–935.
11. Cayla G, Silvain J, Barthelemy O, Connor OS, Payot L, Bellemain A, et al. Trans-radial approach for catheterization in non-ST segment elevation acute coronary syndrome: an analysis of major bleeding complications in the ABOARD Study. Heart 2011; 97:887-891.
12. Poludasu S, Cavusoglu E, Clark LT, Marmur JD. Impact of gender on in-hospital percutaneous coronary interventional outcomes in African-Americans. J Invasive Cardiol 2007;19(3):129-30.
13. Chua S, Liao C, Hung H, Cheng J, Chiu C, Chang C, et al. Gastrointestinal bleeding and outcomes after percutaneous coronary intervention for ST-Segment Elevation Myocardial Infarction. Am J Crit Care 2011;20(3):218-225.
14. Brener SJ, Moliterno DJ, Lincoff AM, Steinhubl SR, Wolski KE, Topol EJ. Relationship between activated clotting time and ischemic or hemorrhagic complications: analysis of 4 recent randomized clinical trials of percutaneous coronary intervention. Circulation 2004;110(8):994-998.
15. Trimarchi S, Smith DE, Share D, Jani SM, O'Donnell M, McNamara R, et al. Retroperitoneal hematoma after percutaneous coronary intervention: Prevalence, risk factors, management, outcomes, and predictors of mortality. A Report from the BMC2 (Blue Cross Blue Shield of Michigan Cardiovascular Consortium) Registry. J Am Coll Cardiol Intv 2010; 3:845-850.
16. Khan M, Qadir F, Hanif B, Villani A, Ahmedins B. To determine the safety and success of transradial coronary angiography and angioplasty — A local experience. J Pak Med Assoc 2010;60(10):809-13.
17. Jolly SS, Yusuf S, Cairns J, Niemelä K, Xavier D, Widimsky P, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): A randomized, parallel group, multicenter trial. Lancet 2011;377(9775):1409-20.
18. Tizon-Marcos H, Bertrand OF, Rodes-Cabau J, Larose E, Gaudreault V, Bagur R, et al. Impact of female gender and transradial coronary stenting with maximal anti platelet therapy on bleeding and ischemic outcomes. Am Heart J 2009;157(4):740-5.
19. Mehta SK, Frutkin FA, Lindsey JB, House JA, Spertus JA, Rao SV, et al. Bleeding in patients undergoing percutaneous coronary intervention: the development of a clinical risk algorithm from the National Cardiovascular Data Registry. Circ Cardiovasc Intervent 2009; 2:222-229.
20. Hochholzer W, Wiviott SD, Antman EM, Contant CF, Guo J, Giugliano RP. Predictors of bleeding and time dependence of association of bleeding with mortality. Insights from the Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel—Thrombolysis in Myocardial Infarction 38 (TRITON-TIMI 38). Circulation 2011; 123:2681-268.
21. Lincoff AM, Bittl JA, Harrington RA, Feit F, Kleiman NS, Jackman JD, et al. Bivalirudin and provisional glycoprotein IIb/IIIa blockade compared with heparin and planned glycoprotein IIb/IIIa blockade during percutaneous coronary intervention: REPLACE-2 randomized trial. JAMA 2003; 289:853–863.
22. Nikolsky E, Mehran R, Dangas G, Fahy M, Na Y, Pocock SJ, et al. Development and validation of a prognostic risk score for major bleeding in patients undergoing percutaneous coronary intervention via the femoral approach. Eur Heart J 2007; 28:1936–1945.
23. Dauerman HL, Rao SV, Resnic FS, Applegate RJ. Bleeding avoidance strategies consensus and controversy. J Am Coll Cardiol 2011;58(1):1-10.