J Surg Med. 2019;3(9):663-665.
DOI: 10.28982/josam.569158

Research article
Araştırma makalesi

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Effects of mean platelet volume and platelet counts on peripheral biodegradable stent restenosis

Periferik biyoeriyebilir stent restenozu üzerine ortalama trombosit hacminin ve trombosit sayımının etkisi

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Ethics Committee Approval: The study was approved by the Ethical Committee of the Uludag University Faculty of Medicine (Number: 2013-08/20).
Etik Kurul Onayı: Çalışma Uludağ Üniversitesi Tıp Fakültesi Etik Kurulu tarafından onaylandı (Sayı: 2013-08/20).

Conflict of Interest: No conflict of interest was declared by the authors.
Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Financial Disclosure: The authors declared that this study has received no financial support.
Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

Published: 9/17/2019
Yayın Tarihi: 17.09.2019

Abstract

Aim: Thrombocytes play a key role in atherosclerosis and acute vascular events. The purpose of this study is to investigate the association between mean platelet volume (MPV), platelet counts as well as other hematological parameters and biodegradable stent re-stenosis.

Methods: 53 patients who underwent percutaneous biodegradable peripheral stent placement procedure were included in this retrospective cohort study. Blood samples were collected a day before the operation. Patients were followed for a mean of 6 months and Doppler ultrasonography (DUSG) was performed for control examination. According to the DUSG results, patients were divided into two groups: Group 1 included patients with ≥50% in-stent re-stenosis and Group 2, with <50% in-stent re-stenosis.

Results: The mean age of the patients was 58.1 (6.7) years. 6 (11.3%) patients were female and 47 (88.7%) patients were male. Eight (15%) had iliac artery and 45 (84.9%) had superficial femoral artery stenosis. Doppler US reports showed that 11 (20.8%) patients had ≥50% in-stent re-stenosis (Group 1). Re-stenosis rates were higher at younger ages (P=0.020). There was no statistically difference between the groups in terms of gender (P=0.636), MPV (P=0.210), PLT counts (P=0.129) or any other hematologic parameters.

Conclusion: Several studies have shown that some blood parameters, especially MPV, are effective on coronary and peripheral stent stenosis. In our study, we found that none of the hematologic or common blood parameters can predict biodegradable stents re-stenosis.

Keywords: Biodegradable stent, Peripheral arterial disease, Platelet counts, Mean platelet volume

Öz

Amaç: Trombositlerin ateroskleroz ve akut vasküler olaylarda önemli bir rolü vardır. Bu çalışmanın amacı, ortalama trombosit hacmi (MPV), trombosit sayıları ve diğer hematolojik parametreler ile biyoeriyebilir stent stenozu arasında bir ilişki olup olmadığını araştırmaktır.

Yöntemler: Bu retrospektif kohort çalışmaya biyoeriyebilir periferik stentlerle perkütan müdahale yapılan 53 hasta dahil edildi. Kan örnekleri operasyondan bir gün önce alındı. Hastalar ortalama 6 ay takip edildi ve tüm hastalara kontrol amaçlı Doppler ultrasonografi (DUSG) yapıldı. Doppler ultrasonografi sonuçlarına göre hastalar iki gruba ayrıldı: Grup 1'deki hastalarda ≥%50 stentiçi restenoz ve Grup 2'deki hastalarda <%50 stentiçi restenoz mevcuttu.

Bulgular: Hastaların yaş ortalaması 58,1 (6,7) yıl olup, 6 (%11,3) hasta kadın, 47 (%88,7) hasta erkekti. Sekiz (%15) hastada iliak arter darlığı, 45 (%84,9) hastada yüzeyel femoral arter darlığı mevcuttu. Doppler US raporları, 11 (%20,8) hastada, ≥%50 stentiçi re-stenoz (Grup 1) olduğunu gösterdi. Re-stenoz oranları genç yaşta daha yüksekti (P=0,020). İki grup arasında cinsiyet (P=0,636), MPV (P=0,210), PLT sayısı (P=0,129) veya diğer hematolojik parametreler açısından istatistiksel olarak fark yoktu.

Sonuç: Birçok çalışmada özellikle MPV olmak üzere bazı kan parametrelerinin koroner ve periferik stent stenozu üzerinde etkili olduğu gösterilmiştir. Çalışmamızda, hematolojik veya kan parametrelerinin hiçbirinin biyobozunur stentlerin restenozunu öngöremediğini tespit ettik.

Anahtar kelimeler: Biyoeriyebilir stent, Periferik arter hastalığı, Trombosit sayıları, Ortalama trombosit hacmi

How to cite / Atıf için: Akgül E, Engin M, Özyazıcıoğlu AF. Effects of mean platelet volume and platelet counts on peripheral biodegradable stent restenosis. J Surg Med. 2019;3(9):663-665.

Introduction

At common usage peripheral arterial disease (PAD) explains the stenosis of the abdominal aorta and the distal arteries of the abdominal aortic bifurcation. Men and women over 50 years of age are more frequently affected. The principle reason is atherosclerosis, and femoropopliteal section is mostly involved, but many vessels may have stenosed simultaneously [1]. Blood viscosity, collateral circulation, the level, and the severity of stenosis specify the clinical condition. Intermittent claudication (IC) is the main symptom and it due to the disturbed balance of muscle's blood demand and supply. Symptoms initiate with IC, and progress onto pain, palor, pulselessness, paresthesia, paralysis, necrosis, and gangrene.

Biodegradable stents (BDS) consist of non-metallic bio-absorbable materials, causing less intimal hyperplasia and acute thromboembolic events than other bare stents. Intravascular stent fracture is very rare and no residual materials are left after DBS resolves [2]. They are suitable for re-ballooning, re-stenting, or any other interventions due to their absorbable nature, which distinguishes BDS from other stents. Platelets are small cells which include various granules, a microtubular system and an active membrane [3]. The mean platelet volume (MPV) may play an important role in atherosclerotic and thrombotic pathways [4]. In this retrospective study, we aimed to investigate the association between preprocedural platelets as well as other hematologic parameters and in-stent re-stenosis of biodegradable stents.

Materials and methods

This retrospective study was conducted at University of Health Sciences, Bursa Yuksek Ihtisas Training and Research Hospital, and approved by the Ethical Committee of the Uludag University Faculty of Medicine (Number: 2013-08/20). 53 patients who had iliac artery (IA) or superficial femoral artery (SFA) stenosis and were treated with BDS between January 2010 and January 2013 were included in the study.

All patients conformed to Fontain Classification II and III. Preoperative Ankle/Brachial Indexes (ABI) were measured. Those who had histories of peripheral artery operations, acute thrombosis after BDS treatment in the first 24 hours and were deceased within 6 months of the treatment were excluded.

All angiographic interventions were performed by Siemens 792AXA136160 Axiom Artis WEE at the angiography laboratory. Hemogram samples were collected to EDTA-containing tubes and processed with Beckman Coulter LH 750. Contralateral and ipsilateral femoral arteries of 8 and 45 patients were cannulated, respectively. 1 ml heparin (5000 IU) was administered intravenously before stent implantation. A loading dose of 3x75 mg clopidogrel was given orally at the end of the operation and maintained with 1x75 mg per day. Low molecular weight heparin (Enoxaparin Sodium, 1mg/kg once a day) was injected subcutaneously for 10 days following the procedure. Preprocedural hematologic parameters were noted from the patients' data. Arterial Doppler ultrasonography (DUSG) was performed at the 6th postoperative month. In patients with re-stenosis of 50% or more, clinical complaints tend to reoccur and may require re-intervention. Therefore, according to the DUSG reports, patients were categorized as those with ≥50% in-stent re-stenosis (Group 1, n=11) and with ≤50% in-stent re-stenosis (Group 2, n=42). The two groups were compared with respect to mean platelet volume (MPV), platelet count (PLT) and the other parameters.

Statistical analysis

Data was analyzed with the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013). Descriptive statistics were used to present continuous variables (mean, standard deviations, minimum, median, maximum). Chi-Square test was used to compare two groups of nominal variables. As for continuous variables, student t test was used for those with normal distribution and Mann Whitney U test was used for those without. $P<0.05$ was deemed statistically significant.

Results

Six patients (11.3%) were female and 47 (88.7%) were male. The mean age of the patients was 58.1 (6.7) years. Thirty-nine (73.5%) patients had hypertension, 28 (52.8%) had hyperlipidemia, and 16 (30.1%) had chronic obstructive pulmonary disease. Twelve (22.6%) patients underwent coronary bypass surgery or were diagnosed with coronary artery disease (Table 1).

The diagnosis of the arterial stenosis was made by conventional angiography. 36 (67.9%) patients had type A lesions, 11 (20.7%) had type B lesions, and 6 (11.3%) had type C lesions according to the Trans-Atlantic Inter-Society Consensus (TASC) classification. The ABI index scores of 32 (60.3%), 16 (30.1%) and 5 (9.4%) patients ranged between 0.7-0.9, 0.5-0.7 and 0.3-0.5, respectively (Table 2).

Preprocedural PLT, WBC counts and MPV values did not differ among the two groups (P=0.129, P=0.175 and P=0.210, respectively). The low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) levels were similar in two groups, as well (P=0.756 and P=0.088, respectively) (Table 3).

The patients in Group 1 were younger than those in Group 2 (P=0.020).

Table 1: Baseline characteristics of the patients

	Total n=53	Group 1 n=11	Group 2 n=42	*P*-value
Age(years) (mean(SD))	58.1 (6.7)	52.1 (5.1)	59.7 (6.2)	0.020
Male / Female n (%)	47(88.7) / 6(11.3)	10(90.9) / 1(9.1)	37(88) / 5(12)	0.636
Hypertension, n (%)	39(73.5)	8(72.7)	31(73.8)	0.750
Hyperlipidemia, n (%)	28(52.8)	6(54.5)	22(52.3)	0.446
Diabetes mellitus, n (%)	18(33.9)	4(36.3)	14(33.3)	0.348
CAD, n (%)	12(22.6)	3(27.2)	9(21.4)	0.075
COPD, n (%)	16(30.1)	3(27.2)	13(30.9)	0.125
BMI> 30, n (%)	8(15)	2(18.1)	6(14.2)	0.240

SD: Standard deviation, CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, BMI: Body mass index

Table 2: TransAtlantic Inter-Society Consensus (TASC) Classification and Baseline Ankle Brachial Index (ABI) measurements of the patients

	n=53	%
Ankle brachial index		
0.3-0.5	5	9.4
0.5-0.7	16	30.1
0.7-0.9	32	60.3
TASC type A lesion	36	67.9
TASC type B lesion	11	20.7
TASC type C lesion	6	11.3

Table 3: Preoperative hematologic and biochemical parameters of the patients

	Total Mean (SD)	Group 1 Mean (SD)	Group 2 Mean (SD)	*P*-value
Platelet (10^3/μL)	263.4 (108.8)	257.6 (100)	264.9 (112)	0.129
MPV	8.7 (1.9)	8.2 (0.9)	8.8 (2)	0.210
WBC (10^3/μL)	9.1 (2.9)	8.3 (2.2)	9.3 (3.1)	0.175
LDL-C (mg/dL)	118 (38.3)	116.8 (44.9)	119.2 (36.3)	0.756
HDL-C (mg/dL)	42.3 (8.8)	41.3 (7.2)	42.9 (9.1)	0.088
C-reactive protein, mg/dL	9.8 (10.8)	8.1 (11.5)	10.1 (10.4)	0.125
Albumin, g/dL	3.9 (0.7)	3.8 (0.7)	3.9 (0.6)	0.275
Creatinine, mg/dL	0.9 (0.5)	1.0 (0.3)	0.9 (0.6)	0.196
BUN, mg/dl	18.3 (9.1)	18.8 (6.7)	17.8 (9.4)	0.146
Total protein, g/dL	6.7 (0.7)	6.4 (0.9)	6.9 (0.6)	0.075

MPV: Mean platelet volume, LDL-C: Low-density lipoprotein cholesterol, HDL-C: High-density lipoprotein cholesterol, BUN: Blood urea nitrogen

Discussion

Biodegradable stents are made of a poly-L-lactic acid (PLLA) polymer, which is absorbable by the vessels' endothelium. This material is mainly hydrolyzed. The final PLLA degredation products are eliminated by the Krebs cycle and excreted in the urine [5]. PLLA is also used in orthopedic implants, resorbable sutures, and soft-tissue implants [5,6].

The stents preserve their flexibility and radial strength during the first 6 months. According to a long-term follow-up report, 3 years are required for complete elimination of PLLA material from human coronary arteries [7]. Treatment of de novo lesions in peripheral arteries with biodegradable stents has similar outcomes with metal stents. Angiographic imaging data are comparable among metal stents and biodegradable stents in reaching a high patency rate at the first year [8].

Thrombocytes play a significant role in atherosclerosis and acute vascular events. Their activation capacity is directly proportional to their size, so MPV not only indicates their size, but also their activity [9]. Many studies report that elevated MPV values are related to coronary in-stent restenosis and are a risk factor for PAD [10,11]. Elevated MPV values accompany ischemic stroke, acute coronary syndrome, diabetes mellitus, and preeclampsia [12]. There are also studies showing that MPV is an early marker for peripheral bare metallic stent re-stenosis [13,14]. In contrast, Karauzum et al. [13] claim that low MPV levels have protective effects on in-stent re-stenosis. In our study, there was no statistically significant difference between the groups in terms of MPV values, and no association to in-stent re-stenosis. There are contradictions in the literature and more extensive research is needed to eliminate this complexity. For our own research, we believe that this result depends on the type of the stent used.

Smoking, diabetes mellitus, and hyperlipidemia are demonstrated predictors for PAD and in-stent re-stenosis [15]. Although taking precautions against these factors may decrease in-stent re-stenosis in the short term, stent obstructions cannot be prevented in the long term [16]. Therefore, all precautions should be taken to provide stent patency. In our study, DM, hyperlipidemia, hypertension, gender, or BMI was not proven to have a statistically significant relationship with in-stent re-stenosis. This finding is interesting, because it does not match the literature data.

Limitations

The main limitation of the study was the small number of patients and the retrospective design. In addition, restenosis was evaluated with DUSG, which is noninvasive and performer-dependent.

Conclusion

The purpose of this study was to compare the obstruction rates according to hematological parameters which could be simply measured and take precautions if needed. But none of the hematologic parameters were found to be associated with biodegradable stents' re-stenosis. This finding that contradicts with the literature may be due to the different raw materials of biodegradable stents. Further, larger scale studies are to support this opinion.

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This paper has been checked for language accuracy by JOSAM editors.
The National Library of Medicine (NLM) citation style guide has been used in this paper.

Suggested citation: Patrias K. Citing medicine: the NLM style guide for authors, editors, and publishers [Internet]. 2nd ed. Wendling DL, technical editor. Bethesda (MD): National Library of Medicine (US); 2007-[updated 2015 Oct 2; cited Year Month Day]. Available from: http://www.nlm.nih.gov/citingmedicine