Med. J. Cairo Univ., Vol. 90, No. 6, September: 1721-1728, 2022
www.medicaljournalofcairouniversity.net

The Effect of Statins on the Patency Rate of Peripheral Vessels after Balloon Angioplasty

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Abstract

Background: Statins (hydroxymethylglutaryl-coenzyme A reductase inhibitors) have long been recognized to substantially decrease cardiovascular events in people with peripheral vascular dysfunction.

Aim of Study: The aim of the research was to assess the effect of routine use of statins after plain balloon angioplasty of infrainguinal vessels to increase the patency rate.

Patients and Methods: This was a randomized controlled research to assess the effect of routine normal utilization of statins after plain balloon angioplasty of infrainguinal vessels to increase the patency rate. We included 270 patients with infrainguinal POBA. We blindly randomized the patients into 2 groups, first with routine postoperative statins use (150). The second groups without postoperative statins use (120). We exclude all patients who have used drug coated balloons.

Results: ABI in group I was much lower than in group II, whereas technical success was substantially better in group I than in group II. However, there is no discernible difference in terms of complications or length of stay in the hospital. 12-months and 24-months patency was substantially greater in group I compared to group II.

Conclusions: Statins are of great importance in improving cardiovascular protection, inhibiting the progression of PAD, and improving clinical outcomes after interventional therapy in PAD.

Key Words: *Statins – Peripheral arterial disease – Cardiovascular risk – Balloon angioplasty – Patency rate.*

Introduction

THE atherosclerotic disorder peripheral arterial disease (PAD) is quite frequent. Intermittent claudication causes a decline in quality of life in PAD patients. Patients with PAD are also at a greater incidence of cardiac or cerebrovascular disorders, even if they are asymptomatic. Lifestyle changes, frequent exercise, quitting smoking, and management of cardiovascular risks, such as hypercholesterolemia, are all used to treat PAD **[1]**. Statins have been proven in a rising number of trials to lower cardiovascular risk and improve PAD symptoms. In order to reduce cardiovascular events and death, current recommendations urge that all patients with PAD take statins. Patients with PAD, on the other hand, are less often to be prescribed statins than those with coronary heart illness **[2]**.

PAD is quite common. It is thought that more than 200 million persons worldwide suffer from PAD. The frequency of PAD, identified as an ankle-brachial index (ABI) of <0.9, is 4.3 percent in people aged ≥40 y, but it rises to 14.5 percent in those aged ≥70 y. This illness has a severe human and financial cost. Given the age-related nature of PAD, greater survival and population aging are projected to result in a rise in its prevalence and expense **[3]**.

Given the substantial cardiovascular risk related to PAD, every patient's diagnosis, regardless of symptoms, should be considered as a chance to better manage their cardiovascular risks and avoid future occurrences. As soon as the disease is diagnosed, statins, antiplatelet agents, and antihypertensive medications, which have been demonstrated to enhance functioning and vital outcomes, should be used as much as possible to treat it **[4]**.

Statins have been demonstrated to diminish the chance of CHD, stroke, and PAD, as well as move forward mortality. They have more over demonstrated to be safe, with exceptionally low events of unfavorable outcomes **[5]**.

Statin treatment has more over demonstrated success in increasing pain-free walking time in

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patients with lower limb chronic ischemia. Statins play a part in relapse of plaque with diminishment in lipid substance. These drugs assist stabilize atherosclerotic plaque with thickened fibrous caps and macro-calcification that serves to stabilize the atheromas [6].

Within the underneath the knee (BTK) vessels, percutaneous transluminal tissue angioplasty (PTA) remained the foremost broadly utilized strategy for recanalization, but was altogether constrained by the great restenosis or obstruction rates [7].

As a result, the aim of this study was to assess the impact of routine utilization of statins after plain balloon angioplasty of infrainguinal vessels to increase the patency rate.

Patients and Methods

This was a randomized controlled trial; the study included all patients with infrainguinal POBA during the period from February 2020 to February 2022. Patients were blindly randomized into 2 groups, first with routine postoperative statins use (150 patients). The second group without postoperative statins use (120 patients).

We excluded all patients who have used drug coated balloons. We tried to match the 2 groups regarding the number of diseased vessels.

Patients' demographics, comorbidities, and usage of a statin at the intervention time were all obtained. On a per-limb basis, the indication for the surgery, the location of the lesion, and the degree of the lesion were all noted. Patients were deemed compliant with statin medication if they stayed on it from the time the stent was placed till the final follow-up was documented. The Trans-Atlantic Inter-Society Consensus (TASC II) grading was used to determine the severity of the lesions. All of the intervention were carried out in a fixed-image angiography suite. Stents were selected based on availability and the surgeon's preferences. Before their intervention, patients were given 300mg of clopidogrel agnd 325mg of aspirin. Before percutaneous transluminal angioplasty and stent insertion, heparin was administered to all of the patients in the amount of 5000 units. At the conclusion of the procedure, the anticoagulation was not reversed. All patients were given a 30-day regimen of clopidogrel (75mg daily) and aspirin after the intervention (81mg). An angiographic residual stenosis was classified as a successful intervention.

Periodic clinical evaluations, ABI, and duplex ultrasonography (DUS, Philips iU 22, Philips Healthcare Solutions, Bothell, WA, USA; GE Logiq E9, GE Medical Systems, Milwaukee, WI, USA) were used to calculate graft patency every 3 months at the first postoperative year, and every 6-12 months after that for the next 2 years. CT angiography or femoral arteriography were used to detect if the balloon was failing or occluded in circumstances when the balloon patency on DUS was not visible.

Statistical analysis: A software tool was used to examine all statistical analyses (SPSS 22.0 for Mac; SPSS Inc., Chicago, IL, USA). Visual (histograms and probability plots) and analysis (Kolmogorov-Smirnov and Shapiro-Wilk tests) approaches were used to evaluate if the data were regularly distributed. Numbers and proportions are used to represent different variables. The mean and standard deviation are used to represent dependent variable. Because all ongoing measures were normally distributed, the unpaired sample *t*-test was utilized to analyze quantitative data. The factors of increased primary patency after one year of PTA were determined using logistic regression analysis. A statistically substantial *p*-value of <0.05 was used.

Results

This was a randomized controlled research to assess the effect of routine utilization of statins after plain balloon angioplasty of infrainguinal vessels to increase the patency rate. We included 270 patients with infrainguinal POBA. We blindly randomized the patients into 2 groups, first with routine postoperative statins use. The second groups without postoperative stain use.

We exclude all patients who have used drug coated balloons.

Table (1) shows that there is a significant difference regarding hypertension and dyslipidemia prevalence.

Table (2) shows that TASC and Rutherford classes were comparable in both groups while number of vessels runoff and lesion length was nearly similar.

Table (3) shows that post. ABI in group I was much lower than in group II, whereas technical success was substantially better in group I than in group II. However, there is no discernible difference in terms of complications or length of stay in the hospital.

Table (4) and Fig. (1) shows that 12-months and 24-months patency was substantially greater in group I compared to group II.

Table (1): Basic features in both groups.

	Group I (Statin) (n=150)	Group II (No-statin) (n=120)	*p*-value
Age (years):			
Mean ± SD	57±12	58±8	.434
Gender, n (%):			
Males n (%)	71 (47.3)	55 (45.8)	.806
Females	79 (52.7)	65 (54.2)	
BMI (kg/m^2):			
Mean ± SD	27±3.12	26.29±3.21	.068
Comorbidities, n (%):			
Diabetes mellitus	51 (34.0)	43 (35.8)	.753
Hypertension	132 (88.0)	94 (78.3)	.033
Smoking	50 (33.3)	42 (35.0)	.774
Dyslipidemia	54 (36.0)	58 (48.3)	.041
History of CAD	26 (17.3)	22 (18.3)	.831
History of MI	17 (11.3)	17 (14.2)	.486
Prior PCI	9 (6)	14 (11.7)	.097
Prior CABG	8 (5.3)	3 (2.5)	.243
COPD	41 (27.3)	25 (20.8)	.217
CKD	20 (13.3)	12 (10.0)	.400
Presentation, n (%):			
Claudication	69 (46)	48 (40)	.323
CLI	81 (54)	72 (60)	
Pre. ABI:			
Mean ± SD	0.547±0.129	0.529±0.131	.259
SBP (mmHg):			
Mean ± SD	190±16	187±14	.107
DBP (mmHg):			
Mean ± SD	101±8	99±10	.069

- For numerical and categorical data, independent *t*-tests or Chi-square tests were utilized.

CAD : Coronary artery disease.
MI : Myocardial infarction.
PCI : Percutaneous coronary intervention.
CABG : Coronary artery bypass graft.
COPD : Chronic obstructive pulmonary disease.
CKD : Chronic kidney disease.
CLI : Critical limb ischemia.
ABI : Ankle brachial index.

Table (2): Clinical characteristics in both groups.

	Group I (Statin) (n=150)	Group II (No-statin) (n=120)	*p*-value
Statin type, n (%):			
Simvastatin	150 (100%)	–	
TASC classification, n (%):			
A	56 (37.3)	43 (35.8)	.786
B	59 (39.3)	49 (40.8)	
C	25 (16.7)	23 (19.2)	
D	10 (6.7)	5 (4.2)	
Rutherford Class, n (%):			
2	27 (18)	20 (16.7)	.886
3	94 (62.7)	73 (60.8)	
4	23 (15.3)	20 (16.7)	
5	6 (4)	7 (5.8)	
Number of vessels runoff, n (%):			
1 vessel	58 (38.7)	41 (34.2)	.346
2 vessels	62 (41.3)	46 (38.3)	
3 vessels	30 (20.0)	33 (27.5)	
Lesion length (mm):			
Mean ± SD	136.2±81.6	132.9±85.3	.747

- For numerical and categorical data, independent *t*-tests or Chi-square tests were utilized.

TASC: Trans-Atlantic Inter-Society Consensus on Peripheral Arterial Disorder Management.

Table (3): Postoperative data in both groups.

	Group I (Statin) (n=150)	Group II (No-statin) (n=120)	*p*-value
Post. ABI:			
Mean ± SD	0.793±0.211	0.885±0.279	0.002
Technical success, n (%)	140 (93.3)	102 (85)	0.026
Complications, n (%):			
Pseudoaneurysm	2 (1.3)	3 (2.5)	0.413
Rupture	0	1 (0.83)	
Medication, n (%):			
Clopidogrel	125 (83.3)	120 (100)	<0.001
Cilostazol	51 (34)	49 (40)	0.249
Hospital stay (days):			
Mean ±SD	1.74±1.59	1.86±1.63	0.632

- For numerical and categorical data, independent *t*-tests or Chi-square tests were utilized.

Table (4): Patency in both group.

	Group I (Statin) (n=150)	Group II (No-statin) (n=120)	*p*-value
Patency			
12 months:			
Mean ±SD	97.5±2.61	84.7±4.29	<0.001
24 months:			
Mean ±SD	78.9±6.88	53.8±9.13	<0.001

- Independent *t*-test was used for numerical.

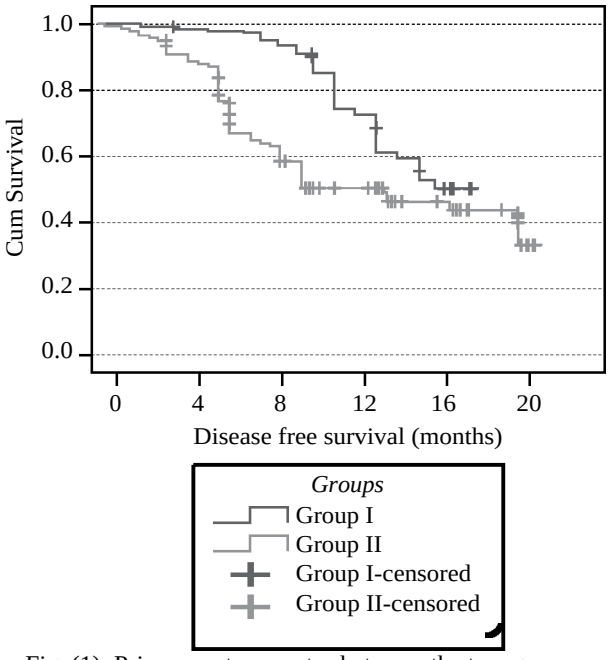

Fig. (1): Primary patency rates between the two groups.

Discussion

Patients with PAD are more often have a number of cardiovascular risks, as well as additional conditions that raise cardiovascular risk, like metabolic disorder, hepatic steatosis, or chronic renal failure **[8]**. Furthermore, atherosclerosis invasion of other vascular areas, like the coronary or cerebral, is common in these individuals. As a result, PAD might be used as a predictor of atherosclerosis in other areas or susceptibility to poly-vascular interaction **[9]**.

This was a randomized trial that looked at the effect of routine use of statins after plain balloon angioplasty of infrainguinal vessels to increase the patency rate. We included all patients with infrainguinal POBA. We blindly randomized the patients into 2 groups, 1st with routine postoperative statins use. The second groups without postoperative statins use. We excluded all patients who have used drug coated balloons. We tried to match the 2 groups regarding the number of diseased vessels. We followed-up the patients for 2 years clinically, by ABI and by duplex US.

In the present study, Mean ± SD of age was 57±12 and 58±8 years in group 1 and group 2 respectively; majority of cases in both groups were female. There was a substantial variance in the prevalence of hypertension and dyslipidemia, but there were no substantial variations in demographic variables across groups.

In comparison with Dosluogluet al., **[10]** over the course of the trial, 717 patient received revascularization, 397 of whom were on statins and 320 of whom were not. Open revascularization was done in 25% of statin-treated patients vs 29% of non-statin-treated patients (p=0.399). Statin usage rose from 49% before December 31, 2005 to 64% (p<0.001) after that date. In the statin group, there was a higher incidence of Caucasian race, CAD, diabetes, hypertension, and hyperlipidemia. The non-statin group, on the other hand, included more patients with CLI (77 percent vs 57 percent, p<0.001), non-ambulatory status (25.3 percent vs 12.3 percent, p<0.001), and a reduced BMI (25.4± 5.0 vs 27.3±4.6kg/m^2, p<0.001).

Sarıcaoğluet al., **[11]** was conducted on A sum of 128 individual (113 male, 15 female; median age: 63.4 9.9 years; range, 32 to 87 years) who had PTA for FP lesions from August 2016 and April 2018 were retrospectively examined and prospectively allocated. High blood pressure and diabetes were found to be prevalent in 59.4 percent and 55.5 percent of the population, respectively. Mean ± SD of age was 63.4±9.9 years.

In research done by Kup et al., **[12]** reported thatninety-four patients treated with PTA were selected consecutively and retrospectively and were separated into two groups based onthe high - or moderate-dose statin treatments they were given. We identified 94 patients [77 (78.7%) male, 61.7±8.4] who underwent PTA during the study period. Mean ± SD of age was 61.3±8.1 and 62.1±8.6 years in group 1 and group 2 respectively, and majority of cases were male.

Jung et al., **[13]** reported that when the patient characteristics of the two groups were examined, group II patients were younger (median, 69 years vs. 66 years; p=0.024) and more hypertensive (60.8 percent vs. 74.6 percent; p=0.017) than group I patients (short-term graft patency). There were more limbs in Group II with claudication as a reason for LEAB (51.2 percent vs. 70.9 percent, p=0.001), but no substantial variations in other comorbidities or blood test findings.

Statins are competitive inhibitors of the rate-limiting step in cholesterol production, hydroxymethylglutaryl (HMG) CoA reductase. They occupy a part of HMG CoA's binding site, preventing this substrate from reaching the enzyme's active site. Statins are one of the most important medications in the primary and secondary protection of cardiovascular diseases **[14]**.

Statin treatment has been found to decrease all-cause death and cardiovascular (CV) incidences in individuals with lower extremity artery disease (LEAD) (from asymptomatic to extreme instances) in observational investigations and restricted randomized clinical trials (RCTs) **[15]**.

A systematic review of Kumbhani et al., **[16]** in whichLipid decreasingtreatment in subjects with atherosclerosis of the lower limbs is linked with a 20% drop in overall CV incidents and a non-substantial 14 percent decrease in all-cause death, according to 18 trials involving 10,000 patients with cholesterol concentrations ranging from normal to raised. In the Reduction of Atherothrombosis for Continued Health (REACH) registry, statin usage was linked to an 18% decreased risk of poor limb prognosis.

In the current study, the main statin type used was Simvastatin, majority of cases in both groups were of grade B TASC classification by 59 (39.3) and 49 (40.8) in group 1 and group 2 respectively, while as regard Rutherford Class; majority of cases in both groups were of class 3, with non-significant differences between groups regarding each of TASC classification and Rutherford Class.

On the other hand, as regard number of vessels runoff; majority of cases in both groups had 2 vessels runoff, and Mean ± SD of lesion length was 136.2±81.6mm and 132.9±85.3mm in group 1 and group 2 respectivelywith no substantial variations between groups regarding number of vessels runoff and lesion length.

Kiguchi et al., **[17]** found no substantial variations between the two groups in terms of TASC II lesion classification (p=0.41), run off classification (p=0.59), and calcification score (p=0.51), which agrees with our results.

While in the study of Sarıcaoğlu et al., **[11]** reported A total of 128 individuals were enrolled in the research, including 143 FP lesions. Hypertension and diabetes were found to be prevalent in 59.4 percent and 55.5 percent of the population, respectively. The majority of the patients (63.3%) had moderate claudication (Rutherford Class 3), and the proximal superficial femoral artery (SFA) was the highest prevalent lesion location (82.5%).

In comparison with the study of Noh et al., **[18]** which The goal of this investigation was to see whether the quantity and quality of infrapopliteal runoff channels had an effect on primary patency following SFA angioplasty with stenting in claudication patients. Seventeen limbs (11.1%) had no runoff vessels discovered, 35 limbs (22.8%) had one vessel, 59 limbs (38.6%) had two vessels, and 42 limbs (27.5%) had three vessels, according to the study. There were 53 (34.6%) and 100 (65.4%) limbs in the low runoff (zero or one vessel) and excellent runoff (two or three vessels) categories, respectively. TASC II A was assigned to 25 limbs (16.3 percent), TASC II B to 71 limbs (46.4 percent), TASC II C to 37 limbs (24.2 percent), and TASC II D to 20 limbs (13.1 percent).

In this investigation; we found that post. ABI in group I was much lower than in group II, whereas technical success was significantly higher in group I than in group II. Clopidogrel was also substantially more common in group II. However, there is no discernible difference in terms of complications or length of stay in the hospital.

In comparison with the study of Foley et al., [19] they reported that The two groups did not vary substantially in terms of baseline ankle brachial indexes, toe brachial indexes, or angiographic vessel runoff. The LMI group had a baseline ankle brachial index of 0.55±0.29 while the HI group had a baseline ankle brachial index of 0.52±0.30 (p=0.58), indicating a population with developed PAD. On angiography, the most of patients showed 1vessel runoff, which was consistent with this.

Following therapy for peripheral arterial illness, it is critical to enhance the ABI. At 12 months, there was a substantial elevation in the ABIs and Rutherford classes in all lesions, even the complicated ones (p<0.001), similar to Pastromas et al., [20]and Iida et al., **[21]**. In the research by Sarcaolu et al., **[11]** 81.8 percent of the patients exhibited minimal claudication symptoms or were asymptomatic at the conclusion of the follow-up period.

There has been little research on the impact of lipid-lowering drugs, particularly statins, on the rates of primary patency of peripheral endovascular procedures.

Aiello et al., **[22]** looked at the link between statins and clinical results following CLI endovascular intervention at all lower extremity values and found that patients who took statins had better

overall survival, primary and secondary patency, and limb salvage rates than those who didn't.

In patients with CLI who had tibial endovascular procedures, Fernandez et al., **[23]** observed no link between periprocedural statin medication and limb salvage or wound healing. This disparity might be related to the fact that one of the trials focused only on tibial treatments, whereas the other did not.

Finally; in our study we found that 12-months and 24-months patency was considerably greater in group I compared to group II.

On the other hand; de Grijs et al., **[24]** reported in their study thatthe 250 patients, at the study's follow-up, 96 patients, 50 of whom use statin and 46 of whom were controls, encountered stent failure. Kaplan-Meier estimates of statin group patency rates were 79.9% at 12 months, 55.3 percent at 24 months, and 40.2 percent at 36 months, compared to 68.2 percent, 49.2 percent, and 28.0 percent in the control group, respectively.

A meta-analysis by Romiti et al., **[25]** Infrapopliteal angioplasty for the management of CLI was shown to have 1-year primary and secondary patency rates of 58 percent and 68 percent, respectively.

Another study of Fernandez et al., **[23]** showed At infrapopliteal angioplasty, main patency was 33 percent after one year, secondary patency was 56 percent, and limb salvage was 75 percent.

Study limitations:

There are a few flaws in our research. For starters, our research was conducted in a single location. Second, just a tiny percentage of the patients were included in our research. Third, the treatments were not carried out by a single team, and despite the fact that all of the operators were skilled interventional cardiologists, The method of revascularization was left to the decision of the operator.

Conclusion:

Statins are of great importance in improving cardiovascular protection, inhibiting the progression of PAD, and improving clinical outcomes after interventional therapy in PAD. Further multicentered and randomized clinical studies are needed to clarify the possible causal relationship.

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تأثير الستاتين على معدل سلامة الأوعية الدموية الطرفية بعد التوسيع بواسطة البالونات

مقدمة : من المعروف منذ فترة طويلة أن الستاتينات (مثبطات إنزيم اختزال هيدروكسي ميثيل غلوتاريل أ) تقلل إلى حد كبير أحداث القلب والأوعية الدموية لدى الأشخاص الذين يعانون من اختلال وظيفي في الأوعية الدموية الطرفية.

الهدف من الرسالة : كان الهدف من البحث هو تقييم تأثير الاستخدام الروتيني للعقاقير المخفضة للكوليسترول بعد رأب الوعاء بالبالون العادي للأوعية تحت اللسان لزيادة معدل المباح.

الطريقة : تم اختيار هذا البحث العشوائي للرقابة لتقييم تأثير الاستخدام الطبيعي للعقاقير المخفضة للكوليسترول بعد رأب الوعاء بالبالون العادي للأوعية تحت اللسان لزيادة معدل المباح. قمنا بتضمين ٢٧٠ مريضاً مصاباً بفرط نشاط الغدة النخامية تحت اللسان. قمنا بتقسيم المرضى عشوائياً بشكل أعمى إلى مجموعتين، أولاً باستخدام الستاتينات الروتينية بعد الجراحة (١٥٠). المجموعات الثانية لا تتناول الستاتين بعد العملية الجراحية (١٢٠). نستبعد جميع المرضى الذين استخدموا البالونات المغلفة بالدواء تمت الدراسة في مستشفى اسوان وحلوان الجامعي ومستشفى شبين الكوم التعليمي وكانت مدة الدراسة سنتين.

النتائج : مؤشر الضغط الكاحلي العضدي في المجموعة الأولى كان أقل بكثير من المجموعة الثانية، في حين أن النجاح الفني كان أفضل بكثير في المجموعة الأولى منه في المجموعة الثانية. كان عقار كلوبيدوجريل أيضاً أكثر شيوعاً في المجموعة الثانية. ومع ذلك، لا يوجد فرق واضح من حيث المضاعفات أو مدة الإقامة في المستشفى. كان السداد لمدة ١٢ شهراً و ٢٤ شهراً أكبر بكثير في المجموعة الأولى مقارنة بالمجموعة الثانية.

الاستنتاجات : للستاتينات أهمية كبيرة في تحسين حماية القلب والأوعية الدموية، وتثبيط تطور اعتلال الشرايين المحيطية، وتحسين النتائج السريرية بعد العلاج التدخلي في اعتلال الشرايين المحيطية.