Comparison and Assessment of Outcome of Peripheral Intraarterial Intervention in Patients with Non - Tobacco & Tobacco Consumption

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Abstract

Background: We know that, tobacco consumption has the potential role in the management of the diseases and their outcomes. We plan this study to emphasise the role of the tobacco consumption and how it effects the management and prognosis. Our aim is to assess the effect of tobacco consumption on the outcome of peripheral intraarterial intervention in patients with peripheral arterial disease. To achieve our aim, we made objectives; first is to assess pre and post intervention clinical status of patients consuming tobacco. Second is to assess pre and post intervention clinical status of patients not consuming tobacco. Third is to compare the outcomes of peripheral intraarterial interventions in patient consuming & not consuming tobacco.**Material and Methods:**It was prospective observational study. Over the two years of time period. Diagnosed patients of Peripheral Arterial Disease (PAD) / Chronic Limb Ischemia (CLI), were included. All the patients evaluated for clinical signs /symptoms of PAD/CLI, prior to endovascular treatment, after the procedure (at the time of discharge), &at least one-year follow-up OF EACH patient to assess prognosis with outcomes. Informed and all needful consents took from all the patients before including them in the study and procedures.**Results:**50 % of the patients with grade 0 of pain had a habit of consuming tobacco, 61.22% with grade 1 had habit of tobacco consumption, 83.33% with grade 2 had habit of tobacco consumption and all(100%) with grade 3 and grade 4 of tobacco consumption had habit of tobacco. had our observation under these points. 28.57% of the patients with amputation had history of tobacco consumption and 68.52% with no amputation had history of tobacco consumption.28.57% of the patients with necrosis had history of tobacco consumption and 68.52% with no necrosis had history of tobacco consumption.62.50% of the patients with recurrence/relapse had history of tobacco consumption and 64.14% with no recurrence/relapse had history of tobacco consumption.**Conclusion:**In our study the post procedure pain is significantly high in tobacco consumer group. Which eventually decreases as the treatment progresses. significant association was found between amputation (necrosis) and history of non-tobacco consumption. Significant difference in the number of patients having relapse of disease due to various reasons. More number of patients were from tobacco consumption group and majority of the patients require the post IAI (Intra Arterial Intervention) due to the irregular intake of anticoagulant drugs.

Keywords: Tubacco, Angioplasty, Angiography, Angiography results, Post angiography, Pain & Vascular disease.

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Introduction

Since the even unwritten history to the present day of mankind, there are so many diseases have been discovered and their treatments are invented. The peripheral arterial diseases are stake a significant amount among them. There are several modalities / methods are available for the treatment of peripheral arterial diseases but intra-arterial interventions are the one of the best and top most. But as per each method it also has its own merits and complications so the vascular intervention has some limitations to give clinical & prognostic out comes which are dependents on the various factors clinical to social and so on. Those are keenly associated with the food & other habitual consumption practices of patients in past. These are among reasons which effect the course of treatment the most.

In the concern of increasing tobacco consumption not only in our society but worldwide now a days.Which is the one of the major causes of morbidity and mortality in association with the significant accounts for the some of the major complicated disease. Tobacco use is the single most important cause of PAD. Smoking has been comprehensively implicated in the pathogenesis of PAD by multiple investigations documenting that tobacco:[1] is the strongest risk factor for the development of de novo PAD;[2] fosters progression of limb arterial disease;[3] reduces the longevity of revascularization procedures;[4] increases rates of amputation and profoundly decreases patient survival.[5] Many clinicians assume that all PAD patients are current smokers and that it is unrealistic to expect them to quit smoking. However. Published data confirm that a high percentage of PAD patients quit successfully. For example.Only approximately 30-40'1. Of individuals with stable claudication are current smokers. Although most of these individuals had smoked previously.[6] Peripheral arterial disease (PAD) affects approximately 20% of adults older than 55 years and is a powerful predictor of myocardial infarction, stroke, and death due to vascular causes. The goals of treatment are to prevent future major coronary and cerebrovascular events and improve leg symptoms.[7]

So well, tobacco consumption has the potential role in the management of the diseases and their outcomes. We plan this study to emphasise the role of the tobacco consumption and how it effects the management and prognosis.

Aims and Objectives

Our first aim is to assess the effect of tobacco consumption on the outcome of peripheral intraarterial intervention in patients with peripheral arterial disease.

To achieve our aim, we made objectives; first is to assess pre and post intervention clinical status of patients consuming tobacco. Second is to assess pre and post intervention clinical status of patients not consuming tobacco. Third is to compare the outcomes of peripheral intraarterial interventions in patient consuming & not consuming tobacco.

Material and Methods

It was prospective observational study. Over the two years of time period.

Patient selection:

Diagnosed patients of Peripheral Arterial Disease (PAD) / Chronic Limb Ischemia (CLI), who presented / referred to us were included. All the patients evaluated for clinical signs /symptoms of PAD/CLI, prior to endovascular treatment, after the procedure (at the time of discharge), & follow-up (whenever possible) to assess prognosis with outcomes.

Informed consent took from all the patients before including them in the study.
The institutional ethics committee approval for this prospective study was taken.

Inclusion criteria

1. Patient who was diagnosed with PAD on colour Doppler / Contrast CT/ MRI and undergone Digital Subtraction Angiography (D.S.A) and/or endovascular treatment in our interventional radiology department.
2. Patients with more than 5 years of tobacco consumption habit in any manner and daily were only she/he include in study.
3. Patency of lumen of stenotic or occluded artery should be remain up to 50%.
4. Length of stenotic or occlusive segment of artery should be reduce at least 50%.
5. Patients who given consent to include in study.

Exclusion Criteria

1. Symptomatic cases due to Trauma undergoing endovascular management.
2. Contrast allergy.
3. Patients not willing to give informed consent.

Sample size

61 patients selected as first come first basis.

Equipment

All the included subjects underwent Conventional Angiogram – Arteriogram & Interventional Endovascular procedure performed with Digital Subtraction Angiography Machine by Philips Allura FD20 Cath Lab System.

Technique

In this study all the necessary clinical investigations done before the intervention then the patient underwent one of the following intra-arterial interventions

1. DSA Technique in Diagnostic Angiography
2. Endovascular Management Approach (Flowchart) And Techniques
3. Angioplasty (POBA)
4. Angioplasty with Stenting (DETAILS)
5. Intra-Arterial Thrombolysis (IAT)
6. Penumbra Device - Off Label Usage
7. Percutaneous Catheter Techniques (Aspiration, Mechanical Thrombolysis, Or Thrombolytic Therapy) in treatment of peripheral arterial disease.

Results

Table 1:Comparison of grading of post procedure pain in non-tobacco and tobacco consumer patient.

Grading of Pain	Tobacco Consumption		Total	χ2-value
	Yes	No		
Grade 0	2(50%)	2(50%)	4(6.56%)	2.60
Grade 1	30(61.22%)	19(38.78%)	49(80.33%)	p=0.62,NS
Grade 2	5(83.33%)	1(16.67%)	6(9.84%)	
Grade 3	1(100%)	0(0%)	1(1.64%)	
Grade 4	1(100%)	0(0%)	1(1.64%)	
Total	39(63.93%)	22(36.07%)	61(100%)	

50% of the patients with grade 0 of pain had a habit of consuming tobacco, 61.22% with grade 1 had habit of tobacco consumption, 83.33% with grade 2 had habit of tobacco consumption and all(100%) with grade 3 and grade 4 of tobacco consumption had habit of tobacco. By using chi-square test statistically no significant association was found between grading of pain and habit of consumption. (χ2-value=2.60,p=0.62).
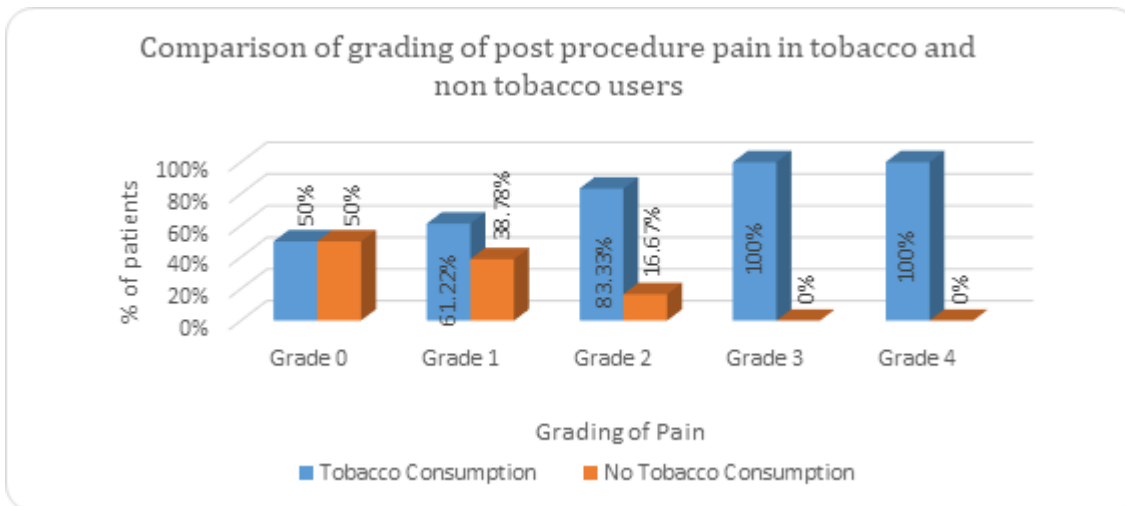

Figure 1: ?

Table 2: Comparison of amputation in tobacco user and non-tobacco users

Amputation	Tobacco Consumption		Total	χ2-value
	Yes	**No**		
Yes	2(28.57%)	5(71.43%)	7(11.48%)	4.28
No	37(68.52%)	17(31.48%)	54(88.52%)	p=0.028,S
Total	39(63.93%)	22(36.07%)	61(100%)	

(Table 2) 28.57% of the patients with amputation had history of tobacco consumption and 68.52% with no amputation had history of tobacco consumption. By using chi-square test statistically significant association was found between amputation and history of tobacco consumption.(χ2-value=4.28,p-value=0.028).
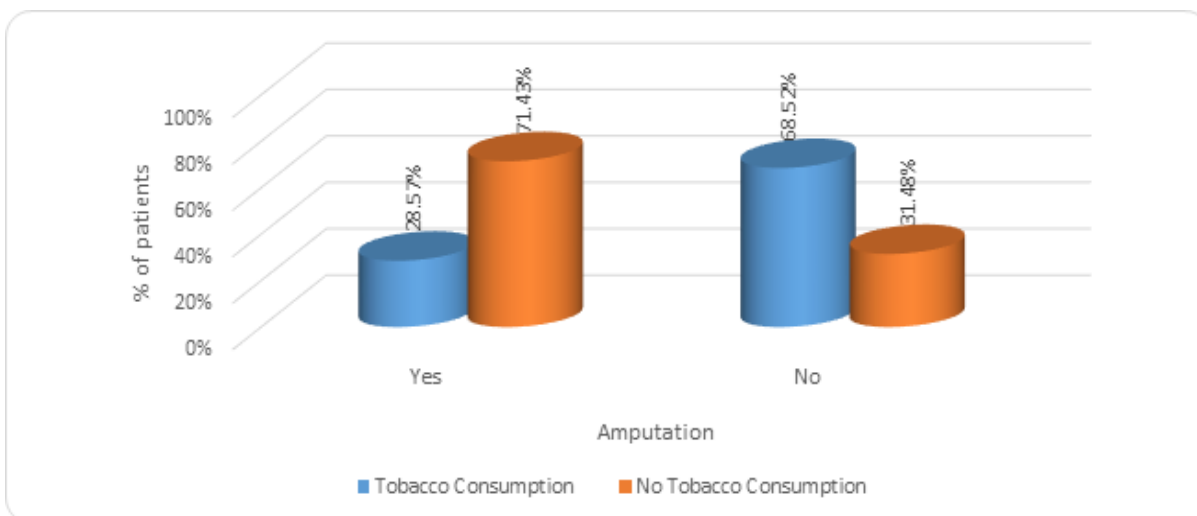

Figure 2: Comparison of amputation in tobacco and non-tobacco users

Table 3: Comparison of Necrosis in tobacco and non-tobacco users

Necrosis	Tobacco Consumption		Total	χ2-value
	Yes	No		
Yes	2(28.57%)	5(71.43%)	7(11.48%)	4.28
No	37(68.52%)	17(31.48%)	54(88.52%)	p=0.028,S
Total	39(63.93%)	22(36.07%)	61(100%)	

(Table 3) 28.57% of the patients with necrosis had history of tobacco consumption and 68.52% with no necrosis had history of tobacco consumption. By using chi-square test statistically significant association was found between necrosis and history of tobacco consumption. (χ2-value=4.28, p-value=0.028).
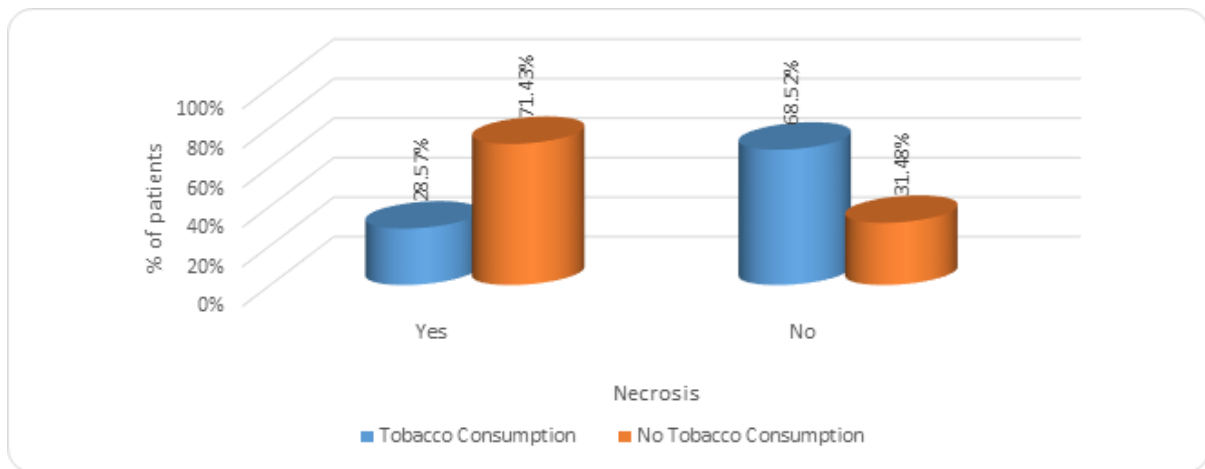

Figure 3: Comparison of Necrosis in tobacco and non-tobacco users

Table 4: Comparison of Recurrence/Relapse in tobacco and non tobacco users

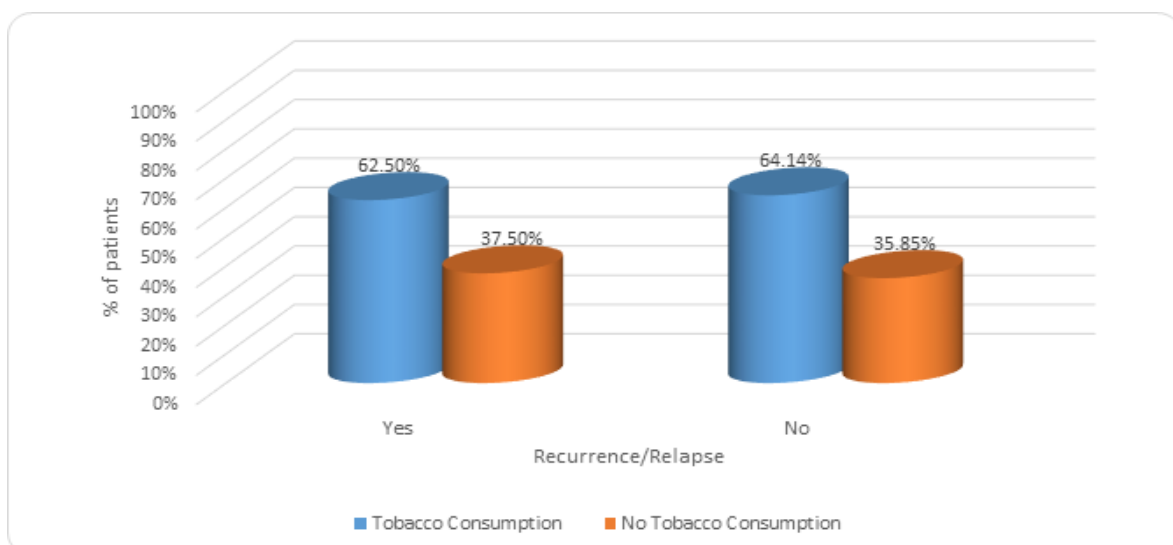| Recurrence/ Relapse	Tobacco Consumption		Total	χ2-value
	Yes	No		
Yes	5(62.50%)	3(37.50%)	8(13.11%)	0.008
No	34(64.14%)	19(35.85%)	53(86.89%)	p=0.92,NS
Total	39(63.93%)	22(36.07%)	61(100%)	

Figure 4: Comparison of Recurrence/Relapse in tobacco and non tobacco users
62.50% of the patients with recurrence/relapse had history of tobacco consumption and 64.14% with no recurrence/relapse had history of tobacco consumption. By using chi-square test statistically no significant association was found between recurrence/relapse and history of tobacco consumption (χ2-value=0.008,p-value=0.92).

Table 5: Comparison of drug intake in tobacco and non tobacco users

Drug Intake	Tobacco Consumption		Total	χ2-value
	Yes	No		
Regular	31(65.96%)	16(34.04%)	47(77.05%)	0.36
Irregular	8(57.14%)	6(42.86%)	14(22.95%)	p=0.54,NS
Total	39(63.93%)	22(36.07%)	61(100%)	

65.96% of the patients with drug intake had history of tobacco consumption and 57.14% with no drug intake had history of tobacco consumption. By using chi-square test statistically no significant association was found between drug intake and history of tobacco consumption. (χ2-value=0.36, p-value=0.54).
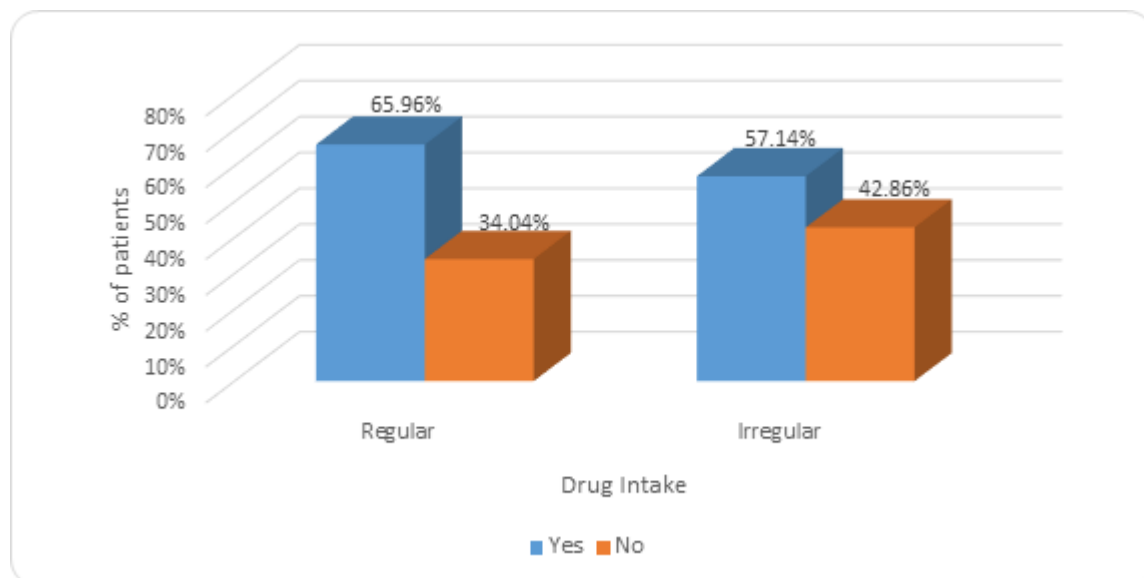
Figure 5: Comparison of drug intake in tobacco and non-tobacco users

Discussion
In our study the post procedure pain is significantly high in tobacco consumer group. Which eventually decreases as the treatment progresses. There is no study in the past which claim for analysis of the pain factor in the intraarterial intervention. This study may make the mile stone and lead for the future studies in concern to the pain factor in its management. Overall results the average of grading of pain was on higher side in the tobacco consumer group.
In resultant there is significant association was found between amputation (necrosis) and history of non-tobacco consumption. Which means there are certain other factors like diabetes,etc also play significant role in the healing process. That's why majority of amputation (necrosis) were held in non-tobacco consumer group. That is similar to the study in which show that, "In non-tobacco consumers Peripheral Arterial Disease (PAD) is a highly prevalent atherosclerotic syndrome associated with significant morbidity and mortality. It is defined by atherosclerotic obstruction of the abdominal aorta and arteries to the legs that reduces arterial flow during exercise and/or at rest, and is a common manifestation of

systemic atherosclerosis. PAD represents a marker for premature cardiovascular events, and in patients with PAD, even in the absence of a history of myocardial infarction (MI) or ischemic stroke, they have approximately the same relative risk of death from cardiovascular causes as do patients with a history of coronary or cerebrovascular disease. In addition, their death rate from all causes was approximately equal in men and women and was elevated even in asymptomatic patients. The major risk factors for PAD are the well-defined atherosclerotic risks such as diabetes mellitus, cigarette smoking, advanced age, hyperlipidaemia, and hypertension".[8]

Resultsof our studyshow that significant difference in the number of patients having relapse of disease due to various reasons. More number of patients were from tobacco consumption group and majority of the patients require the post IAI (Intra Arterial Intervention) due to the irregular intake of anticoagulant drugs. It is to the study that mention "that patients with PAD manifest platelet hyper-aggregability, increased levels of soluble platelet activation markers, enhanced thrombin generation and altered fibrinolysis potential. Many of these markers predict subsequent cardiovascular events. Available randomised trials and meta-analyses show that most available antithrombotic agents prevent major cardiovascular events and death in patients with PAD, including aspirin, aspirin/dipyridamole, clopidogrel, ticlopidine, picotamide and oral anticoagulants".[9]

In our study none of the patient having no signs of malignancy. Which is similar to the study in which; mostly male patients with advanced peripheral arterial disease having no history of clinically apparent malignancy for 5 years preceding entry. Analysis showed a 37% reduction in overall cancer incidence with iron reduction and reduced cancer-specific and all-cause mortality among patients who developed cancer in the iron reduction arm compared with those in the control arm. Reduced cancer risk and cancer-specific mortality were intent-to-treat findings based on the original randomization, whereas the difference in all-cause mortality in patients who developed cancer was defined by the occurrence of cancer after randomization. Risk of new malignancy was lower with iron reduction for several common tumor types.[10]

Conclusion

Present study is the prospective type OF observational study in which we focus on the awareness and perception of the people in the society, also to assess the awareness about tobacco consumption, intra-arterial disease and the outcome of intervention. A closed ended questionnaire had been used for assessment, which consist of general information, awareness about tobacco using habits. The participants were divided in two groups first is tobacco consumption and second is non-tobacco consumption. It shows that tobacco consumer group had suffer a lot more even during the treatment and have bad prognosis also. This group had underwent recurrent or rebound of disease.

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