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Clinical Study of Cases of Lower Limb Ischemia

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I. Introduction

Lower limb ischemia is a peripheral arterial stenosis or occlusion is predominantly caused by atherosclerosis and/or thromboembolic diseases which results in obstruction of blood flow in the arteries exclusive of the coronary and intracranial vessels. Stenosis and occlusion produce signs and symptoms that are related to organs supplied by the artery as lower limb- claudication, rest pain and gangrene. [(1)] Although only 12% of people younger than 50 years of age suffer from symptoms of intermittent claudication, this figure rises to 5% in those aged 50 to 70years and to 10% in those older than 70 years. [(2)] Ischemia inhibits the ability of the wound to heal, further complicated by development of infection and gangrene. [(3)] Intermittent claudication, heralded by pain in leg muscles during ambulation is the earliest and the most classic symptom among patients with peripheral arterial disease. [(4)] Peripheral arterial disease is an important manifestation of atherosclerosis involving the arteries of legs. [(5)] Vascular surgeons continue to encounter complications of atherosclerosis as their most common clinical challenge. [(6)] Thromboangitis obliterans (TAO) is an inflammatory occlusive disease primarily involving the medium sized muscular and smaller arteries in extremities, with smoking as the strong associated causative factor. [(7)] The clinical course of TAO is influenced by whether the patient quits smoking or not. If he continues to smoke there is progressive arterial insufficiency.[(8)]

II. Aims And Objectives

(1)To study clinical features of lower limb ischemia. (2)To study risk factors of lower limb ischemia.(3)To study management of lower limb ischemia.

III. Material And Methods

This retrospective study included 50 cases of lower limb ischemia admitted in tertiary care hospital attached to medical college during the period from October 2018 to October 2019. Approval from institutional ethical committee was taken. All the details of lower limb ischemia patients regarding onset, duration, and progression of disease with associated symptoms were taken from patients case files taken from medical record section. The method of study consisted of taking a good clinical history in a chronological order. A thorough clinical examination was carried out personally to find out and establish clinically first, the presence of vascular obstruction. Detailed vascular examination was done. The degree of vascular inadequancy and extent of the spread of disease was assessed clinically by noting the colour change, extent and spread of gangrene and absence of peripheral pulses in the affected limbs. This together with history of the patient regarding the distribution and type of pain.

Later after clinical scrutiny, essential laboratory investigations as all routine blood investigation, FBS, PP2BS,PT/APTT/INR. were done to look for the presence of atherosclerotic risk factors as smoking, diabetes mellitus and hypertension. Patients were further evaluated objectively by doppler scanning whenever feasible to assess the level and degree of obstruction objectively. The treatment of each patient was individualized with the aim to achieve foot salvage whenever feasible. A record of patient's progress and response to various modalities of treatment was made.

INCLUSION CRITERIA;

- Patients presenting with signs and symptoms of peripheral arterial disease of the lower extremities like intermittent claudication, rest pain, ulceration and gangrene.
- Patients with the evidence of lower limb arterial occlusive disease on doppler study.

EXCLUSION CRITERIA

- Patients with peripheral arterial disease of regions other than the lower extremities.

IV. Observation

This retrospective study includes 50 patients of lower limb ischemia disease admitted in tertiary care hospital attached to medical college during period of 2018 to 2019. They were of 30-90 years of age. All the details about history, presenting symptoms and co-morbid conditions and management and outcome are taken from case file.

TABLE – 1 AGE DISTRIBUTION

AGE GROUP (IN YEARS)	NUMBER OF PATIENT		PERCENTAGE OF PATIENTS (%)	
	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
31-40	00	03	00	08
41-50	01	05	07	14
51-60	05	10	29	30
61-70	08	11	57	31
71-80	01	02	07	06
81-90	00	04	00	11
TOTAL	14	36	100	100

•Maximum number of patients are between 60 and 70 years of age group. Lower limb ischemia is seen youngest at the age of 30 years and oldest at the age of 90 years. Majority of the cases in atherosclerosis are above the age of 60 years while in the TAO group of patients, majority cases belong to the 40 – 70 years of age group.

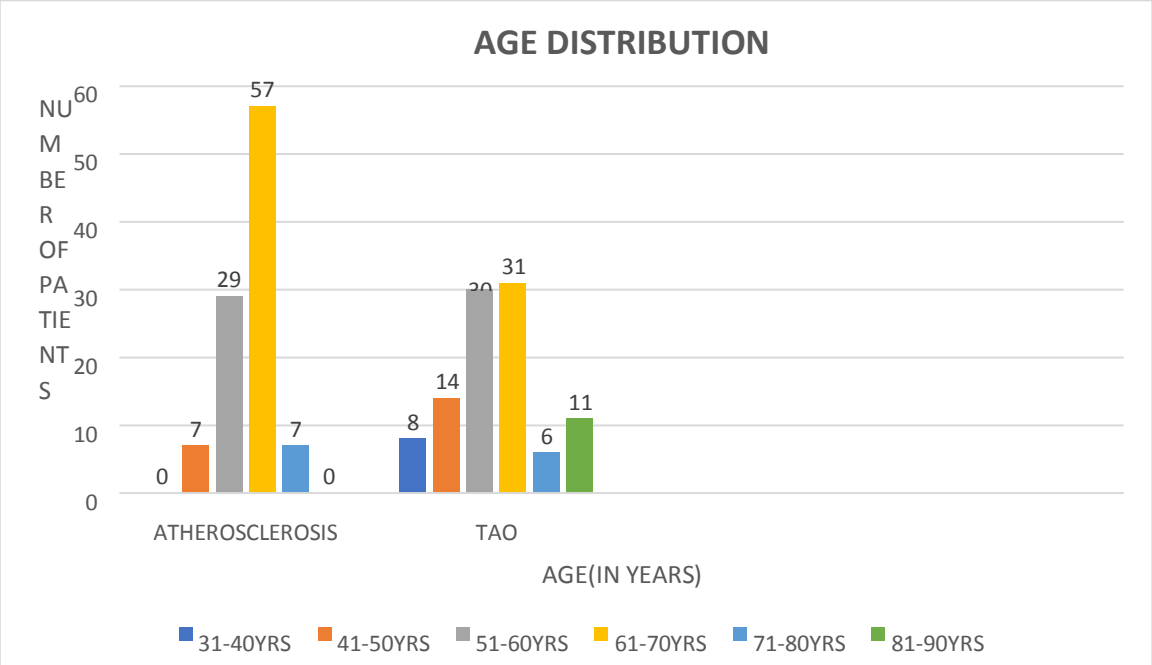
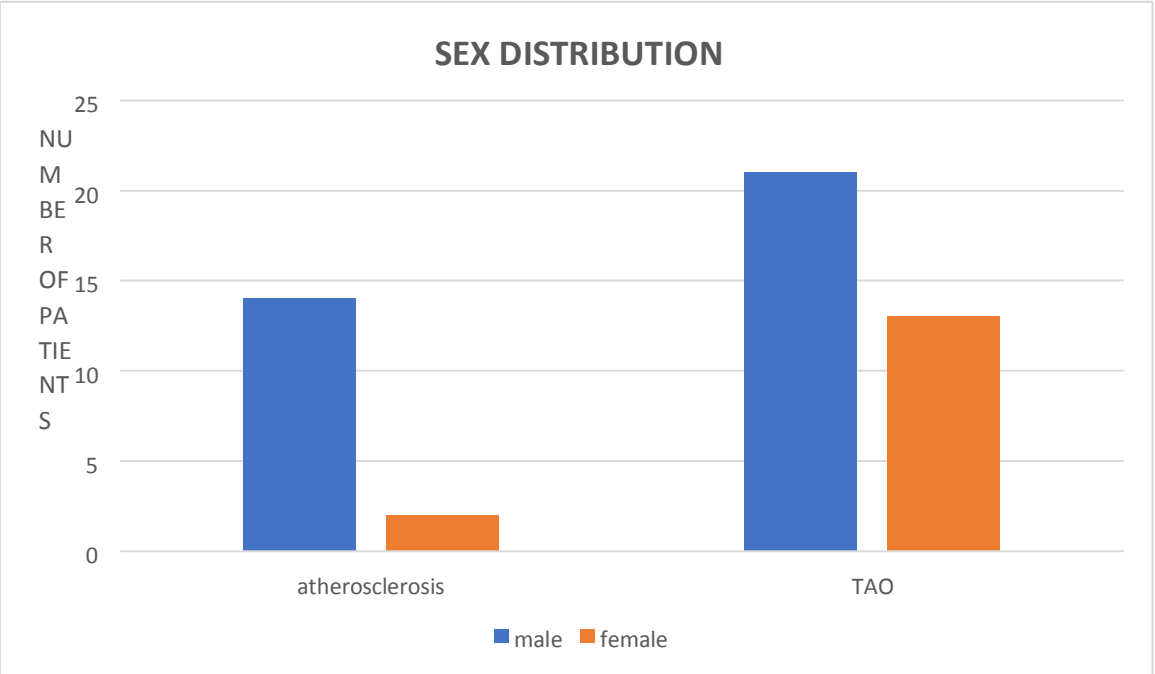


TABLE – 2 SEX DISTRIBUTION

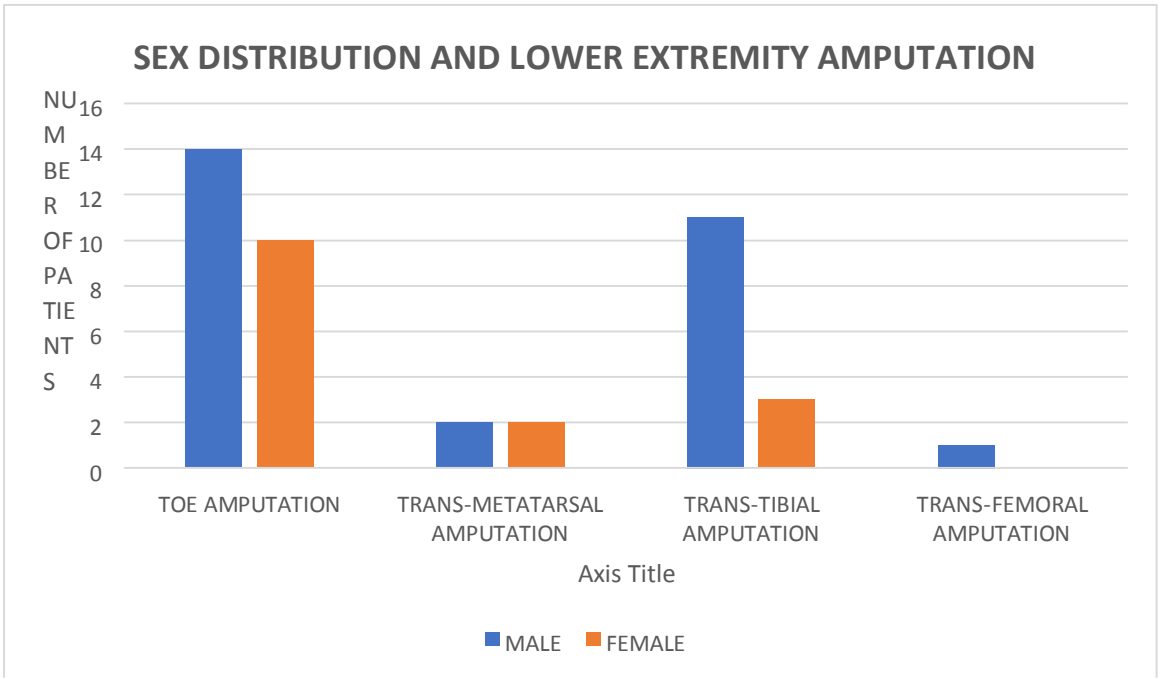
SEX	NUMBER OF PATIENTS		PERCENTAGE OF PATIENTS (%)	
	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
MALE	14	21	87	62
FEMALE	02	13	13	38
TOTAL	16	34	100	100



In our study, we found that males are affected more than females in both Atherosclerosis and TAO group of patients

TABLE – 3
SEX DISTRIBUTION AND LOWER EXTREMITY AMPUTATION

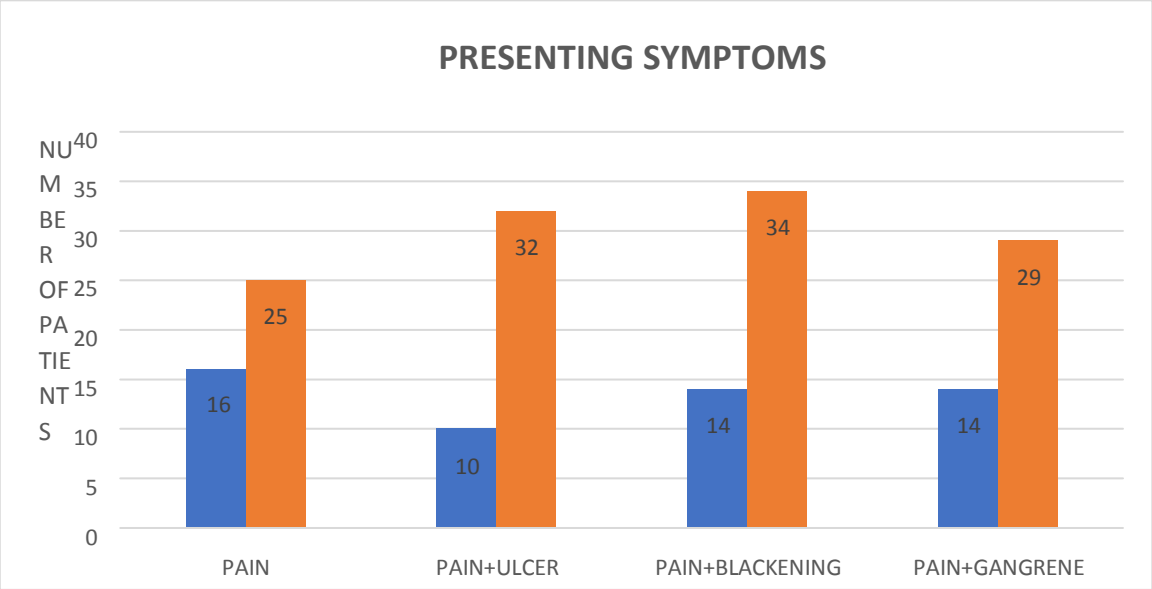
SEX	TOE	TRANS-METATARSAL	TRANS-TIBIAL	TRANS-FEMORAL	CONSERVATIVE TREATMENT
MALE	14	02	11	01	07
FEMALE	10	02	03	00	00



The most common amputation done in both males and females is Toe amputation.

TABLE – 4 PRESENTING SYMPTOMS

SYMPTOMS	NUMBER OF PATIENTS		PERCENTAGE OF PATIENTS (%)	
	ATHERO SCLEROSIS	TAO	ATHERO SCLEROSIS	TAO
PAIN	16	34	100	100
PAIN+ULCER	10	25	63	74
PAIN+BLACKENING	14	32	88	94
PAIN+GANGRENE	14	29	88	85



The clinical presentation in our study shows that most of the patients presented with complaints of pain, followed by blackening, gangrene and ulcer.
The incidence of pain and gangrene is almost equal in both Atherosclerosis and TAO groups.

TABLE – 5 ASSOCIATED RISK FACTORS IN PATIENTS WITH LOWER LIMB ISCHEMIA

ASSOCIATED RISK FACTORS	NUMBER OF PATIENTS		PERCENTAGE OF PATIENTS (%)	
	ATHERO SCLEROSIS	TAO	ATHERO SCLEROSIS	TAO
HYPERTENSION	5	16	31	47
SMOKING	14	20	87	59
DIABETES MELLITUS	10	23	62	67

The most common risk factor found in patients of atherosclerosis is smoking and in TAO is diabetes mellitus and smoking.

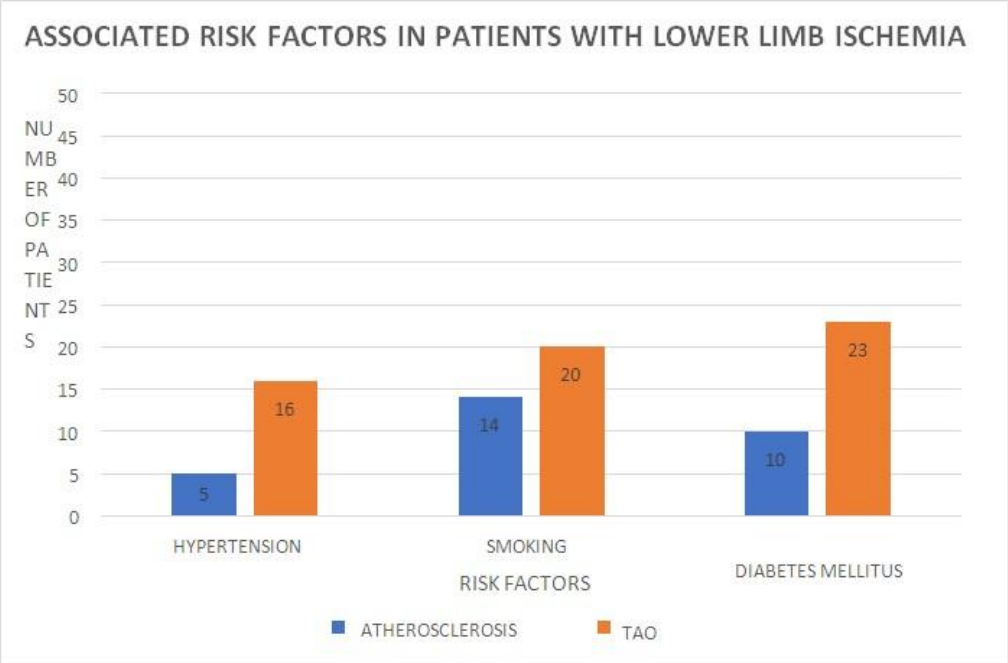
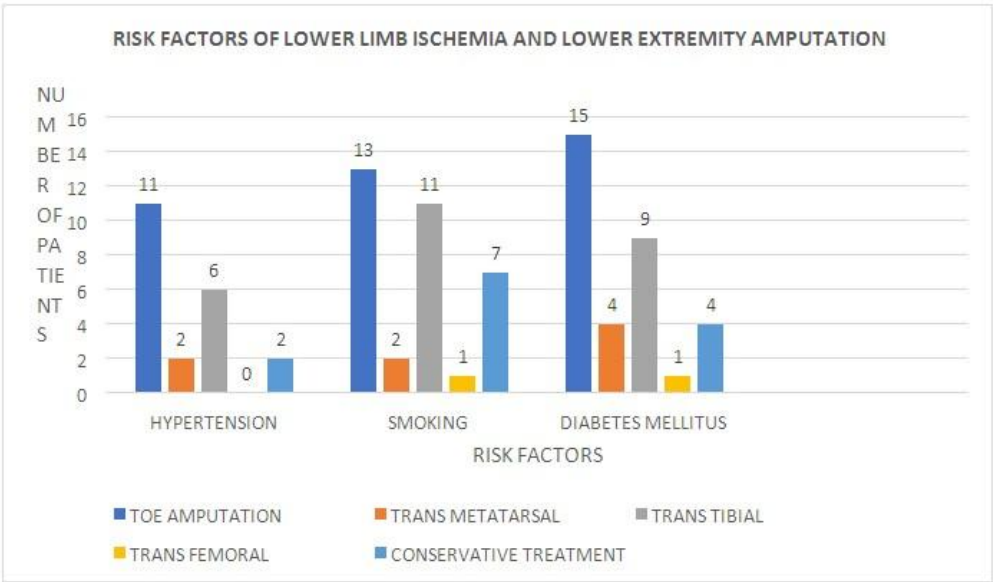


TABLE - 6

RISK FACTORS	TOE AMPUTATION	TRANS-METATARSAL	TRANS-TIBIAL	TRANS-FEMORAL	CONS TRE
HYPERTENSION	11	02	06	00	
SMOKING	13	02	11	01	
DIABETES MELLITUS	15	04	09	01	

RISK FACTORS OF LOWER LIMB ISCHEMIA AND LOWER EXTREMITY AMPUTATION



The most common amputation in patients with above risk factors is toe amputation.
Toe amputation and Trans metatarsal amputation is more common in patients with diabetes as compared to patients with other risk factors.
Trans-tibial amputation is more common in patients with smoking as risk factor as compared to patients with other risk factors.

TABLE – 7 DURATION OF SMOKING

NUMBER OF YEARS	NUMBER OF PATIENTS		PERCENTAGE OF PATIENTS (%)	
	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
<10	00	06	00	63
11-20	03	06	19	18
21-30	10	11	60	32
31-40	01	02	16	06

The average duration of smoking in our study is 25years and most of the patients had smoking history of 21-30 years for both atherosclerosis and TAO group.

TABLE - 8 PERIPHERAL PULSATION

ARTERIES	ABSENT IN NUMBER		PERCENTAGE OF PATIENTS (%)	
	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
DPA	15	27	94	79
ATA	15	12	94	35
PTA	15	10	94	29
PA	15	02	94	06
FA	04	02	25	06

The study shows that arterial pulsations absent in TAO patients are distal arteries and in atherosclerotic patients are proximal ones.

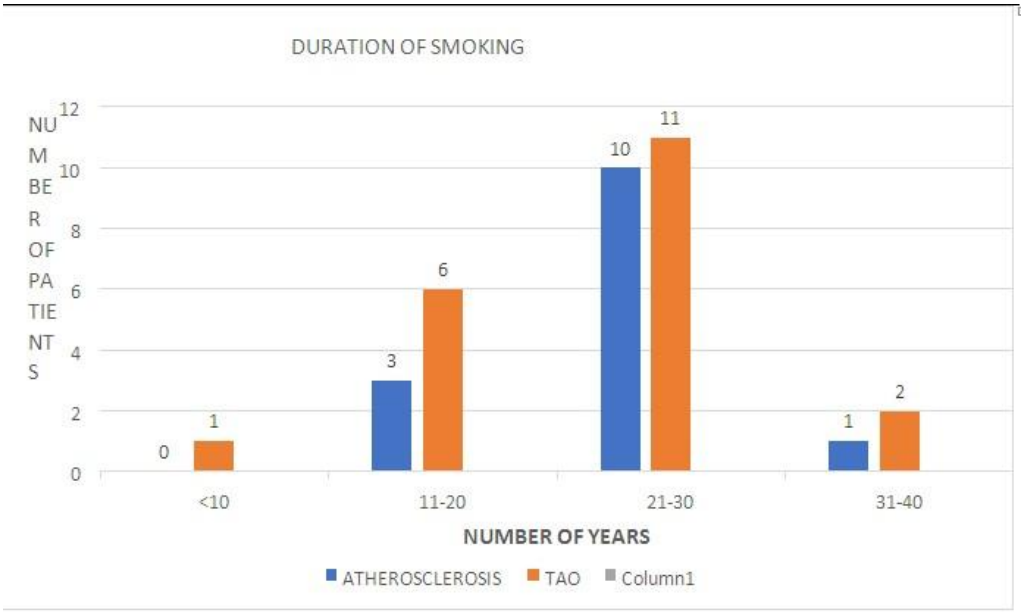
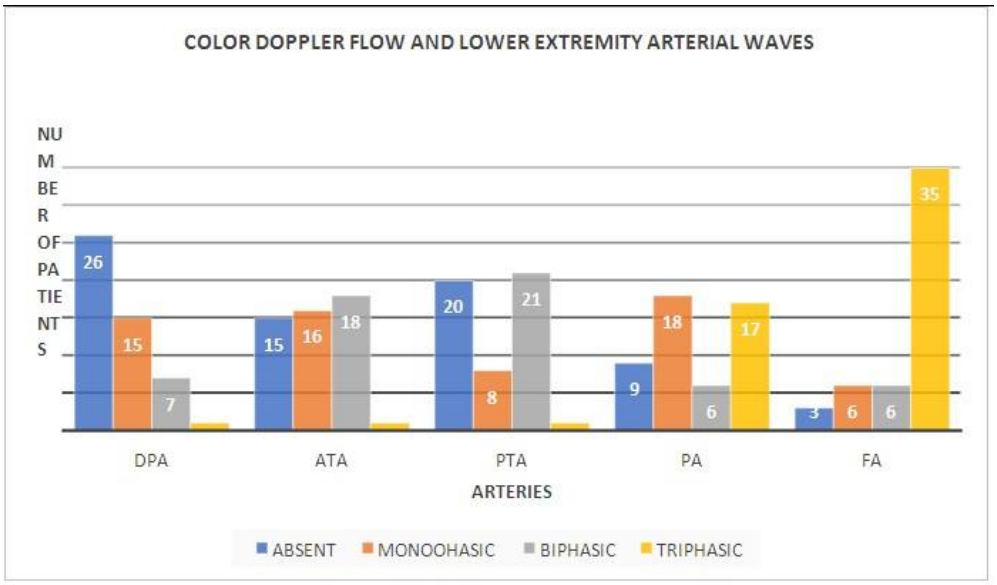


TABLE – 9 COLOR DOPPLER FLOW AND LOWER EXTREMITY ARTERIAL WAVES

ARTERIES	COLOR DOPPLER FLOW			
	ABSENT	MONOPHASIC	BIPHASIC	TRIPHASIC
DPA	26	15	07	01
ATA	15	16	18	10
PTA	20	08	21	01

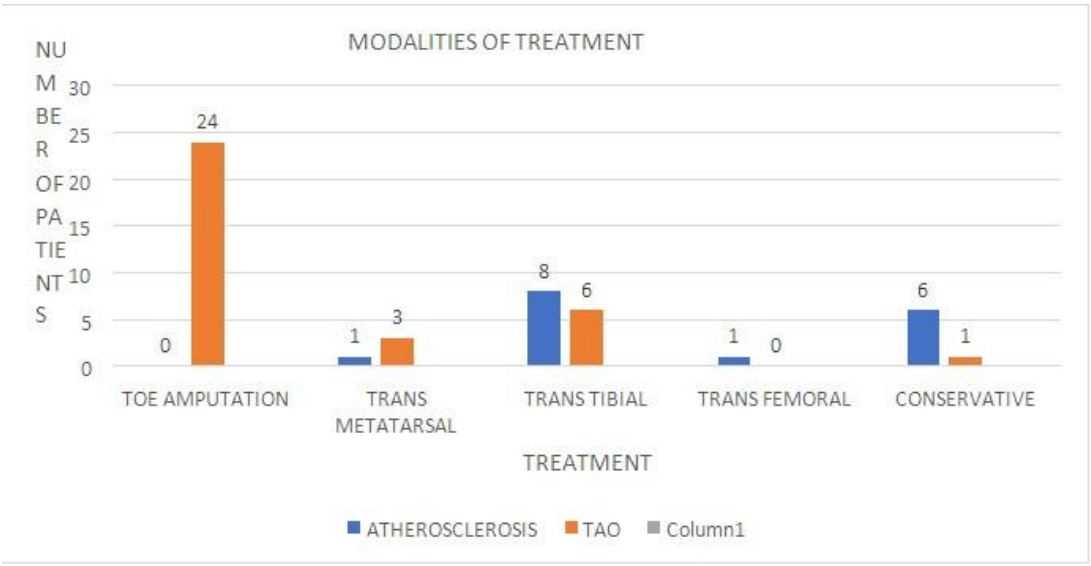
PA	09	18	06	17
FA	03	06	06	35



The most common involved artery is Dorsalis pedis artery followed by Posterior tibial artery then Anterior tibial artery. Femoral artery is least affected.

TABLE -10

TREATMENT	NUMBER OF PATIENTS			NUMBER OF PATIENTS IN PERCENTAGE (%)	
	ATHEROSCLEROSIS	TAO	TOTAL	ATHEROSCLEROSIS	TAO
TOE AMPUTATION	00	24	24	00	70
TRANS METATARSAL	01	03	04	06	09
TRANS TIBIAL	08	06	14	50	18
TRANS FEMORAL	01	00	01	06	00
CONSERVATIVE	06	01	07	38	03



In the study majority of patients of TAO underwent Toe Amputation (74%) and of Atherosclerosis underwent Trans tibial amputation (50%).

TABLE-11 POST OP RECOVERY

ATHEROSCLEROSIS					
TREATMENT	**NUMBER OF CASE**	**UNEVENTFUL RECOVERY**	**REVISION AMPUTATION**	**SECONDARY SUTURING**	**DEATH**
TOE AMPUTATION	00	00	00	00	00
TRANS METATARSAL	01	00	00	00	01
TRANS TIBIAL	08	04	03	01	00
TRANS FEMORAL	01	01	00	00	00
CONSERVATIVE	06	05	00	00	01
TOTAL	16	10	03	00	00

The study shows treatment and post-operative recovery in atherosclerosis cases. Among 16 cases 10 patients underwent amputation (1 TMT, 8 Trans Tibial, 1 Trans Femoral) and 06 patient treated conservatively**.** Out of 8 patients of transtibial amputation ,4 patients got uneventful recovery,3 patients underwent reamputation and 1 got secondary suturing.

Out of 16 cases, 5 cases were referred to higher centre for vascular surgeon opinion and management and 2 got expired due to secondary complications

TAO					
TREATMENT	**NUMBER OF CASES**	**UNEVENTFUL RECOVERY**	**REVISION AMPUTATION**	**SECONDARY SUTURING**	**DEATH**
TOE AMPUTATION	24	23	01	00	00
TRANS METATARSAL	03	03	00	00	00
TRANS TIBIAL	06	05	01	00	00
TRANS FEMORAL	00	00	00	00	00
CONSERVATIVE	01	01	00	00	00
TOTAL	34	32	02	00	00

The study shows treatment and post-operative recovery of TAO cases.

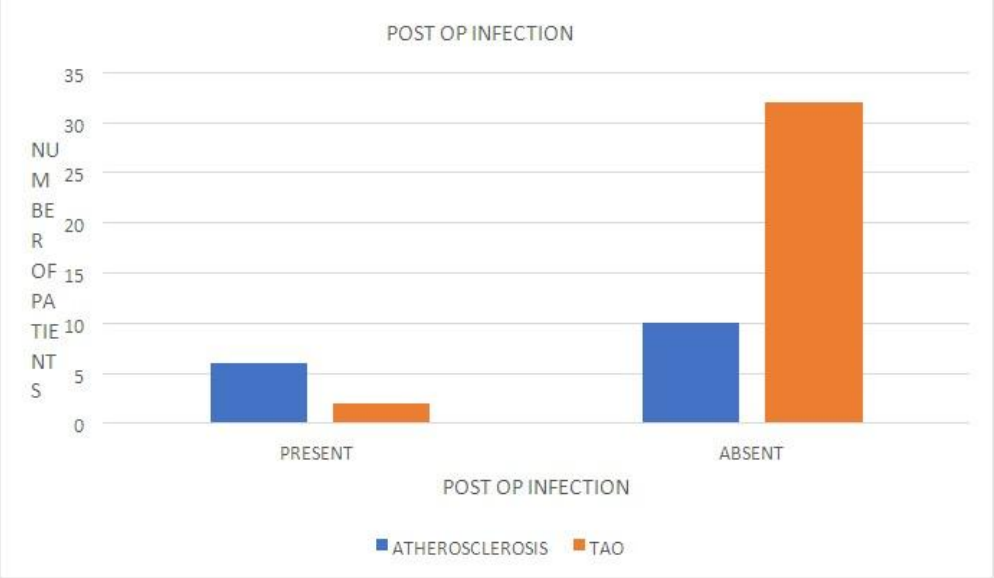
Among 34 cases, 33 patients underwent amputation (24) TOE Amputation, 3 TMT, 6 Trans Tibial) and 01 patient treated conservatively.

Out of 24 patients of toe amputation, 23 patients got uneventful recovery and 1 patient underwent reamputation.

Out of 6 cases of Trans tibial amputation, 5 patients got uneventful recovery and 1 patient underwent reamputation.

TABLE – 12 POST-OP INFECTION

	NUMBER OF PATIENTS			**NUMBER OF PATIENTS IN PERCENTAGE (%)**	
POST OP INFECTION	**ATHERO-SCLEROSIS**	**TAO**	**TOTAL**	**ATHEROSCLEROSIS**	**TAO**
PRESENT	06	02	08	38	06
ABSENT	10	32	42	62	94



The study shows that post-op infection is more common in atherosclerosis group of patients than in TAO group. In the study out of 16 cases of atherosclerosis 6 patients developed post-op infection while out of 32 cases of TAO only 2 cases developed post-op infection.

TABLE NO-13

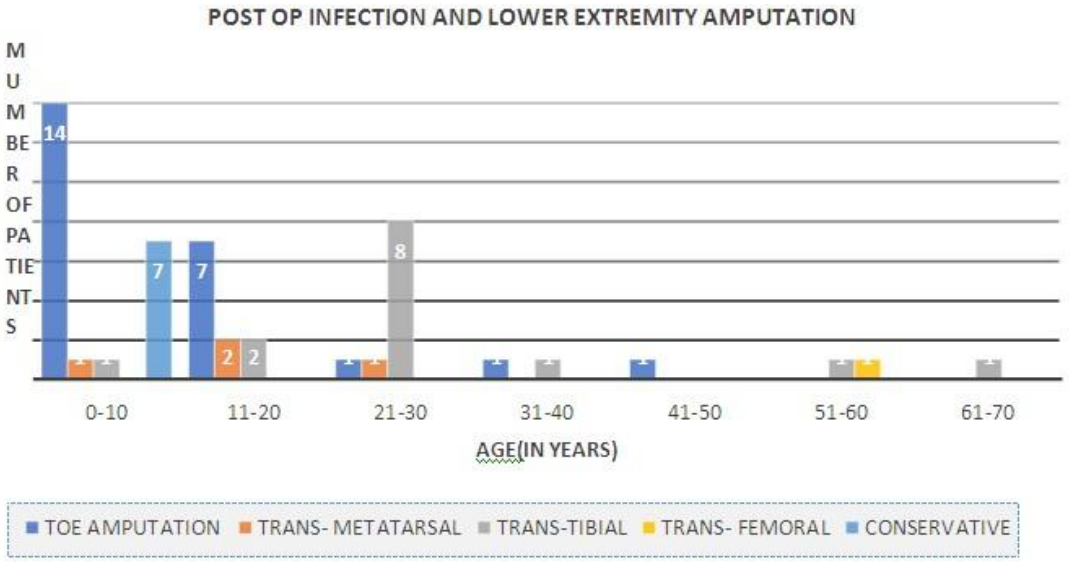
POST OP INFECTION AND LOWER EXTREMITY AMPUTATION

OPERATION	POST OP INFECTION			
	PRESENT		ABSENT	
	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
TOE AMPUTATION	00	01	00	23
TRANS METATARSAL AMPUTATION	01	00	00	03
TRANS TIBIAL	04	01	04	05
TRANS FEMORAL	00	00	01	00

Post-op infection is more common in trans tibial amputation followed by toe amputation and trans metatarsal amputation.

TABLE – 14 HOSPITAL STAY AND MANAGEMENT OF LOWER LIMB ISCHEMIA

HOSPITAL STAY IN DAYS	TOE AMPUTATION	TRANS-METATARSAL	TRANS-TIBIAL	TRANS-FEMORAL	CONSER-VATIVE	TOTAL
0-10	14	01	01	00	07	22
11-20	07	02	02	00	00	13
21-30	01	01	08	00	00	10
31-40	01	00	01	00	00	02
41-50	01	00	00	00	00	01
51-60	00	00	01	01	00	02
61-70	00	00	01	00	00	01



The shortest duration of hospital stay is of patients undergoing toe amputation while the longest duration of hospital stay is of patients undergoing further higher amputation.
The average duration of hospital stay ranges from 1- 30 days.

TABLE NO-15 LOWER LIMB ISCHEMIA AND RECOVERY OF PATIENT

	NUMBER	PERCENTAGE (%)
NUMBER OF PATIENTS WHO LOST LIFE DURING MANAGEMENT	02	04
NUMBER OF PATIENTS WHO RECOVERED COMPLETELY	41	82
NUMBER OF PATIENTS WHO WERE REFERRED TO HIGHER CENTRE TO VASCULAR SURGEON	07	14

Of all the cases of lower limb ischemia, 82% cases recovered completely and 14% cases were referred to higher center.

V. Discussion

Lower limb ischemia is one of the most common condition seen in any surgical ward of general hospital. It may be followed by major complications like extremity amputation and death.The study included 50 patients of lower limb ischemia disease admitted in tertiary care hospital attached to a medical college during period of 2018 to 2019. All the details about history, presenting symptoms, co-morbid conditions and management and outcome are taken from case files.
Data from case files is analyzed and following parameters assessed and compared with other similar studies. Comparative studies are mentioned below:

1) Clinical study of peripheral arterial occlusive disease of lower extremitiesSuresh clement h, M. Arun kumar, S. Ramchander[9]
2) Clinical study on evaluation of various parameters in chronic lower limb ischemia – K.B.S Prabhakar, Purushottam G, Sriharsha B [10]
3) Study of case of Peripheral arterial disease of lower limb extremity- Dr.Keerthhas H.P
4) Clinical study of peripheral arterial occlusive disease of lower extremities. - Prasad C, Santosh Nayak K [11]
5) The clinical profile of TAO and Arteriosclerosis obliterans. -Nigam R. [12]

1) Comparison of age distribution:

STUDY	YEARS	
	ATHEROSCLEROSIS	TAO
This Study	60-70	30-60
K.B.S Prabhakar, Purushotham G, Sriharsha B	50-70	30-50

Dr.Keerthhas H.P	60-70	30-50
Prasad C, Santosh Nayak K	50-60	30-50

From above mentioned studies it is observed that maximum patients belonged to 60-70 years age group.

2) Comparison of sex distribution:

STUDY	ATHEROSCLEROSIS		TAO	
	MALE (%)	FEMALE (%)	MALE (%)	FEMALE (%)
This study	87	13	62	38
K.B.S Prabhakar, Purushotham G, Sriharsha B	92	08	100	00
Dr.Keerthhas H.P	92	08	100	00
Prasad C, Santosh Nayak K	92	08	100	00

From above mentioned studies it is found that lower limb ischemic diseases are more common in males than females.

3) Comparison of presenting symptoms:

STUDY	PAIN (%)		PAIN+GANGRENE (%)		PAIN+ULCER (%)	
	ATHERO-SCLEROSIS	TAO	ATHERO-SCLEROSIS	TAO	ATHERO-SCLEROSIS	TAO
This study	100	100	88	85	63	74
K.B.S Prabhakar, Purushotham G, Sriharsha B	100	100	81	79	19	21
Dr. Keerthhas H.P	100	100	81	79	19	21
Suresh clement h, M. Arun Kumar, S. Ramchander	100	100	81	79	19	21
Prasad C, Santosh Nayak K	100	100	81	79	19	21

The comparison of above studies shows that pain is the commonest presenting symptom. The pain could be intermittent claudication or even rest pain. Other common symptoms include gangrene followed by ulcer. Many patients have more than one symptom at the time of presentation, indicating Lower limb ischemia has a multifactorial presentation.

4) Comparisons of comorbid conditions:

STUDY	SMOKING (%)		DIABETES MELLITUS (%)		HYPERTENSION (%)	
	ATHERO-SCLEROSIS	TAO	ATHERO-SCLEROSIS	TAO	ATHERO-SCLEROSIS	TAO
This study	87	59	62	67	31	47
K.B.S Prabhakar, Purushotha m G, Sriharsha B	61	100	75	00	25	00

Dr. Keerthhas H.P	61	100	53	00	25	00
Suresh clement h, M. Arun Kumar, S. Ramchande	61	100	53	00	25	00
r						
Prasad C, Santosh Nayak K	61	100	53	00	25	00
Nigam R.	72	98	40	00	-	-

From above mentioned comparison of studies we found that most of patient are smokers and also have diabetes mellitus and hypertension.

5) Comparison of arterial doppler finding:

STUDY	**DPA (%)**		**ATA & PTA (%)**		**PA (%)**		**FA (%)**	
	ATHERO SCLEROSIS	**TAO**	**ATHERO SCLEROSIS**	**TAO**	**ATHERO SCLEROSIS**	**TAO**	**ATHERO SCLEROSIS**	**TAO**
This study	94	79	94	35	94	06	25	06
K.B.S Prabhakar, Purushot ham G, Sriharsh a B	100	29	36	71	50	00	14	00
Dr. Keerthh as H.P	100	29	36	71	50	00	14	00
Suresh clement h, M. Arun	100	29	36	71	50	00	14	00
Kumar, S. Ramchander								
Prasad C, Santosh Nayak K	100	29	36	71	50	00	14	00

From above mentioned comparison of study we found that DPApulsation is commonly absent in cases of lower limb ischemia disease followed by ATAand PTApulsation. Majority of patients of atherosclerosis group have proximal vessels disease and of TAO group have distal vessels disease.

6) Comparison of treatment

STUDY	**AMPUTATION (%)**	**CONSERVATIVE (%)**
This study	86	14
K.B.S Prabhakar, Purushotham G, Sriharsha B	95	05
Dr.Keerthhas H.P	96	04
Suresh clement h, M. Arun Kumar, S. Ramchandra	95	05
Prasad C, Santosh Nayak K	96	04

From above mentioned comparison of study most of the patients of lower limb ischemia disease are treated surgically.

7) Comparison of duration of hospital stay:

STUDY	DURATION IN DAYS
This study	1 – 30
Prasad C, Santosh Nayak K	1 – 20

From above mentioned comparison of study most of the patients have a hospital stay for a period ranging from 1 – 30 days.

8) Comparison of end result of management:

	UNEVENTFUL RECOVERY (%)		REVISION AMPUTATION (%)		SECONDARY CLOSURE (%)		DEATH (%)	
STUDY	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO	ATHEROSCLEROSIS	TAO
This study	62	94	19	06	06	00	13	00
K.B.S Prabhakar, Purushotham G, Sriharsha B	44	57	06	07	44	36	00	00
Dr. Keerthhas H.P	44	57	06	07	50	36	00	00
Suresh clementh, M. Arun Kumar, S. Ramchander	44	57	06	07	50	36	00	00

From above mentioned comparison of study most of the patients recovered uneventfully with some of them undergone revised amputation and secondary closure.

VI. Summary

Lower limb ischemia is one of the most common condition seen in any surgical ward of general hospital. It may be followed by major complications like extremity amputation and death.

The study included 50 patients of lower limb ischemia diseases admitted in tertiary care hospital attached to medical college during period of 2018 to 2019. All the details about history, presenting symptoms, co-morbid conditions and management and outcome are taken from case files. All the end results of these 50 patients were accessed.

- To summarize the outcome of study, following facts can be laid down.
- Lower limb ischemia disease is common in 60-70 years of age group suggesting that the older age group of society is at higher risk.
- Majority of the cases in Atherosclerosis are above the age of 60 years while in the TAO group of patients majority belong to the 40 – 60 years age group.
- Amputation is most commonly performed in 51-70 years age group. Outcome is good in this age group. After age of 70 outcome of amputation becomes poor as with advancing age immunity reduces thus patient either requires re-amputation and/or gets expired.
- Lower limb ischemia disease is more common in males as compared to females.
- Pain is the commonest presenting symptom in lower limb ischemia disease followed by gangrene and ulcer. Pain could be intermittent claudication or even rest pain.
- The most common risk factor found among patients of atherosclerosis is smoking and among patients of TAO is diabetes mellitus and smoking.
- Smokers have poor outcome after TMT amputation as smoking leads to peripheral arterial vaso occlusion leading to poor blood supply and poor healing of stump.

- Most patients have duration of smoking of 20-30 years, patients with shorter duration of smoking have good outcome and patients with longer duration of diabetic history have poor outcome and either require r eamputation at higher level or get expired.
- DPApulsation is commonly absent in cases of lower limb ischemia disease followed by ATAand PTApulsation. FAis less commonly involved.
- In TAO group of patients, distal arterial pulsations are absent and in Atherosclerotic group proximal arterial pulsations are absent commonly.
- Most of the patients have no palpable pulse at DPA, ATA, PTA level with absent/monophasic waves seen on Arterial Colour Doppler study. Majority of such patients either require re-amputation and/or get expired.

Most of the patients of Lower limb ischemia disease are treated surgically in the form of amputation ranging from toe to above knee level with majority receiving toe amputation. And rest of the patients are treated conservatively or referred to vascular surgeon.

- Majority of patients of TAO underwent Toe Amputation (74%) and of atherosclerosis underwent Trans tibial amputation (50%).
- Amputation stops further spread of infection and gangrene and leads to early healing.
- The study shows that post op infection is most common in atherosclerosis group then TAO group of patients as out of 16 cases of atherosclerosis 6 patients developed post op infection and out of 32 cases of TAO only 2 cases developed post op infection.
- Post op infection is more common in trans tibial amputation followed by toe amputation and trans metatarsal amputation.
- In atherosclerosis group of 16 patients, 10 patients got uneventful recovery and 4 required re amputation and 2 got expired.
- In TAO group of 34 patients, 32 cases got uneventful recovery and 2 cases required re amputation.
- Most of the patients require hospital stay for a period ranging from 1 – 30 days. Toe amputation requires shortest hospital stay while higher level amputation requires the longest.
- Overall this study helped us to analyse the outcome of lower limb ischemia patients.

VII. Conclusion

Lower limb ischemia disease is the disease affecting the peripheral arteries causing narrowing and hardening of the vessels. This leads to less supply of blood and nutrients to distal parts causing pain and later gangrene.
As per the study-

- Lower limb ischaemia is more common in males as compared to females as out of 50 cases in the study only 15 females got the disease.
- TAO and atherosclerosis are the etiologies for the lower limb ischemia in these cases.
- TAO presents at a younger age group whereas atherosclerosis presents in the older age group.
- Gangrene is limited to the distal limb in the TAO cases and extends to the proximal limb in atherosclerosis group.
- Ischaemic claudication and rest pain are the most common symptoms followed by gangrene and ischaemic ulcer.
- Smoking and diabetes appear to be the major risk factors for both TAO and Atherosclerosis
- Doppler findings correlate with the disease presentation as TAO has a more infra-popliteal obstruction and atherosclerosis shows more proximal obstruction.
- Conservative treatment consists of antiplatelet agents, anticoagulants, vasodilator agents, antidiabetic drugs, anti-hypertensive agents, and smoking cessation.
- In study 43 cases required some form of surgery with 15 of them suffered limb loss due to late presentation with gangrenous changes thus leaving no scope for limb salvage. And 7 cases were referred to higher centre for vascular surgeon opinion.
- Post operatively 5 of the cases required revision amputation, 2 of the cases required secondary closure following post op infection and 2 cases got expired during treatment.

Awareness of disease among patients, education about

Peripheral arterial disease and early presentation, early diagnosis and its management with re-vascularization measures are most beneficial in limb salvage. Cessation of smoking is helpful in further progression of the disease.

Longer hospital stays in patients with amputation increases the psychological burden which further gets aggravated by re amputation at higher level thus affecting the physical, social, economic and psychological aspect of patients. Mortality occurs due to septicaemia by fulminant infection, metabolic complication of diabetes mellitus or some other cardiopulmonary cause.

Patients with major amputation get benefit by provision of rehabilitation in the form of crutches and artificial limb and in selected cases of amputation no prosthesis is required and patient walks without any support. This study is limited due to small sample size and for Further more study, more cases are required.

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