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Study to Evaluate the Pharmacoeconomics in Diabetic Foot Ulcer Management

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ABSTRACT

***Background*: Diabetic foot ulceration (DFU) is one of the macrovascular complications of diabetes, its prevalence was estimated to be about 8-11% of individuals with uncontrolled diabetes experience for long time. The pathogenic cascade of DFU is a combination of vascular complications of peripheral arteries, Peripheral neuropathy and the raised blood glucose makes it as a non-healing ulcer followed by secondary infection which will progress to end with leg Amputation. The recurrent nature of Diabetic foot ulcer can impact on the health status as well as the economical stability of the affected patients and are associated with the major health care consumption with high cost.**

***Methodology*: It was a Mono centered prospective observational comparative study conducted in the department of general surgery for 6 months duration.**

***Results*: Total samples of 100 diabetic foot ulcer patients were enrolled into the study, 74 (74%) were males and 26 (26%) were females. The age group between51-60 and 61-70 years was observed as the highest percentage 27% (27). Highest percentage 42% (42) of patients were none (without any comorbidities) followed by 32(32%) patients are with combined (more than one comorbidity like HTN, CKD, CAD…etc.) with utmost percentage of 43% was peripheral neuropathy. 23 patients were diagnosed with gangrene and23 patients underwent major amputation, The economic burden of diabetic foot ulcer for conservative treatment was slightly more when compared to amputated patients.**

***Conclusion*: Study concludes that, economic burden on diabetic foot ulcer in conservative patients was slightly more while compared to amputated patients by descriptive statistics even the statistical analysis shown less significant difference. Because the necessity rate for extra hospitalization and medical services was more for conservative treatment (Debridement, Fasciotomy, Incision and Drainage) when compared to amputation patients with diabetic foot ulcer. whereas in the pharmaco-economics there was not much significant difference among both amputated and conservative patients.**

Keywords: Diabetic foot ulcer, evaluation, management, pharmacoeconomics.

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I. Introduction

Diabetic foot is a severe complication associated with diabetes that shows the presentation of deep lesions of tissues intermingled with neurological disorders and peripheral vascular disease of lower limbs. Complications from diabetes mellitus result in both lower quality of life and higher cost of treatment [1]. One of the most common diabetic related complications is the diabetic foot problem. Diabetic foot ulceration is a common late-stage complication of diabetes, with 19-34% of individuals with diabetes experiencing a diabetic foot ulcer in their lifetime [2]. This complication is caused by peripheral arterial disease or peripheral neuropathy brings about poor ulcer healing, infection or even leg amputation. Diabetic foot ulcer has a large impact on the health status and quality of the affected patients and is associated with the major health care consumption and high cost [3].

The annual estimate of worldwide diabetes foot ulcers was found to be around 26 million, it is important to note that, all diabetic patients will not develop with the risk of diabetes foot ulcer [4]. 50% of patients with diabetes foot ulcer suffer from comorbidities like Peripheral artery disease which is occasionally caused due to atherosclerosis [5]; Peripheral artery disease is a risk factor in wound healing and lowers limb amputations. The characters of diabetic foot include an Infection, ulceration or destruction of deep tissues associated with neurological abnormalities and various degrees of peripheral vascular diseases in the lower limb [6]. It is a complication of type 2 diabetes, where

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neuropathy results in loss of protective sensation, peripheral artery disease and foot deformity combined with a history of foot ulceration and any level of lower extremity amputation are a major risk factor for diabetic foot ulcer. Once the patient's foot ulcer progresses to diabetic foot infection, they suffer from recurrent and prolonged hospitalization further leads to amputations of their foot which increases the rates of mortality and financial burden [7].

The quality of life for patients with diabetic foot ulcers will be compromised as foot ulcers can precede to permanent disability challenges the patient in mobility, poor psychosocial adjustment, and lower self-perceptions of healthy life [8]. It is found that the survival rate also decreases for patients with diabetic foot ulcer compared to diabetes patients non foot ulcer patients. Micro and macro-vascular changes play a major pathologic role in the development of diabetic foot ulcers which can be neuropathic or ischemic. Compromised immunity, weak tissue reparative process and altered foot anatomy further deteriorate wound condition, also Infections can complicate the wound, slows its recovery and significantly leads to amputations [9].

II. Methodology

A. Study Design and Patients

This prospective comparative study included 100 patients diagnosed with Diabetic foot ulcers and suggested for conservative treatment, minor amputation, major amputation, debridment, fasciotomy, incision and drainage were included into the study from the General surgery department, Sri Venkateswara Institute of Medical Sciences, SPMC(W) – Tirupati, according to the inclusion and exclusion criteria by using Functional expenses of direct medical and non-medical cost & indirect cost.

Additional data like – No. of Emergency visits No. of IP admissions 30 days read mission's Mean IP length of stay No. of visit for debridement/dressings.

B. Methods

The overall cost and economic impact of diabetes is difficult to estimate because of the wide variation in methods used in various studies, leading to differences in results [10].

A structured data collection form with patient's demographic details like age, sex, weight, family history, past medical history, past medication history, social history, patient personal history. A study specific pharmaco-economic expenditure form covering all the direct and indirect medical expenses and non-medical expenses is used to collect the economic expenditure [11].

C. Statistical Analysis

Data on continuous variables was summarized as descriptive statistics: mean and standard deviation. A comparison of means was made. Categorical data was presented as number and percentage and comparisons if any was done. Results with $p<0.05$ were considered as significant.

The collected data was initially entered into the Microsoft excel spread sheet then it is transferred to SPSS. Student t test, the major analytical method that suits the study was performed in order to find the significance. The different variables from the obtained data such as gender, age, diagnosis, before and after pain scores, and anxiety scores were collected and analyzed. The obtained results were presented in tabular and graphical forms using Microsoft Word and Excel.

III. Results

A. Gender Distribution:

From the department of general surgery, a total number of 100 patients with diabetic foot ulcer were included in our study. Out of 100 patients, 74 (74%) were males and 26 (26%) were females as shown below.

TABLE I: Gender Categorization of Diabetic Foot Ulcer Patients

S.No	Gender	Frequency distribution of gender (n=100)	Percentage of gender distribution (%)
1	Males	74	74
2	Females	26	26

B. Age Distribution

Number of 100 patients of diabetic foot ulcer, it was observed that highest percentage 27% (27) of patients were in the age groups between 51-60,61-70 years followed by age group between 41-50 (19%) years, 71-80 (13%), 81-90 (6%) years whereas age group of 21-30 (1%) was found the least.

TABLE II: Age group Categorization of Diabetic Foot Ulcer Patients

S.No	Age group	Frequency distribution of age (n=100)	Percentage of age distribution (%)
1	21-30	1	1
2	31-40	7	7
3	41-50	19	19
4	51-60	27	27
5	61-70	27	27
6	71-80	13	13
7	81-90	6	6

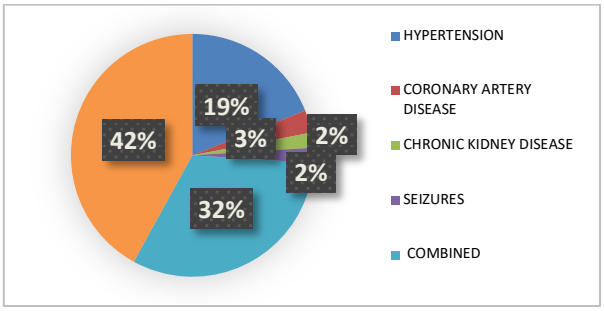

Fig. 1. Distribution of Comorbid Diseases.

C. Comorbidities

Out of 100 diabetic foot ulcer patients, it was observed that highest percentage 42% (42) of patients were none (without any comorbidities) followed by 32(32%) patients are with combined (more than one comorbidity like HTN, CKD, CAD…etc.), 19 (19%) patients with hypertension, 3 (3%) patients with coronary artery disease. While 2 (2%) patients with chronic kidney disease and seizures were found at least.

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D. Risk Factors

Peripheral Neuropathy and Peripheral arterial disease (PAD) are the most common risk factors seen among our patients. The utmost percentage of 43% was peripheral neuropathy followed by 42% was others (retinopathy, poor glycaemic control, alcohol, poor circulation, dry skin, smoking, Previous foot ulcers and amputations) and peripheral artery disease was 15%. These details are depicted in Table III.

TABLE III: RISK FACTORS AMONG DIABETIC FOOT ULCER PATIENTS

S.No	Risk factors	Frequency distribution of risk (n=100)	Percentage of risk distribution (%)
1	Peripheral artery disease	15	15
2	Peripheral neuropathy	43	43
3	Others	42	42

E. Diagnosis

All the 100 diabetic foot ulcer patients can be grouped based on Diagnosis like Gangrene, Foot ulcer, Necrotizing fasciitis, non-healing ulcer, cellulites, Diabetic foot, Plantar abscess. In that 23 patients were diagnosed with gangrene followed by 22 patients with cellulitis,14 patients with diabetic foot,11 patients with necrotizing fasciitis,11 patients with plantar abscess,10 patients with non-healing ulcer, remaining 9 patients were diagnosed with foot ulcer. These details are represented in Table IV.

TABLE IV: DIAGNOSIS AMONG DIABETIC FOOT ULCER PATIENTS

S.No	Diagnosis	Frequency distribution of diagnosis (n=100)	Percentage of diagnosis (%)
1	Gangrene	23	23
2	Foot ulcer	9	9
3	Necrotizing fasciitis	11	11
4	Non healing ulcer	10	10
5	Cellulitis	22	22
6	Diabetic foot	14	14
7	Plantar abscess	11	11

F. Management

The management is majorly divided into two groups amputation and conservative treatment. Among 100 patients, 23 patients underwent major amputation, 20 patients with debridment+antibiotic therapy, 19 patients with minor amputation, 16 patients with debridement+fasciotomy+antibiotics, 13 patients with antibiotic therapy, 3 patients with Incision and drainage + antibiotics and 2 patients with fasciotomy+ antibiotics, 2 patients with fasciotomy+incision and drainage + antibiotics, 2 patients with debridement+ incision and drainage + antibiotics. These details are represented in Table V.

IV. PHARMACOECONOMICS EVALUATION

A. Direct Medical Expenses in Diabetic Foot Ulcer Patients

Out of 100 patients in this study, 42 have undergone the amputation and the remaining 58 patients are with conservative treatment. In Direct Medical cost includes the cost like procedure cost, medical cost, Laboratory cost, Examination cost, Antibiotics, Cost of complications and IP stay in hospital. The average cost of both amputated patients and conservative patients are represented in Table VI.

TABLE VI: DIRECT MEDICAL EXPENSES IN DIABETIC FOOT ULCER PATIENTS

S.No	Treatment	Average cost in amputation (Rupees)	Average cost in conservative treatment (Rupees)
1	Procedure cost	32822	14327
2	Medical cost	7742	6757
3	Laboratory cost	3207	2637
4	Examination cost	2519	1621
5	Antibiotics	977	1241
6	Cost of complications	817	887
7	IP stay in hospital	1730	1324

B. Indirect Medical Cost of Both Amputated and Conservative Treatment Patients

We observed the average indirect cost of both amputated and conservative treatment by comparing both treatments. In that the loss of productivity, loss of retirement, Transportation cost and home nursing cost is high in conservative treatment patients compared to the amputated patients. The average costs of indirect expenses are mentioned below.

TABLE VII: INDIRECT MEDICAL COST IN DIABETIC FOOT ULCER PATIENTS

S.No	Indirect medical expenses	Average cost in amputated patients (Rupees)	Average cost in Conservative treatment (Rupees)
1	Loss of productivity	16952	29121
2	Loss due to retirement	361	604
3	Transportation cost	5054	6640
4	Home nursing cost	7129	8530

TABLE V: TREATMENT DISTRIBUTION AMONG DIABETIC FOOT ULCER PATIENTS

S.No	Treatment Options	Treatment	Frequency distribution (n=100)	Percentage of treatment (%)
1	Amputation	Minor amputation	19	19
		Major amputation	23	23
2	Conservative management	Antibiotic therapy	13	13
		Debridement+antibiotics	20	20
		Fasciotomy + antibiotics	2	2
		Incision and drainage + antibiotics	3	3
		Debridement+fasciotomy+antibiotics	16	16
		Fasciotomy+incision and drainage + antibiotics	2	2
		Debridement+ incision and drainage + antibiotics	2	2

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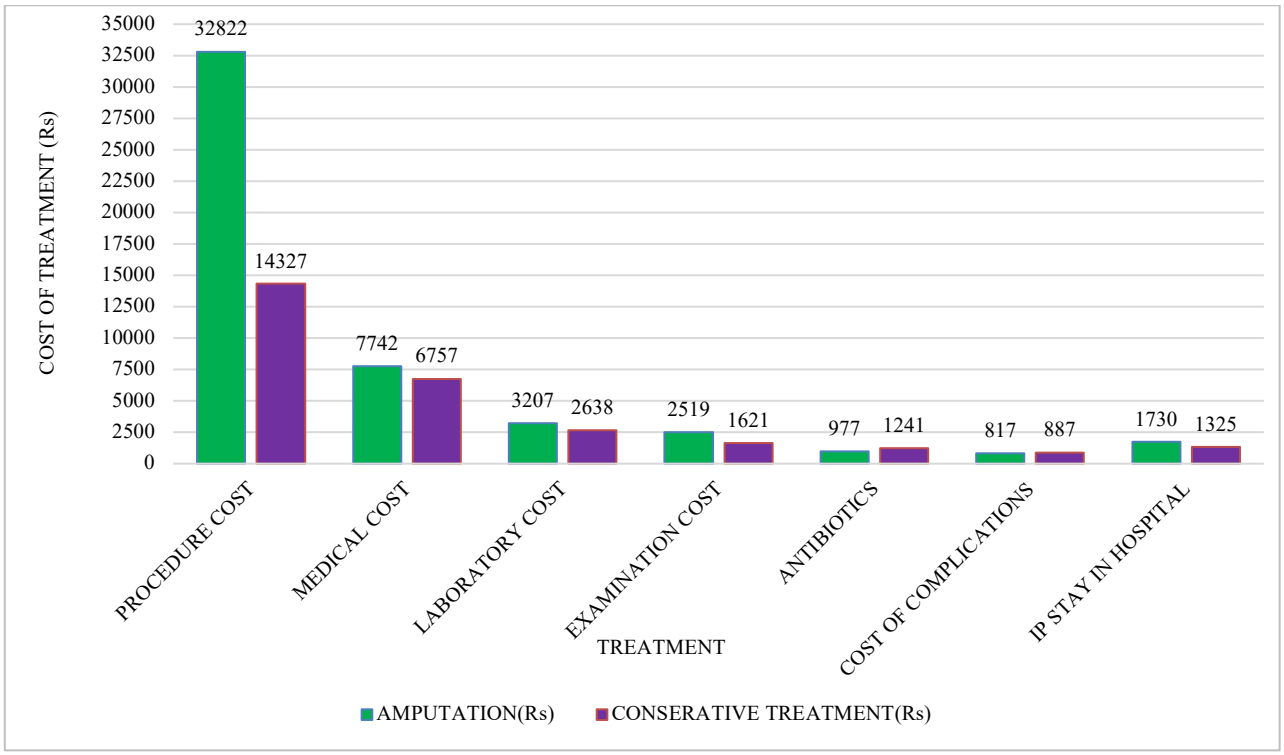

Fig. 2.Direct medical expenses in Diabetic foot ulcer patients.

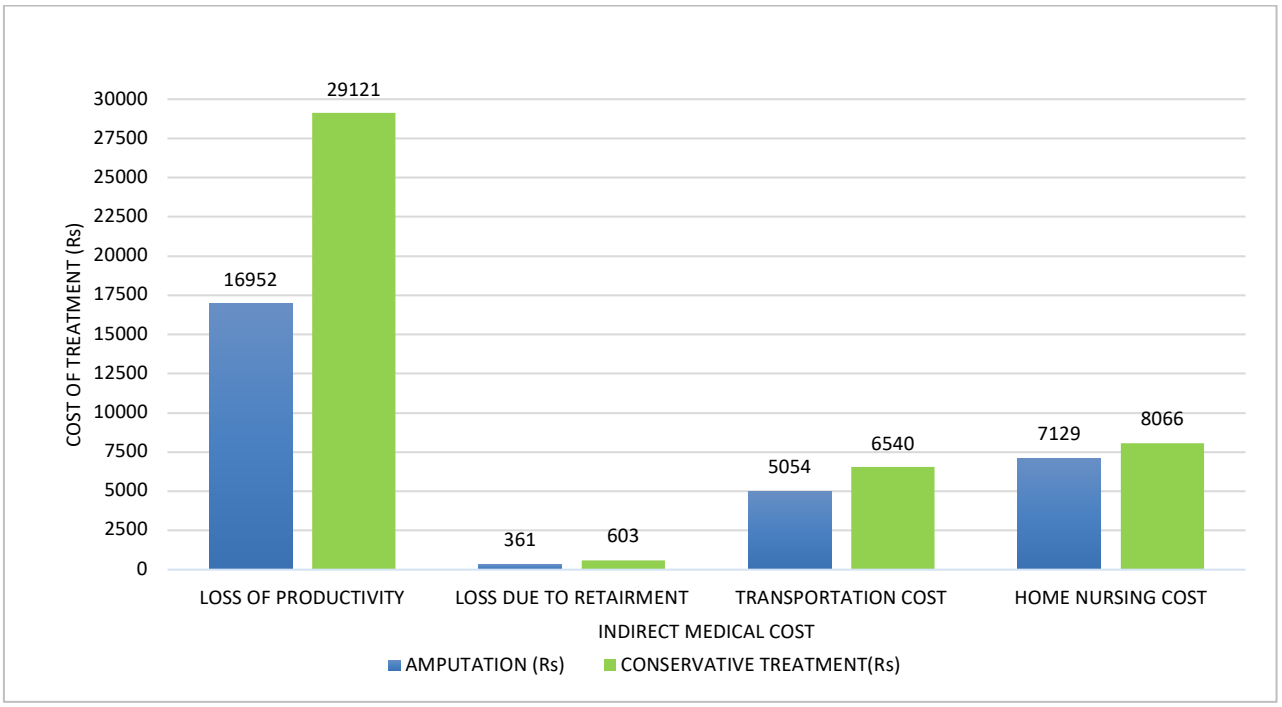

Fig. 3. Indirect medical expenses in Diabetic foot ulcer patients.

C. Extra Medical Service Expenses in Diabetic Foot Ulcer Patients

Among diabetic foot ulcer patients, the no. of emergency visit costs is high in conservative patients i.e., 19199Rs, no. of IP admission cost is more in amputated patients i.e., 2621Rs, 30 days readmissions, mean IP length of stay, no. of visits debridement costs are more in conservative treatment patients than the amputated patients and their expenses are as shown below.

TABLE VIII: EXTRA MEDICAL SERVICE EXPENSES IN DIABETIC FOOT ULCER PATIENTS

S.No	Activities	Average cost in Amputated patients (Rupees)	Average cost in conservative treatment (Rupees)
1	No. of emergency visits	15537	19199
2	No. of IP admissions	2621	9077
3	30 days readmissions	420	2048
4	Mean IP length of stay	300	550
5	No. of visits debridement's	281	2000

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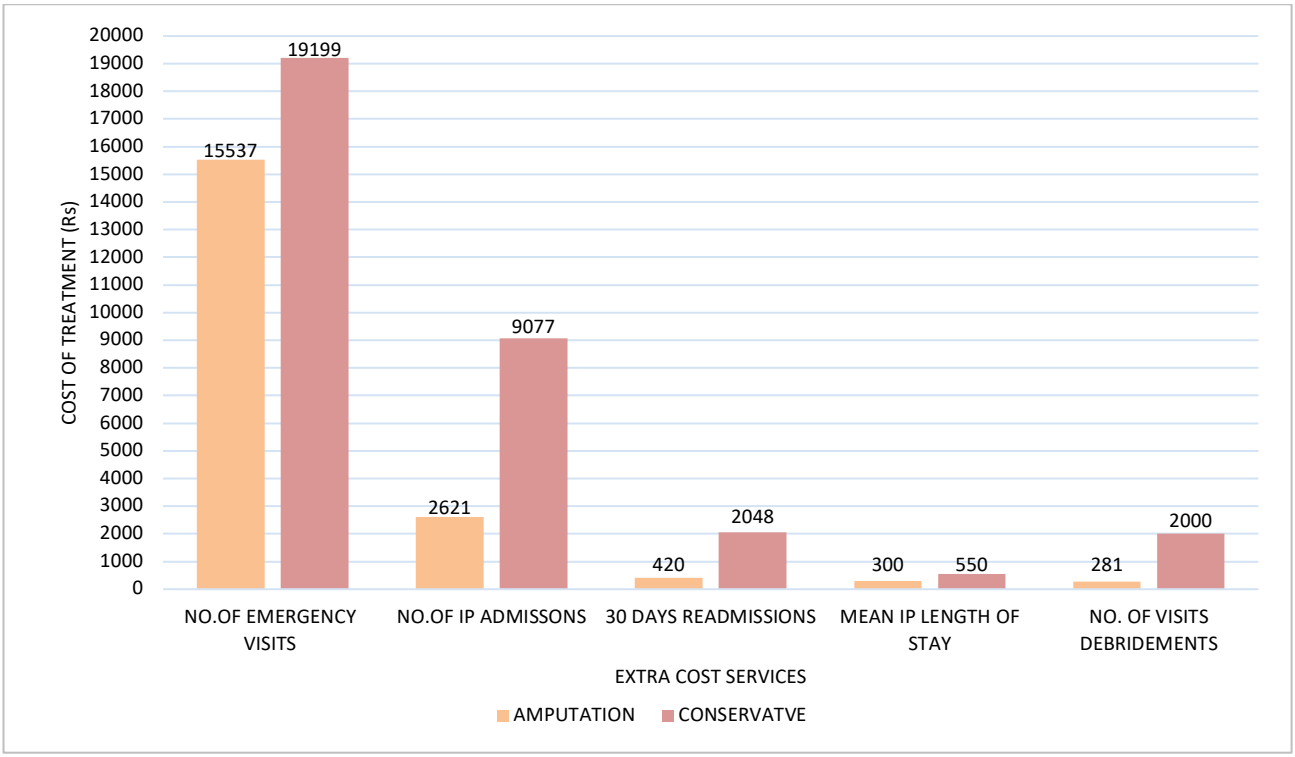

Fig. 3. Extra medical service expenses in Diabetic foot ulcer patients.

V. Statistical Evaluation of Pharmaco-economics

Statistical evaluation for comparison of pharmaco-economics was performed with the student t-test has been done with the help of SPSS 17.0 statistical tool. The main method used to find out t-value and p-value is student t-test. The degree of freedom is 98 (n-1). The level of significance was taken as 0.05%.

TABLE IX: Student T-Test Statistics

	Mean	Sd	D.f	T-value	P-value
Student t-test statistics: total medical cost					
Amputation	36754	7933± 6114	98	1.298	0.1975
Conservative	28821				
Student t- test statistics: total indirect medical cost					
Amputation	29682	9577±9643	98	0.9931	0.3231
Conservative	39259				
Student t- test statistics: total cost of extra medical services					
Amputation	26268	2041±1087	98	0.1878	0.8514
Conservative	24226				

At 0.05% level of significance (Confidence Interval-95%), P-value obtained was above 0.05, thus the study was not significant for student t-test. It implies that economic burden of both amputation and conservative treatment was not having as much significant difference.

A. Frequency of Hospitalization of Diabetic Foot Ulcer Patients

We observed the frequency of medical services i.e., No. of emergency visits, No. of IP admissions, No. of OP visits, 30 days readmissions, mean IP length of stay and No. of visit debridement's are more in conservative treatment patients compared to the amputated people as shown in Table X.

TABLE X: Frequency of Hospitalization in Diabetic Foot Ulcer Patients

S.No	Activities	Frequency in amputated patients(no.)	Frequency in conservative treatment(no.)
1	No. of emergency visits	32	37
2	No. of IP admissions	21	29
3	No. of OP visits	60	175
4	30 days readmissions	5	8
5	Mean IP length of stay	4	16
6	No. of visit debridement	28	42

VI. Discussion

The present study was carried out with 100 patients who were diagnosed with Diabetic foot ulcers and suggested for conservative treatment, minor amputation, major amputation, debridment, fasciotomy, incision and drainage were enrolled into the study from the General surgery department, Sri Venkateswara Institute of Medical Sciences, SPMC(W) – Tirupati.

Many literatures and surveys concluded that males are more prevalent in diabetic foot ulcer than females. A study conducted by Hopkins[4] on economic burden of illness associated with diabetic foot ulcers explains that females are with 36.9% and males are with 63.1% diabetic foot ulcer patients. Our study population also reflected the same prevalence of diabetic foot patients is more in males (44%) than in study females (26%).

We understood that age is also one of the important risk factors for diabetic foot ulcer. In our study we observed that 1 (1%) of members in between 21-30 years of age, 7 (7%) members in 31-40 years of age, 19 (19%) members in 41-50 years of age, the prevalence in the age between (51-60) and 61 to 70 are same and more prone to the diabetic foot ulcer infection and i.e., 27 (27%) and 13 (13%) members in 71-80 years of age and 6(6%) members in 81-90 years of age.

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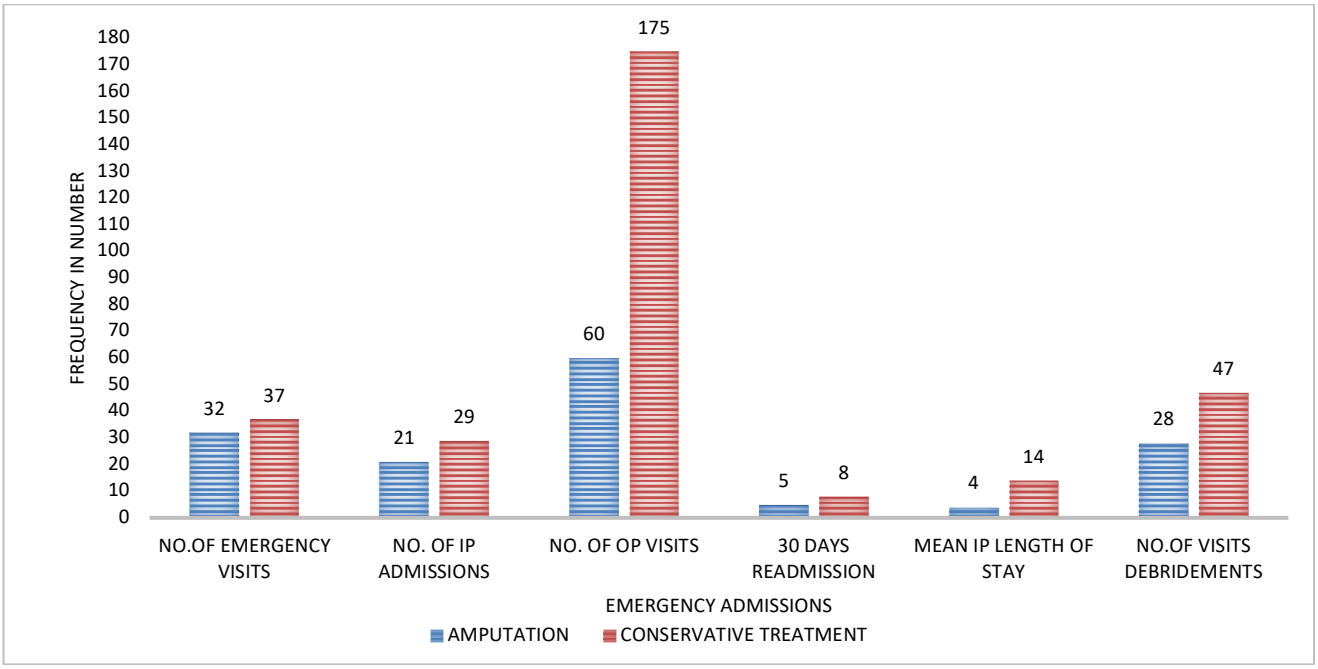

Fig. 4. Frequency of seeking extra Medical Services.

Considering the comorbidities, in our study we observed that 19(19%) patients with Hypertension, 3(3%) patients with coronary artery disease, 2 (2%) patients with chronic kidney disease, 2 (2%) patients with Seizures and 32 (32%) patients with combined disease i.e., Hypertension, Coronary artery disease, chronic kidney disease in the single patient.

Moreover, in this study 43 (43%) of the patients was suffering from peripheral neuropathy, 15 (15%) was due to peripheral artery disease and remaining 42% of the patients with other risk factors like retinopathy, poor glycemic control, alcohol, poor circulation, dry skin, smoking and previous foot ulcers and amputations.

Considering the ulcer/disease patterns, in our study we observed that 23 (23%) patients withgangrene, 9 (9%) patients with foot ulcer, 11(11%) with necrotizing fasciitis, 10 (10%) with non-healing ulcers, 22 (22%) patients with cellulites, 14 (14%) patients with diabetic foot and remaining 11 (11%) patients with plantar abscess.

Furthermore, 23(23%) patients underwent major amputations, 20(20%) patients with debridement + Antibiotic thearpy19 (19%) patients with minor amputation, 16 (16%) patients with debridement + fasciotomy + antibiotic, 13 (13%) patients with antibiotic therapy, 3(3%) patients with incision and drainage +antibiotics, and 2 (2%)patients with fasciotomy + antibiotics, 2(2%) patient with fasciotomy + incision and drainage + antibiotic, 2 (2%) patients with debridement + incision and drainage + antibiotics.

In the present study, the direct medical expenses in diabetic footpatient were figured out. The procedure cost of the amputated patients was more 32822Rs than in conservative treatment 14327Rs, the medical cost of the amputated patients was more 7742Rs than the conservative treatment 6757Rs, the laboratory cost of amputated patient is 3207Rs and conservative treatment is 2637Rs, the examination cost is more in amputated patients 2519Rs, than the conservative treatment is 1621Rs, the antibiotics cost is more in conservative treatment 1241Rsthan the amputated patients 977Rs, cost of complications are more in conservative treatment 887Rs than the amputated patients 817rs and IP stay in hospital cost is more in amputation patients 1730Rs than the conservative treatment 1324Rs.

In the present study, the direct medical cost expenses of diabetic foot ulcer patients figured out. The procedure cost, medical cost, laboratory cost, examination cost and IP stay in hospital cost was more in amputation patients i.e., 32822Rs,7742Rs,3207Rs,2519Rs and 1730Rs, than the conservative treatment patients i.e.,14327Rs, 6757Rs,2637Rs,1621Rs and 1324Rs. The antibiotics cost and cost of complications was more in conservative treatment i.e., 1241Rs,887Rs than the amputation treatment 977Rs and 817Rs.

It was observed in our study that indirect medical cost of both amputation and conservative treatment people. In that the loss of productivity, loss due to retirement, transportation cost and home nursing cost was higher in conservative treatment people i.e., 29121Rs, 604Rs, 6040Rs and 8530Rs than the amputation people i.e., 16952Rs, 361Rs, 5054Rs and 7129Rs.

Among diabetic foot ulcers patients, the extra medical service cost was evaluated. In that number of emergency visits, 30 days re-admissions, mean IP length of stay and number of debridement was more in conservative treatment i.e., 19199Rs, 2048Rs, 550Rs, 400Rs than the amputated treatment 15537Rs, 420Rs, 300Rs, and 281Rs. The number of IP admissions is more in amputation patients i.e., 9077Rs than the conservative treatment i.e., 2621Rs. We understood that the frequency of hospitalization is also more in the conservative treatment than the amputation patients.

VII. Conclusion

Our study concluded that the economic burden of diabetic foot ulcer in conservative patients was slightly more while compared to amputated patients by descriptive statistics even the statistical analysis showed less significant difference. Because the necessity rate for extra hospitalization and medical services was more for

conservative treatment (Debridement, Fasciotomy, Incision and Drainage) when compared to amputation patients with diabetic foot ulcer. In the pharmaco-economics there was not much significant difference among both amputated and conservative patients.

CONFLICT OF INTEREST

Authors declare that they do not have any conflict of interest.

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