A PROSPECTIVE OBSERVATIONAL STUDY ON DIABETIC INDUCED COMPLICATIONS AND THEIR PRONE TOWARDS SURGERY

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Abstract:

Back ground: This study was mainly aimed to find out the diabetic complications that had been lead to surgey. The Diabetes mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate,fat and protein metabolism resulting from defects in insulin secretion,insulin action, or both.The effects of diabetes mellitus include long-term damage,dysfunction and failure of various organs.

Materials and methods: A prospective observational study was conducted in the Santhiram college & general hospital for 6 months (December 2020 – May 2021)to assess the macro vascular and micro vascular complications of diabetes mellitus and prone to surgery of diabetic complications by using case sheets, prescriptions in tertiary care teaching hospital.

Results: A total of 150 patients are included in this study.In patients with diabetic complications we have observed: Diabetic ulcer with cellulitis in 19, gangrene in 19, peripheral vascular disease in 6, gangrene with cellulitis in 11,Non healing diabetes foot ulcer in 35, Coronary artery disease 24, diabetic retinopathy 25, MI in 11 patients.Among all complications, non healing diabetic foot was observed to be more when compared to other diabetic complications.In the study performed in diabetic induced complications of patients, debridement was performed in 30% patients, Amputation were performed in 13%, skin grating was performed in 13% patients, Angioplasty were performed in 23% patients and lasix surgery performed in 13% patients.

Conclusion: In our study we conclude that out of 150 cases, male patients are more prone to diabetic complications than females.The patient counselling should involve in minimizing the incidence and prevalence of diabetes by conducting the continuing health education and other health programms.

Keywords: Diabetes mellitus, diabetic retinopathy, gangrene, cellulitis, non healing diabetic foot ulcers, coronary artery disease.

INTRODUCTION: Diabetes is a chronic disease with a group of metabolic disorders characterized by high sugar levels in blood (hyperglycemia). It is caused due to deficiency of insulin or resistance to insulin or both. Insulin is secreted by pancreatic β-cells to regulate blood sugar levels.(1) According to recent diabetes atlas, the global prevalence of diabetes is estimated at 415 million (8.8%), which is predicted to rise to 642 million in next 25 years. In India, there are about 69.2 million people with diabetes and are expected to cross 123.5 million by 2040. Moreover, worldwide approximately 193 million diabetics remain undiagnosed predisposing them to the development of several long-term complications of untreated chronic hyperglycemia.(3)etiology of Type2DM is constitutional insulin resistance with relative insulin deficiency. The main factors that contribute to the development of insulin resistance (T2DM) include Age, Obesity , Physical inactivity, Smoking and alcohol, dyslipidemia, hypertension, and cardiovascular disease, Mutations in the insulin gene and Insulin receptors. The symptoms diabetic includes Excessive thirst, frequently urination, extreme hunger, weight loss, Fatigue, polyuria, Dry mouth and skin.(4)The diagnosis of patients with diabetes or pre diabetes some test are needed to performed ,like oral glucose tolerance testing ,fasting blood sugar, Random blood sugar, HbA1c testing etc. HbA1c test is much better than the FGP test for determination risk of cardiovascular disease and death from any cause(4)

The micro complications mainly include: Diabetic neuropathy, nephropathy, and retinopathy. Macro vascular complications include: Coronary heart disease, cerebrovascular disease, peripheral vascular disease (5).When compared to people without diabetes, diabetics have a 30-fold higher risk of lower-extremity amputation owing to infection. Diabetic foot infections that aren't treated well result in lower-extremity amputation in about 10% of patients.(4)**Diabetic retinopathy**(DR) is a condition in which the retina of the eye is damaged as a result of long-term diabetes. In most nations, diabetic retinopathy is the leading cause of blindness. It's frequent in both type 1 (40%) and type 2 diabetes (20%). The most common cause of visual impairment in people with T2DM is fovea involvement due to edema and

hard exudates or ischemia [6].The main risk factors for DR include hyperglycemia and diabetes for a longer period of time. Hypertension, hyperlipidemia, pregnancy, and microalbuminuria are all risk factors. Symptoms of diabetic retinopathy manifest only after damage to the eyes has occurred, and include blurred vision and gradual vision loss, floaters, shadows or missing portions of vision, and difficulty seeing at night. The most significant and prevalent complication of diabetes is related to blood vessels.[7]

Peripheral vascular disease of lower limb extrimities:**Diabetic Foot Ulcer (DFU)** The most dangerous complication of Diabetes Mellitus is Diabetic Foot Ulcer (DFU) .DFU is a kind of diabetes that affects about one-quarter of diabetic people. During the course of the disease, DFU causes 14 to 24 percent of lower extremity amputations. DFU caused 80.000 amputations per year in the United States. Peripheral neuropathy, ischemia, and neuro-ischemia all contribute to the development of DFU. Because of the lack of protective feeling and coordination of the foot muscles caused by neuropathy, mechanical stresses during ambulation are increased. Ischemia is caused by a lack of oxygen in the lower leg, and it can also result in a wound. DFU is caused by a combination of ischemia and neuropathy, which deteriorates the skin integrity of the patient.DFU is a type of DM complication that can be treated. Diet, activity, and therapy adjustments can all have an impact on DFU recovery. DFU will heal 60–80% of the time. However, 10–15 percent will stay germinate, and 5–24 percent will require amputation within 6–18 months more than half of DFU were able to manage the sign of healing with adequate care.[8]

Cellulitis: Cellulitis is a most common bacterial infection of the skin and subcutaneous tissue which is characterised by an inflammatory condition like erythema,swelling,fever,redness of the skin,blisters warmth,pian,tenderness and dimpling of the skin[9,10].Cellulitis is mainly occurs when the wounded areas like breaks,cuts,cracks,ulceration,bite wounds are exposed to the streptococci and staphylococcus aureus bacteria. The severity of Non diabetic foot ulcer graded according to the CREST guidelines for cellulitis .Cellulitis usually disappears with appropriate antibiotic treatment if the practitioner correctly diagnoses and treats it quickly.[11]

AIM: To study diabetic induced complications and prone towards surgery

OBJECTIVES:

- To analyse micro and macro vascular complications.
- To find out the causes of diabetic induced surgery based on severity of patients.

- ❖ To analyse the parameters to overcome the complications and as well as surgery.

PARAMETERS ANALYSED : Main parameters in the study includes -

- Laboratory values of RBS, FBS, PPBS
- Laboratory values of HbA1c
- Disease condition of the patient
- Surgical data
- Outcome satisfaction of the patient

METHODOLOGY:

Study design: It is a Prospective observational study.

Sample procedure: The study sample consists of patient with diabetic complications which includes patients with, cellulitis, gangrene,non healing diabetic foot ulcers,myocardial infraction,coronary artery disease with angiogram procedure,retinopathy from general medicine cardiology, ophthalmology inpatient department of selected tertiary care hospital.

Study period: 6 months (December 2020 – May 2021)

Study site: Santhiram General Hospital, Nandyal, which is 1000 bedded Tertiary care teaching Hospital with multi specialisations.

Study Target population:

All patients from Inpatient units of General medicine, surgery Departments of SRMC&GH

Sample size: 150

Study materials/Source of data:

- Case sheets
- Discharge medication charts

STUDY CRITERIA:

Inclusion criteria:

- Patients with informed consent form

- Patients with age group >20years.
- Patient with DM
- Patients with complaint of lack of wound healing, infections
- Patient with diabetic complication
- **Exclusion criteria:**
- Participants unwilling to join the study
- Women with pregnancy
- **METHOD OF DATA COLLECTION:**

This prospective observational study was carried out after obtaining the permission of institutional ethical committee, Santhiram medical college and general hospital, Nandyala A.P, India, with proposal number 150.All patients according to the study criteria, admitted in the Cardiology, General surgery, ophthalmology, between December to May were included in the study.

Proforma was used for collecting data which includes patient demographics, past medical history, family and surgical history, co-morbidities, diagnosis and present medications prescribed for each patient. The data was obtained by direct patient interview and from patient case profiles. Total 150 cases were collected from wards, according to study criteria. All the prescriptions which contain different laboratory values concerning blood sugar and drugs were collected during the study period to analyze the information. And the satisfaction of the patient after surgery was measured by 5-point likert scale which contains excellent, very good, good, average and poor.

STATISTICAL ANALYSIS:

The data was subjected to descriptive and inference statistics using Graphpad Prism 5. Data subjected to mean, standard deviation, standard error and percentages. According to the

ordinal data kruskal wallis test was used to obtain p-value and also Dunn's multiple comparison test was performed between groups. P-value < 0.05 considered as statistically significant.

RESULTS:

TABLE:1

1)Socio-demographic details		No. of patients
Gender N (%)	Males	84(56%)
	Females	66(44%)
2)Area wise population of cases	Urban	35(23%)
	Rural	115(77%)
3)Department wise distribution	General surgery	90
	Cardiology	35
	Opthalmology	25
4)Social history of patient	Alcoholic	36
	Smoker	48
	Both	20
5) Based Family history	Diabetic	87(58%)
	Hypertension	42(28%)
	Diabetic and Hypertension	21(14%)
6)Medication history	H.Actropid	35(23%)
	Glycomet- gp1	32(21%)
	Metformin	37(25%)
	Metformin and H.Actropid	46(25%)

Rural Population(77%) were more effected with diabetic complication when compared to urban Population(23%).

Department wise:Among the 150 patients of our study the general surgery department patients are 90 members cardiology department 35 members and opthamalogy departments 25 members.

NOTE : Due to improper cleaning and the hygienic conditions of the lower limbs and foot the most of the people facing lower limbs extremity problems and the irregular maintainence

of the diet and the medications the more number of patients are admitting in the general surgery ward.

Among the 150 patients of our study the alcoholics were 36 members, smokers were 48 members, and both (alcoholic and smokers) were 20 members and the females were excluded.

Among the 150 patients of our study the family history of diabetic was high compare to the hypertension and comorbid condition that was hypertension & diabetic

Among the 150 patients of our study the widely used medications were metformin and H.Actropid of 25%.

Table-2: AGE WISE GENDER DISTRIBUTION

Age	Female	%	Male	%	Total %
31-40	2	3	0	0	1.33
41-50	13	20	13	15	17.33
51-60	26	39	35	43	40.6
61-70	17	26	21	25	25.33
71-80	8	12	13	15	14
81-90	0	0	2	2	1.33
Total	**66**	**100**	**84**	**100**	**100%**

Note: As no people diagnosed with the diabetic prone to surgery below 30 years

Table.3: Self maintenance

Indication	Diet Maintenance	Physical Activity
Yes	36	30
No	114	120
Total	**150**	**150**

Note: Due to the lack of self maintainence like diabetic diet and physical activity the more popupation facing a diabetic complications.

Table.4: Laboratory parameters

Range	RBS			FBSM			PPBS		
	M	F	%	M	F	%	M	F	%
100-140	2	2	3	25	16	27	20	10	20
141-180	26	22	32	30	25	37	27	25	34.66

181-230	30	24	36	20	14	23	22	10	21.33
231-270	2	2	3	4	7	7	11	10	14
271-310	6	6	8	3	2	3	2	6	5.33
311-350	8	3	8	2	2	3	2	5	4.66
350 - Above	10	7	10	0	0	0	0	0	0
Total	**84**	**66**	**100**	**84**	**66**	**100**	**84**	**66**	**100**

RBS = Random blood sugar, FBS = fasting blood sugar measurement, PPBS = Post prandial blood sugar

The Table describes that among the 150 patients of our study the highest RBS value ranges from 181-230 (36%) and the lowest RBS value ranges from 100-140 (2.66%). Among the 150 patients of our study the highest FBS value ranges from 141-180 (36.66%) and the lowest FBS value ranges from 311-350 (2.66%). And among the 150 patients of our study the highest PPBS value ranges from 141-180 (34.66%) and the lowest PPBS value ranges from 311-350 (4.66%).

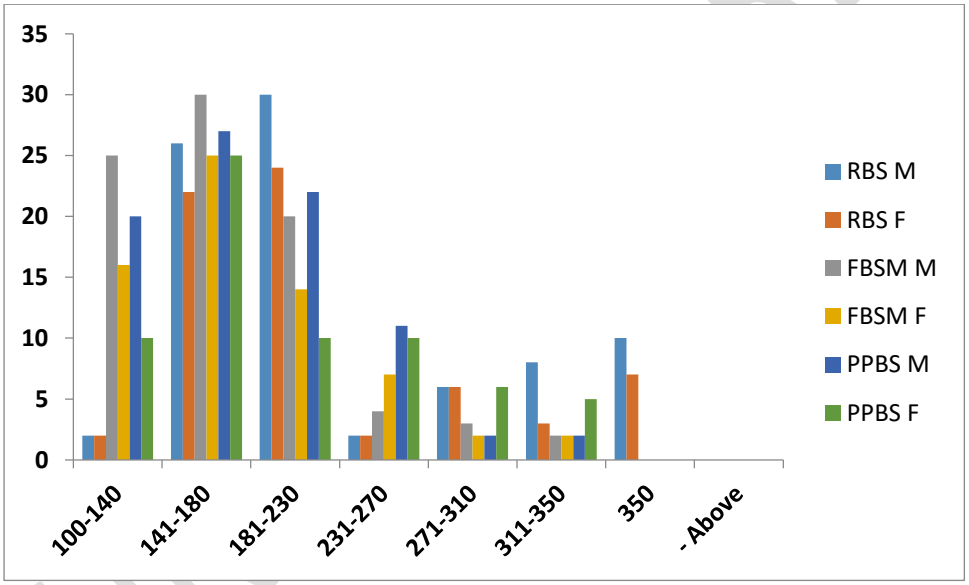

Fig. 1. Blood glucose level

Table.6: HbA1c laboratory parameter

Lab Parameter of HbA1c	No.of Patients
lesser than 6.5	18
greater than 6.5	72
Total	**90**

HbA1c = Hemoglobin A1c

The Table describes that among the 150 patients of our study the highest HBA1c value greater than 6.5 were 72 patients and less than 6.5 were 18 patients found.

TABLE:7-DIAGNOSIS OF THE PATIENTS

Diagnosis	Female	Male	Total	Percentage%
Diabetic ulcer with cellulitis	9	10	19	12.6
Peripheral vascular disease	4	2	6	4
Gangrene	6	13	19	12.6
Gangrene with cellulitis	7	4	11	7.33
Non healing diabetic foot ulcer	15	20	35	23.3
CAD, NSTEMI	10	14	24	16
Diabetic retinopathy	10	15	25	16.6
Myocardial infraction	5	6	11	7.33
Total	**66**	**84**	**150**	**100%**

The Table describes that among the 150 patients of our study based on diagnosis non healing diabetic foot ulcer of male and female(23.3%) was found to high. peripheral vascular disease female and male(4%) was found as low.

Figure.2: Diagnosis of the patients

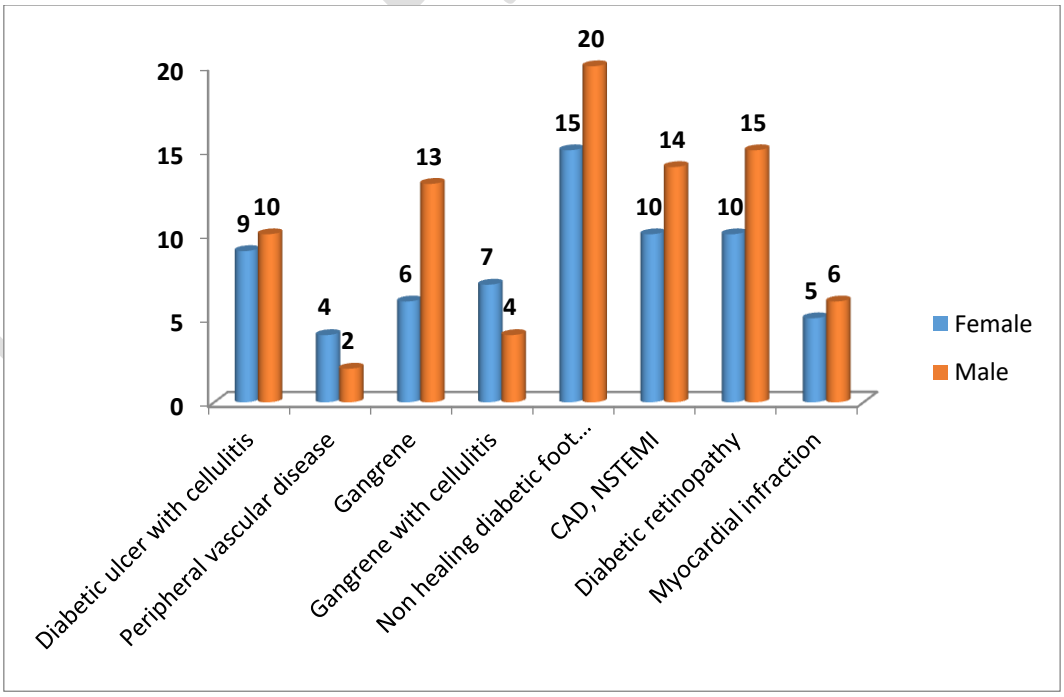

Table.8: SURGICAL PROCEDURE PERFORMED TO THE PATIENT DUE TO COMPLICATION

Surgical Procedure	No. of Patients	Percentage%
Debridement	45	30
Amputation	20	13
Skin grafting	25	17
Angioplasty	35	23
Lasix surgery	25	17
Total	**150**	**100**

Debridment > Angioplasty > Skin grafting = Lasix surgery > Amputation.

Table.9: SURGICAL DATA

Prone to single Surgery	Prone to Re -Surgery	First Aid For Post Surgery
110	40	150

The Table discribes that among the 150 members of our study all 150 members have undergone surgery. Among them 110 members have undergone single surgery, 40 members under gone resurgery.

Note: Due to lack of caring the wound, irregular followups and medications the 40% patients are undergoing re-surgerical producer.

Table.10: Distribution of patients based on antibiotics prescribing

Drugs	No.of Patients	%
Ceftriaxone(monocef)	33	22
Cefoperazone+Salbactum(zostum)	48	32
Ofloxacin+Ornidazole (oflox-OZ)	27	18
Pipercillin+Tazobactum(piptaz)	22	15
Amikacin	8	5
Linizolid	12	8
Total	**150**	**100%**

The Table discribes that among the 150 patients of our study Zostum (cefoperazone + salbactum) was the most common prescribed antibiotic in diabetic patients.

Note: The antibiotics are prescribed based on culture sensitivity test.

Table.11: Outcome of the patient after surgery

Outcome	General surgery	Cardiology	Ophthalmology	No.of Patients	%
Excellent	23	32	20	75	50
Very good	25	3	3	31	20.6
Good	23	0	1	24	16
Average	19	0	1	20	13.3
Poor	0	0	0	0	0
Total	**90**	**35**	**25**	**150**	**100**

The Table discribes that among the 150 patients of our study the 50% population outcome was excellent because of proper maintaince of diet, medication, regular followups of hospital.

Figure.3: Outcome of the patient after surgery

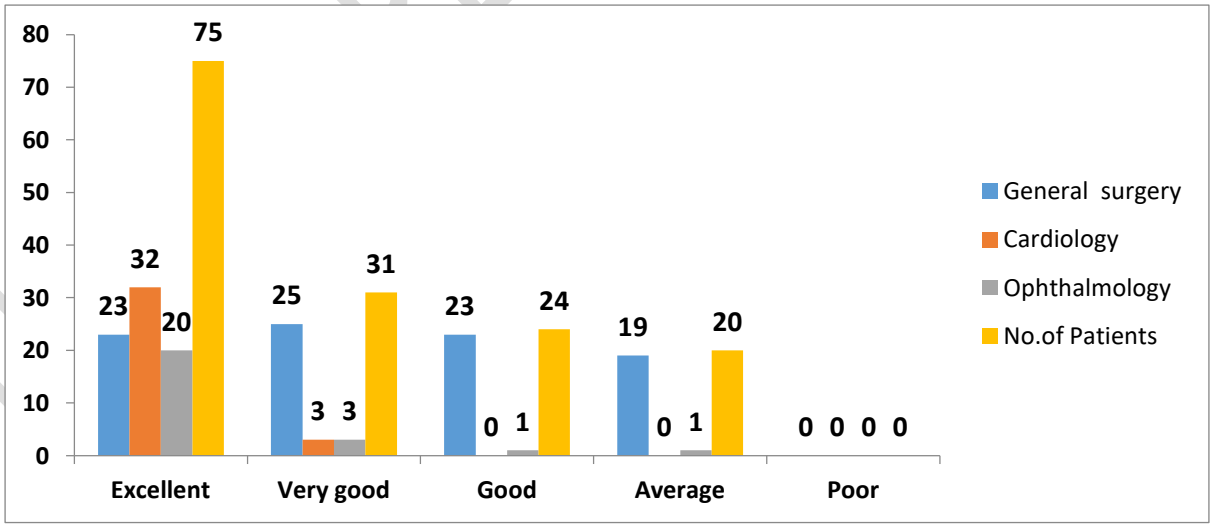

Table.12: Descriptive statistics

Order	Excellent	Very Good	Good	Average	Poor
Number of values	3	3	3	3	3
Minimum	20.0000	3.00000	0.0	0.0	0.0
25% Percentile	20.0000	3.00000	0.0	0.0	0.0
Median	23.0000	3.00000	1.00000	1.00000	0.0
75% Percentile	32.0000	25.0000	23.0000	19.0000	0.0
Maximum	32.0000	25.0000	23.0000	19.0000	0.0
Mean	25.0000	10.3333	8.00000	6.66667	0.0
Std. Deviation	6.24500	12.7017	13.0000	10.6927	0.0
Std. Error	3.60555	7.33333	7.50555	6.17342	0.0
Lower 95% CI	9.48663	-21.2193	-24.2937	-19.8953	0.0
Upper 95% CI	40.5134	41.8860	40.2937	33.2286	0.0

Std. = Standard

CI = Confidence Interval

Figure.4: Outcome of the patient after surgery mean with SEM

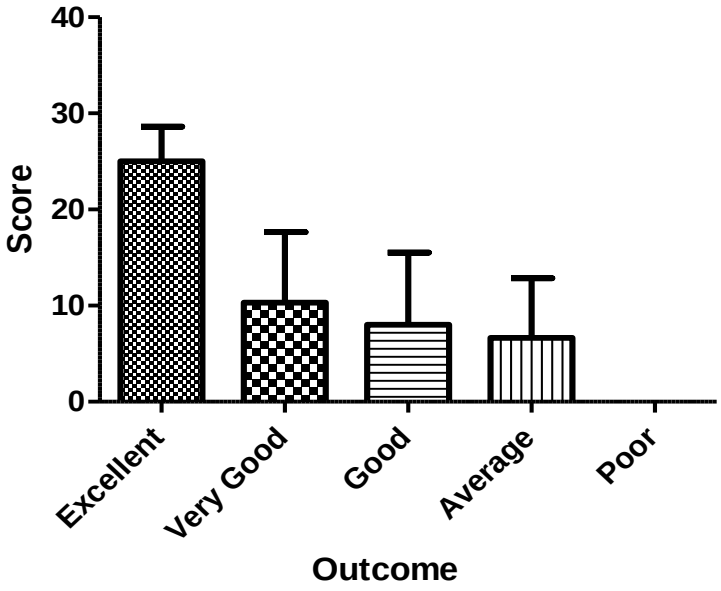

Table.13: Inference statistics

Kruskal-Wallis test		
P value	**0.0653**	
Exact or approximate P value?	Gaussian Approximation	
Do the medians vary signif. (P < 0.05)	No	
Number of groups	5	
Kruskal-Wallis statistic	8.83799	
Dunn's Multiple Comparison Test	Difference in rank sum	Significant? P < 0.05?
Excellent vs Very Good	2.50000	No
Excellent vs Good	5.50000	No

Excellent vs Average	6.33333	No
Excellent vs Poor	9.83333	No
Very Good vs Good	3.00000	No
Very Good vs Average	3.83333	No
Very Good vs Poor	7.33333	No
Good vs Average	0.833333	No
Good vs Poor	4.33333	No
Average vs Poor	3.50000	No

P-Value: < 0.05 = Considered as Significant

After performing non-parametric Kruskal wallis test for ordinal data the obtained p- value was 0.0653. That means it was not statistically significant. Why because the value > 0.05 slightly. Eventhough it was not statistically significant, but it was significant clinically. The values were explain the data was clinically significant.

DISCUSSION:

Among 150 patients of our study patients suffering from diabetic complication were observed more in the age group of 51-60 years (females- 39% and males -43%) and less observed at age group of 31-40 years and 81-90 years (females 3% and males-0) and .Males were more affected when compare to females.

Among the 150 patients of our study the diet maintenance was followed only by 36 members and not followed by 114 members, and the physical activity was followed only by 30 members and not followed by 120 members. So due to lack of proper diet maintenance and

physical activity most of the participants suffering from to diabetic complications that we observed in our study.

The Laboratory values of RBS, FBSM, PPBS were monitered and with this observed thing was that 25% patients are not taken care about their health condition. The highest number of patients was existed in the range of 141-180 and 181 –230. Even though after taking hypoglycemic agents patient remained with abnormality in lab parameters. However the value above 200 also have chance to get complications if the blood sugar persisted for long time. In the same way the other laboratory parameter for knowing blood sugar status was HbA1c. In this laboratory value approximately half of the patients that was 72 patients have HbA1c value greater than 6.5, this indicates chances for getting more complications in the patients; further may leads to surgery as well according the condition of the patient. Based on HbA1c value we observed that most of the patients suffering hyperglycemia from more than 3 months.

The diabetic patients need to care 0f themselves otherwise it leads to diabetic complications. In severe conditions physician could suggest for surgery. The patients outcome in this study after surgery was expressed highly as excellent, very good, good minorly on average. The values obtained are clinically significant, but statistically not significant because p- value was 0.0653.

From the study we observed disease conditions of the patient were diabetic ulcers, peripheral vascular disease, gangrene, gangrene with cellulitis, non healing diabetic foot ulcers and diabetic retinopathy. Among the 150 patients of our study based on diagnosis non healing diabetic foot ulcer of male and female(23.3%) was found to high When compared to other diabetic complication mainly non healing diabetic ulcer was developed because of the uncontrolled blood sugar levels and improper self maintenane.

surgical procedure was performed basede on diabetic complication. In that most of the patients undergone for debridement when compare to other surgical procedures because of most of the cases are non healing diabetic foot ulcer and cellulitis where the surgical procedure performed was Debridement (removing of necrotised are dead tissue)

Total 150 members of our study all 150 members have undergone to surgery. Among them 110 members have undergone single surgery, 40 members under gone resurgery. Due to lack of caring the wound, irregular followups and medications the 40% patients are undergoing re-surgerical producer.

Among the 150 patients of our study Zostum (cefoperazone + salbactum) was the most commonly prescribed antibiotic that we observed in our study when compared to other antibiotics. Diabetic patients prescribed antibiotics based on culture sensitivity test.

Among the 150 patients of our study we observed the 50% population outcome was excellent, 31% population outcome was very good, 24% population outcome was good and the remaing 20%population outcome was average.Due to the irregular followups and medication and lack of care the 13% population were at average outcome.

Outcome satisfaction of the patient were also estimated bt using 5 – point likert scale. All the patients who were undergone to various surgical procedures expressed their satisfaction. In total of 150 patients 75 patients were expressed their outcomme as excellent, 31 as very good, 24 as good, 20 as average and zero for the poor respectively. These indicates the data was clinically significant.

CONCLUSION:

In our study we conclude that out of 150 cases Male patients are more prone to diabetic complications than females.The surgical data also explains the need of

controlling of blood sugar levels. All the patients in our study undergone for different surgical procedures. Those were debriment, amputation, skin grafting, angioplasty and lasix surgery. These data also suggests to patients to control blood sugar levels.

All the health care professionals in this regard conducted counselling and explained about the diabetes disease, controlling of the blood sugar levels and its importance. Diabetes is a world wide health care problem, in view of this concern all the health care professionals like physicians, pharmacists and nurses should involved to minimize the incidence and prevalence of diabetes by conducting the continuing health education and other health programms. Ultimately this may help in minizing the number of cases in across the world.

CONSENT: Informed consent from was obtained from the participants**.**

ETHICAL APPROVAL: The ethical committee considered protocol revision and the IRB board complicated a review. Institutional Review board members approved for further research.The ethical Committee has reviewed and approved without any changes.

ACKNOWLEDEMENT: The authors of principal, dean,teaching and non teaching staff, faculty members of Santhiram Medical &General Hospital for supporting our prospective observational study.Also, we thank santhiram college of pharmacy for providing the hospital facility and special features**.**

COMPETING INTERESTS: We declared no conflict of interest because all the authors contributed equally to start the research.

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