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A N0n Interventional Data Collection Study To Determine The Necessity Of Insulin Dependency For Diabetic Patients Related To Age And Weight

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ABSTRACT
I. Background: Insulin is the most common drug using to control diabetes mellitus and the current study is designed to determine the role and usage of insulin especially related to age and weight of the subjects.
II.Aim: The main of the study is to determine the insulin dependency of diabetic patients correlated to age and weight
III.Method: In this prospective observational study total 20 subjects of either sex data was collected of age 18 yrs and above and who are diagnosed with Diabetic mellitus Type 1 and Diabetic mellitus Type 2 and they should on Insulin treatment.
IV.ResultsSummary:
The final summary of the data collection data are as follows
In group A, no of population n=10, we have observed that the mean weight of population was 71.4 % and of mean age group 34.1 % are treating with only oral diabetic drugs and are not using any insulin therapy and all the population are with good quality of life with mean 3.8 %.
In group B, no of population n=10, we have observed that the mean weight of population was 88.3 % and of mean age group 79.7% are treating with oral diabetic drugs and 0.5 % of population with addition of insulin therapy along with oral diabetic drugs and 11.2 % population are not with good quality of life.
Conclusion: the final conclusion of the data collection was the population of less weight and low age group are leading with good quality of life with using only oral diabetic drugs and the population with higher age group and more weight are not leading good quality of life and they are dependent on insulin along with oral anti diabetic drugs.

Keywords: Diabetic patients; Observational data collection; Insulin Dependency; Age & Weight.

I. BACKGROUND OF THE STUDY

Diabetes Mellitus defined as Decreased or absent insulin activity results in diabetes mellitus, a condition of high blood sugar level (hyperglycemia). There are two types of the disease.

- In diabetes mellitus type 1, the beta cells are destroyed by an autoimmune reaction so that insulin can no longer be synthesized or be secreted into the blood.
- In diabetes mellitus type 2, the destruction of beta cells is less pronounced than in type 1, and is not due to an autoimmune process.
- Instead, there is an accumulation of amyloid in the pancreatic islets, which likely disrupts their anatomy and physiology. The pathogenesis of type 2 diabetes is not well understood but reduced population of islet beta-cells, reduced secretory function of islet beta-cells that survive, and peripheral tissue insulin resistance are known to be involved. Type 2 diabetes is characterized by increased glucagon secretion which is unaffected by, and unresponsive to the concentration of blood glucose. But insulin is still secreted into the blood in response to the blood glucose. As a result, glucose accumulates in the blood.
- The human insulin protein is composed of 51 amino acids, and has a molecular mass of 5808 Da. It is a heterodimer of an A-chain and a B-chain, which are linked together by disulfide bonds. Insulin's structure varies slightly between species of animals. Insulin from animal sources differs somewhat in effectiveness (in carbohydrate metabolism effects) from human insulin because of these

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variations. Porcine insulin is especially close to the human version, and was widely used to treat type 1 diabetics before human insulin could be produced in large quantities by recombinant DNA technologies.

II.AIM:

The main of the study is to determine the insulin MGH dependency of diabetic patients correlated to age and Weight

III.METHOD:

In this prospective observational study total 20 subjects of either sex data were collected of age 18 yrs and above and who are diagnosed with Diabetic mellitus Type 1 and Diabetic mellitus Type 2 and they should on Insulin treatment&The study designed to collect the patients in the single visit and the following data will be captured.

The acceptance of the patient to give their data in the form of informed consent form.

Patient demographics will be collected.

Patient past medical history will be collected.

The patient data will be collected in two groups.

Group 1: Data:

The patient's data will be categorized in to two group.

In group 1 the patient age should be below 50 years

The patients BMI should be normal

Group 2: Data:

In group 2 the patient age should be above 50 years

The patients BMI should be abnormal

Before the start of the study, the study protocol, ICF, and any other essential documents will be submitted to the Institutional Ethics Committee with a cover letter or form listing the documents submitted, their dates and versions of issue for which approval is sought.

As per institutional requirements, the study protocol and any other appropriate documents will be submitted to scientific committees for approval. The study team will forward to the sponsor, or designee, a copy of the Institutional Ethics Committee approval of this protocol, ICF.

The study team will also keep documentation of study approval by internal scientific committees as per institutional requirements.

Sample size & Statistical Analysis Plan The total sample size calculated for the study in two groups was 20 Group 1: n =10

Group 2: n = 10

Total n NO of patient's data planned to collect in the study 20.

The above study will be analysed in standard excel sheet with calculating n number patients using insulin comparing in both groups and percentage of patients depends on the insulin and having high BMI.

TABLE-1
WEIGHT DIFFERENCE BETWEEN TWO GROUPS

Patient ID	Group A patient's weight	Patient ID	Group B patients' weight
1	72	11	80
2	85	12	89
3	79	13	96
4	85	14	92
5	70	15	88
6	72	16	79
7	55	17	86
8	69	18	84
9	68	19	96
10	59	20	93

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TABLE-2

QUALITY OF LIFE DIFFERENCE BETWEEN TWO GROUPS

Patient ID	Group A Patients quality of life	Patient ID	Group B Patients quality of life
1	3	11	14
2	4	12	14
3	4	13	13
4	3	14	11
5	4	15	10
6	3	16	12
7	4	17	11
8	4	18	8
9	4	19	10
10	5	20	9

TABLE-3

FINAL DATA REPORT

Patient ID	wt.	Age	Insulin treatment	Quality of life	Patient ID	wt.	Age	Insulin treatment	Quality of life
1	72	30	0	3	11	80	75	0	14
2	85	31	0	4	12	89	79	1	14
3	79	36	0	4	13	96	80	0	13
4	85	35	0	3	14	92	82	1	11
5	70	27	0	4	15	88	86	1	10
6	72	35	0	3	16	79	75	0	12
7	55	41	0	4	17	86	79	1	11
8	69	41	0	4	18	84	84	0	8
9	68	32	0	4	19	96	76	1	10
10	59	33	0	5	20	93	81	0	9
Mean	**71.4 %**	**34.1 %**	**0 %**	**3.8 %**	**Mean**	**88.3 %**	**79.7 %**	**0.5 %**	**11.2 %**

GROUP -A		**GROUP -B**	
N no of population	10	N no of population	10
Weight	71.4 %	Weight	88.3 %
Age	34.1 %	Age	79.7 %
Insulin treatment	0 %	Insulin treatment	0.5 %
Quality of life	3.8 %	Quality of life	11.2 %

IV.RESULTS & SUMMARY:

The final summary of the data collection data are as follows

In group A, no of population n=10, we have observed that the mean weight of population was 71.4 % and of mean age group 34.1 % are treating with only oral diabetic drugs and are not using any insulin therapy and all the population are with good quality of life with mean 3.8 %.

In group B, no of population n=10, we have observed that the mean weight of population was 88.3 % and of mean age group 79.7% are treating with oral diabetic drugs and 0.5 % of population with addition of insulin therapy along with oral diabetic drugs and 11.2 % population are not with good quality of life.

CONCLUSION:

The final conclusion of the data collection was the population of less weight and low age

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group are leading with good quality of life with using only oral diabetic drugs and the population with higher age group and more weight are not leading good quality of life and they are dependent on insulin along with oral anti diabetic drugs.

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