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A Single Centric Non-Interventional Observational Study to Determine the Decreased Anti Diabetic Drug Dose Usage Inweight Diabetic Patients and Non-Weight Lossdiabetic Patients

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ABSTRACT

I. Background: Type 2 diabetes mellitus (DM) in obese patients is a particularly important condition. Data fromthe Behavioral Risk Factor Surveillance System showed that overweight (BMI 25–29.9), obese(BMI 30–39.9), and morbidly obese (BMI≥40) US adults had 1.59, 3.44 and 7.37 times higherodds, respectively, of diagnosed DM, compared to those with normal(BMI 18.5–25) Further, on average, obese individuals with DM have a higher prevalence of end-organdamage and are at higher risk for cause-specific mortality compared to obese individuals withoutDM .Obesity and DM in unison also generate immense health care costs

DM in obese patients is predominantly related to insulin resistance; thus, intentional weight loss, by improving insulin resistance, decreases the risk of incident diabetes, and in patients with existing diabetes results in better glycemic control. The quantitative association betweenimprovement in glycemia with weight loss and dose reductions or discontinuation of antidiabeticmedications is not well studied. This association would be clinically useful in treating,counselling and motivating patients in their weight loss efforts.

In this study of overweight and obese patients from two University-based weight managementclinics, we studied the association between the percentage of weight loss and dose reductions ordiscontinuation of anti-diabetic medications

II.Aim: The Main Aim of this study is Intentional weight loss, primarily by improving insulin resistance, is known to decrease the need for anti-diabetic medications, we assess the magnitude of weightloss that resulted in dose reductions or discontinuation of anti-diabetic medications in overweightor obese patients with type 2 diabetes (DM) undergoing weight loss treatment.

III.Method: This is a non-interventional, single center, observational study conducting on Approx. 10confirmed diabetic patients.

- No study medication will be prescribed or administered as a part of study procedure.
- Patients, who have been treated as per Investigators' routine clinical practice will be screened in study.
- Patients, who have been treated as per Investigators' routine clinicalpractice will be enrolled in study.

No of Groups: 02
(Group A- 5) & (Group B- 5)
No of Visits: 02
1) Visit 01 base line / enrolment day
2) Visit 02 at the end of the study on 122+ 2 days

Inclusion Criteria:

- Male or female patients with 18 years or above
- Patients who have provide written Informed Consent
- Patients with previously diagnosed with Type 1 and Type 2 Diabetes
- BMI (Body Mass Index) ≥ 30
- Laboratory Test reports of (FBS, PPBS)
- Gender

Exclusion Criteria:

Following data will be captured during study visit:

- Demographic data
- Weight and height
- Vital Signs: Blood Pressure (in sitting position) and Heart rate
- Medical & Surgical History & relevant lab reports.
- Concomitant Medications
- Laboratory Test (FBS, PPBS)

Before the start of the study, the study protocol, ICF, and any other essential documents

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will besubmitted 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: For eligible patients, baseline data would becollected i.e. demographic information,weight, height, BP, heart rate, medical & surgical history, Profile FBS, PPBS and concomitantmedications at visit 1 and visit 2.Final Data collected from the two groups will be analysed.

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

1:Data Analysis of Base Line Visit:

VISIT 01													
S.no	Date of ICF	Date of Enrolment	Date of Previous Visit	Date of Next Scheduled Visit	Height	Weight	BMI	Temp	BP	RR	PR	FBS	PPBS
1	12-12-2018	12-12-2018	10-09-2018	31-12-2018	1.62	80	30.5	98.6	120/80	24	96	140	190
2	12-12-2018	12-12-2018	10-09-2018	31-12-2018	1.73	92	30.7	97.8	125/85	26	99	170	220
3	12-12-2018	12-12-2018	13-09-2018	03-01-2019	1.58	78	31.2	98.3	120/80	25	97	165	254
4	14-12-2018	14-12-2018	13-09-2018	03-01-2019	1.62	79	30.1	97.5	125/90	22	98	135	196
5	14-12-2018	14-12-2018	15-09-2018	05-01-2019	1.67	86	30.8	97.4	120/80	25	97	165	210
6	15-12-2018	15-12-2018	15-09-2018	05-01-2019	1.57	74	30.0	96.4	140/90	26	99	170	267
7	15-12-2018	15-12-2018	17-09-2018	07-01-2019	1.65	84	30.9	98.2	120/85	27	96	158	198
8	15-12-2018	15-12-2018	17-09-2018	07-01-2019	1.66	83	30.1	98.6	130/90	25	94	160	195
9	16-12-2018	16-12-2018	18-09-2018	08-01-2019	1.72	89	30.1	97.4	130/85	23	96	136	187
10	16-12-2018	16-12-2018	18-09-2018	08-01-2019	1.69	86	30.1	98.4	120/80	24	95	145	178

2: Data Analysis of End of theVisit:

VISIT 02										
S.no	Date of VISIT 2	Height	Weight	BMI	Temp	BP	RR	PR	FBS	PPBS
1	31-12-2018	1.62	73	27.8	98.6	120/80	24	96	120	135
2	31-12-2018	1.73	85	28.4	97.8	125/80	23	97	130	160
3	03-01-2019	1.58	68	27.2	97.8	130/85	22	95	130	145
4	03-01-2019	1.62	68	25.9	98.3	120/80	2	94	100	130
5	05-01-2019	1.67	78	28.0	97.8	125/85	25	96	127	170
6	05-01-2019	1.57	69	28.0	98.6	120/80	26	94	100	130
7	07-01-2019	1.65	78	28.7	97.8	130/85	22	95	120	140
8	07-01-2019	1.66	77	27.9	98.2	120/85	23	96	130	138
9	08-01-2019	1.72	82	27.7	97.9	120/80	24	95	140	160
10	08-01-2019	1.69	80	28.0	97.6	130/80	25	94	115	142

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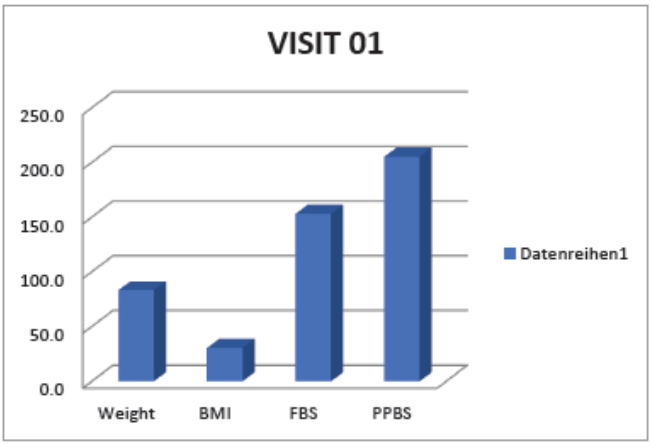
3:Data Analysis of Base Line Visit:

AVERAGE VALUES OF TOTAL STUDY POPULATION				
S.no	Weight	BMI	FBS	PPBS
1	83.1	30.5	154.4	209.5

EXPERIMENTAL RESULTS



4: Data Analysis of End of theVisit:

AVERAGE VALUES TOTAL STUDY POPULATION				
S.no	Weight	BMI	FBS	PPBS
2	75.8	27.8	121.2	145.0

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RESULTS & SUMMARY:

The final summary of the data collection data are as follows

The summary and conclusion for the below mentioned study is as follows:For the study title "A single centric non-interventional observational study to determine thedecreased anti diabetic drug dose usage in weight loss diabetic patients and non-Weight lossdiabetic patients", we have collected the data of total 10 humans after getting the InstitutionalEthics Approval.In the total study population, all the 10 subjects are confirmed diabetic patients and with BMI >30. All the 10 subjects accepted to participate in the study and signed in Informed ConsentForm and accepted to donate their clinical data and required medical report.

CONCLUSION:

The final conclusion of the data collection was we observed and concluded that there is a drasticdecrease in FBS & PPBS values due to weight loss of the patients between baseline visit andend of the visit. Finally, we concluded that due to weight loss and decreased FBS & PPBSvalues, there is decreased usage of anti-diabetic drugs. So, there is necessary weightmanagement required for diabetic patients to overcome the usage of anti-diabetic drugs.

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