PREAMBLE

Post Graduate Education and Research in Ayurveda started in 1952 at Jamnagar Gujarat by Govt. of India. Now, **Institute for Post Graduate Teaching & Research in Ayurveda [IPGT & RA]**, a constituent research institute of Gujarat Ayurved University, Jamnagar, is a premier postgraduate training and research centre in Ayurveda. It is the first post graduate teaching institute of the country, and has achieved many milestones in the development of Ayurveda within and outside the country. This is the only Ayurveda institute in the world that has designated as WHO Collaborating Centre for Traditional medicines (WHOCC) (Ayurveda).

Ayurveda since ancient times treating diseases of mankind; bestows the human with good, healthy and happy life. These age old practices have been developed after careful observations and conclusions drawn after careful researches for thousands of years. There are many single drugs and poly herbal formulations which are helpful to the patients without any untoward effects. Following the principles of Ayurveda, supported with modern scientific knowledge, newer formulations too are being added to the Ayurveda pharmacopoeia. Many such new drugs / formulations require proper evidence to suit the needs of present legal requirements and globalization as safe drug. Shouldering this responsibility of strengthening evidences, IPGT & RA started providing services of conducting clinical and experimental trials of such formulations for pharmaceutical industries.

MB Life Science Pvt. Ltd. is a pharmaceutical establishment in Ayurveda, having national market. One of their R&D formulations is DIACEA capsule, which is indicated for the management glucose and Lipid metabolism especially for Type – 2 Diabetes. It is tested clinically for its efficacy on patients of Diabetes Mellitus [type – 2] at this institute. The OPD of Rog Nidan department has around 50% of total OPD patients are of DM type – 2 visiting for the management of the disease and hence this project was given to the department.

Now, the work has been completed successfully, with encouraging results. It gives us immense pleasure to submit this project report to the research sponsoring agency i.e. MB Life Science Pvt. Ltd.

[Prof. Dr. A. B. Thakar]
Director
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Project Details

Project sponsored by : M/s MB Life Science Pvt. Ltd., Delhi

Project Ethical clearance from IEC: PGT/7-A/Ethics/2016-17/3794 Date: 07.02.2017

CTRI No. : CTRI/2018/01/011256

Project duration : One Year

First enrolment date : 13.05.2017

Last enrolment date : 28.12.2017

Total project cost : 6, 41,800/-

Abbreviation

DLC	**: Differential Leukocyte Count**
ESR	**: Erythrocyte Sedimentation Rate**
Etc.	**: Etcetera**
FBS	**: Fasting Blood Sugar**
Gm.	**: Gram**
Hb.	**: Haemoglobin**
HbA1C%	**: Glycated Haemoglobin percentage**
HS	**: Highly significant**
Kg. / m^2	**: Kilogram per meter square**
LFT	**: Liver Function Test**
Mg.	**: Milligram**
NS	**: Non significant**
P	**: Probability**
PP2	**: Post Prandial 2 (2 hours after meal)**
RFT	**: Renal Function Test**
S	**: Significant**
S.	**: Serum**
SD	**: Standard deviation**
SE	**: Standard Error**
TLC	**: Total Leukocyte Count**

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Madhumeha vis-à-vis Diabetes Mellitus (Type - 2)

As per International Diabetes Federation [IDF] India's prevalence of diabetes (especially type - 2) among 20-79 year olds is 9.2%. India is just second to China.[1] World Health Organization (WHO) reports refer India as potential diabetic capital of the world, with number of patient of diabetes expected to increase from three to six crores by 2025. Other reports revels that Gujarat is second after Tamil Nadu on the fast track in acquiring diabetic patients. Other figure says that about 10% of Gujarat population is at least at borderline Diabetic.

Type II Diabetes Mellitus is a metabolic syndrome usually characterized by variable degrees of insulin resistance, impaired insulin secretion, and increased glucose production. Distinct genetic and metabolic defects in insulin action and or secretion give rise to the common phenotype of hyperglycaemia in Type II Diabetes Mellitus. Various Oral hypoglycaemic agents, Insulin formulations, Life style modification plans consisting dietary management and exercise, are some of the important efforts towards the management of Diabetes. In spite of these, a safer and effective remedy is needed. Increased side effects, lack of effective treatment for complications, high cost of new drugs and resistance to the drugs are some reasons for renewed public interest in Ayurvedic medicines.

Prameha is *Tridoshaja Vyadhi*, even though *Acharyas* have mainly emphasized on vitiation of Kapha *Dosha*, *Kleda* and *Meda Dhatu* .

In Ayurveda disease *Prameha* (having 20 subtypes) is described along with it all required details like start from etiological factors (*Nidana*), patho-physiology (*Samprapti*), pre-monitory symptoms (*Purvarua*), Characteristic features of urine in different types of *Prameha*, prognosis (*Sadhyasadhyata*), management (*Chikitsa*) as well as preventive aspects.

As far as *Madhumeha* is concerned, there are two type of *Madhumeha* is mentioned in classics 1. *Madhumeha* as one of *Vataj Prameha* and another one, occur due to *Avarana* of *Vayu* by vitiated *Meda*, *Mamsa*, Kapha and Pitta.

References:

[1]http//timesofindia.indiatimes.com, Kounteya Sinha, TNN | Dec 14, 2011, 03.36AM IST, "India's diabetes burden to cross 100 million by 2030

Nidana (Causative factors):

Sedentary lifestyle, excess indulgence of curd, indulgence of meat of aquatic and mushy animals, milk and other bakery product, to have fresh grains, dishes prepared from jaggery and its various products as well as all the diet, dietary habits or physical / mental activities that leads to vitiation of Kapha and similar property *Dhatus* are the pioneer reasons for disease *Prameha* especially *Madhumeha* (type - 2).

Purvaroopa (Pre monitory symptoms):

Knitting of hairs, sweet taste in mouth [*Mukha maadhurya*], burning and numbness in palm and sole [*Hasta-pada daaha* and *supti*], feeling of dryness in mouth [*Asya shushkata*], lethargy [*Alasya*], feeling of stickiness in hair follicles [*chidreshu upadeha*], crawling of ants towards voided urine [*Mutre Pipalikabhisarana*], feeling like ants are crawling on the body [*Sharire Pipalika Abhisarana*] , very bad smell from the body [*Sharire visra gandha*], feeling of sleepiness whole the day [*Nidra - Tandra sarvakaala*].

Roopa (symptoms):

When above mentioned premonitory symptoms remain continue along with cardinal symptom of the disease i.e. excess and turbid urination [*Prabhut Avil Mutrata*], the same is considered as *Rupa* of the disease.

Samprapti (Patho-physiology):

Due to various etiological factors *Meda* [body fat], *Mamsa* [muscle tissue], Pitta and Kapha gets vitiate and obstructs the path of *Vaayu*. Then *Vaayu* aggravates and bring Ojas (essence of *Dhatus*) out from the body and develops *Madhumeha* is the basic pathogenesis of *Madhumeha*.

Chikitsa (Management):

To avoid causative factors is the first line of treatment for any disease. Further based on body constitution of the patient (*Sthool* – Over weight and *Krish* – underweight) patients is advocated bio purification (*Shodhan*) followed by *Shamana* or direct *Shamana* and *Bringhan* respectively. Dietetic changes and lifestyle modification are must be maintained in these patients. Further the drug / formulations those are having *katu*, *tikta*, *Kashaya* in taste, *Laghu*, *Ruksha Guna*, moreover can pacify *Meda*, *Mamsa dhatu* and Kapha, Pitta *Dosha* can be useful to manage the condition.

Diabetes Mellitus (Type - 2)

Causative factors:

These may be divided in to two i.e. genetic susceptibility and acquired i.e. environmental factors those include overeating, especially when combined with obesity and underactivity. Obesity probably acts as a diabetogenic factor (through increasing resistance to the action of insulin) only in those who are genetically predisposed both to insulin resistance and to beta cell failure. The risk of developing type 2 diabetes increases tenfold in people with a body mass index > 30 kg/m^2.

Patho-physiology:

Three major pathological abnormalities involved in the process of type 2 DM are-

1. Insulin resistance
2. Deranged insulin secretion
3. Increased hepatic glucose production

Role of Stress in pathogenesis of Type 2 Diabetes:

Stress is a potential contributor to chronic hyperglycaemia in diabetes as well as it has long been shown to have major effects on metabolic activity. It stimulates the release of various hormones, which can result in elevated blood glucose levels. In diabetes, stress-induced increases in glucose cannot be metabolized properly. Furthermore, regulation of these stress hormones may be abnormal in diabetes. Stress blocks the body from releasing insulin in people with type 2 diabetes, so cutting stress may be more helpful for these people.

In acute condition of stress, increased blood sugar level is managed by increase secretion of insulin. Thus beta cells of pancreas also have to stimulate more insulin to homostat high blood sugar. But if stress remains for long time, the beta cells are exhausted and because of their degeneration failed to maintain the hemostat. As a result blood sugar level pathologically goes up and causes diabetes. Disturbed psychological factors negatively affect Hypothalamo-Hypophyseal axis and stimulate adrenal cortex to release glucocorticoids hormones. As a consequence high levels of glucocorticoids during the stress, increases pathological glycogenolysis and protein catabolism, causes hyperglycaemia. Furthermore it is also caused by glucocorticoids due to insulin

inhibiting and high secreting glucagon effect. Impulses of stress are received by ANS, which are conveyed to its sympathetic neurons. The neurotransmitters catecholamine, epinephrine and nor epinephrine increase with responding to stress and tension. Such neurotransmitters are bound with insulin receptor of cell and work as Insulin antagonist, which lead to hyperglycaemia in diabetic individual.

Drug Review

The trial drug Diacea capsules were supplied by the sponsoring agency **M/s MB Life Science Pvt. Ltd.** 16, Vaishali enclave, 2nd Floor, Pitam Pura, DELHI - 110088

Licence number: L-174/AYUR

Betch N. Medicines of two different batches as mentioned below were used.

Sr. No.	Batch Number	Manufacturing Date	Expiry Date
1.	DIA.0109	09/2015	08/2017
2.	DIA0207	07/2017	06/2019

The contents and other details of ingredients of Capsule Diaceaare as follows:

1. Asana

Latin Name : Pterocarpus marcupium Roxb.
Rasa : Katu, Tikta, Kashay
Guna : Laghu, Rukhsa
Virya : Ushna
Vipaka : Katu
Karma :Kushthagna, Rasayana, Raktadoshahara
Doshaghnata : Kapha – Pitta Shamaka, Raktashodhaka, Kushthaghna, Rasayana
Part used : heart wood
Chemical constituents : alkaloids and resin
Therapeutic uses : Kushtha, Prameha, Medodosha

2. Meshshringi

Latin Name : Gymnema sylvestre R. Br.

Rasa : Tikta, Kashaya

Guna : Laghu, Ruksha

Virya : Ushna

Vipaka : Katu

Karma : Dipana, Vishagna

Doshaghnata : Vata – Kaphahara

Part used : Leaves

Chemical constituents :Glucuronic acid, galacturonic acid,

Therapeutic uses : Krimi, Kustha, Prameha

3. Methika

Latin Name : Trigonellafoenum–graecum Linn

Rasa : Tikta

Guna : Snigdha

Virya : Ushna

Vipaka : Katu

Karma : Dipan, Ruchya

Doshaghnata : Kapha – Vatahara

Part used : Seeds

Chemical constituents : Alkaloid, sapogeninus, and mucilage

Therapeutic uses : Prameha, Jwara, Aruchi

4. Jambu Beej

Latin Name : Syzygium cuminii Linn.

Rasa : Madhur, Amla, Kashaya

Guna : Guru, Ruksha

Virya : Shita

Vipaka : Katu

Karma : Grahi, Vishtambhi

Doshaghnata : Kapha-Pittahara, Vatal

Part used : Seeds

Chemical constituents : Glycoside (Jambolin), Tannin, Ellegic acid and Gallic acid

Therapeutic uses : Madhumeha, Udakameha

5. Karavellaka

Latin Name : Momordica charantia Linn.

Rasa : Katu, Tikta

Guna : Laghu

Virya : Ushna

Vipaka : Katu

Karma :Bhedi, Dipana, Hridya, Raktadoshahara

Doshaghnata : Kapha - Vatahara

Part used : Fruits

Chemical constituents : Alkaloid (Momoridicine) and Glycosides

Therapeutic uses : Jwara, Kushtha, Pandu, Prameha, Raktavikara

6. Trikatu

a. Shunthi

Latin Name : Zingiber officinale Roxb.

Rasa : Katu

Guna : Laghu, Snigdha

Virya : Ushna

Vipaka : Madhura

Karma :Aamdoshahara, Anulomana, Dipan, PAchan, Hridya

Doshaghnata : Vata-Kaphaapaha

Part used : Dried rhizome

Chemical constituents : Essential oil, gingerol, shogaol, resinous matter and starch

Therapeutic uses : Agnimandya, Adhman, Pandu

b. Marich

Latin Name : Piper nigrum Linn.

Rasa : Katu, Tikta

Guna : Laghu, Ruksha, Tikhna

Virya : Ushna

Vipaka : Katu

Karma : Dipana, Chhedana, Medohara, Ruchya, Hridroga

Doshaghnata : Kapha-Vatajit, Pittakara

Part used : Dried fruits

Chemical constituents : Piperine, Chavicine, Piperidine, Piperetine and essential Oil

Therapeutic uses : Krimiroga, Twakroga

c. Pippali

Latin Name : Piper longum Linn.

Rasa : Madhur, Katu, Tikta

Guna : Laghu, Snigdha

Virya : Anushna

Vipaka : Madhur

Karma :Dipana, Hridya, Ruchya, Rasayana

Doshaghnata : Tridoshahara especially Vata-Kaphahara

Part used : Fruits

Chemical constituents : Essential oil and Alkaloids

Therapeutic uses : Kshaya, Kustha, Prameha, Aamdoshahara

7. Trivrit

Latin Name : Operculina turpethum Linn.

Rasa : Madhur, Katu, Tikta, Kashaya

Guna : Laghu, Ruksha, Tikshna

Virya : Ushna

Vipaka : Katu

Karma :Virechana

Doshaghnata : Kapha-Pitta hara, Vatala

Part used : Dried roots

Chemical constituents : Resinous Glycosides

Therapeutic uses : Jwara, Kustha, Malabandha

8. Saptarangi

Latin Name : Alstonia scholaris Linn.

Rasa : Tikta, Kashaya

Guna : Sara, Snigdha

Virya : Ushna

Vipaka : Katu

Karma :Anulomana, Dipana, Kushthagna, Jwaraghna, RaktaShodhaka

Doshaghnata : Tridoshagna

Part used : Stem bark

Chemical constituents : Alkaloids (echitemine, ditamine, echitamidine)

Therapeutic uses : Jwara, Sandrameha, Krimiroga

9. Guduchi

Latin Name : Tinospora cordifolia Willd.

Rasa : Tikta, Kashaya

Guna : Laghu

Virya : Ushna

Vipaka : Madhura

Karma :Balya, Dipana, Rasayana

Doshaghnata : Tridosha Shamak, Raktashodhaka

Part used : Stem

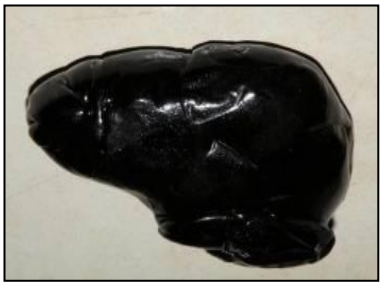
Chemical constituents : Terpenoids and alkaloids

Therapeutic uses : Jwara, Kustha, Prameha, Pandu

10. Kutaki

Latin Name	: Picrorhizakurroa Royleex. Benth.
Rasa	: Katu, Tikta
Guna	: Laghu,
Virya	:Ushna
Vipaka	: Katu
Karma	:Hridya, Dipani, Bhedini, Jwarahara
Doshaghnata	: Kapha-Pitta shamaka
Part used	: Dried Rhizome
Chemical constituents	: Picrorhizin
Therapeutic uses	: Arodhaka, Daha, Kustha

11. Shelajatu



Chemical name	: Mineral Pitch
Rasa	: Tikta, Lavan
Guna	: Laghu
Virya	: Ushna
Vipaka	:Katu
Karma	:Rasayana,
Doshaghnata	:TridoshaShamak
Therapeutic uses	:Pandu, Prameha

12. Yashad bhasma

Chemical name	: Zinc
Rasa	: Kashaya, Tikta
Guna	: Laghu
Virya	: Shita
Vipaka	:Madhur
Karma	:Chakshushya, Pramehagna, Jwaraghna
Doshaghnata	: Kapha-Pitta Shamak
Therapeutic uses	:Prameha, Jwara, Rajyakshma

13. Ashwagandha

Latin Name	: Withania somnifera Dunal.
Rasa	: Tikta, Kashaya
Guna	: Laghu
Virya	: Ushna
Vipaka	: Madhura
Karma	:Rasayana, Balya
Doshaghnata	: Vata-Kaphaapaha
Part used	: Dried root
Chemical constituents	: Alkaloida and withanolaids
Therapeutic uses	**:** Daurbalya, Klaibya

Clinical study

Aims & objects:

1. To assess the clinical efficacy and safety of Capsule Diacea in the management of Diabetes Mellitus Type – 2 (*Madhumeha*)
2. To assess the symptomatic / subjective improvement by Capsule Diacea in the management of Diabetes Mellitus type – 2

Materials & Methods:

Plan of Clinical Study:

Study type	**:** Interventional
Purpose	**:** Treatment
Masking	**:** Open label, single arm
Timing	**:** Prospective
End point	**:** Efficacy
Duration of therapy	: 3 month
No of Group	**:** One
Subjects	**:** 50 patients
Duration of the study	**:** 1 year

Selection of patients for the study:

- For the purpose, newly diagnosed case of Diabetes Mellitus and fulfilling the diagnostic and inclusion criteria and willing to give their consent to participate in the clinical trial, were selected from OPD of I.P.G.T. & RA, Hospital, Gujarat Ayurved University, Jamnagar irrespective of their sex, caste, religion, habitat.
- Known case of DM patient having uncontrolled blood sugar with current medications were also included in the trial.

Pre-treatment Observation:

After selection, all the selected patients were provided details of objectives of clinical trial and their consent were taken; such patients were registered and studied. After preliminary registration, diagnostic medical history was taken according to both Ayurveda and modern clinical methods on the basis of specially prepared Case Record Form [CRF].

Diagnostic criteria:

Person with raised blood glucose level as per WHO criteria[2] for diagnosis of Diabetes with or without symptoms of the disease were considered.

- Symptoms (such as polyuria, polydipsia, unexplained weight loss, calf muscle pain,etc.) **and**
- Fasting Blood Glucose ≥126mg./ dl **OR**
- Post Prandial Blood Sugar ≥200 mg. / dl **OR**
- HbA1C≥ A1C ≥ 6.5%.

Inclusion criteria:

1. Patients of 25 – 50 years of age in either sex.
2. Newly diagnosed case or known case of diabetes with uncontrolled blood sugar. **(Here capsule Diacea were given as an adjuvant with their current medications.)**

[2] www.who.int>diaeres>publications accessed on 18th January 2017

Exclusion criteria:

1. Patients with the major complications of Diabetes Mellitus.
2. Patients suffering from brittle diabetes mellitus.
3. Patients who have a past history of IHD, MI, Stroke etc. within the last 6 months.
4. Patient with poorly controlled Hypertension (≥160 / 100 mm Hg)
5. Patients with concurrent serious Hepatic Dysfunction, Renal Dysfunction, uncontrolled Pulmonary Dysfunction or other concurrent severe disease or Malignancy.
6. Pregnant / Lactating women.
7. Patient on steroids, oral contraceptive pills or oestrogen replacement therapy.
8. Alcoholics and/or drug abusers.
9. Patients suffering from major systemic illness necessitating long term treatment.
10. Patient with h/o hypersensitivity to trial drugs or their ingredients.
11. In the investigator's opinion, patients unlikely to comply with study procedures.

Investigations:

- Routine haematological assessment like Hb., TLC, DLC, ESR (westergreen method) as well as Urine routine and microscopic examination were carried only before starting trial drug. It was just to rule out other pathogenesis.
- Biochemical investigations:
- Fasting, PP2 blood sugar, Fasting S. Insulin. Urine sugar at interval of one month
- Lipid profile, LFT, RFT, HbA1C% - before starting and at the end of the treatment.

Drug, Dose and Duration:

Drug : DIACEA Capsule

Dose : 2 capsule twice a day (each of 650 mg.),

20 minutes before Breakfast and dinner

Anupana : Warm water

Root of Administration: Oral

Duration : 3 months

Ingredients of Capsule Diacea: as supplied by the project sponsoring agency

Do's & Don'ts: All the subjects during the course of clinical trial were advised specific diet and life style modifications which were as follow:

Do's: consumption of diet which is *Laghu, Ruksha* and bitter, astringent in taste will be advised like, use of flour of *Yava*, beans like Chana, *Kulattha, Adhaki, Mudga* vegetables which are bitter in taste or light to digest like *Gvar*, *Karela*, *Parwar*, fruits having low glycemic index like orange, apple etc. were advised. Patients were advised to have light walk for 20 minutes daily.

Don'ts: Heavy dietetic articles made from fine flour, flour of *Maasha* (black gram), curd, any other articles having Guru, *Snigdha* or *Pichchhila* property, *Viruddha Aahara* (incompatible food), sweets, cold water, cold beverages, ice creams, bakery items, daytime sleeping, excess sleep, excess of stress or complete sedentary life style was advised to be avoided.

Criteria for Assessment:

- Assessment of subjective Parameters.
- Assessment of laboratory investigations like, FBS, PP2BS, HbA1C% and S. insulin (fasting) level.
- Changes taken place in Lipid profile, Liver function as well as renal function were also noted and assessed for safety assessment purpose.

Statistical analysis: subjective criteria were assessed by Wilcoxon sign rank test whereas objective criteria were assessed by paired 't' test. **Sigma stat software** has been used for statistical analysis.

Washout period:

There were no washout period and the patients were allowed to have their medicine as it is and capsule Diacea were given as an adjuvant of the medicine.

Overall Assessment of Therapy:

It was assessed on the basis of the following criteria :

1. Excellent response -100% relief in subjective symptoms along with normal blood sugar level
2. Markedly Improved –improvement between >75 -≤99%
3. Moderately improved – improvement between >50 to ≤75%
4. Mild Improved –improvement between >25 to ≤49%
5. Unchanged-Less than 25% improvement

Ethical issues:

This clinical study has obtained Ethical clearance from the **Institutional Ethics Committee of IPGT & RA** [Ref. No. PGT/7-A/Ethics/2016-17/3794 Date: 07.02.2017]. **Informed consent** was obtained from each patient before the commencement of clinical study during enrolment phase. The study has also been registered in CTRI vide no.CTRI/2018/01/011256.

Observations:

Status of the patients:

No. of patients Screened	No. of patients Registered	No. of patients completed the trial	No. of patients Dropped out
57	54	50	04

As per above mentioned table total 57 patients were screened for the trial. Out of those total 54 patients were registered, among those 50 completed the treatment and 04 were dropped out from the study.

Reason for dropped out:

Two patients whose blood sugar did not responded in first monthly investigation as well as were not feeling well with the medicine and hence left the medicine in between whereas rest two left the treatment due to their personal reasons.

Demographic data:

Table: 01 Demographic data to 54 patients registered for the trial.

Data	Details	No. of Patients	Percentage
Age (in years)	>40 - ≤50	37	68.52 years
Gender	Male	30	55.56 %
	Female	24	44.44 %
Marital status	Married	51	94.44 %
	Divorcee	01	1.85 %
	Widow	02	3.70 %
Education	Primary	23	42.59 %
Nature of work	Hard work	21	38.9 %
	Office work	19	35.19 %
	House wife	14	25.93 %
Socio – eco. Status	Poor	12	22.22 %
	Lower middle	10	18.52 %
	Middle	29	53.70 %
	Upper middle	03	5.56 %
Area of resident	Urban	27	50 %
	Semi urban	15	27.78 %
	Slum	04	7.41 %
	Rural	08	14.81 %

Age:majority i.e. 68.52% of the patients' age was between40-50 years. Gender**:** maximum i.e. 55.56% of patients were male followed by female (44.44%).Marital status: maximum 94.44% of patients were married followed by widow (3.70%) and divorce (1.85%). Education: maximum i.e. 42.59% of the patients had only primary education. Type of work:Maximum i.e.38.9% wasdoing hard work followed by office work (35.19%) and house wife (25.93%). As far as socio economic status is concerned, maximum i.e. 53.70% of the patients were from middle class group followed by poor(22.22%) and lower middle class (18.52%). Only 5.56% of the patients were from upper middle income group.Area of resident: maximum i.e. 50% of the patients were

from urban area followed by semi-urban area (27.78%), rural area (14.81%) and slum area (7.41%).

Table: 02 Disease duration wise distributions of 54 patients of Diabetes Mellitus

Sr. No.	Chronicity	Present in No. of Pts.	Percentage
1.	0 to 6 Month	14	25.93
2.	> 6 month - 1 year	08	14.81
3.	> 1 year - 5 year	21	38.89
4.	> 5 year - 10 year	09	16.67
5.	>10 year	02	3.70
Total		54	100

As per above mentioned data, in this clinical trial maximum i.e. 38.89% patients were having disease duration between 1 to 5 year followed by 0 to 6 months (25.93%), 5 to 10 year (16.67%) and > 6 month to ≤ 1 year (14.81%), whereas 3.70% were having duration of the disease more than 10 years respectively.

Table: 03 Current medication wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Current Medications	No. of Pts.	Percentage
1.	Ayurvedic	17	31.48
2.	Allopathic	13	24.07
3.	Both	14	25.93
4.	None	10	18.51
Total		54	100

In this trial maximum i.e. 31.48% patients were already taking Ayurvedic medications for their current disease followed by Ayurvedic along with allopathic medications (25.93%) and allopathic medications (24.07%), where as 18.51% patients were not taking any medicines.

Table:04 Presence of family history wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Family History of DM	No. of Pts.	Percentage
1.	Positive	33	61.11
2.	Negative	21	38.89
Total		54	100

In present clinical trial maximum i.e. 61.11% of the patients were having positive family history for Diabetes Mellitus and 38.89% patients were having negative family history for the same.

Personal History:

Table: 05 Sleep habit wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Sleep habit	No. of Pts.	Percentage
1.	Regular	49	90.74
2.	Ir-Regular	05	09.26
Total		54	100

In this trial maximum i.e. 90.74% of the patients was having habit to go for sleep at regular time whereas on 09.26% patients' sleeping time was irregular.

Table: 06 Sleep quality wise distributions of 54 patients of Diabetes Mellitus

Sr. No.	Sleep quality	No. of Pts.	Percentage
1.	Sound	40	74.07
2.	Disturbed	14	25.93
Total		54	100

As above data shows, maximum i.e. 74.07% of the patients were having sound sleep whereas 25.93% patients were having problem of disturbed sleep.

Table: 07 Bowel habit wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Bowel habits	No. of Pts.	Percentage
1.	Regular	38	70.37
2.	Ir-regular	16	29.63
3.	Satisfactory	39	72.22
4.	Non-satisfactory	15	27.78

Out of 54 patient maximum patients (72.22%) were having satisfactory and regular (70.37%) bowel habit, where 29.63% and 27.78% of the patients were having ir-regular and non-satisfactory bowel habit respectively.

Table: 08 Food timing wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Food timing / eating habit	No. of Pts.	Percentage
1.	Regular	50	92.59
2.	Ir-regular	04	7.41
3.	Excess eating	01	1.85
4.	Frequent eating	01	1.85

As far as food timing is concerned; maximum i.e. 92.59% of the patients were taking their food at regular time, only 7.41% of the patients' food timings were irregular. Only 1.85% each were having habit of over eating and frequent eating.

Table: 09 Addiction wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Addiction	No. of Pts.	Percentage
1.	Tobacco chewing	17	31.48
2.	Smoking	02	3.70
3.	Alcohol	02	3.70
4.	Sedatives	00	--

Above data shows that in present clinical trial maximum i.e. 31.48% patients were having addiction of tobacco chewing followed by smoking and alcohol was found in 3.70% each.

Table: 10 Work nature wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Nature of work	No. of Pts.	Percentage
1.	Physical work	41	75.93
2.	Mental work	10	18.52
3.	No work	03	5.56

As per table no. 10 maximum i.e. 75.93% of the patients were doing physical work followed by mental work (18.52%).No work found in 5.56 % of the patients.

Table:11 Presence of mental stress wise distributions of 54 patients of Diabetes Mellitus

Sr. No.	Mental stress	No. of Pts.	Percentage
1.	present	39	72.22
2.	Absent	15	27.78

As per above table maximum 72.22% of the patients were having mental stress (either social, job related or family / personal problem). Only 27.78% did not have any stress.

Table: 12 Average vitals of 54 patients of Diabetes Mellitus.

Sr. No.	Vital		Average value
1.	Temperature (°F)		98.5
2.	Pulse /Min		78.4
3.	Blood Pressure (mm. of Hg.)	Systolic	127.5
		Diastolic	80.3

As per above mentioned table average temperature of the patients was 98.5·F and average pulse rate was 78.4 per minute. Both were within normal range. Average systolic and diastolic blood pressure of the patients under trial was 127.5 and 80.3 mm of Hg. respectively.

Table:13 Status of Holms-Rahe Life Stress Inventory scale in 54 patients of Diabetes Mellitus

Sr. No.	Stress Inventory scale	No. of Patients	Percentage
1.	< 150 points (low susceptibility to stress induce health problem)	38	70.37
2.	150 – 300 points (50% chances of major stress induced health problems)	16	29.63
3.	>300 (80% chances of major stress induced health problems)	00	--
Total		54	100

In this clinical trial maximum i.e. 70.37% of the subjects were having low susceptibility to stress induced health problems where as 29.63% subjects were having 50 percent chances of major stress induced health problems.

Table: 14 Chief complaints wise distribution of 54 patients of Diabetes Mellitus.

Sr. No.	Chief complaints	No. of Pts.	Percentage
1.	Polyuria	46	85.19
2.	Polydipsia	51	94.44
3.	Polyphagia	25	46.30
4.	Calf muscle pain	22	40.74
5.	Burning palm	06	11.11
6.	Burning sole	15	27.78
7.	Numbness in palm	25	46.30
8.	Dryness in mouth	32	59.26
9.	Lethargy	31	57.41
10.	Fatigue	36	66.67
11.	Excessive sweating	48	88.89

Above table data shows that maximum i.e. 94.44% subjects were having complaints of polydipsia followed by excessive sweating (88.89%), polyuria (85.19%), fatigue (66.67%), dryness in mouth (59.26%), and lethargy (57.41%). Polyphagia and numbness in palm found in 46.30% each. Claf-muscle pain was observed in 40.74% of the patients followed by burning sole (27.75%) and burning palm (11.11%).

Table: 15 Average BMI wise distributions of 54 patients of Diabetes Mellitus.

Sr. No.	Average BMI	No. of Pts.	Percentage
1.	Normal (18.5 – 24.99 Kg/m^2)	21	38.89
2.	Below normal (< 18.5 Kg./m^2)	00	--
3.	Over weight(≥25 – 29.99 Kg. / m^2)	22	40.74
4.	Obese (≥ 30 kg. / m^2)	11	20.37
Total			100

As above table shows in present clinical trial among total registered patients, 38.89% patients were having normal BMI whereas maximum i.e. 61.11% patients were either overweight or obese. None of the patients' body weight was below normal.

Table: 16 Different haematological parameters of 54 patients of Diabetes Mellitus.

Sr. No.	Laboratory investigation	Average value
1.	Haemoglobin (Gm. / dL.)	13.46
2.	TLC (per Cu.mm)	7840.74
3.	ESR (mm/1st hour)	26.8
Bio chemical investigations		
4.	FBS (mg. / dL)	197.41
5.	PP2BS (mg. / dL)	263.83
6.	S. Insulin	9.73
7.	S. Cholesterol (mg. / dL)	176.70
8.	Triglyceride (mg. / dL)	217.64
9.	HDL (mg. / dL)	38.43
10.	LDL (mg. / dL)	94.72
11.	VLDL (mg. / dL)	43.44
12.	Blood Urea (mg. / dL)	22.93
13.	S. Creatinine (mg. / dL)	1.19
14.	SGPT	24.43
15.	Alkaline Phosphates	75.24
16.	Hb.A1C%	9.30

As the table shows average haemoglobin of registered patients for the trial remained 13.46 Gm. / dL, TLC 740.74 / Cu.mm., and ESR was 26.8 mm. at the end of 1st hour.

As far as biochemical investigations are concerned, average Fasting blood sugar of the patients were 197.41 mg. / dL, whereas PP2BS was 263.83 gm. / dL Serum insulin level was 9.73 IU before starting the treatment. HbA1C% level was 9.30%. As far as lipid profile is concerned, S.Cholesterol, Triglyceride, HDL, LDL and VLDL level value was 176.70mg. / dL, 217.64mg. / dL, 38.43 mg. / dL, 94.72md. / dL and 43.44 mg. / dL respectively. Blood Urea (22.93 mg. / dL) S. Creatinine level (1.19 mg./ gL) was within normal range. SGPT and Alk. Phosphates were 24.43 and 75.24 respectively.

EFFECT OF THERAPY

Table : 17 Effect of Capsule Diacea on subjective parameters on patients of Diabetes Mellitus

symptoms	Mean		Diff.	%	SD+	SE ±	W	P	Remark
	BT	AT							
Polyuria (n=42)	1.57	0.60	0.98	62.12	0.941	0.133	-482	<0.001	HS
Polydipsia(N=49)	2.57	2.45	0.12	4.76	0.746	0.106	-55.	0.207	NS
Polyphagia(N=23)	1.17	0.22	0.96	81.48	0.760	0.108	-173.	<0.001	HS
Calf muscle pain (n=20)	1.84	0.16	1.68	91.42	1.083	0.153	-179	<0.001	HS
Burning palm n=4	1.0	00	1	100	0.274	0.039	-10	0.125	NS
Burning sole n=15	1.47	0.2	1.27	86.36	0.780	0.110	-96	<0.001	HS
Numbness n=22	1.05	0.09	0.95	91.30	0.575	0.081	-231	<0.001	HS
Dryness in mouth n=33	1.73	0.51	1.21	70.18	1.030	0.146	-411	<0.001	HS
Lethargy N=30	1.4	0.27	1.13	80.95	0.957	0.135	-336	<0.001	HS
Fatigue N=32	1.84	0.41	1.44	77.97	1.085	0.153	-366	<0.001	HS
Excess sweat n=45	2.18	0.87	1.31	60.20	1.119	0.158	-699	<0.001	HS

While going through table no.17 it reveals that, except polydipsia and burning palm; reduction in rest of all the symptoms i.e. Polyuria (62.12%), polyphagia (81.18%), calf muscle pain (91.42%), burning sole (86.36%), numbness (91.30%), dryness in mouth (70.18), lethargy (80.95%), fatigue (77.95%), excess sweat (60.20%) remained highly significant (P<0.001). Polydipsia reduced only 4.76% and remained insignificant. (P = 0.207) whereas burning palm was relieved by 100%, but remained insignificant. (P=0.125)

Table:18 Effect of Capsule Diacea on Fasting Blood Sugar level on various category patients of Diabetes Mellitus

	Mean		Different	%	SD	SE	t	P	Remarks
FBS	BT	AT							
All patients (n=50)	199.2	190.5	8.7	4.37	38.910	5.503	1.581	0.120	NS
Patients with BMI ≥ 25 (n=30)	195	182.57	12.43	6.38	43.200	7.887	1.576	0.126	NS
Patients with BMI < 25 (n=20)	205.5	202.4	3.1	1.51	31.638	7.074	0.438	0.666	NS

As per above shown table, at the end of the therapy fasting blood sugar of all 50 was reduced by 8.7%%, but the value remain statistically insignificant. (P=0.400).

After classifying the patient in normal weight and overweight patients; the sugar level reduced better (6.38%) in overweight person as compare to normal weight patients (1.51%) but again both remain insignificant.(P= 0.126 and 0.666 respectively)

Table:19 Effect of Capsule Diacea on PP2BS level on various category patients of Diabetes Mellitus

	Mean		Different	%	SD	SE	t	P	Remarks
PP2BS	BT	AT							
All the patients (n=50)	265	257.98	7.02	2.65	66.752	9.440	**0.744**	0.461	NS
Patients with BMI ≥ 25 (n=30)	253.50	229.53	23.97	9.46	57.138	10.432	**2.297**	0.029	S
Patients with BMI < 25 (n=20)	282.25	295.65	-13.4	-4.75	69.772	15.602	**-0.859**	0.401	NS

As per above shown calculation, at the end of the therapy PP2BS was reduced by 2.65%, but it remain statistically insignificant (P=0.461). While categorising the patients in normal weight and overweight, in overweight patients PP2Bs reduced by 9.46% and remain significant at level 0.029, on the contrary patients with normal BMI the PP2BS increased by 4.75% but the value remain insignificant.(P=0.401)

Table:20 Effect of S. Insulin level on blood sugar level at the end of treatment in 50 patients of Diabetes Mellitus

S. Insulin level ↓ (31)			S. Insulin level ↑ (19)		
Sugar level	**No. of Patients**	**%**	**Sugar level**	**No. of Patients.**	**%**
FBS ↓	18	58.56	**FBS ↓**	12	63.16
FBS ↑	13	41.94	**FBS ↑**	7	36.84
PP2BS ↓	18	58.56	**PP2BS ↓**	10	52.63
PP2BS ↑	13	45.16	**PP2BS ↑**	9	47.37

As per above shown table out of 50 patients, 31 patients i.e. 62% of the patients S. insulin level was reduced at the end of the therapy. Out of those patients, 58.56% patients each, fasting as well as PP2 blood sugar level was reduced whereas 41.94% and 45.16% patients' fasting and PP2 blood sugar level was found increased at the end of the therapy.

Serum insulin level was found increased in only 19 patients, out of those fasting and PP2 blood sugar level was found reduced in 63.16% and 52.63% patients respectively, whereas in 36.84% and 47.37% of the patients it was found increased respectively

Table:21 Effect of Capsule Diacea on Lipid profile on 50 patients of Diabetes Mellitus

	Mean		Different	%	SD	SE	t	P	Remarks
Lipid Profile (mg./dL)	**BT**	**AT**							
Cholesterol	177.6	178.24	-0.64	-0.36	33.168	4.691	-0.136	0.892	NS
Triglyceride	225.780	222.160	3.620	1.60	81.202	11.484	0.315	0.754	NS
HDL	37.940	39.500	-1.560	4.11	6.021	0.851	-1.832	0.073	NS
LDL	94.380	91.840	2.540	2.69	21.274	3.009	0.844	0.403	NS
VLDL	45.160	44.280	0.880	1.95	16.167	2.286	0.385	0.702	NS

As per above mentioned table, Cholesterol was increased by 0.36%, whereas Triglyceride, LDL and VLDL was decreased by 1.60%, 2.69% and 1.95% respectively. S. HDL level was increased by 4.11% at the end of the therapy. All the results remained insignificant at the level of P=0.892, 0.754, 0.403,, 0.702 and 0.073 respectively.

Table:22 Effect of Capsule Diacea on Renal Function Test (RFT) on 50 patients of Diabetes Mellitus

Renal Function Test	Mean		Different	%	SD	SE	t	P	Remarks
	BT	AT							
Blood Urea	22.760	23.420	-0.660	2.90	6.841	0.967	-0.682	0.498	NS
S. Creatinine	1.210	1.042	0.168	14	1.162	0.164	1.022	0.312	NS

As per above mentioned table at the end of the therapy, blood urea was increased by 2.90% whereas S. Creatinine level was reduced by 14%. But both the value remained statistically insignificant at p = 0.498 and 0.312 respectively.

Table :23 Effect of Capsule Diacea on Liver Function Test (LFT) on 50 patients of Diabetes Mellitus

Liver Function Test	Mean		Different	%	SD	SE	t	P	Remarks
	BT	AT							
SGPT	24.560	24.560	0	-	-	-	-	-	
Alkaline Phosphates	75.780	79.200	-3.420	4.51	19.275	2.726	-1.255	0.216	NS

At the end of the therapy, SGPT value remained same as previous, whereas Alkaline Phosphates was increased by 4.51% though it remained statistically insignificant. (P=0.216)

Table:24 Effect of Capsule Diacea on HbA1C% (Glycosylated Haemoglobin) on 50 patients of Diabetes Mellitus

	Mean		Different	%	SD	SE	t	P	Remarks
	BT	AT							
HbA1C%	9.396	8.916	0.480	5.11	1.414	0.200	2.400	0.020	S

At the end of the therapy HbA1C% was decreased by 5.11% and it remaine significant. (P=0.022)

Table:25 Effect of Capsule Diacea on weight of patients of Diabetes Mellitus

Weight in Kg.	Mean		Different	%	SD	SE	t	P	Remarks
	BT	AT							
All the patients (n=50)	69.260	67.620	1.640	2.37	1.987	0.281	5.385	<0.001	HS
Patients with BMI ≥ 25 (n=30)	74.033	71.967	2.067	2.78	1.874	0.342	6.040	<0.001	HS
Patients with BMI < 25 (n=20)	62.100	61.100	1.000	1.61	2.026	0.453	2.207	0.040	S

Above mentioned table shows that, weight of all the 50 patients was reduced by 2.37% and it remained highly significant. (P<0.001). After categorising the patients according to their BMI, highly significant improvement (P<0.001) was found in weight reduction for overweight or obese patients (2.78%) and in patients with normal weight it was reduced by 1.61% and statistically remained significant (P=0.040)

Table:26 Effect of Capsule Diacea on BMI of patients of Diabetes Mellitus

BMI (Kg/m²)	Mean		Different	%	SD	SE	t	P	Remarks
	BT	AT							
All the patients (n=50)	26.40	25.75	0.645	2.44	0.780	0.110	5.844	<0.001	HS
Patients with BMI ≥ 25 (n=30)	28.755	27.927	0.828	2.88	0.724	0.132	6.265	<0.001	HS
Patients with BMI < 25 (n=20)	22.861	22.491	0.370	1.62	0.799	0.179	2.074	0.052	NS

Above mentioned table shows that, BMI reduced in all the patients of the clinical trial by 2.44% and it remained highly significant. (P<0.001) Again after categorising the patients as per their BMI, highly significant reduction (P<0.001) was found in higher BMI patients (2.88%) whereas in patients with normal BMI (<25 Kg/M²) it reduced by 1.62% but statistically it remain insignificant (P= 0.052)

Comprehensive Assessment

Comprehensive assessment:	Subjective improvement		Overall improvement	
	No. of Patients	Percentage	No. of Patients	Percentage
Excellent response	14	28	--	--
Markedly improved	12	24	--	--
Moderately improved	15	30	10	20
Mild improved	02	04	19	38
Unchanged	06	12	11	22

Discussion:

The clinical study entitled "*Evaluation of Clinical Efficacy & Safety of Capsule Diacea in the Management of Diabetes Mellitus Type-2 (Madhumeha)*" (An open labelled single arm randomized clinical study) was aimed to assess the efficacy of a marketed

product Capsule Diacea of M/s. MB Life Science laboratory Pvt. Ltd. on Diabetes Mellitus (Type - 2) patients age between 25 to 50 years. It is a single armed study, wherein the effect of Capsule were given in Type – 2 Diabetes Mellitus patients newly diagnosed or known case of the disease having uncontrolled blood sugar with their current medications. The basic evaluation of all the patients were made as per the specially prepared CRF and investigations like Hb., TLC, DLC, ESR, to rule out other pathology, S. Insulin (Fasting), Fasting as well as Post Prandial blood sugar and Hb.A1C% to assess anti diabetic effect, Lipid profile to assess effect on fat metabolism and LFT, RFT were carried out to assess safety of the medicine.

The patients of type – 2 Diabetes Mellitus either newly diagnosed case or known case of either sex, age between 25 – 50 years recruited for the study were selected from OPD of the department of *Roga Nidan Vikriti Vigyan*, IPGT & RA, Jamnagar. All the details of the patients were recorded in the specially prepared CRF, after taking informed consent from the patients. Total of 54 patients were registered for present clinical trial out of those 50 patients completed the trial.

The general observations are presented in table format which shows that the disease Type – 2 Diabetes Mellitus can occur irrespective of gender, occupation or cast. Average age of the patients was 41 years i.e. decline phase (*Parihani Kala*) of the body as per Acharya *Shushruta*.

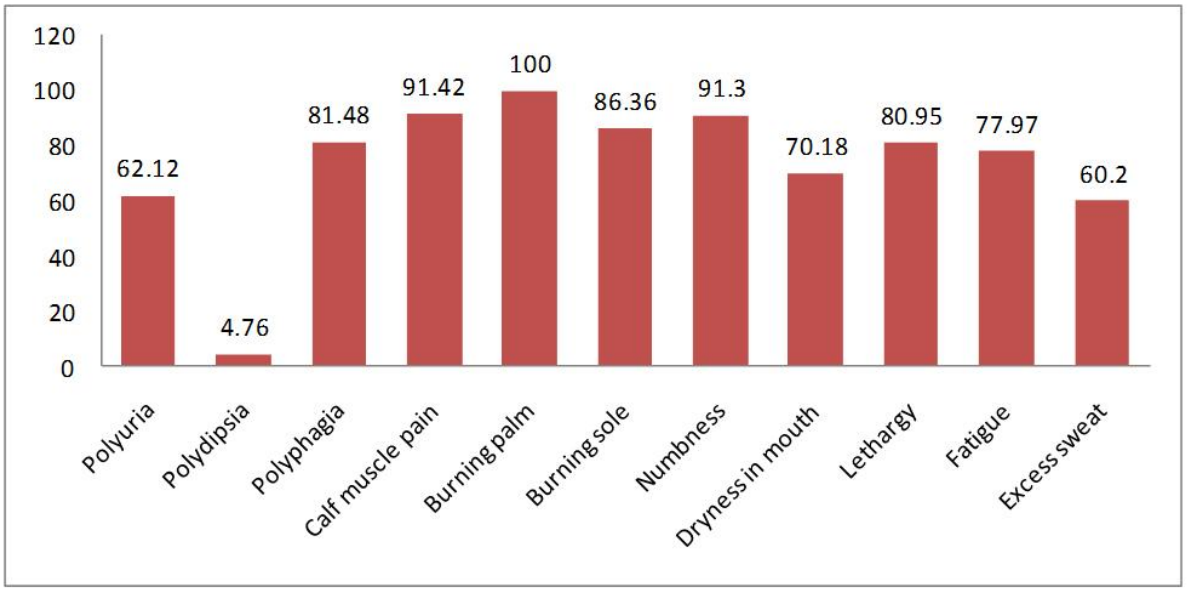
When the history of present and past illness was enquired with, it was observed that, majority of the patients were having the disease more than one year chronic that shows chronic nature of the disease. In majority of the patients positive family history was found and that shows importance of genetic predisposition of the disease. Again about 4/5 of the patient were taking either allopathic or other conservative medicines and still having uncontrolled blood sugar level as well as different symptoms of the disease were present. In majority of the patients of this trial, mental stress found positive and as per Holm and Rahe life stress inventory scale it found between 150 – 300 point i.e. those patient were having 50% chances of major stress induced health problems as stress plays major role to develop the disease and make it worsen also.

Further majority of the patients Body Mass Index (BMI) was higher than normal. They were either overweight or obese. (33 obese, 21 normal weight). As *Meda Vriddhi* and its vitiation is one of major cause for the disease diabetes.

Effect of therapy:

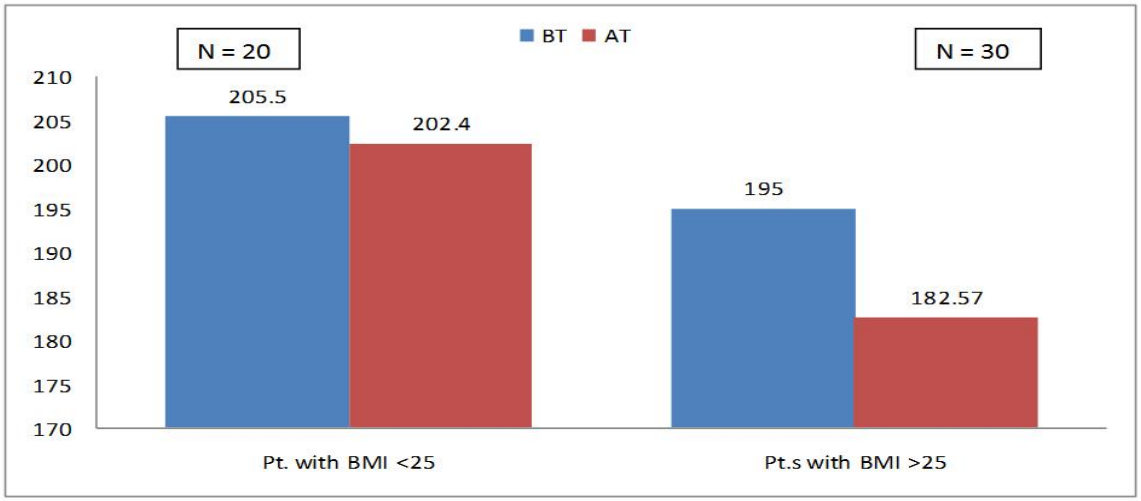
In the assessment, improvement in symptoms polyuria, polydipsia, polyphagia calf muscle pain, burning palm, excess sweating etc. were analyzed. Routine as well specific blood investigation like Fasting and Post prandial Blood sugar, S. Insulin (fasting) and glucose marker i.e. HbA1C% were analyzed.

Effect of Capsule Diacea on subjective parameter of Type – 2 Diabetes Mellitus.



All the symptoms were improved fairly at the end of the course and remained highly significant except burning palm and polydipsia. Burning palm was improved 100% but total number of patients having the symptoms was only four hence statistical analysis was not possible.

Effect of capsule Diacea on Fasting blood sugar with normal and overweight patients



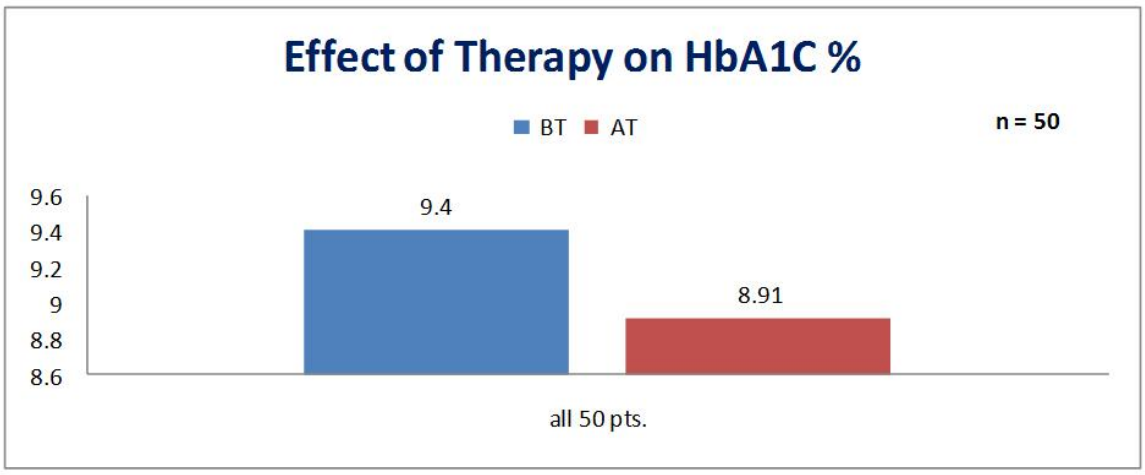
Reduction in Fasting blood sugar was only 1.5% and statistically insignificant, hence as per classical concept the patients were divided as per their body mass index. In both the category improvement in fasting blood sugar level was reduced 1.5% (patients with normal BMI) and 6.37% (in patients with BMI> 25 Kg./M^2) respectively.

Effect of capsule Diacea on PP_2BSin normal and overweight patients

Post prandial blood sugar level analyzed in two ways.

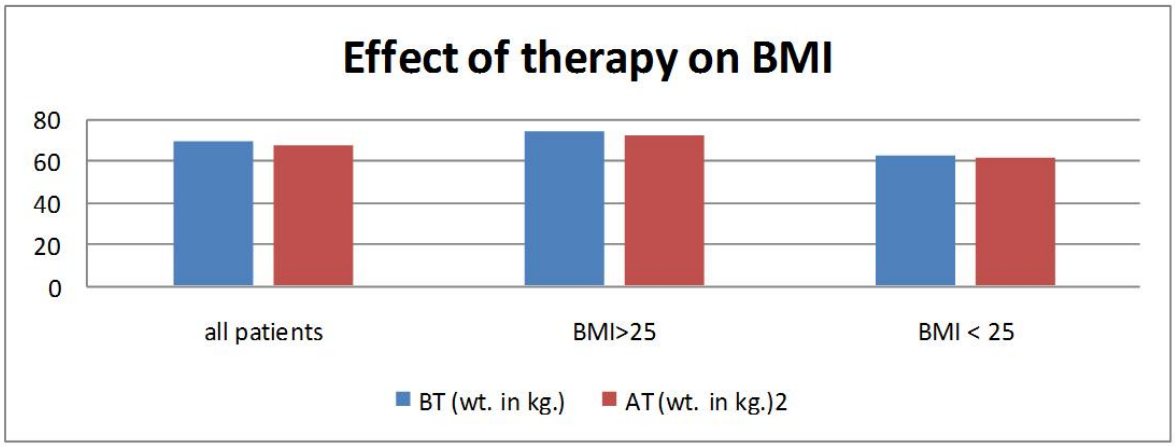
1. Reduction found in blood sugar level in all the patients together, it was only 2.65% and statistically remained insignificant.
2. After categories the patients as per their body mass index. In overweight patients, improvement in PP2BS was 9.46% and remained statistically significant too. Where as in normal weight patients the blood sugar was increased by 4.75%.

Effect of capsule Diacea on HbA1C% in normal and overweight patients



HbA1C%, the marker for blood sugar level was improved by 5.21% and remained statistically significant.

Improvement in BMI of various category patients of type – 2 Diabetes Mellitus



At the end of therapy BMI was improved by 2.44% in all the patients together, whereas in overweight it was improved by 2.88 % and both the improvement remained highly significant whereas improvement in reduction in BMI in patients of normal weight was 1.62 % and it was remained statistically insignificant.

Conclusion:

The clinical study entitled "*Evaluation of Clinical Efficacy & Safety of Capsule Diacea in the Management of Diabetes Mellitus Type-2 (Madhumeha)"* (An open labeled single arm clinical study) was aimed to assess the efficacy of a marketed product Capsule Diacea of M/s. MB Life Science laboratory Pvt. Ltd. on Diabetes Mellitus (Type - 2) patients age between 25 to 50 years. It is a single armed study, wherein the effect of Capsule were given to Type – 2 Diabetes Mellitus patients newly diagnosed or to the known case of the disease having uncontrolled blood sugar with their current medications. The basic evaluation of all the patients were made as per the specially prepared CRF and investigations like Hb., TLC, DLC, ESR, to rule out other pathology, S. Insulin (Fasting), Fasting as well as Post Prandial blood sugar and Hb.A1C% to assess anti diabetic effect, Lipid profile to assess effect on fat metabolism and LFT, RFT were carried out to assess safety of the medicine. Total 54 patients were registered and 50 completed the course. After analysing the data (subjective and objective both), the following conclusions are drawn.

In this project, internal use of Diacea capsule in a dose of 2 Cap. Twice a day before breakfast and dinner, Anupana with luke worm water for 3 months in Type -2 Diabetes Mellitus also reduced BMI in case of higher than normal shown significant result.

ADR (Adverse drug reaction):-

Any ADR was not found during the trial.