

CLINICAL TRIAL OF "DIAB V"

Evaluation of the efficacy of "DIAB V" in the management of Type 2 DIABETES"

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Reason: (HETU)

Ayurved is a science that considers any disease from its origin to its treatment. It is to prevent disease from its recurrence. This is the need of today's mankind suffering from various diseases to get treated by natural way of healing. So is our step further to use modern technology, knowledge available, diagnostic help combine with Non Toxic, Non Narcotics, Non Metallic, Non Animal ingredient, purely Herbal Ayurvedic formulations to achieve this goal.

Introduction:

The food that people eat provides the body with glucose, which is used by the cells as a source of energy. An organ called the pancreas makes insulin to control blood Glucose. Diabetes can be caused by too little insulin, resistance to insulin, or both. If insulin isn't available or doesn't work correctly to move glucose from the blood into cells, glucose will stay in the blood. High blood glucose levels are toxic, and cells that don't get glucose are lacking the fuel they need.

Causes

To understand diabetes, it is important to first understand the normal process by which food is broken down and used by the body for energy. Several things happen when food is digested:

- A sugar called glucose enters the bloodstream. Glucose is a source of fuel for the body.
- The role of insulin is to move glucose from the bloodstream into muscle, fat, and liver cells, where it can be used as fuel.
- People with diabetes have high blood sugar because their body cannot move sugar into fat, liver, and muscle cells to be stored for energy. This is because either:
 - Their pancreas does not make enough insulin
 - Their cells do not respond to insulin normally
 - Both of the above

The Facts on Diabetes

Diabetes is a condition where people don't produce enough insulin to meet their body's needs and/or their cells don't respond properly to insulin. Insulin is important because it moves glucose, a simple sugar, into the body's cells from the blood. It also has a number of other effects on metabolism.

There are two main kinds of diabetes: type 1 diabetes and type 2 diabetes. More than 90% of all people with diabetes have type 2. Overall, more than 30 million people in India have diabetes. Only about two-thirds of people with type 2 diabetes are aware of it and are receiving treatment because, for many people, early symptoms are not noticeable without testing.

Type 1 diabetes occurs when the pancreas cannot make insulin. Everyone with type 1 diabetes requires insulin injections.

Type 2 diabetes occurs when the pancreas does not make enough insulin or the body does not use insulin properly. It usually occurs in adults, although in some cases children may be affected. People with type 2 diabetes usually have a family history of this condition and are most often overweight. People with type 2 diabetes may eventually need insulin injections. This condition occurs most commonly in people of First Nations descent, Hispanics, and North Americans of African descent. Another less common form is gestational diabetes, a temporary condition that occurs during pregnancy.

Cause: (KARAN)

- Type 1 diabetes is an autoimmune disorder.
- Combination of genetic predisposition and additional factors provoke the immune system into attacking and killing the insulin-producing cells in the pancreas.
- Insulin resistance.
- Obesity
- Pregnancy
- Lack of exercise
- Excess food intake
- Excess sugar intake
- Certain medications

Predisposing factors: (NIDAN):

- Being 40 years of age or older
- blood vessel disease (e.g., damage to blood vessels in the eyes, nerves, kidneys, heart, brain, or arms and legs)
- High blood pressure
- High cholesterol
- History of gestational diabetes
- HIV infection
- Mental health disorders (e.g., bipolar disorder, depression, schizophrenia)
- Obstructive sleep apnea
- Polycystic ovary syndrome
- Prediabetes or impaired fasting glucose
- use of certain medications

Symptoms and Complications (LAKSHAN and Upadrav)

- × Weight loss despite normal or excessive food intake.
- × Persistent, mild thirst.
- × Frequent Urination
- × Fatigue
- × Blurred vision.
- × Recurring vaginal yeast infections in women.
- × Heart disease
- × High blood pressure

× Diabetic Foot

Investigations: (PARIKSHAN)

Diabetes is diagnosed with simple blood tests.

Diabetes can be diagnosed if the level of glucose in your blood after 8 hours of fasting is 100 or higher. If your fasting blood glucose is between 90 to 120, then a person may have a condition known as impaired fasting glucose or prediabetes, which may later develop into diabetes.

Diabetes can also be diagnosed using a blood test called Hb A1C (also called glycated hemoglobin), which reflects the average blood glucose levels over the past 2 to 3 months. In Diabetes the A1C level is 6.5% or greater.

Prevention: (NIDAN PARIVARJAN)

- Type 1 diabetes is not preventable.
- Type 2 diabetes can be prevented by adopting lifestyle changes that include eating a healthy diet and exercising.

More than most conditions, treating diabetes require a significant amount of real effort on the person's part. Coping with diabetes is a lifelong challenge.

In addition, some studies have shown that certain oral Ayurvedic anti diabetes medications may play a role in preventing the development of type 2 diabetes for people who are at high risk of developing it.

Lifestyle changes and medications may prevent approximately 30% to 60% of type 2 diabetes.

This prevents the symptoms of diabetes and the long-term complications of the condition.

Treatment: CHIKITSA

People with type 1 diabetes need insulin* continuously to survive.

There are three important things a person can do to treat type 2 diabetes:

- make lifestyle changes such as diet and exercise
- use medication
- monitor blood glucose levels
- Ayurvedic Medications are very effective at treating diabetes and reducing the symptoms and long-term effects of the condition.

Ayurvedic treatment: (CHIKITSA)

Apart from various drugs available in Ayurved we have selected a patented Ayurvedic herbal medicine named “DIAB V”, manufactured by “VeerHealth Care”, Ahmedabad, India.

Drug review: (AUSHADHI VIVECHAN)

Contains of DIAB V TABLET

- ✓ GUDMAR
- ✓ KARELA
- ✓ NEEM
- ✓ BEL PATRA
- ✓ METHI BIJA
- ✓ JAMBU

| Hindi Name | MG | Botanical Name | Properties |
|------------|----------|-----------------------------|--|
| GUDMAR | 83.33 mg | Gymnema sylvestre | Gudmar suppresses the taste of sweet foods and consequently reduces the desire to eat. reduces blood sugar levels. Treats problems like hyperglycemias. |
| KARELA | 83.33 mg | Momordica charantia | Bitter melon, also known as bitter gourd considered the most bitter among all fruits and vegetables. The fruit contains at least three active substances with anti-diabetic properties, including charantia, which has been confirmed to have blood glucose-lowering effect, vicine and an insulin-like compound known as polypeptide-p. |
| NEEM | 83.33 mg | Azadirachta indica | Neem contains chemicals that exerts hypoglycaemic and anti hyperglycaemic effect which help reduce blood sugar levels. |
| BELPATRA | 83.33 mg | Aegle marmelos | Belpatra is bitter and acrid. It stimulates production of bile, so is valuable in managing Diabetes and reducing excess urination. It is a restorative and increases body's resistance and immunity. |
| METHI BIJA | 83.33 mg | Trigonella foenum - graecum | Fenugreek seeds are rich source of trigonelline, lysine and l-tryptophan. The seeds also contain a large amount of saponins and An unusual amino acid (4HO-Ile), so far found only in fenugreek, has possible anti- |

| | | | |
|-------|----------|-----------------|--|
| | | | diabetic properties such as enhancing insulin secretion under hyperglycemic conditions, and increasing insulin sensitivity |
| JAMBU | 83.33 mg | Syzygium cumini | Jamun is used for diabetes and diseases of the pancreas. It contains oleanolic acid which is used to treat diabetes because it quickly reduces blood sugar |

Method:

The clinical study was planned by **VAIDYA VINOD C MEHTA, BAMS (MUMBAI UNI)** and **DR MANAN V MEHTA, MBBS (MUMBAI UNI)**, in and around Mumbai and Ahmedabad.

Plan of Study:

The study was planned by the doctors and volunteers to evaluate the clinical efficacy of “DIAB V” Tablet in the management of Diabetes.

Inclusion criteria:

Patients suffering from Diabetes, at least from 6 or more months.

Exclusion criteria:

Patients with severe dehydration, Toxic symptoms, sub or unconscious, Renal failure, sever hypoglycaemia, Old Age, Pregnant woman, children below 12 years.

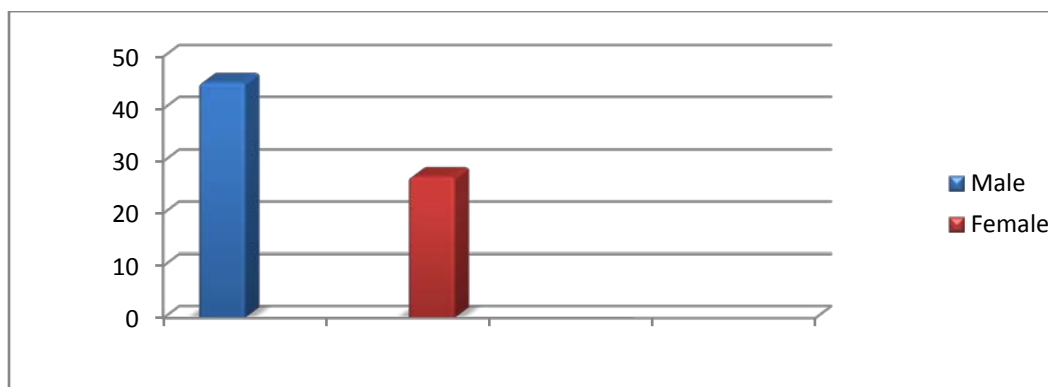
Study procedure:

Total 72 patients were selected for the study.

Each patient's complete medical history including personal data, a description of symptoms was taken. All the patients underwent a thorough clinical and pathological examination.

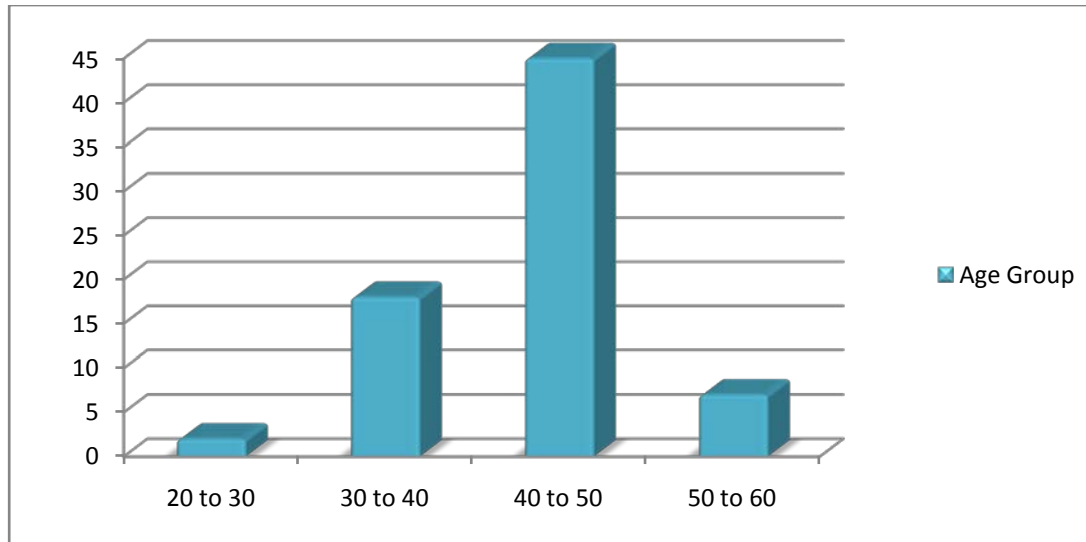
Gender:

| | |
|---------------|----|
| Male | 45 |
| Female | 27 |
| Total | 72 |

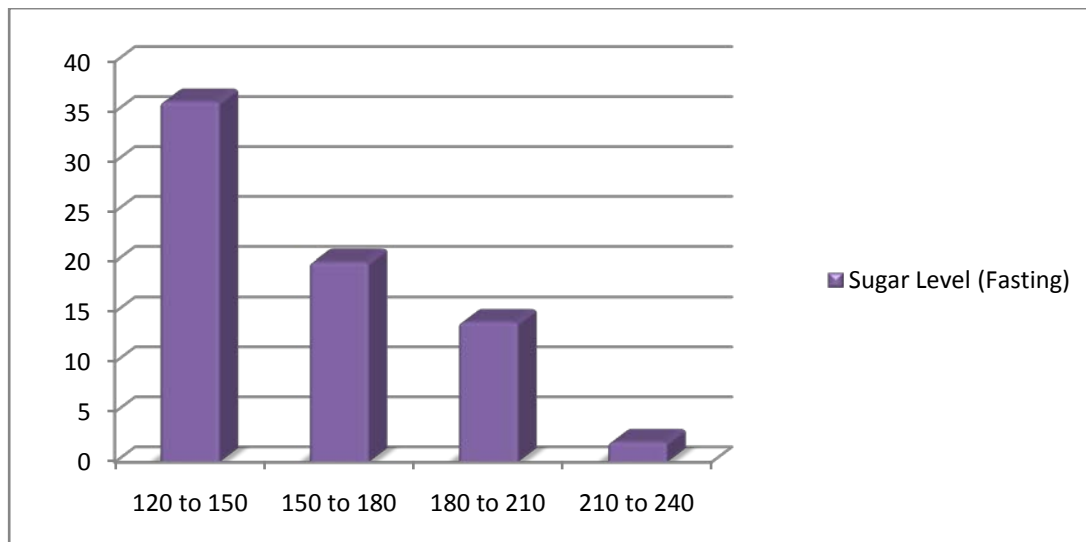


Age:

| | |
|-----------------|----|
| 20 to 30 | 2 |
| 30 to 40 | 18 |
| 40 to 50 | 45 |
| 50 to 60 | 7 |
| Total | 72 |

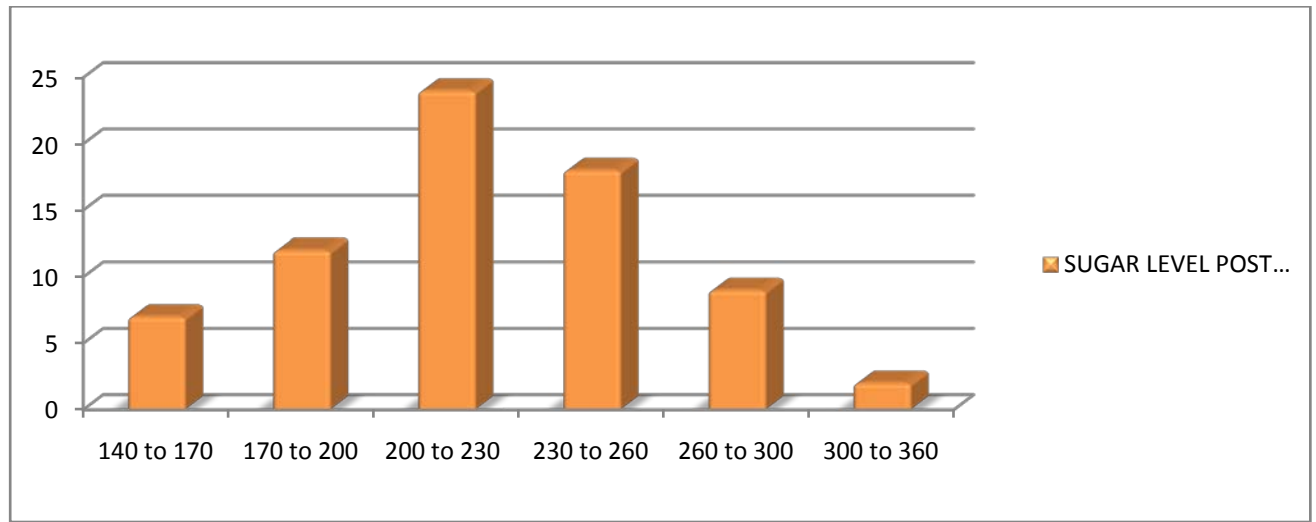
**SYMPTOMS: SUGAR LEVEL FASTING**

| | |
|-------------------|----|
| 120 TO 150 | 36 |
| 150 TO 180 | 20 |
| 180 TO 210 | 14 |
| 210 TO 240 | 2 |
| TOTAL | 72 |



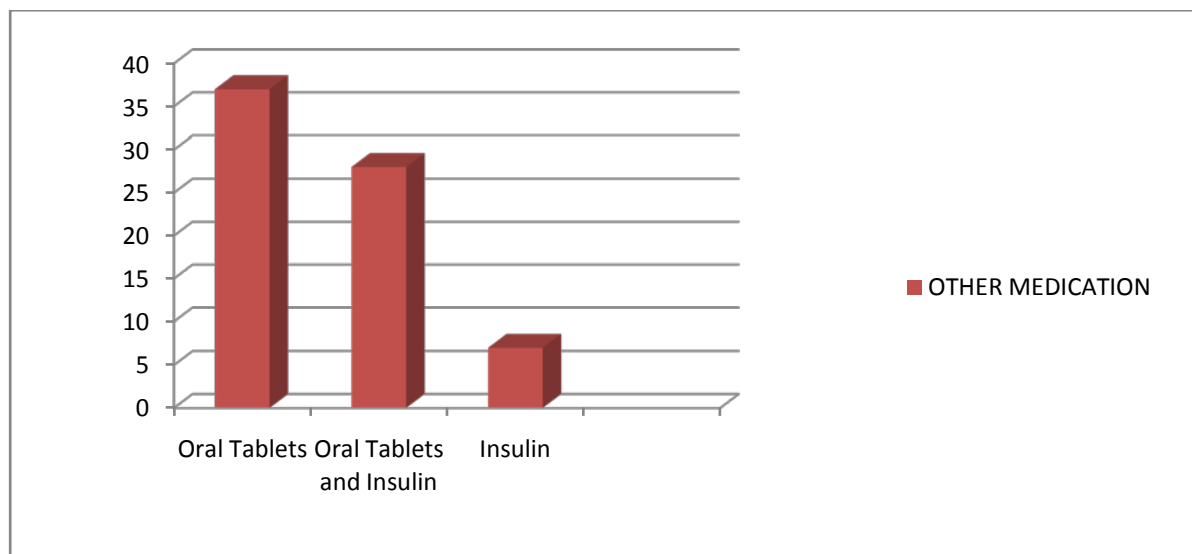
SYMPTOMS: SUGAR LEVEL POST LUNCH

| | |
|--------------|-----------|
| 140 TO 170 | 7 |
| 170 TO 200 | 12 |
| 200 TO 230 | 24 |
| 230 TO 260 | 18 |
| 260 TO 300 | 9 |
| 300 TO 360 | 2 |
| TOTAL | 72 |



OTHER MEDICATION

| | |
|--------------------------|-----------|
| ORAL TABLETS | 37 |
| ORAL TABLETS AND INSULIN | 28 |
| INSULIN | 7 |
| TOTAL | 72 |



Dosage:

2 tablets of "DIAB V" were given to every one 2 times a day. with water, after Lunch and After Dinner.

Health Plan: (VIHAR)

Physical activity is crucial for a person with diabetes

- it helps control blood glucose
 - it helps keep weight down
 - it helps keep blood pressure down
 - it helps raise good cholesterol levels
 - it helps lower bad cholesterol levels
- Fast walking
 - Swimming
 - Cycling 5-10 km/ph
 - Dancing
 - Regular exercise, 5 days of 30 minutes was prescribed.
 - Joining gym was advised, with proper track of speed, heart rate, calories burnt per minute/hour, their progress, etc.

Diet (AHAR): To have: (PATHYA)

Three things were explained to patients.

- What they eat
- How much they eat
- When they eat
- A diet plan was tailored according to patients Sugar level, weight, age and gender.
- At the base there are foods rich in carbohydrates, such as grains, fruit and vegetables, Fibre, Dark green leafy vegetables was suggested.
- Carbohydrates 45% to 65%
- Proteins 15% to 20%
- Fats 10% to 20 %

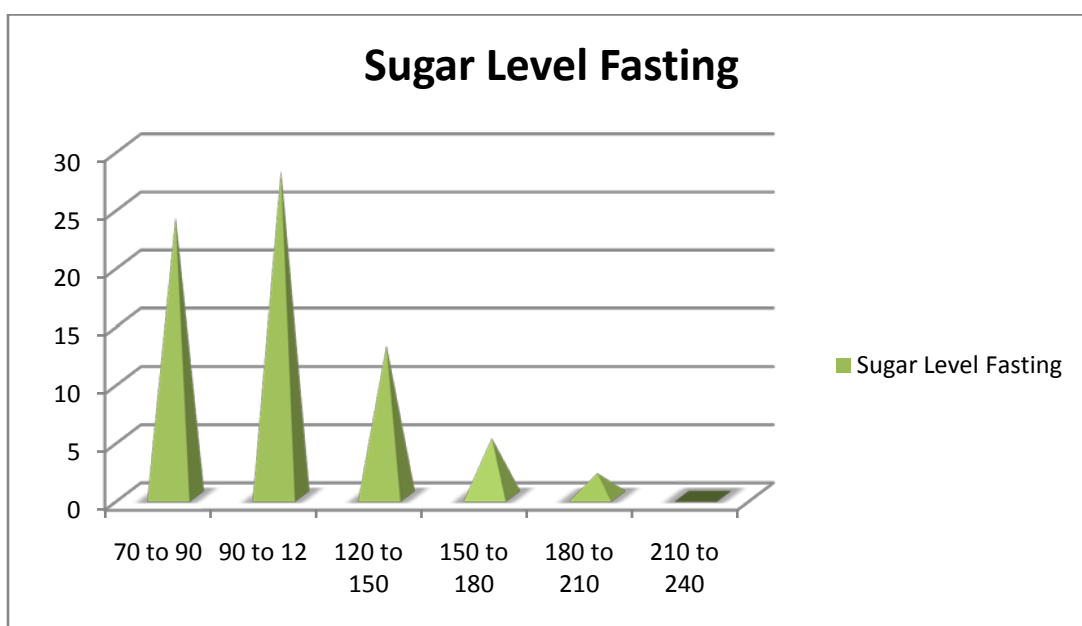
Diet not to have: (APATHYA)

- Sweets, Sugar
- Eggs, Fish, Mutton, Chicken
- Fried, stalled food
- Outside eatables
- Curd, Buttermilk
- Mava Sweets
- Cheese, Butter

Assessment of result: (UPSHAY) after administration of DIAB V for 30 days, the following result was achieved.

Symptoms: Sugar Level Fasting

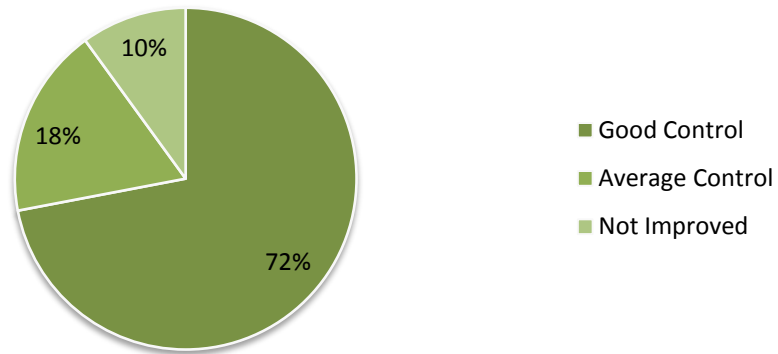
| | |
|-------------------|----|
| 70 TO 90 | 24 |
| 90 TO 120 | 28 |
| 120 TO 150 | 13 |
| 150 TO 180 | 5 |
| 180 TO 210 | 2 |
| 210 TO 240 | 0 |
| TOTAL | 72 |



Average Control Fasting

| | |
|------------------------|-------|
| GOOD CONTROL | 72 % |
| AVERAGE CONTROL | 18 % |
| NOT IMPROVED | 10 % |
| Total | 100 % |

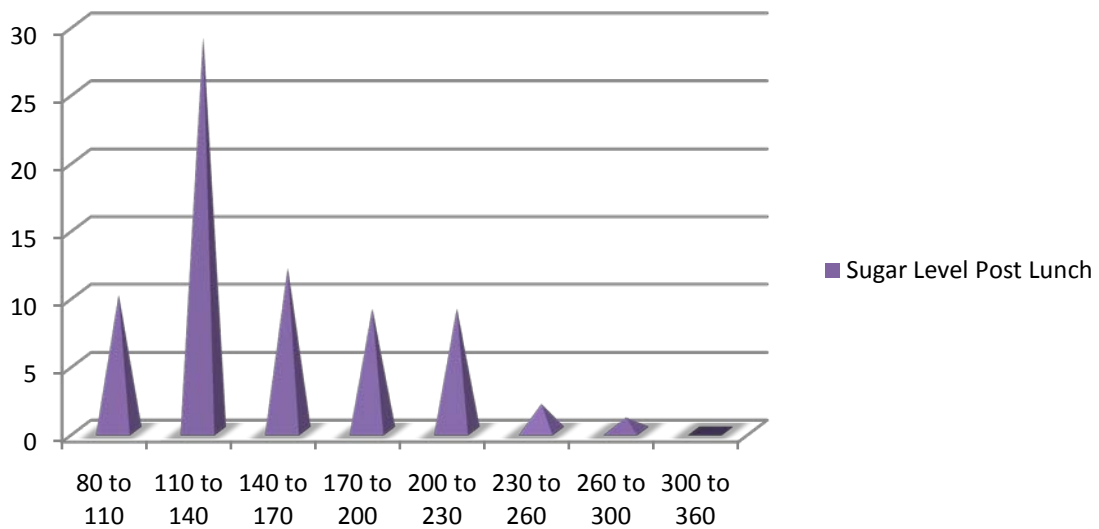
Average Control Fasting



Symptoms: Sugar Level Post Lunch

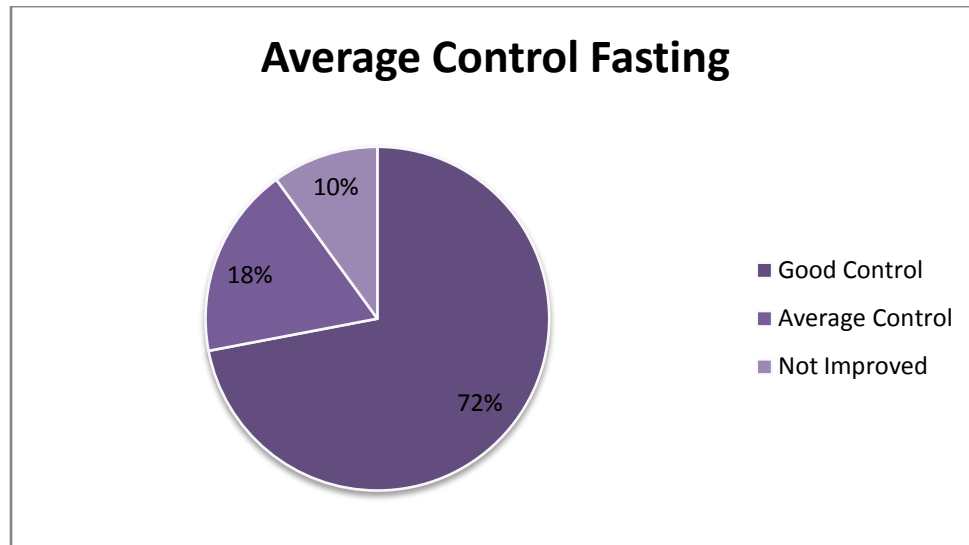
| | |
|--------------|-----------|
| 80 TO 110 | 10 |
| 110 TO 140 | 29 |
| 140 TO 170 | 12 |
| 170 TO 200 | 9 |
| 200 TO 230 | 9 |
| 230 TO 260 | 2 |
| 260 TO 300 | 1 |
| 300 TO 360 | 0 |
| TOTAL | 72 |

Sugar Level Post Lunch



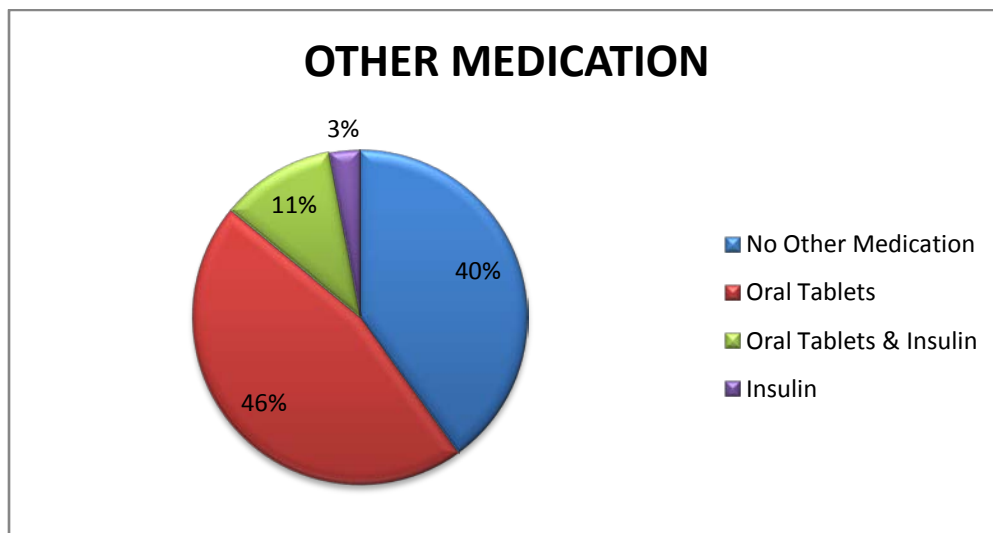
Average Control Post Lunch

| | |
|------------------------|-------|
| GOOD CONTROL | 54 % |
| AVERAGE CONTROL | 30 % |
| NOT IMPROVED | 16% |
| Total | 100 % |



OTHER MEDICATION

| | | |
|---------------------------------|----|-------|
| NO OTHER MEDICATION | 29 | 40 % |
| ORAL TABLETS | 33 | 46 % |
| ORAL TABLETS AND INSULIN | 8 | 11 % |
| INSULIN | 2 | 3 % |
| TOTAL | 72 | 100 % |



Conclusion:

According to result data it is established that "DIAB V" is effective in curing fasting and post lunch Diabetes in 63 % of patients, shown average control in 24% and was not found effective in 13 %. 40 % patients became independent of any other medications.