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# Study To Evaluate The Add On Effect Of *Atasi* On Type 2 Diabetes Mellitus

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**ABSTRACT:** Diabetes is a silent killer affecting millions and millions of people and poses a grave threat to the earth's population. Previously Diabetes has considered as a disorder of elderly, now a day's status has changed, and it has become a major cause of morbidity and mortality affecting the youth and middle aged people. On etiological basis Diabetes has classified into two main types as type 1 and type 2. Type -2 Diabetes Mellitus is a metabolic disorder presented by Hyperglycemia due to defects in insulin secretion, action or both. Both forms of Diabetes can lead to several microvascular and macrovascular multisystem complications. One way to keep diabetes and its complications under control is; early detection of the disease and to adopt the healthy lifestyle. W.H.O. emphasizes on the using of traditional drugs with the lowest side effects to control Diabetes symptoms. Ayurvedic literature explains it under the heading of *Prameha/Madhumeha. Madhumeha* (subtype of *Vataj Prameha*) is a disease which resembles with Diabetes Mellitus. Type 2 Diabetes Mellitus is mainly associated with *Avaranjanya samprapti* and *sthool pramehi* or *Apathyanimittaja Pramehi* can be correlated to patients of Type 2 Diabetes Mellitus. Acharya *Sushrutha* and *Charaka* emphasized the importance of diet and exercise in the management of Diabetes. Both has mentioned that patients of Diabetes should take the diet combined with Flaxseed oil (C.Chi.6/20, S. Chi.31/5) and several researches also proved the positive effect of *Atasi* on inflammation, glycemic control and oxidative stress. Thus for present study *Atasi* has selected and clinical trial was conducted on 60 patients of Type 2 D.M. for 45 days. These patients were divided into 2 groups as group A (*Atasi*) and group B (Placebo). After 45 days, results showed significant improvement on subjective and objective parameters in group A i.e. *Atasi* group

**Keywords:-** *Atasi Beej,* Diabetes, Diet, Hyperglycemia, *Madhumeha*

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## INTRODUCTION:

Diabetes is a silent killer affecting millions and millions of people and poses a grave threat to the earth's population. It is a lifestyle disorder, gaining the status of a potential epidemic in India. Previously Diabetes has considered as a disorder of elderly, now a day's status has changed and it has become a major cause of morbidity and mortality affecting the youth and middle aged people.[1] On aetiological basis Diabetes has classified into two main types as type 1 and type 2. Type -2 Diabetes Mellitus is a metabolic disorder presented by Hyperglycemia due to defects in insulin secretion, action or both. It alters metabolism of Carbohydrates, proteins and fat in the body. Both forms of Diabetes can lead to several microvascular and macrovascular multisystem complications. One way to keep diabetes and its complications under control is; early detection of the disease and to adopt the healthy lifestyle. W.H.O. emphasizes on the using of traditional drugs with the lowest side effects to control Diabetes symptoms. Ayurvedic literature explain it under the heading of *Prameha/ Madhumeha*. *Madhumeha* (subtype of *Vataj Prameha*) is a disease which resembles with Diabetes Mellitus. Type 2 Diabetes Mellitus is mainly associated with *Avaranjanya samprapti* and *sthool pramehi* or *Apathyanimittaja Pramehi* can be correlated to patients of Type 2 Diabetes Mellitus. *Acharya Sushrutha* and *Charaka* emphasized the importance of diet and exercise in the management of Diabetes. Both has mentioned that patients of Diabetes should take the diet combined with Flaxseed oil (C.Chi.6/20, S. Chi.31/5). Several researches also proved the positive effect of *Atasi* on inflammation, glycemic

control and oxidative stress. By keeping all this fact in mind for the present study *Atasi* has selected and clinical trial was done on 60 patients of Type 2 D.M.

## AIM AND OBJECTIVES

To evaluate the efficacy of Flaxseed on Blood Sugar level in Type2Diabetes Mellitus cases.

## MATERIALS AND METHOD:

### PLAN OF STUDY

Diagnosed patients of Type2 D.M. were selected from OPD and IPD of Department of *Swasthavritta, Panchakarma, Kayachikitsa* of Pt. Khushilal Sharma Govt. (Auto.) Ayurveda College and Institute Bhopal, M.P. The selected subjects those who are already under the treatment and taking modern oral hypoglycemic drug will be considered for intervention. It would be advised to patient to continue same oral hypoglycemic drug with same dose as was before the initiation of present trial regimen.

**Inclusion criteria**

1. The patients of Age group between 25-60 years.
2. Both sex patients were be included.

**Exclusion criteria**

1. Patients below the Age 25years and above 60 years.
2. Patients with Type l Diabetes Mellitus.
3. Patients having secondary Diabetes Mellitus.
4. Patients suffering from any severe systemic illness.

**STUDY DESIGN:**

This study will be designed as a clinical study and the sample will be selected and divided into two groups with simple random sampling technique.

**SAMPLE SIZE:** Total 60 patients (30 patients in each group).

**Group A:** Flaxseed Group

Patients of this group will be advised 6 gm Flaxseed twice daily after meal.

**Group B:** Control Group

Patients of this group were advised wheat flour placebo capsule in BD dose.

**Duration of study**- 45 days.

The result has analyzed by calculating **Wilcoxon matched-pairs signed-ranks test, Mann- Witney U-statistic, paired and unpaired t test**. Graph Pad InStat-3 software was used for statistical analysis.

**Subjective Assessment:** Subjective analysis is based on **10 Clinical symptoms, which** name is mention below.

1. ***PrabhutaMutrata*** **[Polyuria]**
2. ***AavilaMutrata*** **[Turbidity of Urine]**
3. ***Kshudaadhikya*** **(Polyphagia)**
4. ***Trishnaadhikya*** **(Polydipsia)**
5. ***Gala-taalu Shosha*** **(Dryness of mouth)**
6. ***Kara-padatala Daha*** **(Burning sensation in palms & sole)**
7. ***Daurbalya*** **(General Weakness)**
8. ***Atisweda*** **(Perspiration)**

For the assessment, the clinical symptoms which so ever presented by the patients, were graded into four grades (0-3scale) on the basis of severity, before and after the completion of treatment plan.

**Grading:**

| | |
|---|---|
| 0 | No complaint |
| 1 | Presence of mild complaint |
| 2 | Presence of moderate complaint |
| 3 | Presence of severe complaint |

## Objective Assessment:

Objective assessment was done on the following basis

- Blood Sugar Fasting (8hr)
- Blood Sugar Post prandial after 2 hours.

## OBSERVATIONS AND RESULT:

In this present study total 60 patients of *Prameha* were registered, out of which 46 patients completed the course of treatment and 14 patients discontinued before the completion of treatment course. (Table No. 1). In group A, 21 patients have completed the course of treatment out of 30 patients and In group B, 25 patients have completed the course of treatment out of 30 patients.

1. In this study majority of the patients 43.33 % were reported in the age group of 51– 60 years followed by 33.33 % in the age group of 41 - 50 years.(Table No. 2)
2. In the present study maximum i.e. 98.33% of patients were Hindu, where as 1.66% of patients were Muslim.(Table No. 3)
3. In the present study maximum i.e. 96.66% of patients were married, where as 3.33% of patients were unmarried.(Table No. 4)
4. On considering the nature of occupation, it was found that maximum i.e. 60% patients were doing Desk work. 21.66 % were belongs to field with physical where as 18.33 % patients were concern to field with intellectual work.(Table No. 5)

5. In the present study maximum number of patients 65% were belonging to vegetarian and 35% patients were taking mixed diet(Table No. 6)

**Effect of therapy on Symptoms -** (Table No.7)

On intra group comparison of group A, mean difference of all the symptoms except Avila *Mutrata* before treatment and after treatment was found statistically extremely significant, very significant and significant which suggests that *ATASI* group is effective in relieving the symptoms. On intra group comparison of group B, mean difference of all the symptoms except *prabhutamutrata* before treatment and after treatment was found statistically insignificant. This suggests that *placebo* group is not effective in relieving the symptoms.

On inter group comparison, on the basis of M.D. of both the groups we can inferred that group A is better than group B.(Table 7)

**Blood sugar level**

In group A, on intra group comparison statistically mean difference of FBS before treatment and after treatment was found very significant, which indicates that *ATASI* is effective in improvement of FBS. On intra group comparison in group B, statistically mean difference of FBS before treatment and after treatment was found not significant.

On inter group comparison of group A and group B, on the basis of M.D. of both the groups, we can inferred that improvement of FBS in Group A is better than Group B.

On intra group comparison of group A, statistically mean difference of PPBS before treatment and after treatment was found extremely significant, which indicates that *ATASI* is effective in improvement of PPBS. On intra group comparison of group B statistically mean difference of PPBS before treatment and after treatment was found not significant.

On inter group comparison of group A and group B, on the basis of M.D. of both the groups; it inferred that improvement of PPBS in Group A is better than Group B.( Table No.8-9)

Above observations indicates that flaxseed group provided better relief to patients in comparison to placebo capsule.

**Table No. 1 Distribution of Patients of *Prameha.***

| Status of treatment | Group A | Group B | Total |
|---|---|---|---|
| **Registered** | 30 | 30 | 60 |
| **Discontinued** | 9 | 5 | 14 |
| **Completed** | 21 | 25 | 46 |

**DEMOGRAPHIC DATA:**

**Table No. 2 Age wise distribution of Patients.**

| Age (in year) | No. of Patients | Percentage (%) |
|---|---|---|
| **25-40** | 14 | 23.33 |
| **41-50** | 20 | 33.33 |
| **51-60** | 26 | 43.33 |
| **Total** | 60 | 100 |

**Table No.3 Religion wise distribution Patients**

| Religion | No. of Patients | Percentage (%) |
|---|---|---|
| **Hindu** | 59 | 98.33 |
| **Muslim** | 1 | 1.66 |
| **Sikkha** | 0 | 0 |
| **Jain** | 0 | 0 |
| **Christian** | 0 | 0 |
| **Total** | 60 | 100 |

**Table No. 4 Marital status wise distribution of Patients.**

| Marital status | No. of Patients | Percentage (%) |
|---|---|---|
| **Married** | 58 | 96.66 |
| **Unmarried** | 2 | 3.33 |
| **Total** | 60 | 100 |

**Table No. 5 Occupation wise distribution of Patients**

| Occupation | No. of Patients | Percentage (%) |
|---|---|---|
| **Desk work** | 36 | 60.00 |
| **Field with physical** | 13 | 21.66 |
| **Field with intellectual** | 11 | 18.33 |
| **Total** | 60 | 100 |

**Table No. 6 *Ahara* wise distribution of patients**

| *Ahara* | No. of Patients | Percentage (%) |
|---|---|---|
| **Vegetarian** | **39** | **65** |
| **Mixed(Veg.+Nonveg)** | **21** | **35** |
| **Total** | **60** | **100** |

**Table No. 7 Effect of treatment on Symptoms.**

| Sign and Symptoms | Group | Mean | | MD | % Relif | SD | SE | Wilcoxon matched-pairs signed & p value |
|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | |
| *Prabhut Mutrata* (Polyuria) | A (n=21) | 1.1900 | 0.6190 | 0.5714 | 47.98 | 0.5976 | 0.1304 | W=66, N=11 P=0.0005,ES*** |
| | B (n=25) | 0.9600 | 0.7600 | 0.2000 | 20.83 | 0.4082 | 0.0816 | W=15, N=5 P=0.0313,S* |
| | Mann- Witney U-statistic = 145, p = 0.0534, NS | | | | | | | |
| *Avil Mutrata* (Turbidity of Urine) | A (n=21) | 0.3810 | 0.2381 | 0.1429 | 37.27 | 0.3586 | 0.0782 | W=6, N=3 P=0.1250,NS |
| | B (n=25) | 0.2400 | 0.2800 | 0.0400 | 10 | 0.3512 | 0.0702 | W= 2, N=3 P= 0.3750,NS |
| | Mann- Witney U-statistic = 220.50, p = 0.9895, NS | | | | | | | |
| *Kshudha Adhikya* (Polyphagia) | A (n=21) | 1.286 | 0.4762 | 0.8095 | 62.94 | 0.7496 | 0.1636 | W=91, N=13 P=0.0001,ES*** |
| | B (n=25) | 1.160 | 1.040 | 0.1200 | 10.34 | 0.7257 | 0.1451 | W=21, N=13 p=0.2487, NS |
| | Mann- Witney U-statistic = 127.50 , p = 0.0187 S* | | | | | | | |
| *Trushna Adhikya* (Polydipsia) | A (n=21) | 1.476 | 0.7619 | 0.7143 | 48.39 | 0.7171 | 0.1565 | W=78, N=12 P=0.0002,ES*** |
| | B (n=25) | 1.040 | 0.9600 | 0.0800 | 7.69 | 0.2769 | 0.0553 | W=3, N=2 P=0.2500, NS |
| | Mann- Witney U-statistic = 103.5, p =0.0026 VS** | | | | | | | |
| *Gal-Talu Shosh* | A (n=21) | 0.7143 | 0.2857 | 0.4286 | 60.00 | 0.6761 | 0.1475 | W=28, N=7 P=0.0078,VS** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| (Dryness of mouth) | B (n=25) | 0.9600 | 0.9200 | 0.0400 | 4.16 | 0.2000 | 0.0400 | W=1, N=1 P=0.5000,NS |
| | Mann- Witney U-statistic = 156.5, p = 0.0953 NS | | | | | | | |
| *Kar-Pad daha* (Burning sensation in palms & sole) | A (n=21) | 0.6190 | 0.3333 | 0.2857 | 46.15 | 0.4629 | 0.1010 | W=21, N=14 P=0.0156,S* |
| | B (n=25) | 1.040 | 1.000 | 0.0400 | 3.84 | 0.0400 | 0.6758 | W= 6, N=11 P=0.4155, NS |
| | Mann- Witney U-statistic = 122.50, p = 0.0131 S* | | | | | | | |
| *Daurbalya* (General debility) | A (n=21) | 0.8095 | 0.4286 | 0.3810 | 47.06 | 0.4976 | 0.1086 | W=36, N=8 P=0.0039,VS** |
| | B (n=25) | 1.040 | 0.7600 | 0.2800 | 26.92 | 0.5416 | 0.1083 | W=35, N=9 P=0.0195,NS |
| | Mann- Witney U-statistic = 210, p = 0.7974 NS | | | | | | | |
| *Atisweda* (Exessive Perspiration) | A (n=21) | 0.8095 | 0.3810 | 0.4286 | 52.94 | 0.5976 | 0.1304 | W=36, N=8 P=0.0039,VS** |
| | B (n=25) | 0.8800 | 0.7600 | 0.1200 | 13.63 | 0.3317 | 0.06633 | W=6, N=3 p=0.1250,NS |
| | Mann-Witney U-statistic = 156.50,p=0.0976 NS | | | | | | | |

**NOTE: p <0.0001 ES ****, p = 0.0001 to 0.001 ES ***, p = 0.001 to 0.01 VS **, P= 0.01 to 0.05 S*, p >0.05 NS**

**Table No. 8 Effect on FBS**

| Group | Mean | | MD | SD | SE | Paired t test | p value |
|---|---|---|---|---|---|---|---|
| | BT | AT | | | | | |
| **A** (n=21) | 170.17 | 149.45 | 20.714 | 32.832 | 7.165 | t=2.891 | p=0.0045, VS** |
| **B** (n=25) | 147.27 | 149.11 | -1.839 | 21.742 | 4.264 | t=0.4313 | p=0.3350, NS |
| **Unpaired t test** p=0.0020 , t =3.313 VS** | | | | | | | |

**NOTE: p=0.001 to 0.01** VS**,**p >0.05 NS**

**Table No. 9 Effect on PPBS**

| Group | Mean | | MD | SD | SE | Paired t test | p value |
|---|---|---|---|---|---|---|---|
| | BT | AT | | | | | |
| **A** (n=21) | 245.14 | 192.21 | 52.932 | 66.333 | 14.142 | t=3.743 | P=0.0006, ES*** |
| **B** (n=25) | 211.88 | 206.98 | 4.900 | 43.498 | 8.531 | t=0.574 | p=0.2854, NS |
| **Unpaired t test** p=0.0030 , t =3.158 VS** | | | | | | | |

**NOTE: p =0.0001 to 0.001** VS **, **P>0.05 NS**

## DISCUSSION:

In group A significant reduction was found in all symptoms like *Prabhut Mutrata, Kshudha Adhikya, Trushna Adhikya, Gal-Talu Shosha, Kar-Pad daha, Daurbalya, Atisweda* except *Avil Mutrata.* While in group B significant reduction was not found in all symptoms except *Prabhuta Mutrata*. (Table No.7)

**Possible Justification for effect of therapy on symptoms-**

Due to "*Bahudrava: shleshma dosha vishesha*:" in prameha, excessive formation of *Kleda* and *Ama* in the body causes increased frequency and quantity of urination. Atasi due to water binding property and madhurtikta rasa, katuvipaka and ushnaveeryaacts as Kleda, Meda, Shlesmashoshaka.Thus, reduces the symptom ***PrabhutaMutrata.*** In Diabetes Mellitus, obstruction of channel through Kapha and Medadhatu produces Vatavriddhi, which is responsible for Kshudh Adhikya. Atasi has Vatashamak property and due to high fiber content it helps to stop cravings. Thus, subsides ***kshudh Adhikya. Trushna Adhikya and Gal-Talu Shosha*** are the result of excessive excretion of Drava dhatu through Prabhuta Mutrata. Atasi has Picchila, Guru, Snigdhaguna and reduces Prabhuta Mutrata simultaneously improve ***Pipasa Adhikya and Gal-Talu Shosha Daurbalya*** is produced due to inadequate nourishment of Dhatu. Flaxseeds has the rich source of omega-3 fatty acid, alpha- linolenic acid, short chain polyunsaturated fatty acid, soluble and insoluble fibers, proteins and antioxidants which gives the adequate nourishment of the Dhatu hence cure the *Daurbalya.* Due to the Antioxidant, Anti inflammatory, Anti obesity properties of flaxseed and their effects on the oxidative stress this might be responsible for reduction of ***Atisweda***.

**Effect of therapy on Blood sugar**

In Group A significant reduction was found in FBS and PPBS. While in group B insignificant reduction was found in FBS and PPBS. Reduction of blood sugar level could be due to lower content of glycaemic carbohydrates and higher content of dietary fibers of flaxseeds.[2] (Table No.8-9)

**PROBABLE MODE OF ACTION OF THERAPY**

1. *Tikta ras and Katu Vipaka* improves *jatharagni* and corrects digestion and metabolism.
2. Due to Guru, Snigdhaguna, Madhur rasa and Ushna Veerya it pacifies Vata.
3. Because of Madhur, Tikta rasa and Guru guna it pacifies Pitta.

Due to Tikta rasa, Katu Vipaka and Ushna Veerya it cleans the shrotas, alleviates Kapha dosha and corrects *Medadhatu dushti*. Thus, relieves the symptoms of Prameha. Flaxseeds are rich source of ALA (Omega-3 fatty acid). dietary fibers, high quality proteins, antioxidants and Lignans. It also contains almost no digestible or glycemic carbohydrates. Various studies proved its hypoglycemic, hypolipidemic, antihypertensive, antioxidant, antifungal,

anticancer and anti-inflammatory properties.[3]

The exact mechanism by which flaxseed exerts its effect on glycemic control is not known. but the possible explanation is as follows-

1. Flax has 3 fibers insoluble, soluble and mucilage fiber (a type of soluble fiber).These fibers fill up the stomach and take long time to digest. Soluble fiber slows down the absorption of glucose and helps the body to manage glucose levels and insulin production smoothly. Thus, flaxseed help to reduces obesity and improve glycemic control.[4]
2. Lignin (SDG) present in flaxseed has strong antioxidant property which attributes to decreased inflammation and insulin resistance. Thus responsible for delaying the development of Diabetes Mellitus.[5]
3. Omega-3 fatty acid present in flaxseed is also associated with improvements in insulin sensitivity and glycemic control.[6] Which helps to prevent further complications.
4. Cholesterol lowering effect may be due to bile acids binding activity of fiber and lignan present in flaxseed.[7]

## CONCLUSION:

1. Study group kept on *Atasi* shown better effect than Placebo group with respect to subjective and objective parameters in Type 2 Diabetes Mellitus patients.
2. *Atasi* can be use as an safe and healthy addition to the diet for Type 2 Diabetes Mellitus patients.

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