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## Pharmaco-therapeutic Evaluation of *Rudantyadi Yog (Kalpit Yog)* in Management of *Madhumeha*

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### ABSTRACT:

Diabetes Mellitus is one of the world's major diseases. The WHO additionally assesses that 80% of diabetes passing happen in low and centre salary nations. As per a World Health Organization (WHO) reality sheet on diabetes, an expected 3.4 million passing's are caused because of high blood sugar. It has been additionally evaluated that the worldwide weight of type-2 diabetes is relied upon to increment to 438 million by 2030 from 285 million individuals (recorded in 2010). So additionally, for India this extension is surveyed to be 58%, from 51 million people in 2010 to 87 million out of 2030. It is a well known fact that oral hypoglycemic agents used in modern medicine only maintains the normal blood glucose level & when used lifelong cause various adverse effects like Hypoglycemia. So current clinical study is planned to evaluate the "Pharmaco-therapeutic Evaluation of *Rudantyadi Yog (Kalpit Yog)* in Management of *Madhumeha*".

The study was conducted on 40 clinically diagnosed patients of *Madhumeha*. They are randomly allocated into two groups after screening. Group-A (*Rudantyadi Yog*) a trial group medicine & Group-B (*Mamajjak Ghan Vati*) a control group medicine. Observation & result assessed on the basis of difference in the score of sign and symptoms. All the details regarding the study are further detailed.

**Keywords:** *Madhumeha*, Diabetes Mellitus, *Rudantyadi Yog*, *Mamajjak Ghan Vati*.

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## INTRODUCTION

Ayurveda is viewed as the most seasoned recuperating science. In Sanskrit, Ayurveda signifies "The Science of Life". Ayurveda information started in India over 5000 years prior and is frequently called as the "Mother of All Healing". It comes from old Vedic culture and was educated for a large number of years in an oral custom from the cultivated experts to their followers. With the goal that current work entitled **“Pharmaco-therapeutic Evaluation of *Rudantyadi Yog (Kalpit Yog)* in Management of *Madhumeha.*”** was planned & carried out.

Ayurveda is the traditional science of medicine practiced in India since centuries. It is the science for long life which cures not only the disease but also teaches how to live healthy & prevents the diseases.

Today, Stress is a part of our lives. Because of invention of new technology, people become more mechanical, because of this materialistic world and run after money, there is increase in stress which leads to various physical and psychological disorders and various diseases like Hypertension, Heart disease, and most harmful Diabetes Mellitus. Sometimes Diabetes type II is described as a life style disease because it is more common in people who don't do enough physical activity and who are overweight. Overweight, diet, no exercise, smoking, alcohol intake may each independently influence a person's risk of getting Diabetes.

In *Ayurved*, there are 20 forms of *Prameha*: out of which 4 are *Vataja Prameha*, 6 are *Pittaja Prameha* and remaining 10 are *Kaphaja Prameha*. All forms of not treated

to eventually develop into *Madhumeha*<sup>1</sup> (Diabetes Mellitus).

According to the Modern science, two type of Diabetes are referred to as type I (insulin dependent) & type II (noninsulin dependent). Diabetes Mellitus is a gathering of metabolic ailment, portrayed by Hyperglycemia coming about because of deformities in insulin emission, insulin activity or both. Normally blood glucose level is tightly controlled by insulin, a hormone produced by the Pancreas. In patients with diabetes, the nonattendance or deficient creation of insulin causes hyperglycemia. It alters metabolism of Carbohydrates, proteins and fat in the body. It is characterized by high level of blood glucose and subsequent excretions through urine.

Acharyas of Ayurveda doesn't confine the quantity of dravyas to their writings. They permit the handy utilization of comparative dravyas which are not clarified by them in the event of non-accessibility of the one referenced in the content.

## AIMS AND OBJECTIVES

Clinical study to know the efficacy of *Rudanti (Cressa Cretica)* & *Kapitha (Limonia acidissima)* in *Madhumeha*.

## MATERIAL & METHODS

### Collection of drugs

Drug *Rudanti* was collected by the scholar herself from *Narayanapuram* City at *Luni* Junction in Jodhpur District with the help of the Shri Mota Ram & local villagers. The second drug *Kapitha* was collected by the scholar herself with the help of her elder sister *Mangla Dhakar* from *Badisadri* in Chittorgarh District.

### PREPARATION OF MEDICINE

After bringing 35 kilograms of *Rudanti* from *Narayanapuram* City, near *Luni* Junction to Jodhpur city & dried it for one month in shade. After drying *Rudanti* lost its weight and remained 20.400 kg. In this manner, 18 kilograms of *Kapitha Patra* brought from *Badisadri* to Jodhpur and also dried it in the shade for one month. After drying it, the weight of the *Kapitha Patra* was reduced to 10.450 kg. After that both the *Rudanti and Kapitha Patra* were brought to Dr. Sarvepalli Radhakrishnan Rajasthan Ayurveda University, Jodhpur and weighed it again. After that the 10 kilograms of *Kapith Patra* was used to make fine powder with the help of Pulverizers machine and 15 kilograms of *Rudanti* was used to make *Yavkut* using

Disintegrator machine for making the *Kwath*. *Yavkut* is kept in a container containing 12 litres of water for 12 hours to make *Kwath*. On the next day, put the container having *Yavkut* in it on the gas and stirred it time to time. In the evening the *Kwath* was prepared from this *Yavkut*. After that *Kwath* was filtered by the filtrate in the other pan. This *Kwath* is called as *Rudanti Kwath*. On the third day *Rudanti Kwath* was again boiled for two days for making *Rudanti Ghana* from this *Rudanti Kwath*. On the fifth day *Rudanti Ghana* was prepared. *Rudanti Ghana* was weighed. The weight of the *Rudanti Ghana* was 8 kilograms. 8 kilograms of *Kapitha Churna* & 8 kilograms of *Rudanti Ghana* were used to make *Rudantyadi Yog*. *Rudantyadi Yog* was left to dry for one day. After drying *Rudantyadi Yog*, 500 mg of capsule were filled with the help of capsule maker machine available at the pharmacy. 500 mg capsules (8000 capsules) are sealed in airtight bag and stored in the Department of *Dravyaguna*.

**Following materials and methods were adopted for the present research study-**

#### **A. Selection of Patients**

40 *Madhumeha* patients of Group A & B would be selected from OPD of Dr. **S.R.**

Rajasthan *Ayurved*, University and hospital Jodhpur randomly, for study a special Performa would be prepared incorporating all the sign and symptoms of *Madhumeha* based on both *Ayurvedic* and Modern clinical literature and accordingly the detailed history, physical examination would be performed and investigations would be done with pathological laboratory confirmation on all patients.

#### **Inclusion Criteria**

- (a) Diagnosed and confirmed cases of Diabetes Mellitus type II, on the basis of the laboratory investigations.
- (b) Patients between the age group of 18 - 60 years.

#### **Exclusion Criteria**

Following patients would be excluded from clinical trial

- Patients having Type - DM I [IDDM]
- Age below 18 and above 60 years.
- Patient of type II DM who are on Insulin therapy.
- DM with complications - Retinopathy, Neuropathy, Nephropathy etc.
- Uncontrolled DM.
- Drug induced DM.

- FBS [ $>250\text{mg/dl}$ ]
- PPBS [ $>300\text{mg/dl}$ ]
- DM with coronary artery disease.

### A. STUDY DESIGN

**Drug :-**

**Group (A) :-** *Rudantyadi Yog*.

**Group (B) :-** *Mamajjak Ghan Vati*.

**Dose :-**

*Rudantyadi Yog* 1gm TDS (3gm/day) with luke warm water.

*Mamajjak Ghan Vati* 1gm TDS (3gm/day) with luke warm water.

**Drug Duration :-** Two months (60 days)

**Type of Study :-** Open

**Randomization:-** Simple Random Sampling.

### C. Clinical Study

1. Written informed consent would be obtained from every patient.
2. Case history would be taken and special case record form would be prepared.
3. Clinical findings would be recorded as per case Performa.

The patients would be selected randomly divided in two groups, namely Group-A and Group-B examined clinically along with laboratory investigation.

- **Group (A):-** *Rudantyadi Yog* with luke warm water 20 patients would be registered in this group. The patient would be administrated 1gm of *Rudantyadi Yog* thrice a day with luke warm water empty stomach.

- **Group (B) :-** *Mamajjak Ghan Vati* with luke warm water 20 patients would be registered in this group. The patient would be administrated 1gm of *Mamajjak Ghan Vati* thrice a day with luke warm water empty stomach.

### D. CRITERIA FOR ASSESSMENT

The effect of trial drug would be assessed in terms of Subjective & Laboratory parameters.

#### (A) Subjective Assessment

All the patients registered for clinical trial would be asked for any changes in their clinical manifestations. Special symptom of *Madhumeha* (DM) which would be looked into includes-

1. *Prabhutaavilmutrata*<sup>2</sup> (Polyurea) increasing frequency of urine & turbid urine
2. *Pipasa*(Polydypsia) feeling of thirst
3. *Kshudha* (Appetite)
4. *Tandra* (Drowsiness)

5. *Kara-Pada-Tala-Daha/Supti* (Burning sensation/Numbness in palm and soles) Following investigations would be assessed for objective assessment.
6. *Aalasya / Utsahahani* (General Disability)
7. *Panduvarnamutrata* (Yellowish-white urine)
8. *Pindikodveshtan* (Cramps in claws)
9. *Avilmutrata* (Turbidity in urine)
- Blood Sugar level
    - (i) Fasting (F.B.S.)
    - (ii) Post Prandial (P.P.B.S.)
  - Urine Test
    - Sugar & Routine Examination.

**(B) Objective Assessment**

**G. CONTENT OF TRIAL DRUG**

Hypothetical compound has been taken for the clinical trial which includes the following drugs:

S.No.	Constituents	Quantity	Ratio
1	<i>Rudanti Ghan</i> <sup>3</sup>	8 Kg	1 Part
2	<i>Kapitha Patra Churn</i> <sup>4</sup>	8 Kg	1 Part

**H. PREPARATION OF CONTROL GROUP MEDICINE**

*Ativisha* (*Aconitum heterophyllum*; 2 parts).

***Mamajjaka Ghan Vati*<sup>5</sup>**

*Mamajjaka Ghan Vati* was ordered from Shree Narayan *Aushadh Bhandar*, Pharmacy in Jamnagar, Gujarat.

*Mamajjaka* was described in *Lakshmanadi Varga of Shodhala Nighantu*.

*Mamajjaka Ghan Vati* contains

*Mamajjaka* extract (8 parts)

*Katuki* (*Picrorrhiza kurroa*; 2 parts)

*Pippali* (*Piper longum*; 2 parts)

**ETHICAL APPROVAL & REGISTRATION OF TRIAL**

❖ Ethical Clearance Sr. No:-  
DSRRAU/UCA/IEC /18-19/121

(Institutional Ethics Committee  
DSRRAU, Jodhpur)

❖ CTRI Registration No:-  
REF/2019/08/027531

## 2. OBSERVATION

For the clinical study, 40 clinically diagnosed and confirmed cases of Diabetes were registered. The study was carried out by following complete protocol in 40 cases.

❖ **Marital Status:-** 97.5% patients were married, 2.5% patients were unmarried. Since responsibilities increase after the married life, stress may be the possible reason.

❖ **Educational status:-** 12.50% patients were uneducated. 37.50% patients were primary educated. 50% patients were educated. Lack of education renders delay in detection of the disease and worsens the condition.

❖ **Occupation:-** 17.5% patients were housewives 12.5% patients were doing business 42.5% patients were in service. 27.5% patients were doing other works like farmer etc.

❖ **Socioeconomic status:-** Since majority of the patients 50% were diagnosed with diabetes were belonged to middle class, 15% patients were diagnosed with diabetes belonged to

lower middle, 35% patients were belonged to upper middle class. The study shows most of diabetes patients were belonged to middle and upper middle class, lack of physical activity and high nutritious diet may be the possible reason.

❖ **Age wise distribution:-** 2.5% patients were belonged to the age group of 16-30 year, 30% patients were belonged to age group of 31-40 years, 40% patients were belonged to age group of 41-50 years & 27.50% patients were belonged to age group of 51-60 years. Since majority of the patients were belonged to age group of 50-60 years. This shows that as the age increases incidence of diabetes increases.

❖ **Gender:-** 65% patients were of male gender. 35% patients were female gender. The study shows males were affected more with diabetes than female. May be the possible cause was use of substances of addiction, unhygienic food, high quantity of food than females and less working hours than females.

❖ **Koshta:-** 25% patients had *Kroora Koshta*. 75% patients had *Madhyam Koshta*.

- ❖ **Sharirik Prakriti/Manasik Prakriti:-**  
Among the patients registered - 12.5% patients had *Vata Pitta Prakrita*, 40% patients had *Pitta Kaphaj Prakriti*, 47.5% patients had *Vata Kaphaja Prakriti*, 75% patients had *Rajsik*, 17.5% had *Tamasik*, 7.5% had *Satvika Prakriti*. Most of patients were found of *Vata Kaphaja Prakriti* it shows that the *Vata and Kaphaja Dosha* involvement in pathogenesis of diabetes.
- ❖ **Samhanana, Satva, Satmya, Sara:-**  
87.5% had *madhyam samhanana*, 85% patients had *madhyam satva*, 100% had *sarva rasa satmya*. 92.5% had *madhyam sara*.
- ❖ **Food Habits:-** 65% patients were vegetarian. The reason being majority of them being Hindu due to geographical location.
- ❖ **Birth Place:-** 100% patients were from Jangala Pradesh. The reason is being majority of them, Rajasthan is Jangala Pradesh.

The results were calculated.

- Not significant :P>0.05
- Significant : P<0.05
- Very significant : P<0.01
- Extremely significant :P<0.001

- ❖ **Agnibala:-**65% patients were *vishamagni*, 27.5% were *mandagni* & 7.5 patients were *samaagni*. Its indicate that *vishamagni & mandagni* promotes pathogenesis of diabetes.
- ❖ **Abhyavarana Shakti and Jaran Shakti:-** 75% patients had *madhyam* & 25% had *abhyavarana shakti*, 72.5% patients had *madhyam*, 25% patient had *avar* & 2.5% patients had *pravara jharan shakti*.

### 3. RESULTS

All the Results are calculated by using Software: In Stat Graph Pad 3.

#### Inter group study

For Nonparametric Data **Wilcoxon matched-pairs signed ranks test** is used while for Parametric Data **Paired 't' Test** is used and results Calculated in each group. For calculating the Inter group comparison, **Mann-Whitney Test & Unpaired 't' Test** was used.



**Table: Showing effect of therapeutic trial on clinical symptoms in 40 patients of *Madhumeha* (Diabetes) disease based on Intra Group comparison (Wilcox on matched-pairs signed-ranks test)**

Variable	Group	“n”	Mean			Relief %	S.D.	S.E.	“p”	Result
			BT	AT	X					
<i>Prabhutaav ilmutrata</i>	A	20	1.10	0.50	0.50	54.54%	0.5026	0.1124	<0.0001	ES
	B	20	1.80	0.85	0.95	52.77%	0.5104	0.1141	<0.0001	ES
<i>Pipasa</i>	A	20	1.50	0.50	1.00	66.66%	0.5620	0.1257	<0.0001	ES
	B	20	1.90	0.95	0.95	50%	0.2236	0.050	<0.0001	ES
<i>Kshudha</i>	A	20	1.40	0.75	0.65	46.42%	0.5871	0.1313	<0.0001	ES
	B	20	1.10	0.50	0.60	54.54%	0.6806	0.1522	<0.0001	ES
<i>Tandra</i>	A	20	1.65	0.75	0.90	54.54%	0.5525	0.1235	<0.0001	ES
	B	20	2.1	0.90	1.2	57.14%	0.4104	0.0917	<0.0001	ES
<i>Kara-Pada- Tala Daha</i>	A	20	2.1	0.90	1.2	57.14%	0.5501	0.1230	<0.0001	ES
	B	20	1.80	0.85	0.95	52.77%	0.2236	0.0500	<0.0001	ES
<i>Utsahahani</i>	A	20	2.70	1.75	0.95	35.18%	0.2236	0.0500	<0.001	ES
	B	20	2.45	1.20	1.25	51.02%	0.5501	0.1230	<0.001	ES
<i>Panduvarn amutrata</i>	A	20	1.85	0.95	0.90	48.64%	0.5525	0.1235	<0.0001	ES
	B	20	1.50	0.70	0.80	53.33%	0.7678	0.1717	0.0018	ES
<i>Pindikoudv estan</i>	A	20	1.85	1.00	0.85	45.94%	0.7452	0.1666	<0.0001	ES
	B	20	1.60	0.85	0.75	46.87%	0.7164	0.1602	0.0017	ES
<i>Avilmutrata</i>	A	20	1.55	0.50	1.05	67.74%	0.5104	0.1141	<0.0001	ES
	B	20	1.80	0.85	0.95	52.77%	0.2236	0.050	<0.0001	ES

**ABBREVIATION** - BT: Before treatment, AT: After treatment, Diff.: Difference, S.D.: Standard Deviation, S.E.: Standard Error, P: P value, V.S.: Very Significant, S: Significant, E.S.: Extremely-Significant)

**Effect of Therapy Group A**

In patients of group-A showed statistically **Extremely Significant** result changes in all symptoms (P<0.0001).

**Effect of Therapy on Group B**

In patients of group-B showed statistically **Extremely Significant** result changes in all symptoms (P<0.0001).

**Table: Showing the % Relief in Both Groups in Subjective parameters**

Subjective Parameter	% Relief	
	Group-A	Group-B
1. <i>Prabhutaavilmutrata</i> (Polyurea)	54.54%	52.77%
2. <i>Pipasa</i> (Polydypsia)	66.66%	50%
3. <i>Kshudha</i> (Appetite)	46.42%	54.54%
4. <i>Tandra</i> (Drowsiness)	54.54%	57.14%
5. <i>Kara-Pada-Tala-Daha/Supti</i>	57.14%	52.77%
6. <i>Aalasya/Utsahani</i>	35.18%	51.02%
7. <i>Pandu varna mutrata</i>	48.64%	53.33%
8. <i>Pindiko-Udveshtan</i>	45.94%	46.87%
9. <i>Avilmutrata</i>	67.74%	52.77%

1)-In Group-A patients shows up maximum relief percentage respectively in *Avilmutrata* (67.74%) & *Pipasa* (**Polydypsia**) (66.66%).

(**Drowsiness**) (57.14%) *Kshudha* (**Appetite**) (54.54%) & *Pandu varna mutrata* (53.33%).

2) In Group-B patients shows up maximum relief percentage respectively in *Tandra*

## DISCUSSION

Discussion of the study deals with the possible reasoning based on the specific logic to explain and interpret the findings to correlate the same with their causes. All the observations obtained and clinical trial suggest that *Rudantyadi Yog* produce symptomatic relief and effect in the patients of Diabetes and Group A is found more marked. Thus, it is clear from the current

research project that these drugs may be used as effective drug in Diabetes.

### PROBABLE MODE OF ACTION

Ayurvedic mode of action by ayurvedic point of view can be explained as follows as I have already described the properties of both drugs.

<b><i>Rasa panchak of Cressa Cretica</i></b>	
<i>Rasa</i>	<i>Katu (Pungent) &amp; Tikta (Bitter)</i>
<i>Guna</i>	<i>Laghu (Light) &amp; Ruksha (Dry)</i>
<i>Vipaka</i>	<i>katu</i>
<i>Veerya-</i>	<i>Ushna (Hot)</i>

<b><i>Ras panchak of Limonia Acidissima</i></b>	
<i>Ras</i>	<i>Kashaya (astringent), Amal , Madhur</i>
<i>Guna</i>	<i>Tikshna</i>
<i>Vipaka</i>	<i>katu</i>
<i>Veerya</i>	<i>Sheet</i>
<i>Effect on doshas</i>	<i>Alleviates Pitta and Vata Dosha</i>

As we realize that *Prameha is tridoshaja vyadhi* however in *Madhumeha Vata and Kapha* are prevailing. Previously mentioned all medications are assuaged the *Kapha and vata dosha* because of their properties like *Katu Tikta, kashaya, Laghu, Ruksha Guna*

and *Ushan Virya* etc. When we study the *samprapti of Madhumeha* then there is *dushti of dhatus* particularly *Meda, Rakta, Ambu, Vasa, Majja, Rasa Oja* and so on. *Tikta, and Kashaya Rasa* has the property of *Kaphaghana, Agni dipana and Aama*

*pachana* by which it causes *Srotoshudhi* and ultimately *Kapha shamana*. *Ruksha guna* has *Kapha shoshan* property so ultimately *Kapha can shamana*. *Laghu guna* have *laghu paka* and *Kapha hara activity* so *laghu guna* of medication is additionally reason for *Kapha shamana*. *Laghu guna* is established of *vayu and Agni Mahabhoota* so it advances the *Jatharagni*, so ultimately *Ama dosha* die down. *Tikshana guna* of drugs clears the minute channels of the body, due to this *Srotoshudhi* occurs, so ultimately leads to *Kapha Vata shamana*. *Tikshana guna* is constituted of *agni mahabhoota*, due to this *guna* has also *sodhan, lekhen & kaphahara, karma Ushna virya* these medications have *Kapha & Vata shamaka* property As we realize that *ushan* is the inverse to *sheeta*. *Sheeta* is the regular property of *Vata and Kapha*. The *Ruksha* property of medications (*Kapha shoshan*) in the wake of following up on the *Kapha* it loses its power to aggravate the *Vata*. *Vitiating of Vayu, Doshas* place from either squandering of *Dhatu*s or check in section. However, here due to *ushna virya* the deterrent of section become clear so *vata* cannot be bother So from above conversation we can infer that all the medications have *Kapha and Vata shamaka* property all the medication has property of

*Agni dipana and Ama pachan Kaphaghna srotoshudhi* and clears the *margavarodha*, So this is the plausible method of *samprapti vighatans* of the *Madhumeha*. These herbs might be demonstrating hypoglycemic impact by modifying liver digestion which is the principle organ, contributes 75 percent of body digestion and digestion is unhinged in Diabetes, obviously pancreas which is wellspring of insulin for guideline of blood glucose level in the body, yet the most evident site of insulin opposition in NIDDM is in liver and muscles. The liver is more delicate than muscles, with the impact of insulin liver become touchy to insulin, during the medication treatment and control the digestion by following up on liver straightforwardly to build glycolysis and might be decline the gluconeogenesis. Another method of activity we can portray above. I see that when the glucose level was stature, the medication activity was generally quick.

## CONCLUSION

The current research project entitled “Pharmaco-therapeutic Evaluation of *Rudantyadi Yog* (Kalpit Yog) in Management of *Madhumeha*.” following observations can be concluded as that in antiquated time just upper affordable

gatherings individuals were experiencing this malady yet as indicated by this investigation I saw that this illness is spreading in center just as lower salary bunches individuals however rate is less. Males are increasingly inclined to Diabetes as contrast with female. Urban people are progressively inclined to this disease as contrast with country regions people. Total subjective parameter result of *Rudantyadi Yog* is 52.97%. Total subjective parameter result of *Mahamajjak Ghan Vati* is 52.35%. Total objective parameter result of *Rudantyadi Yog* is 38.79% and that of *Mahamajjak Ghan Vati* is 37.70. Total result of *Rudantyadi Yog* is 50.39% & *Mahamajjak Ghanvati* is 49.69%. More result of *Rudantyadi Yog* was seen on *Avilmutrata & Polydepsia*. Less result of *Rudantyadi Yog* was seen in *Alasaya*. More result of *Mahamajjaka Ghan Vati* was seen on *Kshudha & Tandra*, less result in *Pindiko-Udveshtan*. Both *Rudantyadi Yog* and *Mamajjak Ghan Vati* are found clinically huge in suggestive help and lab boundaries yet *Rudantyadi Yog* is progressively compelling in *Prabhuta avilmutrata* (Polyuria), *Kshudha*, *Tandra*, *Kar-pada tala daha*, *Panduvarnamutrata* (Yellowish-white pee), *Pindiko-Udvestan*, and *Avilmutrata*. It can be reasoned that the

proposed sedate *Rudantyadi Yog* in ebb and flow research display anti-hyperglycemic movement and can be utilized as a medication in patients of *Madhumeha* (Diabetes Mellitus). According to this examination information shows that following multi decade, this sickness is more happen. According to the family ancestry of the patients this I see that innate factors additionally assume a fundamental job in Diabetes. Drug is likewise following up based on sugar level, when the sugar level was high. The activity of medication was quick and when the glucose level was not quick getting bring down the activity of medication. The study ought to be completed for longer length for better outcomes. *Rudantyadi Yog* result is also seen well on Type 1 Diabetes Mellitus. So further study can be done using this drug. Since it was time bound investigation with numerous confinements so to evaluate adequacy of detailing, further broadened preliminary ought to be done fusing huge number of patients.

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