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## Evaluation of Efficacy and Safety of Micon Gold in Type 2 Diabetes: A PMS Study

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### ABSTRACT

**Background:** The growing prevalence of type 2 diabetes mellitus (T2DM), which has numerous crippling consequences, is a significant public health issue. Ayurvedic extracts of Jamun, Neem, Karela, and Gudmar are included in the exclusive Micon Gold formulation for T2DM, along with Vasantkusumakar Ras, Shilajit, and other herbs and minerals.

**Methods:** Post-marketing, open label, clinical study. Convenient sampling was done and written informed consent acquired from 30 patients aged  $\geq 18$  years (both male and female) with diagnosed T2DM. End point assessment for efficacy and safety done after 90 days by changes in diabetic panel glycosylated haemoglobin (HbA1c), fasting blood glucose (FBG), and postprandial blood glucose (PPBG) were the primary endpoints. Liver profile and renal profile were the secondary endpoints. Statistical significance was considered at the level of  $p < 0.05$ .

**Results:** Substantial improvements were seen in the parameters: FBG, PPBG, HbA1c ( $p < 0.001$ ) after twice a day administration of Micon Gold for 90 days along with QoL improvements over the domains. Safety metrics remained within the expected ranges, and no anomalies or clinically significant adverse events were identified.

**Conclusion:** Micon Gold administration is both safe and notably effective for usage in T2DM due to potent herbo-mineral composition.

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### INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a metabolic condition that causes chronic hyperglycaemia due to inadequate insulin secretion via malfunctioning pancreatic  $\beta$ cells or insulin dysfunction due to diminished insulin sensitivity. Diet control and lifestyle adjustment are first-line treatments; however, if the disease advances, the use of oral hypoglycaemic medications is considered the next step in treatment [1] An estimated 463 million adults were estimated to have diabetes in 2019, according to a report from the International Diabetes Federation (IDF), and that number is expected to rise to 578 million individuals by 2030 and 700 million by 2045 [2]. The physical, social, and financial outlays associated with T2DM and its consequences pose a significant problem for healthcare systems throughout [3].

In order to establish an effective treatment for diabetes, experts are concentrating increasingly on natural product tactics. Natural products have been used to successfully lower blood glucose levels [4]. Prior systematic reviews have shown the usefulness and safety of various Ayurvedic medications, suggesting that many of them may be used to manage T2DM [5]. Ayurvedic diabetes management involves prescribing a customised diet, way of living, mostly herbal medications, and systemic cleansing therapies. Future projects should take into account how to customise population care to individual patient needs while using advancements in clinical information systems and care integration to optimally manage and

prevent diabetes in the future. Population care for diabetes is still in the process of evolving [6]. The management and techniques of Ayurveda can be used to treat T2DM more effectively. The present study was undertaken to assess the efficacy of Micon Gold capsule for management of hyperglycaemia due to T2DM. Micon Gold is an Ayurvedic proprietary medicine developed, manufactured and marketed by Jamna Herbal Research Limited, Bhopal, Madhya Pradesh, India. Ayurvedic Rasayanas along with herbal extracts as composition for internal administration were selected for the present study as these are made known to be best for diabetes management.

## **MATERIALS AND METHODS**

The present post-marketing, open label, clinical study was undertaken at two establishments situated in Kolkata (R B Diagnostics Pvt. Ltd. & The Ayurveda Clinic and Research Centre). Ethical approval (IECCRI/22-23/15 dated 20/12/2022) was obtained from Independent Ethics Committee (Clinical Research) India, a CDSCO approved independent ethics committee founded by Independent Research Ethics Society. The study was also registered for CTRI (CTRI/2023/02/049894) on 20/02/2023. Objective of the study was to explore the efficacy on hyperglycaemia in T2DM. Participants provided written informed consent and was informed about the detailed nature of the study and assurance was provided on voluntary participation. Convenient sampling technique was used to recruit the 30 participants from the outpatient clinic who came for regular health check-ups and consultation.

Patients were included based on age  $\geq 25$  years (both male and female) with diagnosed T2DM; diabetics those who were on oral hypoglycaemics without insulin; fit and no need for any hospital administration; willing to perform all study related procedures including the use of study medicine, allow the physical and biochemical assessments. Exclusion criteria was poorly controlled diabetes; renal impairment; poorly controlled diabetes mellitus; pregnant; unstable medical or psychiatric illness; chronic & acute disorders requiring hospital admission; known HIV-positive, Hepatitis B or C status; inability to carry out visits, maintain current medication regimen and unwillingness to participate in all components of the study. The end point assessment of treatment effect after 90 days of treatment were based on both changes and success on Physical assessment (height, weight, blood pressure, pulse and respiratory rate); Blood tests (HbA1c, FBG, PPBG). Along with Quality of Life - WHOQOL; [7] Drug safety parameters Complete Blood Count (CBC), Renal Function Test (RFT) & Liver Function Test (LFT).

Once the case record form had been completed, the data was checked and corrected by the investigator. After coding, cleaning and editing data was entered into the computer through Statistical Package for Social Sciences (SPSS version 25) software for analysis. Statistical significance was considered at the level of  $p < 0.05$  in all the efficacy parameters. Before and after treatment was compared by Paired Samples t-Test.

Jamna Herbal Research Limited has developed and marketing the products (Micon Gold capsule) after getting manufacturing licence from Office of the Drug Controller (AYUSH), Bhopal, Madhya Pradesh, where observed the effects and communicated on label and promotional materials. The drug review as mentioned in Ayurvedic Pharmacopoeia of India [8], Ayurvedic Formulary of India [9] and Ayurvedic texts [10] shows their effectiveness. These Ayurvedic drugs are scientific formulation of herbo-mineral compounds intended to evaluate the efficacy on hyperglycaemia due to T2DM with oral intake of Micon Gold capsule (2 capsules twice daily). The study adhered to the Good Clinical Practice and New Drug & Clinical Trial Rules, 2019.

## RESULTS

Socio-demographic information showed 30 participants, comprising both male (46.67%) and female (53.33%). Participants' ages ranged from 33 - 71, with a mean age of 51.93 ( $\pm 8.824$  SD) years. The patients' levels of education varied; 50% (15) of them had completed their graduation. Occupation wise most patients were homemakers (females) and full time employed (males) consisted of 33.33% each. Marital status showed 83.33% were married. Normal physical activity was reported by 63.33% patients, while 30% were indulged in mild physical activities. Regular bowel clearance (once/day) was observed in 93.33% but 6.67% were passing irregular bowel twice/day. Adequate sleep was reported by all patients, among them on average 80% were attaining less than 7 hours of sleep. (Figure 1).

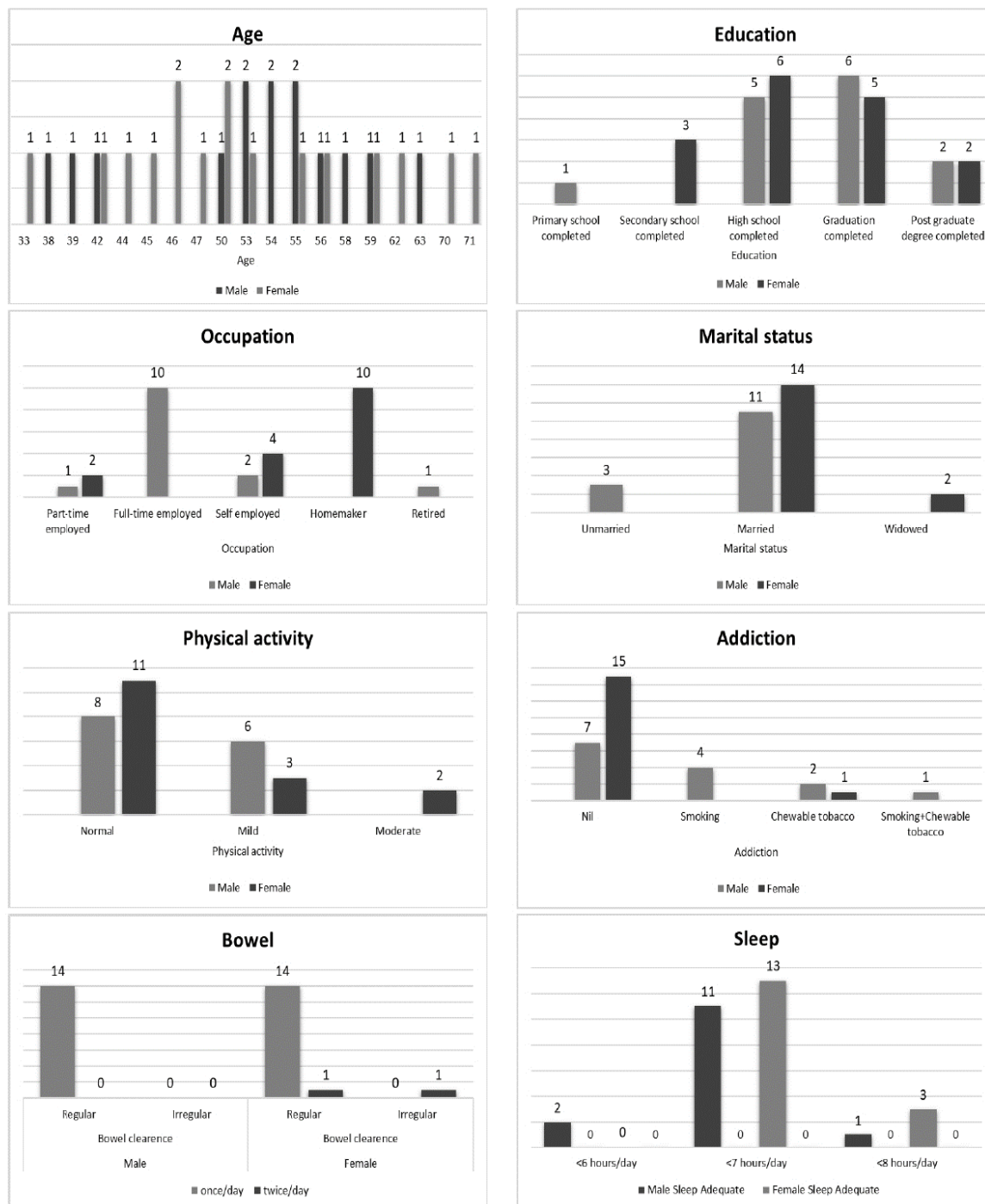


Fig. 1. Socio-demographic distribution of the participants

**Physical Assessment:** showed that the physical parameters regarding BMI, pulse, blood pressure and respiratory rate remained maintained before and after treatment and there were not much noticeable changes in their mean, even though statistically significant changes were observed in BMI and pulse (Figure 2 and Table 1).

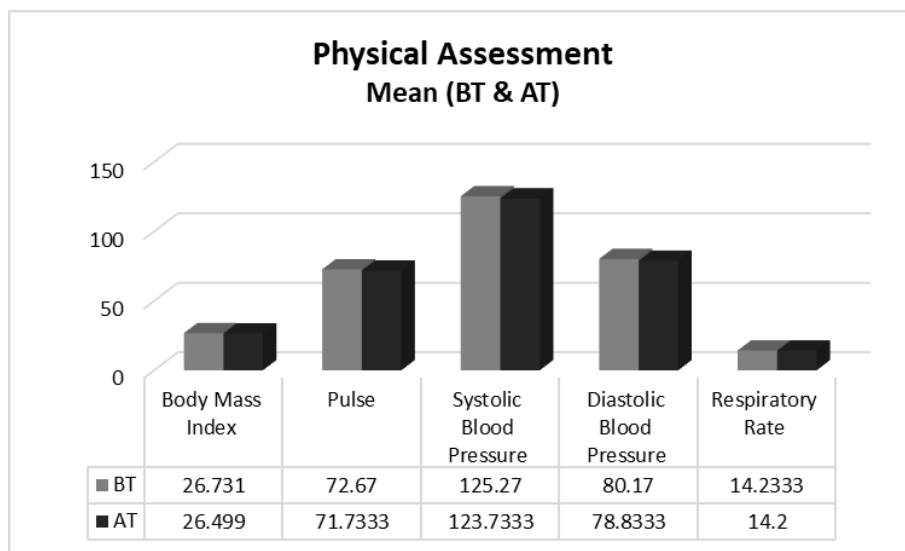


Fig. 2. Physical Assessment parameter(mean) before and after treatment

**Biochemical Assessment:** marked reduction (improvement) on the parameters FBG (28.49%), PPBG (27.33%) and HbA1c (7.5%) was comparably noticed before and after treatment. Also, highly statistical significance was noted at the level of  $p < 0.001$  level showing efficacy of administered drug (Micon Gold) on the biochemical parameters of hyperglycaemia (Figure 3 and Table 1).

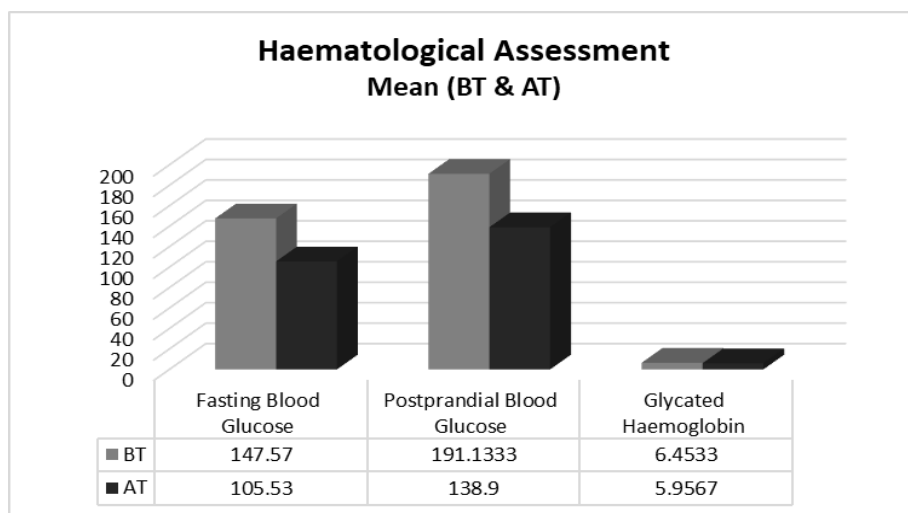


Fig. 3. Haematological Assessment parameter(mean) before and after treatment

**Quality of life assessment:** The WHOQOL domains showed perceivable improvements related before and after treatment. Statistically significant improvements were also observed on all the domains *i.e.* physical health, psychological, social relationships and environment (Figure 4 and Table 1).

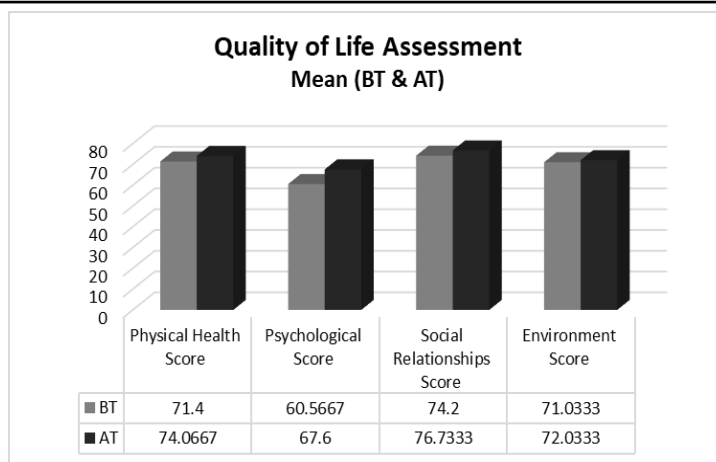


Fig. 4. Quality of Life Assessment parameter(mean) before and after treatment

**Table 1. Assessment parameters findings before and after treatment.**

	Paired Differences			t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean			
<b>Physical Assessment</b>						
Body Mass Index	0.23200	0.13795	0.02519	9.211	29	0.001
Pulse	0.93333	2.37709	0.43400	2.151	29	0.040
Systolic Blood Pressure	1.53333	4.96007	0.90558	1.693	29	0.101
Diastolic Blood Pressure	1.33333	4.07121	0.74330	1.794	29	0.083
Respiratory Rate	0.03333	0.31984	0.05839	0.571	29	0.573
<b>Haematological Assessment</b>						
Fasting Blood Glucose	42.033	15.267	2.787	15.080	29	0.001
Postprandial Blood Glucose	52.23333	21.01671	3.83711	13.613	29	0.001
Glycated Haemoglobin	0.49667	0.19025	0.03473	14.299	29	0.001
<b>Quality of Life Assessment (WHOQOL)</b>						
DOMAIN 1 (Physical Health)	-2.66667	4.47471	0.81697	-3.264	29	0.003
DOMAIN 2 (Psychological)	-7.03333	10.36401	1.89220	-3.717	29	0.001
DOMAIN 3 (Social Relationships)	-2.53333	6.56917	1.19936	-2.112	29	0.043
DOMAIN 4 (Environment)	-1.00000	2.27429	0.41523	-2.408	29	0.023

Complete Blood Count, Liver Function Test and Renal Function Test stayed within the normal limits (Table 2), no abnormalities and no clinical adverse events were observed after 90 days of Micon Gold administration.

**Table 2. Safety parameters findings before and after treatment.**

	Paired Differences			t	Df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean			
Urea	1.667	2.940	0.537	3.105	29	0.004
Creatinine	0.02200	0.10176	0.01858	1.184	29	0.246
Total Bilirubin	0.01900	0.09316	0.01701	1.117	29	0.273

Conjugated Bilirubin	0.02533	0.09239	0.01687	1.502	29	0.144
Unconjugated Bilirubin	-0.00633	0.12322	0.02250	-0.282	29	0.780
SGOT	5.700	13.983	2.553	2.233	29	0.033
SGPT	7.133	14.277	2.607	2.737	29	0.010
Alkaline Phosphatase	0.900	12.582	2.297	0.392	29	0.698
Total Protein	-0.0867	0.5029	0.0918	-0.944	29	0.353
Albumin	-0.0367	0.2918	0.0533	-0.688	29	0.497
Globulin	-0.0490	0.3954	0.0722	-0.679	29	0.503
AG Ratio	0.00300	0.15901	0.02903	0.103	29	0.918
Haemoglobin %	-0.48667	0.57938	0.10578	-4.601	29	0.001
Erythrocytes	-0.15333	0.20297	0.03706	-4.138	29	0.001
Leucocytes	813.333	991.162	180.961	4.495	29	0.001
Neutrophils	0.767	4.861	0.888	0.864	29	0.395
Lymphocytes	-1.667	4.172	0.762	-2.188	29	0.037
Monocytes	0.733	1.964	0.359	2.045	29	0.050
Eosinophils	0.233	1.104	0.202	1.157	29	0.257
Platelet Count	14.300	5.484	1.001	14.281	29	0.001
PCV	-0.08833	0.53089	0.09693	-0.911	29	0.370
MCV	-2.360	2.722	0.497	-4.748	29	0.001
MCH	-1.969	7.298	1.332	-1.478	29	0.150
MCHC	0.069	0.338	0.062	1.124	29	0.270

## DISCUSSION

A complicated endocrine and metabolic condition, T2DM. Various levels of insulin resistance, pancreatic and cell malfunction, and other endocrinology abnormalities interact with genetic and ecological variables to harm organs of the body [11-14]. The overall quality of life for T2DM patients has increased as a result of the introduction of numerous treatment choices in recent years. Glycemic management and the avoidance of problems in T2DM are still difficult, nonetheless, as a result of the variability of the aetiologies and consequences of T2DM. Worldwide, a sizable number of scientific studies have been carried out aimed at improving T2DM management [15-17]. T2DM can be avoided by altering one's lifestyle, controlling one's nutrition, and managing overweight and obesity. The general public's education is still crucial for containing this new disease. Despite new research into the pathophysiology of the disease, novel medications are still being produced and there is no solution in sight. The management should be adapted to enhance the T2DM patient's quality of life [18].

Diabetes mellitus (DM) was referred to as Madhumeha in Ayurveda. This traditional, scientifically supported system of medicine listed numerous plants and compositions for its administration [19]. Acharya Vagbhatta finest explains Madhumeha. According to him, Madhumeha might come about in two different ways one through Dhatukshaya's aggravation of Vata, other by Vata being obstructed as a result of Doshas covering it. Due to the loss of Oja, Madhumeha, which is brought on by Dhatukshaya, presents as a skinny and asthenic person. The imbalance in Ojas is what all of this is, or Ojakshaya. The vitiated Kapha and Meda in Margavaranjanya Madhumeha hinder Vata's movement. Once again vitiated, the blocked Vata takes Ojas to Basti and manifests Madhumeha [20]. A multi-pronged and

individualised strategy is utilised to control the disease through dietary changes and Ayurvedic medications, which can be made from substances derived from plants, animals, or minerals. The mechanism of action is thought to involve both pancreatic and extra pancreatic actions [21].

The purpose of this study was to offer proof of the efficacy of Ayurvedic herbo-mineral drug therapy (Micon Gold) for patients with T2DM to improve glycaemic status. The ingredients in Micon Gold that lessen hyperglycaemia are Vasant Kusumakar Rasa, Shuddha Pravala Pishti, Trivanga Bhasma, Shilajit [9], Tejpatra Ghanasatva, Jamun Ghanasatva, Karela Ghanasatva, Bilva Phal Ghanasatva, Neem Patra Ghanasatva, Arjun Ghanasatva, Guduchi Ghanasatva and Gurmar Ghanasatva [8,10].

Micon Gold capsule reduced hyperglycaemia due to its unique composition. There was a highly significant ( $p < 0.001$ ) reduction in the mean haematological markers [FBG (28.49%), PPBG (27.33%) and HbA1c (7.5%)]. Also, significant ( $p < 0.05$ ) improvements on WHOQOL domains for QoL. There were clinically significant changes physical assessment for BMI and other parameters didn't deviate from normality. Likewise, the other haematological parameters CBC, RFT and LFT was observed to be within normal limits and had no significant deviations from normalcy. Moreover, no such clinically significant adverse reactions (either reported by patients, or observed by the investigators), and the overall compliance to the treatment was excellent. According to the available research, a variety of Ayurvedic medications can help T2DM patients improve their glycaemic control. High-quality RCTs should be carried out and reported in order to strengthen the evidence base in light of the limitations of the already available evidence [22]. Correspondingly, the population size of this study was extremely tiny. This might be a barrier to achieving larger clinical significance. This may be proven in additional patients using RCT and/or cross-over design along with Panchakarma to produce a more ameliorating therapeutic result.

## CONCLUSION

Combining complex, specially created therapies including physical therapy, dietary supplements, medication, yoga, and purification procedures, the Ayurvedic holistic approach to treating diabetes outperforms traditional standard therapy. The constitution-based Ayurvedic approach include treating Madhumeha using a variety of therapies, including Shodhana and Shamana, and avoiding mean-value based medical interventions. In this study, ayurvedic treatment with Micon Gold capsules significantly reduced glycaemic indices and enhanced overall quality of life.

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