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Systematic Review of effects of Shodhana & Shmana Chikitsa in Ayurveda in the Management of Diabetes Mellitus Type-II (*Prameha*)

Punam Sawarkar[1*], Gaurav Sawarkar[2] and Jayashri Hadke[3]

[1]Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod; Datta Meghe Institute of Medical Sciences, Wardha, India.
[2]Department of Rachana Sharir, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod, Wardha, Datta Meghe Institute of Medical Sciences, (Deemed to be University), Maharashtra, India.
[3]Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod, Wardha, Datta Meghe Institute of Medical Sciences, Wardha, India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Systematic Review

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ABSTRACT

Introduction: Diabetes mellitus is a complex metabolic clinical condition. It induces some irreversible pathological changes in the body, which rise to multiple complications. Moreover, the side effects of the established anti-hyperglycemic agents in contemporary science on their long-term use make it more worst. Considering the higher incidence rate of Diabetes mellitus due to faulty lifestyle, it is essential to think over various safe but effective measures in alternative science. i.e., Ayurveda. In Ayurveda, diabetes mellitus can be correlated with *Prameha* or *Madhumeha* due to similarity in signs & clinical features.
Aim & Objective: The prime aim of this study is to study the efficacy and safety of different *Shodhana* & *Shamana Chikitsa* in *Ayurveda* for glucose control & improvement in clinical features during the management of Diabetes Mellitus Type II(*Prameha* W.S.R).

**Corresponding author: E-mail: drsuple.punam@gmail.com;*

Materials & Methods: This is a meta-analysis of *Ayurvedic* interventions in *Shodhana,* or *Shamana Chikitsa* used to manage *Prameha* (Diabetes mellitus type II). On extensive Review of the literature, 42 clinical studies (R.C.T. & N.R.C.T.) fulfilling inclusion criteria & conducted with 1743 participants at different places were critically analyzed. Adequate details of the individual studies were tabulated and discussed.
Observations & Results: It is reflected that the combinations of both these interventions are more effective than only *Shaman Chikitsa* in the management of Diabetes mellitus.
Conclusion: All of these interventions in *Ayurveda* reviewed through this study are appeared to be generally safe and effective, having a prime or adjuvant role. However, *Ayurvedic* physicians should prescribe them based on their clinical judgment, patient's references, type of pathology, chronicity of the disease & strength of the patient.

Keywords: Ayurveda; prameha; diabetes mellitus, meta-analysis.; shodhana; shamana; chikitsa, safe, effective.

1. INTRODUCTION

Diabetes mellitus Type II is a metabolic disorder that causes high glucose levels in the blood. In non-insulin-dependent conditions characterized by peripheral insulin resistance at the cellular level. Diabetes Mellitus currently affects more than 62 million Indians, which is more than 7.2% of the adult population [1]. The average age on onset is 42.5 years in India [2]. The prevalence of Diabetes has been rising more rapidly in low and middle-income countries than in high-income countries [1-4]. It is the leading cause of 2.6% of global blindness & kidney failure [4]. Many textual references & clinical shreds of evidence show more chances of recurrent complications due to uncontrolled sugar. Adults with Diabetes have a two- to three-fold increased risk of heart attacks and strokes.

Its current management includes dietary restrictions, physical activity, oral antidiabetic agents, and insulin regimen, but it offers no permanent relief. Most hypoglycemic agents have adverse effects like Gastrointestinal upset, dizziness, etc. Lactic acidosis induced by them becomes life-threatening multiple times [5]. Considering the above need-based scenario, it becomes imperative to search or review safe & effective interventions for the management of *Prameha* in alternative science, i.e., *Ayurveda.*

In *Ayurveda*, *Madhumeha* (type of *Prameha*) can be correlated with Diabetes II. It is a urinary disorder with an increased frequency of turbid urination. It is *Bahudoshavasthajanya*, *Avaranajanya,* or *Tridoshaja Vyadhi,* which is primarily hereditary or caused due to insalubrious activities [6]. In *Ayurveda*, *Panchakarma* is the essence of *Ayurveda,* and it includes five procedures viz. *Vaman, Virechan, Basti, Nasya* & *Raktamokshana* have immense potential to treat lifestyle disorders like diabetes mellitus because these procedures help remove toxins from the body at the cellular level. Therefore, it has become effective in curing many metabolic diseases. Previous clinical studies conducted with various *Shodhana* procedures or palliative treatments in the form of different herbal or herbo-mineral drugs with lifestyle regulations over diabetic patients showed encouraging results.

1.1 Aim and Objectives

Considering the above scenario, this systemic review study is planned to review various research articles based on the management of *Prameha* with various drugs(herbal or herbo-mineral) or *Shodhana Karma* (*Vaman, Virechan, Basti, Nasya*. etc.) & to make specific treatment protocol for it. The prime objective of this study is to assess the efficacy and safety of *Shodhana* & *Shamana Chikitsa* or their combinations for glucose control in patients with *Prameha*.

2. MATERIALS AND METHODS

2.1 Study Selection

Data regarding all previous *Ayurvedic* clinical studies conducted in patients with *Prameha* is collected from NCBI from 2004 to 2019. References of key articles in only the English language were hand searched. Review studies, Case studies, Animal studies, or Clinical studies in *Ayurveda* on Diabetic complications were excluded from this study.

3. OBSERVATIONS AND RESULTS

Details of the trials included in the study were discussed descriptively as follows:

3.1 Neethu. K. J, et al. [7]

In this study, ten diabetic patients underwent *Virechana* with *Trivrut Lehya,* preceded by *Udwartarna* with *Triphala+Kolakulathadi Choorna,* followed by *Takra Dhara* with *Musta, Amlaki, Asnadi,* and *Takra* for 14 days, followed by *Shodhana Snehapana* with *Moorchita Til Taila* and *Sarvanga Abyanga* with *Moorchita Taila.* After *Sansarjana Karma*, the patient was assessed for clinical features of *Prameha,* which showed significant results, which concluded that *Rookshana Poorvaka Virechana Karma* is highly beneficial in the management of *Sthula Madhumeha* [7].

3.2 Manjunath Akki et al. [8]

In this study, the study population(n=30) was equally divided into two groups, in which group A underwent *Vamana* with *Madanphaladi Yoga* & group B for *Virechana* with *Kalyanaka Guda*. Deepana Pachana preceded the main intervention in each Group with *Trikatu Churna, Shodhana Arohi Snehapana* with *Dhanwantaram Ghrita, Abhangya* with *Murchita Tila Taila* & *Sweda* with *Sukhoshna Jala Snana*. During *Samsarjana*, the patient received placebo capsules and was advised to follow the diet plan.Group.A shows highly significant results in all the parameters compared to Group. B, except in parameters P.P.B.S., U.S.postprandial, and *Pipasadhikya* [8].

3.3 Anchal Lalhal et al. [9]

In this study, the study population(n=20 patients) was equally divided into two. Among them, a group I underwent for *Virechana* was preceded by *Shodhana Snehapana* with *Triphala Ghrita* and followed by *Tryushnadi Gutika* 1 gm T.D.S. with lukewarm water for 45 days. Group II was prescribed only for *Shaman Yoga,* i.e., *Tryushnadi Gutika (Chikitsa*.).The clinical features *Prabhuta Mutrata, Pipasaadhikya, Kshudhaadhikye, Shaithilya, Karapada Suptata, Pindiko Udveshtana, Mukha Shosha* were statistically significantly reduced ($p<0.05$). Moreover, reduction in fasting blood sugar was significantly reduced by 29.88%.In objective parameters, a 29.88% reduction in fasting blood sugar was observed in group-I. In contrast, in patients of group II, a 1.88% reduction was observed, but the intergroup difference was insignificant statistically ($p>0.05$); Group I was found more effective than Group I [9].

3.4 Karda Rinku et al. [10]

In this study, the Group A (n= 30) with *Bhudhatrayadiyog(*20ml *Bhumyamalaki Swaras* with *Churna* of 20 *Maricha* in two divided doses at morning & evening)with lukewarm water orally) was compared with Group B (n= 30) with standard control with modern Drug Metformin 500mg O.D. Patients were assessed with subjective and objective parameters before & after the treatment and percentage relief obtained, and statistical evaluation. It showed statistically significant results especially in, *PrabhutMutrata* (25%), *Atipipasa* (36.84%), *Bahuashee* (33.96%), *Alasya* (30.19%), *Karpada Daha* (35.71%), *Karpada Supti* (42.22%) in Group A while & Group B is more effective in *Prabhut Mutrata* (71.43%), *Atipipasa* (61.67%), *Bahu Ashee* (61.40%), *Alasya* (62.5%), *Karpada Daha* (65.38%), *Karpadsupti* (61.54%) for $p<0.0001$) Bhudhatryadiyog and Metformin are almost equally effective to reduce *Ati Pipasa, Karpadatal Daha & Karpadtal Supti* in *Madhumeha*. It shows that Group B (i.e., Metformin) has shown an overall good effect than Group B (i.e., *Bhudhatryadi Yog)* to reduce the score of symptoms [10].

3.5 Kumar Sanju, et al. 2018

Total 45 Patients recruited in this clinical trial were equally divided into three groups in which Group A with '*Nisha Triphala Yoga*'(Two Capsule of 500 mg B.D. in empty stomach for 30 days), Group B with '*Panchatikta Panchaprasrttika Niruha Vasti* (350 - 400 ml/day) for 30 days & Group C with above both interventions. Group. C was found more effective to reduce clinical features and also statistically effective to reduce F.B.S., P.P.B.S., Blood urea, Sr. Creatinine, S.G.O.T., and S.G.P.T. 21.48%, 14.34%), 4.23%, 5.07%, 5.07% & 3.40% respectively than both Group A & B [11].

3.6 Pathak Mridula et al. 2018

30 Diabetic patients underwent *Shodhana Chikitsa* with *Madhutailika Niruha Vasti* 530ml for eight days, and assessment was done after eight days. The researchers concluded that *Madhutailika Vasti* found to be effective in clinical & statistical improvement and reducing F.B.S. & P.P.B.S. by 8.49% & 9.98%, & HbA1c by 2.25%, respectively [12].

3.7 Vardhan Vishnu et al. 2018

In the present clinical study, 27 patients out of 30 patients completed the study with the intervention with *Niruha Vasti* with *Somavalkaja Kaṣhayam* & *Anuvasana Vasti* with *Somavalkaja Tailam* in *Kala Vasti* regime.Reduction in Subjective parameters.e. *Prabhutamutrata* (47.80%), *Avilamutrata* (42.31%), *Kshudhadhikya* (26.45%), *Pipasadhikya*(41.13%), *Pindikodwestana* (53.56%), *Karapada Daha* (46.63%), *Karapada Suptata* (41.63%), *Atisweda* (%), *Daurbalya* (44.81%) was observed and Objective parameters i.e. FBS & PPBS was decreased by 89.07% & 83.80% respectively [13].

3.8 Dimble Mangesh et al. [14]

Thirty patients underwent the *Panchatikta-Niruha-Vasti* (medicated enema) 430 ml for four consecutive days. On the fifth day, *Sarshapa-Taila*(Mustard-oil) 60ml *Anuvasan Vasti* for 3cycles preceded by *Pachana* with *Hingvashtak-Churna* (1gm with lukewarm water, just before 2meals/day for 5days) and local *Snehana* with *Tila Taila* and *Sarvang Bashpa Svedana* (sudation). Subjective parameters, e.g., Prabhutamutrata, Avilamutrata, were reduced by 14.20% and 14.28%, whereas F.B.S. and P.P.B.S. reduced by 55.13% and 60.54%, respectively [14].

3.9 Varsha Khot et al. [15]

Forty patients were divided equally into two groups and advised to undergo, i.e., Group. A with *Shirodhara* with *Tila Taila* daily once at 8 am and Group B with oral administration of *Jatamansi Churna* 1 gm with *Koshna Jala* for consecutive 21 days. Group B was found more effective than group A especially to reduce F.B.S. & P.P.B.S. by 91.06% and 75.78%, respectively [15].

3.10 Vikas Nariyal et al. [16]

A total of 30 diabetic patients were equally divided into three groups in this clinical study. Group A, group B, and Group C have prescribed *Harishankar Ras* (125 mg twice a day with lukewarm water), *Khadir-Kramuk Kwath* (40 ml B.I.D. in empty stomach), and a combination of both medicines, respectively. Group C was found significantly more effective in reducing the severity of clinical features, e.g., than group A & B *Prabhutamutrata* (71.42%), *Pipasadhikya* (66.66%), *Avilamutrata* (60%), *Karapad Suptata* (84.21%), *Sharir Gauravtva*(53.84%), *Tandra*(63.15%), *Sada* (72%), *Karapada Daha* (80%), *Pandurvarna Mutrata* (54.54%). Moreover, it is also more effective to improve various hematological and biochemical parameters such as E.S.R. (50%), F.B.S. (77.69%), P.P.B.S. (70.41%), Blood urea (96.06%), Sr. Creatinine (90.10%), S.G.O.T. (91.22%), S.G.P.T. (90.74%), Urine Sugar (27.27%), Urine Protein (66.66%) than rest if two groups. The Group effectively reduces blood sugar(both fasting& post-prandial) than group B [16].

3.11 Sija M/ et.al. [17]

In this study, Group. A (n= 15) received *Vidanga Rajanyadi Kashaya*(50ml B.I.D. daily half an hour before food) whereas Grp. B (n=15) received *Nishamalaki Churna*(6gm twice daily half an hour before food with *Ushna Jala*) for 30 days. Both formulations were found more effective in *Prameha*. However, *Vidanga Rajanyadi Kashaya* was more effective than *Nishamalaki Churna* to reduce biochemical parameters such as F.U.S., F.B.S., P.P.B.S. by 86.7%, 36.4%, 38.7%, respectively & subjective parameters such as Polyuria, Polydypsia [17].

3.12 Tank B. et al. [18]

The Clinical trial was carried out with ten patients in each three groups, i.e., Group A with *Darvyadi Kwath* (50ml twice a day with empty stomach), Group. B with *Madhumehari Churna* (5gm twice a day before half-hour for a meal with lukewarm water) & Group. C with both drugs for 30 days. Though all three groups are found effective in reducing blood glucose levels, Grp. C is comparatively more effective in reducing FBS, PPBS & HbA1c by 21.71%,25% & 5.49%, respectively [18].

3.13 Hakkandil Suresh et al. [19]

Thirty patients were equally divided into three groups. They underwent as Group-A with *Somavalka Kashaya Niruha Yoga Vasti*, Group-B with *Niruha Yoga Vasti* with *Somavalka Kashaya* with *Aavapa Dravya* & Group-C with *Somavalka Kashaya Niruha Yoga Vasti* in Trio-vasti pattern. In symptoms, *Prabhutamutrata* showed highly significant in all three groups (as $p<0.001$) after the treatment. In comparison, symptoms like *Avilamutrata, Alasya, Atisweda, Daurbalya & Gurugatrata* showed an insignificant response

(p>0.05) after the treatment in all three groups. Symptoms like *Karapada Daha /Suptata* & *Pipasadhikya* showed a significant response (as p<0.01) after the treatment in all three groups. Group C was found more effective than the rest of the two groups to reduce F.B.S., F.U.S., P.P.U.S. & HbA1C by 25%, 73%, 83% & 5%, respectively, while Group B was more effective than group A & C to decrease P.P.B.S. by 23 [19].

3.14 Gupta V. et al. [20]

In this study, 90 recruited patients were randomly divided into two groups and Group A with cap. *Shilajit* (500 mg twice daily) and Group B with *Asanadi Ghana Vati* (2 Vati twice daily) were studied for three months. Ten patients were dropped from the study.

Group A is statistically more significant than group B, i.e., 79.62%, 74.48%, 80.76%,79.23%, 75.79%,86.84%, 92.85% of the patients had symptomatic relief in case of polyuria, polyphagia, polydipsia, generalized weakness, burning sensation and numbness, and loss of libido respectively. At the same time, group B effectively reduces joint pain & cramps by 87.50% & 94.33%, respectively. Both groups are statistically highly significant (P < 0.001) to reduce F.B.S. and P.P.B.S. However, group A is more effective for P.P.B.S. (20.23%) and group B for F.B.S. (26.03%) [20].

3.15 K. V. Narasimha et al. [21]

One hundred ten clinically diagnosed *Madhumeha* patients were divided randomly into two groups, i.e., Group A (among 54 recruited,44 patients completed the trial) was subjected for *Vamana* with *Madanphalladi Yoga* & *Virechana* with *Trivrit, Haritaki, Aragwadha, Sanaya* + Placebo & Group B (among 56 registered, 18 patients were dropped out) underwent for *Vamana* & *Virechana* with same drugs F/B *Shilajit Yoga* 1 cap.(1000mg) twice daily before food with *Anupana Salasarasdi Gana Kashaya*. Grp. B was found more effective as compared to Grp.A to reduce FBS & PPBS by 33.05% & 28.60 respectively[21].

3.16 Deshpande SV et al. [22]

It is a retrospective study of 15 patients who are newly diagnosed or known cases of Diabetes or Diabetes having for less than a year who were subjected to *Vamana* with *Madanphaladi Yoga* preceded by *Dipana-Pachana* with *Hingvastak Choorna* (3 grams before food for three days) F/B *Shodhana Snehapana* with Cow ghee, *Bahya Snehana* with *Tila Taila* and *Swedana*. After *Samsarjana Karma,* patients were assessed. Significant relief was obtained in Subjective parameters *Daurbalya, Kshudha vriddhi, Pipasavriddhi, Avilamutrata, Naktamutrata, Pindikodweshtana, Swedatipravritti, Hasta Padatala Daha, Shwasakashtata, Pipilika Sancharavat Prachiti,* and *Ksheena Kamechcha*.Moreover,highly significant decrease in FBS & PPBS by 86.74% & 81.88%. respectively was observed after *Vamana* (p<0.005). The researchers concluded that patients receiving such bio-purification as *Vamana* treatment, as the first line of treatment, may respond better to further *Shamana* treatment, leading to better relief from symptoms and sugar and lipid control [22].

3.17 Jena Sonalika et al. [23]

This clinical study was carried out with 50 patients equally divided into three groups with different interventions for one month, i.e., Group I with *Phalatrikadi Kwatha* 50ml+ 1gm of *Haridra Churna*+ 10 ml honey twice daily before a meal (Trial Drug), Group II with Metformin 500mg1 tab O.D. (control drug) and Group III with placebo 50ml +1gm of *Haridra Churna* + 10 ml of Honey twice daily before a meal. Though all three groups effectively correct signs and symptoms of diabetes mellitus, a group I was found more effective to reduce *Daurbalya, Pipasadhikya, Pindikaveshtam*, P.P.B.S. by 74.58%, 94.34%,84.78% &16.66%, respectively. Group II was more effective than the rest of the two groups to decrease F.B.S. by 20.36% & group III significantly reduced *Prabhutamutrata* by 54.48% for p-value 0.001 [23].

3.18 Agarwal Prateek et al. [24]

Among 46 patients recruited in this study are equally divided into two groups with different interventions for one & a half months, i.e., Grp. A underwent *Virechana Karma* with *Trivritadi Leham* (50gm) in a classical manner followed by Oral Hypoglycemic Agent & Grp. B subjected to Classical *Virechana Karma* with *Trivritadi Leham* (50gm) followed by oral administration of *Ayaskriti* (20 ml B.I.D. after meal). Among them, 06 patients dropped out in this study. In both groups, A & B, Polyphagia, Polyuria, Polydipsia, Burning sensation, and Weakness were highly significantly reduced after the completion of

treatment. Moreover, both interventions were effective in relieving blood glucose levels by FBS, PPBS, Sr. triglycerides & Sr. cholesterol 46.23%, 43.26%,56.01% &54.14% respectively .HbA1c shows a significant difference of 1.75 +_ 1.08 in both groups [24].

3.19 Kumar S. et al. [25]

Total 84 Patients were randomly divided into three groups, i.e., Group‑A (n=33) was treated with the trial Drug, i.e., *Mamajjaka* (500mg twice a day), Group B (n=23) was subjected to *Shilajatu* (500mg twice a day) and Group C (n=28) with the modern antidiabetic Drug. After assessment for three months, it was observed that the trial treatment could produce a statistically significant favorable shift in grade scores ($p<0.01$) in most of the symptoms (polyuria, polyphagia, polydipsia, weight loss, weakness, loss of libido, joint). The *Mamajjaka* treated patients have shown a better percentage of fall in F.B.S. (19.47%), in comparison to Shilajatu treated patients (8.93%), while in the case of P.P.B.S., the percentage of reduction was almost equal in both the groups, that is, 24.03% [25].

3.20 Kolhe N. S et al. [26]

Total 30 patients completed the study in which those were randomly and equally divided into three groups, i.e., Grp.1 with *Katak Khadiradi Kashyayam* (20 ml twice daily before meal), Grp.2 with *Niruryadi Gulika* (500 mg 2 tablets with lukewarm water twice daily before meal) & Grp.3 with combinations of both drugs.

After the interventions for 30 days, it was observed that Group 1 was found comparatively more effective to reduce HbA1C by 3.27% than the other two groups, while Group 2 was significantly effective in decrease the severity of clinical symptoms, e.g., *Prabhutamutrata, Kshudhadhikya, Kara Pada Suptata, Atisweda, Klama* & E.S.R. by 50%,27.3%,42.7%,42.9%,46.2%, 40% respectively. On the other hand, Group 3 was found comparatively more effective to improve subjective parameters, e.g., *Avilamutrata, Pipasadhikya, Karapada Daha, Alasya* by 44.4%,41.7%,28.6% &53.3% respectively and to decrease F.B.S., P.P.B.S., F.U.S., P.P.U.S. by 18.51%,18.65%,66.7%, 88.9% respectively. Both Group 1 & group 2 are effective in reducing Avilamutrata, *Pipasadhikya* [26].

3.21 Jindal N. et al. [27]

In this study, 20 diabetic patients were randomly but equally subdivided into two groups, i.e., group A with *Vamana* using *Ikshwaku Beeja Choorna* mixed with Honey in a dose of 4‑8 gm as per the requirement of the patient) and group B with *Virechana* using *Snuhibhavita Katuki* in a dose of 6‑10 g as per the *Kostha*).Deepana Pachana preceded both these interventions with *Trikatu Churna*(3‑6 g/day in two divided doses for 3‑5 days), which was followed by *Aabhyantara Snehapana* with *Triphaladi Ghrita* in increasing dose as per the *Koshtha* and *Agni* of the subject for 3‑7 days, *Sarvanga Abhyanga* with *Tila Taila* and whole body *Swedana* for two & 3 days for group A & B respectively. After *Shodhana* followed by 3-7 days *of Samsarjan Karma*, all patients were assessed for biochemical parameters of Diabetes mellitus. The FBS & PPBS was reduced by 42.3% & 47% respectively after *Vamana*.While the FBS & PPBS was decreased by 51.5% & 34.8% respectively after *Virechan*a.It can be summarized that *Vamana* and *Virechana* cause a marked reduction in F.B.S. and P.P.B.S. levels [27].

3.22 Dass R. K. et al. [28]

Total 22 Obese patients(both pre-diabetes & Diabetes) were subjected to *Vamana* procedure preceded by *Abhyantara Snehapana* with *Shudha Ghrita, Sarvanga Abhyanga* with *Bala Taila* & *Sarvanga Baspa Sweda*. For *Vamana*, all patients were advised to take *Ghrita- Yukta Yavagupana* (Ghee Mixed with Boiled Rice) = 200 - 400 gms approximately according to *Kostha* +*Yastimadhu Kwath* (Decoction of Glycyrrhiza glabra) in the approximate quantity of 3 – 5 liters+ *Madanphala Pippali* in Quantity present in Fist according to patient's hand added with sufficient amount of Honey (50 - 100ml approximately)+ *Saindhav Lavana* (Rock Salt)in 20–30gms approximately) and then all are assessed after *Samsarjana Krama* was according to the *Shuddhi* after *Vamana Karma*. It was observed that *Vamana Karma* provided a statistically significant reduction ($P<0.05$) in S. Triglycerides by 21.66%, but there were insignificant reductions in Fasting blood sugar & S. Cholesterol level by 4.31% & 4.99%, respectively ($P>0.05$). The researchers concluded that emesis therapy has a better role in the prevention of NIDDM in pre-diabetic subjects and also capable of maintaining

long-lasting glycemic control in NIDDM subjects [28].

3.23 Karhade Mukund [29]

A total of 30 patients were subdivided into two groups with two distinct interventions, i.e., Group A with *Vaman Karma* by *Ikshwabeeja Majja Yoga* & Group B with *Virechan Karma* induced by *Abhayadi Modak*.Deepana Pachana precedes both types of interventions with *Trikatu Churna, Snehapana* with *Nimba Taila, Abhangya* with *Moorchita Tila Taila,* and *Sweda* with *Sukoshna Jala Snana*. Samsarjana Karma followed both Shodhana therapies, and during the follow-up period, the patient received placebo capsules for one month.

This study shows that Group B is more highly significant & effective than group A in the case of *Pipasadhikya*($p<0.05$), *Karapada Daha* & *Supta*($p<0.001$), while no statistically significant difference seen in-between group A & Group B in the case of *Prahuta Mutrata, Avila Murata* & objective parameters. In the case of objective parameters, in F.B.S., the mean of Group A is 35.87 & group B is 35.21, while the mean of P.P.B.S. of Group A is 75.67 & group B is 88.60. The mean value of F.U.S. & P.P.U.S. of Group A is 0.233 & 0.60 resp. that of group B is 0.17 & 0.83 respectively [29].

3.24 Tanna Illa et al. [30]

Total 16 patients were subjected to four different interventions, i.e., *Virechana* Group 1 with *Virechana* with 40 ml of decoction of *Aragvadha Majja*-15 gm+*Haritaki Churna* 15 gm+ *Katuki Churna* 5 gm mixed with 20 ml of castor oil along with 250 mg of *Ichchabhedi Rasa*, Oral group1 with *Shamana Yoga,* i.e., *Madhumehahara Yoga, Vasti* group2 with *Pramehahhna Vasti* (Decoction of *Vijayasara, Jambu Beeja, Arjuna, Vitkhadir*a *+Kalka* of *Amalaki, Methibeeja, Tejapatra + Tila Taila*+ honey+ rock salt) & Oral group2 with *Prameha Ghana Vati*.

After two months, all groups are found effective in relieving Subjective& objective parameters, but mark improvement in the oral Group and Basti group are observed 73.3% and 75%, respectively. *Virechana* group1 was found comparatively more effective than other groups to reduce *Avila Mutarta, Mutra Madhurya, Pipasa* & *Bahu Ashanata* by 87.50%, 80.12%,75% & 80% respectively, and *Vasti* group2 was observed comparatively more effective than other groups to decrease *Prabhutamutrata* by 60% [30].

3.25 Singh K. S. et al. [31]

Total 72 patients were divided into two groups, i.e., Grp. A (n=36) with *Saptarangyadi Ghanavati* 5 tabs(each200 mg) T.D.S. after food with Luke warm water and Grp. B (n=36)-*Saptarangyadi Ghanavati* (same dose) in addition to the antidiabetic (Allopathic) medication. Five patients were dropped out of the study. After two months, Group A was found comparatively more effective to improve clinical symptoms, i.e., *Prabhutamutrata, Alasya, Avilamutrata, Kshudhadhikya, Pindikodweshtana* by 69%, 59%, 82.3%,56%, 67%, respectively, and to reduce biochemical parameters such as F.B.S., P.P.B.S. by 12%,24% respectively. On the other hand, Group B was more effective in improving subjective parameters, e.g., *Pipasadhikya, Shrama, Atisweda,* by 64.3%,58%, 32.2%, respectively[31].

3.26 Pandey RK et al. [32]

This clinical study is conducted over 38 *Sthula Pramehi* patients in which they were divided into two groups, viz. Group A (18 patients) with *Vamana* with *Shaman*a(*Neem Giloy Satva* capsule500 mg twice daily after meals) and Group B(20 patients) with *Virechana* with *Shamana* as group A. After 30 days. Grp B was observed comparatively more effective than Grp A in reducing subjective parameters e.g. *Prabhutamutrata, Avilamutrata, Naktamutrata, Pipasadhikya, Swedadhikya, Daurbalya, Kahudhadhikya , Atinidra, Sramaswasa, Mukhamadhurya, Vibandha, Atinidra, Hastapada Daha , Karapada Suptata, Pippilika Sancharti* by 81.51%, 63.46%, 77.59%, 71.74%, 67.75%,36.23%, 56.52%,29.03%, 33.85%, 77.91%, 55.41%, 29.03%, 81.25%, 69.64% & 66.2% respectively. The researchers quoted that *Vamana* very well manages *Kapha* dominant symptoms such as *Prabhutamutrata, and Avilamsutrata.* On the other hand, *Pitta* dominant symptoms *Kara Pada Tala Daha* and *Virechana can easily correct Atisweda.* Vamana Virechana significantly controls symptoms like Kara-pada Suptata, Kshudadhikya, Trishnaadhikya, Gala Talu Shosha, and Pindikodwest*ana*. Though both the procedures relieve the symptoms, it is *Vamana* that provides more relief than *Virechana. Vamana* reduces the levels of F.B.S., P.P.B.S. by 9.86% & 29.525% compared to *Virechana* [32].

3.27 Tanna I. et al. [33]

Total 94 patients were divided equally into two groups, i.e., Grp. A with *Mehamudgara Vati*(250 mg 3 tabs. T.D.S. after food with lukewarm water) & Grp. B with the modern antidiabetic Drug. After three months, Group A was found more effective to reduce *Prabhutamutrata, Kshudhadhikya, Pipasadhikya* & P.P.B.S. by 81.48%,83.33%,78.79% &17 %, respectively, while Group B was observed more effective to reduce *Pindikodwestan, Karapada Dada, Karapada Suptata, Atisweda, Daurbalya* and F.B.S. by 84.37%, 78.95%, 84.93%,67.39%,80.55%&15% respectively [33].

3.28 Thirunavukkarasu M S et al. [34]

It is a single group study of over 20 patients treated with *Kathaka Khadiradi Kashaya*(50ml before food twice daily for 28 days.Due to this intervention, clinical symptoms e.g. *Prabhoota Mootrata, Avila Mootrata, Pipasa, Kara Pada Tala Daha, Kara Pada Tala Supti Mootramadhurya, Atisweda, Dourbalya* were significantly decreased by 38.46%,80.95%,43.2%,60.71%, 50%, 69.23%, 51.3%, 55.26% respectively for $p<0.001$, This study also shows effective results in reducing blood glucose levels FBS & PPBS by 32.55% &14.71%) respectively with Significance=$p<0.001$.The researchers concluded that the Kathaka Khadiradi Kashaya is an ideal remedy in patients suffering from Mild to Moderate Madhumeha [34].

3.29 Parmar Darshan et al. [35]

Total 92 diabetic patients were studied within two groups with intervention with mineral compound orally that is prepared with two distinct methods, i.e., Group A(n=27) with *Vanga Bhasma* by *Ardhagaja Puta*, B (n=25) with *Vanga Bhasma* by *Gaja Puta*, & C (n=23) with *Sahapana*(control group). 250 mg from each sample of Bhasma and 250 mg Sahapana was given in capsule form to open it on palm & mixer made by adding previously given Honey. This mixture was given to licking twice before 45 min of meals study reveals the better effect of Group A than Group B [35].

3.30 Khedekar S et al. [36]

In this clinical study, a total of 126 patients were treated with *Makaradhwaja* prepared from three different types of *Swarna* with *Sahapana,* i.e., Grp A (n=42), *Makaradhwaja* prepared by *Swarnavarkha* (M.K.V.), Grp B (n=42)- *Makaradhwaja* prepared by *Swarna Bhasma* (M.K.B.) &Grp C (n=42)- *Makaradhwaja* prepared by *Swarnapatra* (M.K.P.). After 60 days, Significant relief in all signs – symptoms & blood glucose level (fasting and 2 hr) was found in both Drug treated groups. *Makaradhwaja* prepared by *Swarna Varkha* and *Swarna Bhasma* was found more effective than that prepared by *Swarna Patra,* while *Makaradhwaja* prepared by *Swarna Varkha* is slightly more effective than the prepared by *Swarna Bhasma* [36].

3.31 Pandharkar Gaurangi et al. [37]

In this study, 05 diabetic patients underwent *Virechana* with *Aragvadha KapilaVati* or *Abhayadi Modaka*, preceded by *Arohi Snehpana* with *Mahatiktaka Ghrita* for three days. *Virechana* was repeated every 15 days for three months. After the first cycle of *Shodhana, Shaman Chikitsa*, i. e. *Vasant Kusumakara Rasa* 125mg and *Dhatrinisha Choorna* (500+250mg) were given. Simultaneously, specific diet regimens and exercises like *Suryanamaskara* were also advised to all Study subjects. During this period, Blood Sugar Levels were monitored, and accordingly dosage of OHAs was adjusted. *Shodhanottara Shaman Chikitsa* was found to be effective in lowering Blood Sugar Levels as well as HBA1C levels, as well as it reduces the OHA dependency of type II diabetic patients. Significant improvement was observed in specific symptoms such as *Prabhutamutrata* (83.33%), Frequency of urine(75%), *Pipasaadhikya* (81.82%), *Bahavashi-Kshudha-Adhika* (76.92%), *Daurbalya* (69.23%), *Karpadataladaha* (91.67%) after three months of treatment. The relief % of FBS, PPBS & HbA1c were 52.30%, 42.85% & 70.99% respectively [37].

3.32 Tate P. [38]

Total 56 patients equally divided into two groups, i.e., Group A with *Naga Bhasma* orally(60 mg B.D.) & Group B with *Naga Bhasma* with placebo capsules(1 cap.). After 28 days, significant relief in all signs and symptoms were observed, along with a significant decrease in blood glucose level (fasting and 2 hr) was found in both Drug treated groups. & *Naga Bhasma* prepared by both methods is equally effective [38].

3.33 Thirunavukkarasu MS, et al. [39] Jyothi Kumari [24]

In this trial, the 42 patients were equally divided into two groups and underwent, i.e., group 1 with *Nyagrodhadi Ghanavati* alone and group 2, *Virechana* 200 ml of *Kwatha* prepared with coarse powders of each *Triphala (*100 gms)+ *Katuki (*5 gms) +*Trivrita (*5 gms) along with *Eranda Taila (*50 ml) and *Icchabhedi Rasa* 250 mg preceded by *Goghrita Snehapana &* followed by *Nyagrodhadi Ghanavati*
The *Virechana* and *Nyagrodhadi Ghanavati* group (Combined Therapy) provided statistically highly significant (P<0.001) relief in all subjective parameters of *Prameha*. Post-Prandial Blood Sugar was reduced by 6.43% at statistically insignificant (P<0.10). The researchers concluded that results obtained in the Combined Therapy group are better than the *Shamana* therapy [39].

3.34 Dave Dyauti et al. [40]

Thirty-five patients were divided into two groups, i.e., Group A with *Medoghna Rasayana Vati* (1gm B.D. with lukewarm water) and Group B with *Medoghna Rasayana Vati* with modern antidiabetic medicine same schedule as in Group A. Both groups have provided better relief in signs and symptoms of the *Madhumeha* [40].

3.35 Shilpa G. et al. [41]

In this clinical trial, 30 patients were equally divided into two groups & underwent i. e. Group A with both *Bahya* and *Abhyantara Rukshana* (till attainment of *Samyak Rookshana Lakshana*)followed by *Virechana* & Group B with both *Bahya* and *Abhyantara Snehana*(till attainment of *Samyak Snehana Lakshana*) followed by *Virechana.* After 3 month,Group A was found comparatively more effective than group B to reduce FBS, GTT, BMI & Total Cholesterol by18.73%,18.76% ,12.43% & 19.45% respectively [41].

3.36 Thirunavukkarasu MS et al. [42]

This clinical study has been carried with Group A(n=21) subjected to *Nishakatakadi Churna* alone. Group B(n=16) was advised to undergo *Virechana* with Decoction made up of coarse powder of *Triphala(*100gms)+ *Katuki Chunra (*20-25gms) added with *Eranda Taila (*5-40ml) & *Icchabhedi Rasa* 1-2 tabs (125-250mg) preceded by *Snehapana* with *Shuddha Goghrita. Nishakatakadi Churna followed ita* for 30 days. Carbohydrate and fat-restricted diets were advised for both groups.

Statistically highly significant results were observed in *Prabhutamutrata* (13.69%), *Pipasa Adhika* (13.69%), and *Kshudha Adhika* (20.53%) for P<0.05. *Virechana* provided statistically significant reduction in FBS& PPBS by 10.63% & 23.64% respectively for-value P<0.01. The researchers interpreted that the *Virechana* combined with *Nishakatakadi yoga* effectively controls*Madhumeha* [42].

3.37 Aithal P et al. [43]

In this clinical trial, a total of 24 patients underwent for Group A (n=12) with *Bahya* and *Abhyantara Rukshana*((till attainment of *Samyak Rookshana Lakshana*) followed by *Vamana* procedure whereas in Group B (n=12) with *Bahya* and *Abhyantara Snehan*(till attainment *Samyak Snehana Lakshana*) followed by *Vamana* procedure. After 3 months, *Rukshana Purvaka Vaman* (FBS- 12.96% , PPBS-12.13%, urine sugar- 34%, BMI- 4.44% & weight in kgs-4.40%) is more effective than *Snehana Purvaka Vaman* (FBS- 5.09% , PPBS- 3.38%, urine sugar- 15.82%, BMI- 1.27% & weight in kgs-1.69%). this study reveals that *Rukshana Karma* alone is effective than *Snehan Purva Karma,* followed by *Vamana* [43].

3.38 Pakanikar Satish et al. [44]

In this clinical study, 26 patients were subjected to Group I (n=09) with kernel powder of the *Kuberaksha* seeds in the capsule form & Group II (n=17) with *Kuberaksha Ghanavati* of the kernel with Lukewarm water each for six weeks. Both *Kuberaksha Ghanavati* and the kernel powder of the seed had induced a reduction in blood sugar at a low dose. Still, in the *Ghanavati* group, the blood sugar level was increased but statistically significantly decreased in the kernel powder of the seed at a high dose [44].

3.39 Patel Asha et al. [45]

Total 28 patients were equally divided into two groups, i.e., Group A subjected to a combination of *Virechana* with *Abhayadi Modaka* (preceded by *Deepana Pachana* with *Trikatu Churna*+ *Abhyantara Snehapana* with *Triphala Ghrita)* but followed by *Vidangadi Ghanvati* with *Ushnodak* & Group B received only *Vidangadi Ghanvati*. The total duration of the study was 12 weeks.

Shodhan Purvaka Shamana Chikitsa has induced significant results in clinical & biochemical parameters. The relieving percentages are *Prabhutamutrata* (77.77%), *Avilamutrata* (68.75%), *Pipasadhikya (*78.94%), *Kshudhadhikya* (71.0%), *Pindikodweshtana* (61.76%), *Kara-padatala Daha* (73.33%), *Kara-padatala Suptata*(70.0%),*Daurbalya(*63.63%) and FBS (28.35%), PPBS (31.13%), FUS (42.30%), PPUS (47.61%) & HbA1C (50.25%). This study concluded that Shodhan Purvaka Shamana Chikitsa is better than Shamana Chikitsa [45].

3.40 Harish Ahuja et al. [46]

Total 42 diabetic patients of *Madhumeha* were treated with *Medoghna Rasayana Vati* for 30 days in the first Group (n=27). In the second Group (n=15)., the patients were given *Virechana*(preceded by *Snehapana* with *Goghrita*) with 220 ml of decoction of coarse powder of *Triphala* (50gm)+ *Kutaki* (5gm) followed by *Medoghna Rasayana Vati* for 30 days.

After evaluating the total effect of therapies, it was observed that Group 2 was found highly significant (P<0.001) to reduce F.B.S. & P.P.B.S. by 12.83% &15.08% respectively & to improve chief complaints than the first Group. The researchers stated that the *Virechana* and *Medoghna Rasayana Vati* provided better relief in the patients of *Madhumeha* in comparison to *Medoghna Rasayana Vati* alone [46].

3.41 Anand M. et al. [47]

Twenty-nine patients were divided into three groups, i.e., Group-I with *Pramehaghna Ghana Vati* orally (2 gm a day thrice with lukewarm water for 1 ½ month), Group-II with *Prameh*ghna Basti for 16 days including *Niruha* and *Anuvasana,* and Group-III with Placebo capsule - 500mg thrice a day. The study duration was two months. Strict diet control and exercise were advised to all groups. The researchers concluded that both *Basti* and *Pramehaghna Ghana Vati* offered more encouraging results. Still, percentage relief was more in *Basti* group than rest of two groups & *Basti* can prove better treatment modality for *Avaranjanya Madhumeha* because the drugs used in it acts against the *Kapha, Meda,* and *Kleda* and *Sneha* helpful to normalize *Vata [*47].

3.42 Jani Jalpa et al. [48]

The clinical study was done over a total of 50 patients between two groups, i.e., Group A(n=25) with *Vastraputi Vanga Bhasma* and Group B (n=22) 22 with *Vanga Bhasma* prepared by *Jarana* and *Marana*. A highly Significant result was observed in symptoms like *Prabhutmutrata, Aavilmutrata, Kshudhadhikya, Trishadhikya,* and *Pindikoudvesthana* groups. However, the interventions were not significant & effective in reducing blood glucose levels [48].

4. METHODS

The core observations of all these studies are summated as follows:

4.1 Type of Randomization and Methodology

The number of included trials with different methodology is mentioned in Table 1. Among the total of 42 clinical trials enrolled, 01 trial study was multi-centric, and the rest all were single centric trial studies. Among them, 03 R.C.T.with single-blind while 01 R.C.T. has study design having a double-blind controlled study. The rest of the 38 were simple random studies. The sample size of the studies was found to vary; the minimum sample size was 05 & maximum 126. There are total R.C.T. (1,242 participants) & N.R.C.T. (non-randomized controlled trials with 501 participants. Among all 42 clinical trials, the maximum duration of intervention was three months & the minimum period was 15 days.

4.2 Inclusion-Exclusion Criteria

Confirmed cases of Diabetes Mellitus type II with either sex diagnosed based on clinical features & laboratory investigations were included in maximum clinical trials. All these patients recruited in the studies were from 30 and 65 years, irrespective of gender. Patients with ages between 30-60 years were primarily preferred in these trials. Both obese & non-obese patients of Diabetes mellitus are included. Further details are narrated in Table 2.

Patients having pre-diabetes, Type I DM [IDDM], Diabetes insipidus, Drug-induced, Uncontrolled, or Diabetes Mellitus with complications were excluded from this study. Diabetic patients on Insulin therapy were also not recruited in this study.

4.3 Assessment Parameters

All these studies were critically analyzed based on the type of Subjective or objective criteria used, type of intervention subjected & their therapeutic outcomes reported. Assessment in meta-analysis will be done by comparison of various research findings and their interpretations only. Overview of all clinical studies, it is reflected that objective criteria in the form of hematological parameters such as C.B.C., E.S.R., Biochemical parameters such as Blood sugar both fasting & post-prandial (F.B.S. & P.P.B.S.), HbA1c, GTT Liver profile(LFT), Renal profile(RFT), Lipid profile; anthropometric parameters such as B.M.I. & Weight, Urine sugar (U.S.F. & U.S.P.P.), Turbidity of urine was adopted by most of the studies for the assessment of the result. Whereas subjective parameters, e.g.,., *Hastapadadtaldaha, Kshithilangata, Daurbalya, Pippasadhikya, Karpadyosuptata, Talujivhadantmallotpati, Prabhutmutrata, Kshudhadhikya, Naktamutrata, Atisweda, Sthaulya, Alasya, Avilamutrata, Pindikodweshtana, Bahu Ashee, Aruchi, Agnimandya, Mukha Shotha, Pada Shotha, Shwasa Kashtata, Panduta, Mutralpta, Shayyasana Sheela, Swapna Sheela, Durgandhaja, Savoparodha, Gurugatrata, Shramashwasa, Mukhamadhurya, Vibandha, Pipilike Sancharati (Tingling Sensation), Klaibya, Klama, Sandhishool, Kandu, Anasarka (Sarwangashotha), Shirashool, Hrillas ,Chhardi, Kriyahani, Hridgraha, Baddha Pushishata* were evaluated. The status of *Oja* & *Agni* was also taken into consideration. These details are given in Table 2.

4.4 Type of Intervention

Recruited trials are classified based on the type of treatment modalities or intervention (*Shodhana Chikitsa, Shamana Chikitsa,* or their combination) used to manage *Prameha*. The number of studies with these different interventions is tabulated in Table 3. Among *Shodhana*, these trials are again sub-classified under heads of Only single therapy of *Panchkarma,* i.e., Only *Vamana, Virechana, Vasti,* or comparison/combinations of any two or three that is depicted in Table 4. Among the use of *Shamana Chikitsa*, these trials are again sub-classified under heads as Only herbal drugs, mineral drugs, or combination, i.e., herbo-mineral drugs or Lifestyle modifications with details of the dosages and duration of treatment that are provided in Table 5.

Table 1. Number of trials with different types of methodology

S.N.	Type of methodology	Number of studies
1	Studies with single Group	06
2	Studies with comparative groups	35
	Study with Placebo	03
	Study with diet control lifestyle modifications	05
	Study with an oral hypoglycemic agents	24
3	Open study	02
4	Single-blind Studies	01
5	Double-blind Studies	01
6	Single-center study	41
7	Multi-center study	01

Table 2. Number of trials with the type of Assessment parameters

S.N.	Assessment parameters	Number of studies
1	Studies conducted with only Symptoms of *Prameha*	01
2	Studies conducted with only objective criteria	04
3	Studies with combinations of both	37

Table 3. Number of trials with a specific type of intervention

S.N.	Various treatment modalities	Number of studies
1	Only *Shodhana Chikitsa*	12
2	Only *Shamana Chikitsa,* including Lifestyle modifications	15
3	Combination of both *Shodhana* & *Shamana Chikitsa*	15

Table 4. Number of trials with a specific type of *Shodhana Chikitsa*

S.N.	Type of *Shodhana Chikitsa*	List of drugs	Number of studies
1	Only *Vamana*	*Madanphaladi Yoga, Ikshubeeja Churna* with Honey.	**04**
2	Only *Virechana*	*Trivruta Lehya, Manibhadra Guda* with *Ushnajala, Abhayadi Modak*	**08**
3	Only *Vasti*	*Prameghna Basti, Guduchi Taila (Anuvasan Basti*), *Rukshana Basti, Dhanwantari Taila, Madhutailika (Niruha Basti).Niruha & Anuvasan With Somavalkaja Kashayam & Somvalkaja Taila* respectively, *Somavalka Niruha Yoga Basti* & *Somavalka Niruha* with *Avapa Dravya* & *Somavalka Trio-Basti, Panchatikta Basti.*	**06**
4	Only *Shirodhara*	*Tila Taila*	**01**
5	Comparisons of any two	*Vaman* with *Ikshwakubeeja Choorna* mixed with Honey & *Virechan* with *Snuhibhavita Katuki*, *Vaman* with *Ikshwakubeeja Majja Yoga* & *Virechan* with *Abhayadi Modak*, *Vaman* with *Madanphalladi Yoga* & *Virechan* with *Kalayanaka Guda*, *Vaman* & *Virechan*, *Virechan* with *Aragvadha Majja*-15 gm, *Haritaki Churna*-15 gm, *Katuki Churna*-5 gm along with castor oil (20ml) & *Ichhabhedi Rasa* (250 mg) and *Vasti* with *Pramehaghna Niruha* & *Anuvasana Basti (Kalabasti*), *Panchatikta Basti.*	**06**
6	Combinations of two or three therapy:	List of drugs: *Vaman* with *Madanphaladi Yoga*(M.Y.) followed by *Virechan* with *Trivrita Churna* - 5g & *Danti Churna*- 1g mixed in *Triphala Kwath* 100 ml, *Vaman* & *Virechan, Vaman* with M.Y. followed by *Virechan* with *Trivrita + Haritaki + Aragwadha*.	**02**

4.5 Outcome Measures

All subjective & objective criteria were significantly improved with maximum extent. In clinical studies with *Shaman Chiktsa,* a Single or combination of drugs given to the patients came out to be effective in *Prameha Chikitsa*. Clinical trials with a combination of both *Shodhana* & *Shaman Chikitsa* to assess their effects over Objective variables, i.e., F.B.S., P.P.B.S. & HbA1C is found to be highly significantly effective in almost all studies with no undue effects.

5. RESULTS AND DISCUSSION

Diabetes mellitus is a clinical condition that is strongly characterized by elevated blood sugar levels due to primary or secondary deficiency of insulin. *Acharya Sushruta* has classified the *Prameha* as *Asantarpanoth* & *Santhoparsthanoth Prameha* based on its pathology & he also narrated their specific management according to Hetu [49]. Therefore, the selection of any regime, procedure, or Drug for the management of *Prameha* should be meticulously after assessing this cause. Increased demand for Ayurvedic medicines or interventions due to the high cost and innumerable side effects of allopathic medications is vital.

5.1 Role of *Shodhana Chikitsa*

Panchakarma plays a vital role in preventing & manage Diabetes mellitus successfully as all recommended procedures detoxify the body by eliminating the stagnated, vitiated Doshas out of the body in a smooth manner. *Shodhana* therapy is the first line of treatment for the diabetic patient who is obese or overweight, according to various texts. The role of *Panchakarma f*or the management of *Prameha* can be discussed one by one as follows:

5.1.1 Role of *Vamana*

Vamana is generally indicated by *Acharya Charak,* in *Prameha* especially in obese persons or people with *Kapha –Meda* predominance *Vamana induces Apatarapana* as it minimizes peripheral insulin resistance and increases the utilization of glucose by muscles. It also alleviates *Bahudrava Kapha* & *Meda,* which are

chief pathological factors in the *Prameha*. *Madanphala Yoga* is primarily used as *Vamaka Yoga* in these previous studies as it is *Madhura, Tikta, Laghu, Ruksha, Ushna,* and its *Lekhana* properties subside *Kapha* & *Vata Dosha*. According to Nitin Jindal et al. 2013, *Ikshubeeja Churna* with Honey is also effective for *Vamana* in *Prameha* due to its action similar to other *Vamana* (emetic) drugs [27].

According to Dr. Karkand Mukund. et al.2012, *Ikshwabeeja Majja*(fruit) used as *Vamaka Yoga* removes excessive *Kleda* from the body, lowers down the insulin resistance due to its *Tikta Rasa, Laghu & Ruksha Guna, Katu Vipaka*, Hypo-lipidemic, *Kapha-Pittaghna* actions & its Immune modulatory, anti-oxidant & anti-hyperglycemic nature [29].

5.1.2 Role of *Virechana*

Virechana is used in disorders originated from the vitiation of *Pitta* &*Rakta,* i.e., *Dosha* & *Dushya,* respectively, which is indicated in *Prameha*. *Virechana* reduces various enzymes responsible for this mechanism, and so reduces hepatic glucose production. It is especially useful in the management of *Pittaja Prameha* & its associated complications. Mainly *Piita Rechak Dravyas,* e.g., *Katuka, Triphala, Trivrutta Leha* (*Tikta, Katu Rasa, Kapha Pittahara,* and *Rechaka* properties*)*, *Eranda Taila* are helpful in this condition [7]. *Tikshna Virechana* with *Snuhi, Abhayadi Modak* are useful *Kaphaja Prameha* &*Prameha Pidika*. *Dhatwagnidipana* is induced by *Ushna* & *Tikshna* properties of *Snu*hi & *Tridoshaghna* properties of *Abhayadi Modak* [29,45]. All these *Virechak* drugs are cholagogues in nature which reduces various enzymes responsible for hepatic glucose production & ultimately, reduction in hepatic glucose production occurs. *Virechana* effectively reduces the symptoms of metabolic syndrome as it evacuates several waste products from the body & significantly decreases the levels of fasting blood glucose & serum triglycerides.

Table 5. Number of trials with a specific type of *Shamana Chikitsa*

S.N.	*Shamana Chikitsa*	List of Drugs	Number of studies
1	Only Herbal drugs	*Mustadi Kwath, Vidangadi Ghanavati, Prameha ghna Ghanavati, Nishakatadi Yoga, Kernel Seeds Powder Capsules, Amrutadi Guggula, Kathakadi Khadiradi Kashaya, Nyayagrodhadi Ghanavati, Pathadi Ghanavati, Neem Giloy Satva Capsules, Trayushnadi Gutika, Phalatrikadi Kwatha, Vidanga Rajanyadi Kashaya, Nishamalaki Churna, Darvyadi Ghritam & Kwath, Asanadi Gana Kashaya, Medoghna Rasayana Vati, Trivritadi Leham, Ayaskriti, Mamajjak Churna, Dhatrinisha Churna, Bhuddhatrayadhi Yoga (Bhumyamlika & Maricha), Madhumehari Churna, Harishankhar Rasa, Nisha Triphala Yoga, Katak Khadhiradi Kashaya, Niruryadi Gulika, Mehamudgara Vati, Jatamansi Churna, Somavalka Kashaya.*	**20**
2	Only Mineral drugs	-	**00**
3	Only Herbo-Mineral drugs	*Shilajit, Naga Bhasma, Vanga Bhasma, Vasantkusumakar Rasa, Swarna Patra, Swarna Bhasma, Swarna Varkha.*	**03**
4	Only Lifestyle modifications	Exercise, Control Diet plan, *Pathya- Apathya.*	**01**
5	Comparison of two or three drugs	*Mamajjaka Churna & Tab.Shilajit, Asanadi Ghanavati & Tab.Shilajit,* Placebo Capsule *&* Tab.*Shilajatu, Darvyadi Ghritam* & Tab.*Shilajit*.	**03**
6	Combination of two or three drugs	*Vasantkusumakar Rasa* with *Dhatrinisha Churna, Madhumehari Churna* with *Darvyadi Kwath.*	**02**

5.1.3 Role of *Basti*

According to Kumar Sanju et al. 2018, drugs used in the *Panchatikta Panchaprasrttika Niruha Vasti* possess predominance of *Tikta & Madhura Rasa, Laghu* & *Ushna Guna* & *Kapha-Meda-Kledaghna* properties. Therefore, these drugs directly induce *Lekhana* & regulate glucose metabolism [11]. Such type of *Vasti* formulation cleanses the *Koshtha* by eliminating vitiated toxins(*Malarupi Abadha Meda)* and corrects the intestine's functioning, which in turn regulates the proper absorption of glucose. It also corrects the *Jatharagnimandya* & *Dhatavagnimandya (*glucose metabolism) and enhances glucose absorption in the body. *Prasanta Kumar Sahoo, Shamsa Fiaz,* proves *Raktaprasadana, Chakshyushya, Rasayana properties with anti-inflammatory, lipid-lowering activities Panchatikta Panchaprasrttika Niruha Vasti*. et al. 2016 & Dr. Mangesh Ganpat Dimble et al. [17].

Dr. Mridula Pathak discusses the Pramehghna effect of Madhutailika Vasti et al. 2018 based on its *Dhatusanrakshan* (immune-modulatory), *Strotoshodhan* as well, as *Dhatuvardhana* (maintain tissue regeneration) properties [12]. Antihyperglycemic properties of *Somavalka* is proved by Vishnu Vardhan Narayanam et al. 2018 & Dr. Suresh Hakkandil, et al. 2017 based on its *Kashaya* and *Tikta Rasas, Ushna Guna* & *Virya* and *Katu Vipaka,* along with the predominance of *Vayu, Agni,* and *Akasha Mahabhutas*, *Kapha-Medohara, Kledahara* properties [13,19].

5.2 Role of *Shamana Chikitsa*

From an overview of all these trials, it is reflected that mostly *Kaphghna,* i.e., *Tikta, Katu* & *Kashaya Rasatamaka Dravyas,* are helpful for the management of *Prameha* for *Shamana* purposes. Many research shows that a combination of *Shodhana* and *Shamana* is more effective in controlling Diabetes clinically than the only *Shaman*. *Pramehaghn*a action of these *Shamana* drugs can be explained as follows:

- *Tikta, Katu* & *Kashaya Rasatamaka Dravyas* induce *Agnivardhaka, Kledanashana* &*Stroshodhana* effects by their *Dipana –Pachana* & *Kapha-Medohara, Rukshana, Shoshan* properties. Their *Kaphaghna* and *Medoghana Prabhava* reduces the weight that decreases insulin resistance. It also reduces *Abdhatu Dushti,* which is the chief pathogenesis in the *Prameha*. Due to improvement in *Jatharagni* & *Dhatavagni* by *Dipana –Pachana* properties & *Katu Vipaka*, it leads to normalization of carbohydrate, Fat & protein metabolism, increase in the peripheral glucose utilization & also increases insulin sensitivity. It decreases insulin resistance & insulin insensitivity.
- *Prabhutamutrata, Pipasa, Mukha Shosha, Karapada Daha* get reduced by *Pitta* and *Kapha Shamaka* effect of the predominance *Kashaya Rasa* of these drugs.
- *Laghu, Vishada* & *Ruksha* properties of such drugs bring *Kledanashana &Stroshodhana* as these properties are opposite of *Guru, Pichhila* & *Snigdha Guna* of vitiated *Kapha* & *Meda* in the *Prameha*. These properties also correct *Dhatushaithilya*.
- *Laghu, Vishada* & *Ruksha* properties & *Tikta, Katu* & *Kashaya Rasa,* subsides *Kapha* (*Bahudrava Shleshma*) and *Abaddha Meda* involved in the pathogenesis by their *Virukshana* and *Chedaneeya* actions. Their *Lekhana* properties increase the metabolism of *Meda,* i.e., Fat, due to their anti-inflammatory, lipid-lowering activities.
- *Stotoshodhak* properties of *Vishad Guna* decrease the *Kapha* with *Meda* & corrects *Dhatu Shaithilya*.
- *Ushna Virya* of such drugs corrects the disturbances in the *Samana Vayu* & corrects the *Jatharagni* and Dhatvagni. *Karpada Suptata* and *Sandhi Shoola* get reduced by *Ushna Veerya* by its *Vatanulomak* & *Vata Shamak* property.
- *Agnivardhana* (Improves metabolism) & removes *Kapha Avarana* over *Vata* due to *Katu Vipaka* & *Ushna Virya*.
- The impairment of *Jatharagni* and *Dhatwagni* is corrected by *Ushna Veerya* & *Tikta Rasa*.
- Most of the drugs act over the *Mootravaha Strotasa* due to *Kledahara* & *Grahn* properties that subside the *Sthana Vaigunya*. *Mootra Sangraheenya* action may occur due to their Kashaya & *Tikta Rasa*, *Laghu* & *Ruksha Guna, Katu Vipaka,* which reduces the excessive urination. The nephroprotective action of these drugs avoids renal tissue damage due to diabetes mellitus; therefore, it becomes helpful to prevent diabetic

nephropathy in the future. Excretion of sugar or Oja through urine is also avoided by *Vrushya* properties of such drugs, which prevents further *Dhatu-Shaithilya*.

- Drugs having *Madhura Rasa* acts as a *Rasayana* in the *Prameha,* which induces the *Ojavardhana* effect by nourishing the tissues, pacifying the vitiated *Vata Dosha*, correcting *Apanvayu* & giving strength to the tissues & *Mootravaha Strotas*. Replenishment of *Ojus* diminished in *Prameha* takes place by *Sheeta Virya* and *Madhura Vipaka* of such drugs. Reduction in the symptoms of *Klama* due to nutrition induced by *Madhura Vipaka* by doing *Ojovriddhi*. Ultimately it corrects *Dhatukshaya* by their *Rasayana, Yogvahi* & *Vatashamaka* properties & avoids the formation of complications of *Prameha* or its conversion into *Madhumeha*. *Yogavahi Guna* promotes the deep penetration of the medicine at the level of *Uttaraottara Dhatu* & gives strength to them.
- Rasayana, Anti-oxidant & immunomodulatory improve metabolism, anti-inflammatory properties of such drugs (due to its *Rasayana Guna*), which may stimulate the Beta cells in the pancreas, which secretes the hormone insulin insufficient amount or may increases secretion of endogenous insulin by regeneration or revitalization of the residual beta cells or may check over the destruction of βcell or their necrosis. Improvement in better sensitivity of pancreatic β- cells with the prompt secretion of a large quantity of insulin in response to hyperglycemia due to their pancreatotrophic action can be explained.
- *Lekhana Dravyas* are useful in *Sthula Pramehi,* which are also helpful skin lesions induced in *Prameha* due to its *Rakthaprasadana, Kushtahara,* and *Vranaropana* properties.

In a nutshell, as *Shodhana Chiktsa* destroys the root of disease, it is easily possible to check over the pathogenesis of *Prameha* to avoid the recurrence of diseases & to avoid the side-effects of oral allopathic hypoglycemic agents with the help of above various *Ayurvedic* measures. These drugs may also become helpful to minimize doses of contemporary OHA or even to stop their use in a person with good control by using them in the early stage of the disease [50-56].

6. CONCLUSION

After critical analysis of all studies, it is found that *Ayurvedic* interventions, i.e., *Shodhana Or Shamana Chikitsa*, can successfully manage this condition and significant improvement in clinical features of D.M.This study proves that rational use of *Ayurvedic* interventions can successfully manage D.M. in primary stage or newly diagnosed cases. Moreover, these interventions also proved their supportive or adjuvant role with the contemporary treatment protocol. All reported interventions are pharmacological or non-pharmacological in approach. They have assessed their effectiveness in both prevention & management of the disease to avoid progression of disease& further complications of D.M. Other multi-centric trials with a large sample size are expected in the future to generate more substantial clinical evidence regarding the above interventions.

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CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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