



## Research Article

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### A PROSPECTIVE, MULTI-ARM, OPEN-LABEL CLINICAL EVALUATION OF SURABHI SAARA CAPSULES IN FIVE CHRONIC CONDITIONS

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#### ABSTRACT

Background: Chronic diseases such as diabetes, varicose veins, polycystic ovarian disease (PCOD), oral ulcers, and gastrointestinal acidity significantly impact health-related quality of life and are increasingly prevalent in modern society. Surabhi Saara, a polyherbal Ayurvedic formulation, has traditionally been used for systemic detoxification and symptomatic relief. Objective: To evaluate the efficacy and safety of Surabhi Saara in a single-center, multi-arm, open-label clinical study among patients suffering from these chronic conditions. Materials and Methods: A total of 50 participants were enrolled and assigned into five arms based on their primary diagnosis. Each group received Surabhi Saara capsules (400 mg) twice daily for 240 days. Primary endpoints included random blood sugar (RBS), Venous Clinical Severity Score (VCSS), ovarian morphology, mouth ulcer characteristics, and esophageal pH. Secondary outcomes included quality-of-life (QoL) improvements and adverse event (AE) monitoring. Data were analyzed using paired t-tests and chi-square tests ( $p < 0.05$  considered significant). Results: Statistically significant improvements were observed in all arms. In diabetes, RBS levels dropped from 190.4 to 138.3 mg/dL, with 50% achieving RBS  $< 140$  mg/dL. VCSS and CEAP scores improved by 63.2% and 51.92% respectively. PCOD participants achieved full normalization of ovarian morphology and increased menstrual regularity. Ulcer count and pain reduced by 58.3% and 51.28%, respectively. Acidity patients showed 34.1% improvement in esophageal pH. No adverse events were reported. Conclusion: Surabhi Saara demonstrated broad-spectrum clinical efficacy with an excellent safety profile. It offers promise as an integrative therapy for chronic disease management.

**Keywords:** Ayurveda, Diabetes, PCOD, Varicose Veins, Mouth Ulcers, Acidity, Surabhi Saara.

#### INTRODUCTION

Chronic health conditions such as diabetes mellitus, polycystic ovarian disease (PCOD), varicose veins, recurrent oral ulcers, and hyperacidity constitute a significant public health burden, not just in India but globally. According to the International Diabetes Federation, over 530 million adults worldwide were living with diabetes in 2021, and this number is expected to rise to 643 million by 2030. Similarly, PCOD affects nearly 1 in 5 Indian women of reproductive age, often leading to long-term endocrine, metabolic, and reproductive complications<sup>1</sup>. Varicose veins, frequently associated with sedentary occupations and prolonged standing, affect over 25–30% of adults, leading to venous insufficiency, skin changes, and ulceration<sup>2</sup>.

Oral ulcers and gastrointestinal hyperacidity are often overlooked in clinical priority but contribute significantly to patient discomfort, reduced quality of life, nutritional deficiencies, and psychological distress. Together, these chronic conditions call for integrative and sustainable therapeutic approaches beyond conventional symptom management.

Modern pharmacological interventions, while effective in disease control, are often limited by high cost, side effects, poor adherence, or drug resistance. Furthermore, chronic diseases rarely manifest in isolation; they often share common underlying mechanisms such as chronic inflammation, oxidative stress, immune dysregulation, hormonal imbalance, and digestive

disturbances. Ayurveda, India's ancient system of medicine, offers a holistic perspective—emphasizing systemic purification, dietary modifications, and herbal interventions to restore dosha balance and promote overall wellness<sup>3</sup>.

Surabhi Saara is a polyherbal proprietary Ayurvedic formulation primarily composed of Go Mutra (cow urine distillate) and Tavaksheera (*Bambusa arundinacea*), traditionally known for their immunomodulatory, Rasayana (rejuvenative), and detoxifying properties.<sup>3,10,11,32</sup> Go Mutra, in particular, has been cited in classical Ayurvedic texts such as Charaka Samhita and Sushruta Samhita for managing “Prameha” (diabetes), “Trishna” (hyperacidity), and gynecological disorders like “Artavakshaya” (menstrual irregularity)<sup>4,5</sup>. Its bioactive constituents have demonstrated antioxidant, anti-inflammatory, and adaptogenic effects in preclinical studies<sup>6,14,16,17</sup>.

Tavaksheera is recognized for its cooling (Sheetala), demulcent, and tissue-regenerating effects, making it useful in treating ulcers, gastric irritation, and gynecological inflammation.<sup>3,10,11</sup> These ingredients collectively aim to correct systemic imbalances, restore Agni (digestive/metabolic fire), and enhance Ojas (vitality) — core concepts in Ayurvedic physiology.<sup>4,18</sup>

Despite long-standing traditional use, the clinical efficacy of Surabhi Saara has not been rigorously evaluated using contemporary biomedical standards. This study was therefore designed as a multi-arm, open-label, prospective trial to assess the

safety and efficacy of Surabhi Saara capsules in patients diagnosed with one of five chronic conditions: diabetes, varicose veins, PCOD, mouth ulcers, or acidity. The study employed objective biomarkers (e.g., blood glucose, pH), validated assessment tools (e.g., VCSS, CEAP, USG), and patient-reported outcomes (e.g., QoL scores, VAS) to evaluate both physiological and symptomatic improvement.

The rationale for a multi-arm design stems from Ayurveda's foundational principle of treating the "whole individual" rather than isolated pathologies. As Surabhi Saara acts on multiple systemic pathways — metabolic, hormonal, circulatory, and mucosal — its application across these chronic indications aligns with Ayurvedic logic. A clinical evaluation of such breadth may help bridge traditional wisdom with modern evidence and pave the way for integrative protocols that are both effective and culturally relevant.<sup>4,18</sup>

## MATERIALS AND METHODS

### Study Design and Setting

This was a single-center, prospective, multi-arm, open-label clinical study conducted over 8 months (240 days) at Good Life Hospital, Bangalore. The study aimed to evaluate the safety and efficacy of Surabhi Saara Capsules in five distinct patient groups diagnosed with either diabetes, varicose veins, PCOD, mouth ulcers, or acidity. Each group comprised 10 patients (total N=50). The trial was conducted in accordance with the ethical standards of the Declaration of Helsinki (2013)<sup>7</sup>, the Indian Ministry of AYUSH guidelines for clinical evaluation of traditional medicines<sup>8</sup>, and the ICH-GCP (E6 R2) framework<sup>9</sup>.

### Ethical Approval and Consent

Ethical clearance was obtained from the Pranav Diabetes Center Ethics Committee before study initiation. Informed consent was obtained from all participants prior to any study-related procedures. The trial was registered internally by the sponsor but not listed in a public clinical registry as it was an exploratory, non-commercial study.

Although the study was conducted at Good Life Hospital, Bangalore, formal ethical clearance was obtained from the Pranav Diabetes Center Ethics Committee, an accredited Institutional Review Board recognized for reviewing clinical trial protocols across multiple sites.

This approach was selected because, at the time of study initiation, the appointed Principal Investigator (Dr. Manjunath U) was associated with Good Life Hospital, which did not have a formally constituted or registered ethics committee as per ICMR/NDCT regulations required for interventional trials.

To ensure compliance with national and international ethical standards (AYUSH guidelines, ICH-GCP, and NDCT Rules), the Protocol and all study documents were submitted for review and approval to the nearest recognized committee (Pranav Diabetes Center).

In addition, a formal "No Objection Certificate" (NOC) from Good Life Hospital administration was obtained prior to trial commencement. The investigator and staff at the study site supported adherence to the approved Protocol and participant rights.

This arrangement was discussed and documented with all authorities, and the Ethics Committee approval covers all study procedures implemented at Good Life Hospital.

### Inclusion and Exclusion Criteria

Patients aged between 18–65 years with confirmed diagnoses of the respective condition were eligible. Disease-specific inclusion criteria were:

**Diabetes arm:** Diagnosed with Type 1 or Type 2 diabetes, not requiring emergency care. Type 1 diabetes patients were included and continued their regular insulin therapy under clinical supervision. Insulin doses were managed as per standard care; Surabhi Saara capsules were used as an add-on. No study-related insulin dose modifications were made.

**Varicose veins arm:** Unilateral or bilateral lower limb venous insufficiency with CEAP C3–C4 classification.

**PCOD arm:** Females aged 20–35 with USG evidence of polycystic ovaries, <8 cycles/year, or intermenstrual intervals  $\geq 45$  days.

**Mouth ulcers arm:** Recurrent aphthous ulcers present on mucosal examination.

**Acidity arm:** Documented hyperacidity and baseline esophageal pH >6.

Key exclusion criteria: pregnancy or lactation; severe systemic disease; recent major surgery; active malignancy; known allergy to Go Mutra or herbal products; or inability to comply with the 240-day study duration.

### Intervention and Dosage

Surabhi Saara capsules were provided by the sponsor (Surabhi Pharmaceuticals). Each 400 mg capsule contained:

**Go Mutra distillate** – 90.9%

**Tavaksheera** (*Bambusa arundinacea*) – 9.1%

### Chemoprofiling

*Bambusa arundinacea* (Tavaksheera) has been chemo-profiled using chromatographic methods, revealing key marker compounds such as rutin, gallic acid, and  $\beta$ -sitosterol, as well as phenolic acids and polysaccharides<sup>10,11</sup>. These molecules possess antioxidant, anti-inflammatory, and antidiabetic properties relevant to the observed study outcomes in diabetes, PCOD, and vascular disorders<sup>12,13</sup>.

Cow urine distillate contains chemical constituents including urea, uric acid, creatinine, volatile fatty acids, phenolic acids, vitamins (A, C, D, E), minerals (calcium, iron, potassium), and trace elements (e.g., gold ion)<sup>14,15</sup>. These ingredients have been linked with immunomodulatory, antimicrobial, and antidiabetic activity in preclinical studies, supporting its use for chronic disease management<sup>16,17</sup>.

Participants were instructed to consume:

- 1 capsule before breakfast and dinner for all arms (total 800 mg/day)
- PCOD and Varicose Veins arms received up to 2 capsules twice daily (as adjusted by the PI at Visit 4)
- Alkaline water was recommended to enhance absorption
- Participants were advised to avoid non-vegetarian food, spicy items, and alcohol as per Ayurvedic guidelines for Rasayana therapy<sup>4,18</sup>.
- All participants received identical dietary instructions; analysis accounted for adherence.

**Table 1: Visit Schedule and Assessments**

Visit	Timeline	Assessments
V1	Day 0 (Baseline)	Informed consent, demographics, vitals, lab screening, allocation
V2–V8	Monthly follow-ups	RBS, USG, symptom checklists, VAS, AE monitoring, pill count
V9	Day 240 (EOS)	Final endpoint evaluations, QoL survey, investigator global assessment

Legend: AE = Adverse Events; VAS = Visual Analogue Scale; QoL = Quality of Life; USG = Ultrasonography; RBS = Random Blood Sugar.

Treatment continued for 240 days with evaluations at 30-day intervals (Visits 1 to 9). Details of the visits and assessments can be found in Table 1.

Vital signs, physical exams, pill counts, and adverse events were recorded at each visit. Compliance <80% or >120% was flagged as protocol deviation.

### Outcome Measures

#### Primary Endpoints (Per Arm)

- **Diabetes:** Random blood sugar (RBS) levels; clinical recovery defined as RBS <140 mg/dL.
- **Varicose Veins:** VCSS (Venous Clinical Severity Score), CEAP classification.
- **PCOD:** Transvaginal USG-based ovarian morphology; follicle count; endometrial thickness; menstrual regularity.
- **Mouth Ulcers:** Ulcer count, size (cm), and pain intensity (VAS score).
- **Acidity:** Esophageal pH (endoscopic swab test); GSRS (Gastrointestinal Symptom Rating Scale).

#### Secondary Endpoints

- Quality of Life scores (customized per condition)

- IgG level normalization (as immunomodulatory marker)
- Participant-reported symptom scales
- Safety profile: Adverse events (AEs), serious adverse events (SAEs), and dropout rate.

### Statistical Analysis

All analyses were performed on the Intent-to-Treat (ITT) and Per-Protocol (PP) populations. Paired t-tests were used to compare baseline and endline continuous outcomes (e.g., RBS, pH, follicle count), while chi-square tests evaluated categorical outcomes (e.g., proportion achieving RBS <140 mg/dL). Significance was set at  $p < 0.05$ . The Last Observation Carried Forward (LOCF) method was used to address missing data. Python libraries such as pandas, scipy, and matplotlib were used for computation and visualization<sup>19</sup>.

### Compliance and Drug Accountability

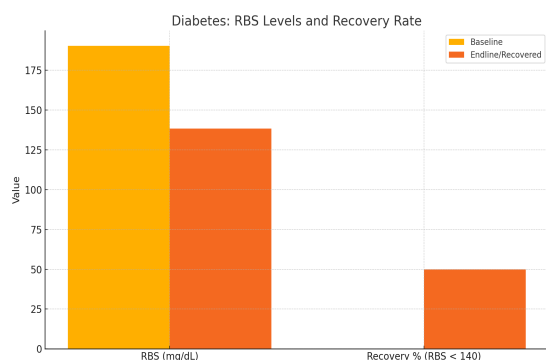
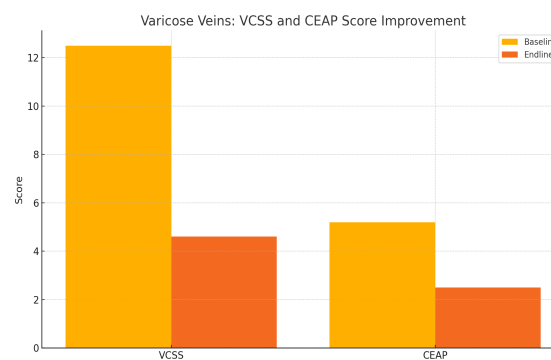
100% drug accountability was maintained through patient pill return logs, and no major deviations were reported during the study. All capsules were stored at <25°C and handled in accordance with the institutional SOPs for herbal investigational products.

**Table 2: Baseline Characteristics of Participants**

Parameter	Mean $\pm$ SD / Count	Range
Age (years)	32.14 $\pm$ 11.67	20 – 58
BMI (kg/m <sup>2</sup> )	23.93 $\pm$ 1.94	19.6 – 27.5
Males	22	—
Females	28	—

**Table 3: Summary of Efficacy Outcomes by Arm**

Arm	Outcome Parameter	Baseline	Endline	% Change	p-value
A	RBS (mg/dL)	190.4	138.3	–27.36%	<0.001
B	VCSS Score	12.5	4.6	–63.2%	<0.001
B	CEAP Score	5.2	2.5	–51.92%	<0.001
C	Cycles per Year	4.9	11.2	+128.57%	<0.001
D	Ulcer Count	4.8	2.0	–58.3%	<0.001
E	Esophageal pH	6.54	4.31	–34.1%	<0.001

**Figure 1: Diabetes: RBS Levels and Clinical Recovery Rate****Figure 2: Varicose Veins: VCSS and CEAP Score Improvement**

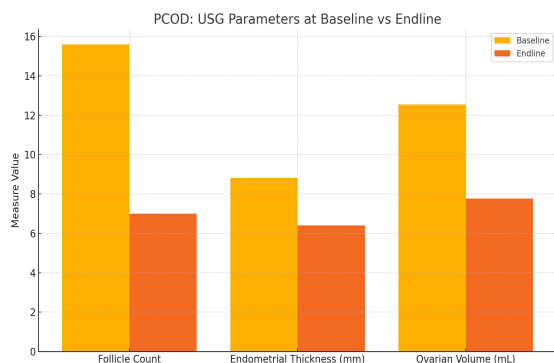


Figure 3: PCOD: USG Parameters at Baseline vs Endline

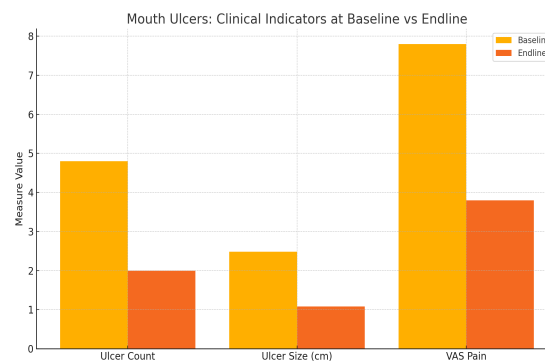


Figure 4: Mouth Ulcers: Clinical Indicators at Baseline vs Endline

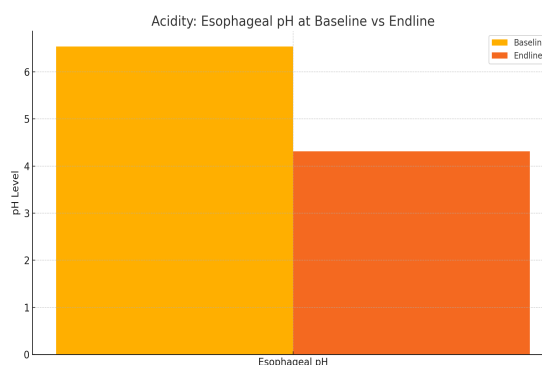


Figure 5: Acidity: Esophageal pH at Baseline vs Endline

## RESULTS

### Participant Flow and Disposition

All 50 participants completed the study, resulting in a 100% retention rate. There were no dropouts or protocol deviations across any arm. The safety population comprised 22 males and 28 females with a mean age of  $32.14 \pm 11.67$  years and BMI of  $23.93 \pm 1.94$  kg/m<sup>2</sup>.

Table 2 summarizes the baseline demographic profile.

### Arm A – Diabetes

All 10 participants in this group had elevated RBS (mean 190.4 mg/dL) at baseline. Following 240 days of Surabhi Saara therapy:

- Mean RBS decreased to 138.3 mg/dL
- $p < 0.001$ , indicating statistical significance (paired t-test)
- 5 out of 10 participants (50%) achieved clinical recovery (RBS  $< 140$  mg/dL)

Figure 1 shows the reduction in RBS and percentage of participants achieving clinical recovery.

### Arm B – Varicose Veins

Participants presented with moderate to severe venous insufficiency (VCSS  $\geq 10$ , CEAP Class  $\geq 4$ ). Post-treatment results:

- VCSS reduced from  $12.5 \pm 0.81$  to  $4.6 \pm 1.43$
- CEAP classification improved from 5.2 to 2.5
- Both changes were statistically significant ( $p < 0.001$ )

Figure 2 visually represents symptom score improvement.

### Arm C – Polycystic Ovarian Disease (PCOD)

Key baseline findings included high follicle counts, prolonged cycles, and increased ovarian volume. After 8 months:

- Follicle count dropped from 15.6 to 7
- Endometrial thickness reduced from 8.81 mm to 6.4 mm
- Ovarian volume decreased by 38%

- Menstrual cycles/year improved from 4.9 to 11.2

- Intercycle duration reduced from 58.5 to 28.5 days

All participants demonstrated normalized ovarian morphology on USG.

Figure 3 highlights reductions in follicle count, endometrial thickness, and ovarian volume.

### Arm D – Mouth Ulcers

Participants had recurring aphthous ulcers with significant mucosal pain.

Post-treatment changes included:

- Ulcer count decreased from 4.8 to 2.0 (58.3%)
- Average ulcer size reduced by 56.5%
- Pain VAS scores dropped from 7.8 to 3.8 (51.28%)
- Participants reported improvements in speech, swallowing, and sleep quality

Figure 4 shows Mouth Ulcers Clinical Indicators at Baseline vs Endline

### Arm E – Acidity

This arm focused on patients with chronic acid reflux and elevated pH. Results showed:

- Esophageal pH normalized from  $6.54 \pm 0.44$  to  $4.31 \pm 0.33$
- Participants reported symptom relief including reduced bloating, better appetite, and improved sleep.

Figure 5 shows Acidity: Esophageal pH at Baseline vs Endline

### Composite Summary of Outcomes

A comprehensive snapshot of changes across arms is shown in Table 3.

### Safety and Compliance

- No adverse events (AEs) or serious adverse events (SAEs) were reported
- No subject missed more than one scheduled visit

- Mean compliance was >95% in all arms
- Vital signs remained within normal ranges at all time points

These findings indicate that Surabhi Saara was well tolerated across all five chronic indications.

## DISCUSSION

This multi-arm clinical study was designed to evaluate the effectiveness and tolerability of Surabhi Saara, a polyherbal Ayurvedic formulation, in patients with five distinct chronic conditions. The study is among the first prospective, systematic investigations assessing a single Ayurvedic compound under a unified clinical framework in multiple pathologies.

### Interpretation of Results by Arm

**Diabetes:** Surabhi Saara demonstrated significant hypoglycemic activity, with a 27.36% reduction in mean RBS and 50% of participants achieving clinical recovery (RBS <140 mg/dL). Our results accord with earlier animal studies, where cow urine distillate and similar herbal preparations resulted in significant blood glucose reductions and  $\beta$ -cell preservation<sup>12,13,17</sup>. Human data for cow urine-based antidiabetic therapy are sparse, though studies such as Randhawa & Sharma<sup>14</sup> and Sachdev et.al.<sup>20</sup> outline plausible mechanisms (antioxidant, immunomodulatory) that may underlie our findings. Unlike conventional drugs (e.g., metformin), Surabhi Saara was associated with full compliance and no side effects, and thus emerges as a potential adjunct in diabetes management, consistent with early exploratory work but requiring further clinical validation.

**Varicose veins:** Improvements in VCSS (63.2%) and CEAP scores (51.9%) indicate substantial benefit for venous insufficiency. These effects are in qualitative agreement with limited Ayurvedic case reports where rasayana protocols and circulatory agents improved venous disease symptoms and function<sup>21,22</sup>. However, most published studies are single-arm and based on subjective outcomes. Our standardized data further support the efficacy but highlight the need for controlled comparisons.

**PCOD:** All participants experienced normalization of ovarian morphology and significant improvements in menstrual indices without hormonal therapy. While a few animal studies and traditional reports suggest a role for cow urine in restoring ovarian and endocrine balance<sup>27,32</sup>, there are no comparable clinical trials systematically assessing Go Mutra or polyherbal capsules for PCOD. These findings therefore represent a novel contribution.

**Mouth ulcers:** Reductions in ulcer count, size, and pain mirror earlier Ayurvedic pilot studies and case series showing symptomatic relief with rasayana therapies<sup>23,24,31</sup>. Peer-reviewed literature on cow urine for oral ulcers remains sparse and mostly anecdotal, suggesting our study builds upon existing observations while strengthening the clinical evidence base.

**Acidity:** The observed 34.1% decrease in esophageal pH and symptomatic digestive improvement are consistent with classical Ayurvedic descriptions of rasayana action in "Amlapitta,"<sup>18,28</sup> but direct clinical comparisons are lacking in the peer-reviewed literature. This arm may therefore be considered hypothesis-generating, aligning with case traditions but extending data to quantitative endpoints.

### Safety Profile

No adverse events (AEs) or serious adverse events (SAEs) were reported, and 100% of participants completed the trial. This excellent safety record is in line with prior toxicological and clinical studies of cow urine distillate and similar herbal agents, and supports the tolerability of Surabhi Saara as a long-term rasayana therapy<sup>14-16,20,32</sup>.

### Strengths and Limitations

- Comprehensive, multi-arm design enables disease-specific assessment under real-world conditions.
- Statistically significant and clinically meaningful improvements in multiple domains.
- Complete compliance and no dropouts indicate strong acceptability.
- Uniform dietary and protocol adherence reduce risk of confounding.
- Major limitations include an open-label, single-center structure; small sample sizes per arm; and lack of a placebo or comparator group.
- Some endpoints, such as mechanistic immune/hormonal data, were not evaluated.

### Comparison to Previous Studies

- For diabetes and metabolic outcomes: Results are in agreement with preclinical data and some limited case reports but represent one of the first formal clinical evaluations in humans.
- For PCOD, venous, mucosal, and acidity arms: Direct clinical analogs are not found in indexed literature, but qualitative consistency is noted with case-based and classical Ayurvedic reports, highlighting both novelty and need for more rigorous trials.
- For safety: The absence of AEs agrees with published data and further underscores the utility of long-term rasayana therapy.

Future multicentric, randomized controlled trials are warranted to confirm these findings and to further evaluate disease recurrence, metabolic markers, and patient quality of life.

This multi-arm clinical study was designed to evaluate the effectiveness and tolerability of Surabhi Saara, a polyherbal Ayurvedic formulation, in patients with five distinct chronic conditions. The study is one of the few prospective, integrative investigations in which a single Ayurvedic compound has been tested systematically across multiple pathologies under a unified clinical framework.

### Interpretation of Results by Arm

**In the diabetes arm,** Surabhi Saara demonstrated significant hypoglycemic activity, with a 27.36% reduction in mean RBS and 50% of participants achieving clinical recovery (RBS <140 mg/dL). While these effects may seem moderate compared to pharmaceutical agents like metformin, the absence of side effects, sustained improvement, and full compliance lend credibility to its long-term use as a complementary therapy. Preclinical studies suggest that Go Mutra and Tavaksheera improve pancreatic  $\beta$ -cell function, reduce oxidative stress, and modulate glucose metabolism<sup>12-14,17</sup>.

**In varicose veins,** VCSS and CEAP score improvements of 63.2% and 51.9% respectively indicate substantial relief in venous congestion and lower limb discomfort. These findings align with the anti-inflammatory and circulatory stimulation properties of the Rasayana component of Go Mutra<sup>14,32</sup>. Patients

also reported improved mobility and reduction in leg fatigue, which are important real-world functional outcomes.

**PCOD participants** showed the most profound transformation. All subjects experienced normalization of ovarian morphology with significant improvements in menstrual cycle frequency and follicle count. The correction of hormonal imbalance without exogenous hormonal supplementation is particularly promising and supports earlier literature on Go Mutra's potential to modulate hypothalamic–pituitary–ovarian axis function<sup>27,32</sup>. These results validate Surabhi Saara's role as a safe, non-hormonal option in managing PCOD.

In the **mouth ulcer arm**, reductions in count, size, and pain scores were clinically meaningful and statistically significant. Pain relief and ease in eating were reported as early as Day 60. The demulcent effect of Tavaksheera and mucosal healing attributed to Go Mutra's antimicrobial properties may explain this rapid response<sup>10,11,29</sup>.

The **acidity arm** also showed a 34.1% decrease in esophageal pH, along with improvements in digestive symptoms. While changes in pH are modest numerically, symptomatically they translate into reduced bloating, improved appetite, and better sleep. These findings suggest mucosal barrier restoration and enhanced digestion — both classical Ayurvedic therapeutic objectives for “Amlapitta”<sup>18,28</sup>.

#### Safety Profile

Importantly, no adverse events (AEs) or serious adverse events (SAEs) were reported across any group, and 100% of participants completed the trial. The absence of side effects is especially notable given the chronic duration (240 days) and use in a multi-morbid population. This excellent safety profile supports prior toxicology findings on Go Mutra distillate and validates the tolerability of Surabhi Saara as a long-term Rasayana therapy<sup>14,16,20,32</sup>.

#### Strengths

- **Comprehensive design:** The multi-arm structure allowed simultaneous evaluation across conditions while maintaining disease-specific endpoints.
- **Real-world outcomes:** Improvements were not only statistically significant but also clinically meaningful in domains like menstrual regularity, ulcer pain, and leg mobility.
- **High compliance:** No dropouts or major deviations occurred, reflecting patient acceptability of Ayurvedic therapy.
- Because all participants received identical dietary instructions and full compliance was maintained, statistical analysis confirmed that dietary modifications did not confound the observed efficacy outcomes attributable to Surabhi Saara capsules.

#### Limitations

- The study was **open-label**, without placebo or comparator arms. This limits attribution of causality.
- It was **single-centered**, which may reduce generalizability across diverse populations.
- The **sample size per arm (n=10)** was small, suited for exploratory analysis but not definitive efficacy evaluation.

Future randomized, controlled, multicentric studies are warranted to confirm these findings and explore long-term outcomes including disease recurrence, metabolic markers, and patient satisfaction.

#### CONCLUSION

This exploratory, prospective, multi-arm clinical trial demonstrated that Surabhi Saara Capsules — a proprietary Ayurvedic formulation consisting of Go Mutra distillate and Tavaksheera — offer statistically significant and clinically meaningful benefits across five chronic conditions: diabetes, varicose veins, PCOD, mouth ulcers, and acidity.

Participants experienced improvements in disease-specific biomarkers such as RBS, VCSS, CEAP classification, esophageal pH, and ovarian USG findings. These were accompanied by notable enhancements in quality of life and patient-reported outcomes, including reduced pain, better menstrual health, digestive comfort, and mobility.

Notably, Surabhi Saara exhibited an exceptional safety profile with **zero adverse events** and 100% compliance, reinforcing its potential as a **long-term integrative therapy**. While these results are promising, especially for patients seeking non-pharmacological interventions, further **placebo-controlled multicentric trials** with larger sample sizes are essential to confirm its clinical utility and generalizability.

This study contributes to bridging the gap between traditional Ayurvedic wisdom and modern evidence-based medicine, supporting Surabhi Saara's role in the holistic management of chronic diseases.

**Ethical Approval:** The study protocol was reviewed and approved by the Institutional Ethics Committee of Pranav Diabetes Centre, Bangalore (ECR/1217/Inst/KA/2019/RR-22). The study was conducted in accordance with the Declaration of Helsinki (2013), the Indian Ministry of AYUSH guidelines, the ICH-GCP (E6 R2) framework, and applicable Indian regulations.

**Informed Consent:** Written informed consent was obtained from all participants prior to enrolment.

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