



## Research Article

### A COMPARATIVE CLINICAL STUDY ON THE EFFICACY OF *RASONADI CHURNA* VERSUS TABLET METFORMIN IN THE MANAGEMENT OF POLYCYSTIC OVARIAN SYNDROME (PCOS)

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#### ABSTRACT

Polycystic Ovarian Syndrome (PCOS) is one of the most common endocrine disorders encountered in women of reproductive age, and in Ayurvedic parlance its presentation closely overlaps with *Nashtartava* and *Artava Kshaya* arising from vitiated *Kapha* and *Vata Dosha* along with *Medodushti*. Modern management largely centres on insulin sensitisers such as Metformin, but long-term compliance and side-effect concerns keep the search for effective, well-tolerated alternatives open. This study was undertaken to compare the effect of *Rasonadi Churna* with Tablet Metformin in the management of PCOS. Forty diagnosed patients of PCOS were enrolled and randomly allocated into two equal groups of twenty each. Group A received *Rasonadi Churna* and Group B received Tablet Metformin. Both groups were assessed before and after treatment on subjective and objective parameters, including menstrual bleeding days, BMI, ovarian volume, and hormonal profile (FSH, LH, Testosterone, Serum Insulin and TSH). Both *Rasonadi Churna* and metformin produced a statistically significant intra-group improvement across nearly all parameters. On inter-group comparison, *Rasonadi Churna* showed a significantly greater improvement in LH levels and in the regulation of bleeding days, while Metformin produced a significantly greater reduction in serum insulin; the two groups were otherwise comparable. *Rasonadi Churna* therefore appears to be a safe and effective Ayurvedic alternative to metformin in PCOS, particularly for restoring menstrual regularity, and merits further evaluation in larger trials.

#### INTRODUCTION

Polycystic Ovarian Syndrome (PCOS) is one of the most common endocrine and metabolic disorders of women in the reproductive age group and a leading cause of anovulatory infertility, menstrual irregularity, and long-term metabolic disturbance. Global prevalence estimates vary widely with the diagnostic criteria applied, and a recent nationwide Indian study spanning five zones of the country and recruiting over nine thousand women reported a weighted prevalence of 19.6% by the Rotterdam criteria and 7.2% by the NIH criteria, with a large proportion of affected women also carrying obesity, dyslipidaemia and other

metabolic comorbidities<sup>[1]</sup>. Community-based data from Indian adolescents have similarly pointed to the need for earlier recognition and intervention<sup>[2]</sup>. The disorder is diagnosed as per the Rotterdam consensus, which requires any two of three features- oligo/anovulation, clinical or biochemical hyperandrogenism, and polycystic ovarian morphology on ultrasonography- after exclusion of related endocrinopathies<sup>[3]</sup>.

Its multifactorial pathogenesis, involving hypothalamic-pituitary-ovarian axis dysfunction and insulin resistance, makes PCOS a therapeutic challenge in contemporary practice. Metformin, an insulin sensitiser, remains the mainstay of conventional pharmacological management; however, gastrointestinal intolerance and questions of long-term compliance continue to drive interest in alternative or adjunctive approaches with a more favourable tolerability profile<sup>[4]</sup>.

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Classical Ayurvedic literature does not describe PCOS as a single entity, but its clinical picture- scanty or absent menstruation, weight gain, and infertility- is best correlated with *Nashtartava*, occurring due to vitiation of *Vata* and *Kapha Dosha* along with *Meda Dhatu*, which obstructs the normal channels (*Artava Vaha Srotas*) responsible for menstruation<sup>[5,6]</sup>. This *Samprapti* of vitiated *Vata-Kapha* with *Medodushti* is described across classical texts in the context of both *Artava Kshaya* and *Nashtartava*<sup>[7,8]</sup>. *Rasonadi Churna*, built around *Rasona* (garlic) and allied *Kapha-Vata Shamaka*, *Medohara* and *Artava Janaka* drugs, is traditionally indicated in such conditions and was chosen for evaluation against the conventional standard, Metformin.

### AIMS AND OBJECTIVES

To study and compare the clinical efficacy of *Rasonadi Churna* and Tablet Metformin in the management of polycystic ovarian syndrome, on subjective parameters (menstrual bleeding days) and objective parameters (BMI, ovarian volume, FSH, LH, testosterone, serum insulin and TSH).

### MATERIALS AND METHODS

This was an open-label, randomised, comparative clinical study conducted at the Department of Prasuti Tantra evum Stree Roga, R. A. Podar Ayurvedic Medical College and Hospital, Worli, Mumbai, on patients diagnosed with PCOS as per Rotterdam criteria<sup>[3]</sup> and satisfying the inclusion/exclusion criteria of the study. After obtaining informed consent, forty eligible patients were randomly allocated into two groups of twenty each: Group A received *Rasonadi Churna* [dose, *Anupana* and duration to be specified], and Group B received Tablet Metformin [dose and duration to be specified]. Patients were assessed at baseline and after completion of

treatment on both subjective and objective parameters.

### Criteria for Selection of Patients

#### Inclusion Criteria

- Women aged 18–35 years diagnosed with PCOS as per the Rotterdam criteria (presence of any two of the three features: oligo-/anovulation, clinical and/or biochemical hyperandrogenism, and polycystic ovarian morphology on ultrasonography).
- Patients willing to give written informed consent to participate in the study.
- Patients willing to comply with the prescribed treatment schedule and follow-up visits for the full duration of the study.

#### Exclusion Criteria

- Pregnant and lactating women.
- Secondary causes of anovulation or hyperandrogenism, such as thyroid dysfunction, hyperprolactinaemia, congenital adrenal hyperplasia, or androgen-secreting tumours.
- Patients who had received hormonal therapy, oral contraceptive pills, or insulin-sensitising agents within the preceding three months.
- Patients with major systemic illness, including uncontrolled diabetes mellitus or significant cardiac, hepatic, or renal disease.
- Known hypersensitivity to the ingredients of the trial drug.

### Subjective and Objective Parameters and their Gradations

The primary subjective parameter- menstrual bleeding pattern- was assessed using a four-point ordinal scale, and objective parameters were assessed against standard laboratory and radiological reference ranges, as summarised below.

**Table A: Gradation of the Subjective Parameter- Menstrual Bleeding Pattern**

| Grade | Clinical Description                                                            |
|-------|---------------------------------------------------------------------------------|
| 0     | Regular cyclical bleeding of normal duration (4–6 days) at 21–35 days intervals |
| 1     | Mild irregularity — bleeding for about 3 days per cycle                         |
| 2     | Oligomenorrhoea — bleeding for 1–2 days, cycle interval >35 days                |
| 3     | Amenorrhoea — no bleeding over the assessment period                            |

**Table B: Objective Parameters — Reference Ranges Used for Grading**

| Parameter               | Unit              | Normal Reference Range                                    |
|-------------------------|-------------------|-----------------------------------------------------------|
| BMI (WHO Asian cut-off) | kg/m <sup>2</sup> | 18.5–22.9 (Overweight 23–24.9; Obese ≥25)                 |
| Ovarian volume          | cm <sup>3</sup>   | <10 (≥10 suggestive of PCOM)                              |
| FSH                     | mIU/mL            | 3.5–12.5 (follicular phase)                               |
| LH                      | mIU/mL            | 2.4–12.6 (follicular phase); LH:FSH >2 suggestive of PCOS |
|                         |                   | <70 (as per laboratory reference)                         |

|  |  |          |
|--|--|----------|
|  |  | 2.6–24.9 |
|  |  | 0.4–4.0  |

### Statistical Analysis

Statistical analysis was carried out using SPSS version 20.0. Demographic data were expressed as frequency and percentage. Ordinal (gradation) variables were analysed intra-group using the Wilcoxon Signed Rank Test and inter-group using the Mann-Whitney U Test. Quantitative data were analysed intra-group using the paired t-test and inter-group using the unpaired t-test. A P-value below 0.05 was taken as statistically significant.

### OBSERVATIONS AND RESULTS

All forty enrolled patients - twenty in each group - completed the study, with no withdrawals or dropouts in either arm.

**Table 1: Patient Enrolment and Completion**

| Group                              | Registered | Dropouts | Completed |
|------------------------------------|------------|----------|-----------|
| Group A ( <i>Rasonadi Churna</i> ) | 20         | 0        | 20        |
| Group B (Tab. Metformin)           | 20         | 0        | 20        |
| <b>Total</b>                       | <b>40</b>  | <b>0</b> | <b>40</b> |

### Demographic Profile

Most participants were aged between 26 and 30 years (37.5% overall), followed closely by the 19–25 and 31–35 years groups, and the two arms were well matched for age. Graduates formed the largest educational category overall (35%), while housewives (40%) and students (32.5%) made up the bulk of the occupational profile in both groups. The majority of patients belonged to the middle socio-economic class (65%) and were married (65%). On constitutional assessment, *Vata-Kapha Prakruti* predominated overall (35%), and body build was medium in most participants (72.5%); bowel movements were normal across the entire cohort. Both groups were, on the whole, demographically comparable, allowing a fair comparison of treatment effect between them.

### Intra-Group Effect- Subjective Parameter (Wilcoxon Signed Rank Test)

The bleeding-pattern grade improved significantly with treatment in both arms. In Group A the mean fell from 1.25 to 0.10, and in Group B from 2.15 to 0.35, both changes being statistically significant ( $p < 0.001$ ), corresponding to an overall effect of 92.00% in Group A and 83.72% in Group B.

**Table 2: Bleeding-Pattern Grade (Intra-Group, Wilcoxon Signed Rank Test)**

| Group   |    | Mean | Median | SD   | SE   | Wilcoxon W | P-value | % Effect | Result |
|---------|----|------|--------|------|------|------------|---------|----------|--------|
| Group A | BT | 1.25 | 1.00   | 0.72 | 0.16 | -4.420     | 0.000   | 92.00    | Sig    |
|         | AT | 0.10 | 0.00   | 0.31 | 0.07 |            |         |          |        |
| Group B | BT | 2.15 | 2.00   | 0.37 | 0.08 | -4.122     | 0.000   | 83.72    | Sig    |
|         | AT | 0.35 | 0.00   | 0.59 | 0.13 |            |         |          |        |

On inter-group comparison using the Mann-Whitney U test, the reduction in bleeding-pattern grade was significantly greater in Group A than in Group B ( $U = 112.00$ ,  $p = 0.017$ ), indicating that *Rasonadi Churna* was more effective than Metformin in normalising menstrual bleeding pattern.

### Intra-Group Effect- Objective Parameters (Paired t-test)

All objective parameters improved significantly from baseline to the end of treatment in both groups.

**Table 3: BMI**

| BMI     |    | Mean  | N  | SD    | SE   | t-Value | P-value | % Change | Result |
|---------|----|-------|----|-------|------|---------|---------|----------|--------|
| Group A | BT | 29.73 | 29 | 4.08  | 0.91 | 4.615   | 0.000   | 8.76     | Sig    |
|         | AT | 27.12 | 27 | 4.36  | 0.98 |         |         |          |        |
| Group B | BT | 32.69 | 29 | 10.02 | 2.24 | 4.765   | 0.000   | 11.11    | Sig    |
|         | AT | 29.06 | 26 | 10.37 | 2.32 |         |         |          |        |

BMI reduced significantly in both groups, by 8.76% in Group A and 11.11% in Group B.

**Table 4: Ovarian Volume- Right Ovary**

| Rt. Ovary |    | Mean  | N  | SD   | SE   | t-Value | P-value | % Change | Result |
|-----------|----|-------|----|------|------|---------|---------|----------|--------|
| Group A   | BT | 15.66 | 14 | 4.61 | 1.03 | 4.242   | 0.000   | 17.62    | Sig    |
|           | AT | 12.9  | 12 | 4.1  | 0.92 |         |         |          |        |
| Group B   | BT | 15.24 | 15 | 2.68 | 0.6  | 5.23    | 0.000   | 14.47    | Sig    |
|           | AT | 13.04 | 13 | 2.6  | 0.58 |         |         |          |        |

**Table 5: Ovarian Volume- Left Ovary**

| Lt. Ovary |    | Mean  | N  | SD   | SE   | t-Value | P-value | % Change | Result |
|-----------|----|-------|----|------|------|---------|---------|----------|--------|
| Group A   | BT | 15.66 | 15 | 3.5  | 0.78 | 6.45    | 0.000   | 17.28    | Sig    |
|           | AT | 12.95 | 13 | 3.5  | 0.78 |         |         |          |        |
| Group B   | BT | 13.09 | 13 | 3.06 | 0.68 | 4.24    | 0.000   | 19.98    | Sig    |
|           | AT | 10.48 | 11 | 1.3  | 0.29 |         |         |          |        |

Right and left ovarian volumes reduced significantly in both groups, the reduction being marginally greater with Metformin on the left side and greater with *Rasonadi Churna* on the right side.

**Table 6: FSH**

| FSH     |    | Mean | N | SD   | SE   | t-Value | P-value | % Change | Result |
|---------|----|------|---|------|------|---------|---------|----------|--------|
| Group A | BT | 7.87 | 7 | 4.17 | 0.93 | 5.35    | 0.000   | 21.33    | Sig    |
|         | AT | 6.19 | 6 | 3.37 | 0.75 |         |         |          |        |
| Group B | BT | 6.48 | 6 | 2.49 | 0.56 | 5.34    | 0.001   | 13.31    | Sig    |
|         | AT | 5.62 | 5 | 2.01 | 0.45 |         |         |          |        |

**Table 7: LH**

| LH      |    | Mean | N | SD   | SE   | t-Value | P-value | % Change | Result |
|---------|----|------|---|------|------|---------|---------|----------|--------|
| Group A | BT | 8.78 | 7 | 4.77 | 1.07 | 4.535   | 0.000   | 24.4     | Sig    |
|         | AT | 6.64 | 6 | 3.29 | 0.74 |         |         |          |        |
| Group B | BT | 6.27 | 4 | 4.51 | 1.01 | 4.64    | 0.001   | 2.95     | Sig    |
|         | AT | 6.08 | 5 | 3.8  | 0.85 |         |         |          |        |

FSH and LH both fell significantly with treatment, but the magnitude of LH reduction was far greater in Group A (24.40%) than in Group B (2.95%), foreshadowing a significant inter-group difference for this parameter.

**Table 8: Testosterone**

| Testosterone |    | Mean  | N  | SD    | SE   | t-Value | P-value | % Change | Result |
|--------------|----|-------|----|-------|------|---------|---------|----------|--------|
| Group A      | BT | 46.88 | 50 | 21.23 | 4.75 | 4.35    | 0.000   | 24.3     | Sig    |
|              | AT | 35.49 | 37 | 19.91 | 4.45 |         |         |          |        |
| Group B      | BT | 50.96 | 49 | 7.79  | 1.74 | 5.04    | 0.000   | 7.48     | Sig    |
|              | AT | 47.15 | 48 | 7.6   | 1.7  |         |         |          |        |

**Table 9: Serum Insulin**

| Serum Insulin |    | Mean  | N  | SD   | SE   | t-Value | P-value | % Change | Result |
|---------------|----|-------|----|------|------|---------|---------|----------|--------|
| Group A       | BT | 10.49 | 9  | 4.23 | 0.95 | 4.35    | 0.000   | 9.83     | Sig    |
|               | AT | 9.46  | 8  | 4.1  | 0.92 |         |         |          |        |
| Group B       | BT | 16.51 | 15 | 3.6  | 0.81 | 4.75    | 0.000   | 16.69    | Sig    |
|               | AT | 13.76 | 14 | 3.51 | 0.78 |         |         |          |        |

Serum insulin decreased significantly in both groups, with a considerably larger percentage fall in Group B (16.69%) than in Group A (9.83%), consistent with Metformin's established insulin-sensitising action.

**Table 10: Serum TSH**

| Sr. TSH |    | Mean | N | SD   | SE   | t-Value | P-value | % Change | Result |
|---------|----|------|---|------|------|---------|---------|----------|--------|
| Group A | BT | 2.54 | 3 | 1.02 | 0.23 | 4.324   | 0.012   | 0.47     | Sig    |
|         | AT | 2.53 | 3 | 0.94 | 0.21 |         |         |          |        |
| Group B | BT | 2.86 | 3 | 1.07 | 0.24 | 4.64    | 0.005   | 3.95     | Sig    |
|         | AT | 2.97 | 3 | 1    | 0.22 |         |         |          |        |

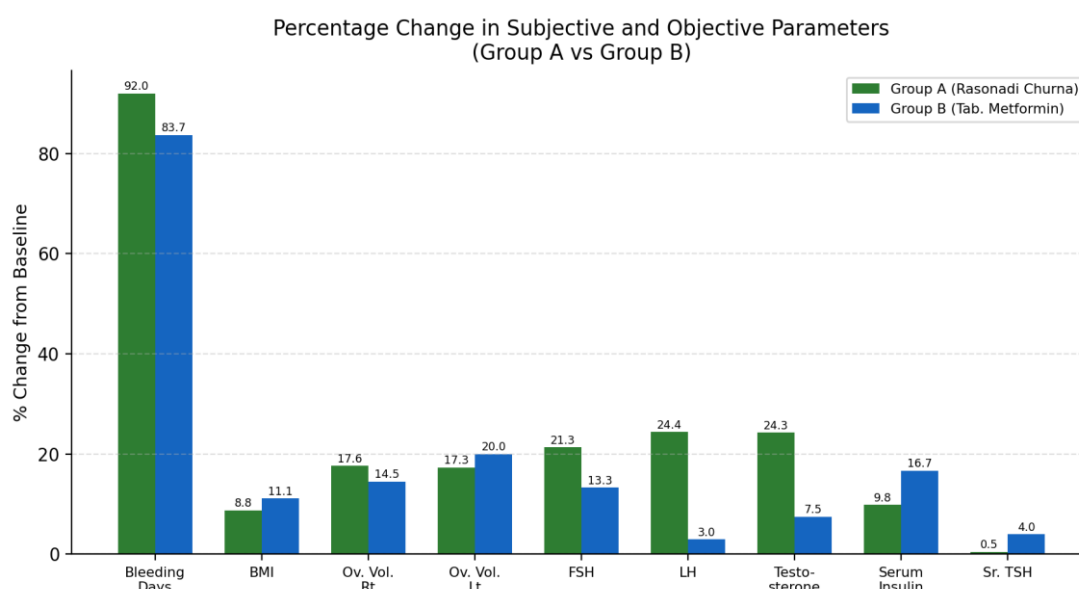


**Figure 1: Percentage Change in Subjective and Objective Parameters- Group A vs Group B**  
**Inter-Group Comparison (Independent/Unpaired t-test)**

When the two groups were compared directly against one another, most parameters showed no statistically significant difference, indicating that *Rasonadi Churna* performed on par with metformin for BMI, ovarian volume (both sides), FSH, testosterone and TSH. Two parameters, however, stood apart: LH improvement was significantly greater with *Rasonadi Churna* ( $t = 2.836$ ,  $p = 0.0073$ ), and reduction in serum insulin was significantly greater with Metformin ( $t = -2.511$ ,  $p = 0.0164$ ).

**Table 11: Inter-Group Comparison - Objective Parameters**

| Variable         | Group | N       | Mean         | SD           | SE          | t-Value | P-value | Result |
|------------------|-------|---------|--------------|--------------|-------------|---------|---------|--------|
| BMI              | A / B | 20 / 20 | 2.61 / 3.63  | 2.91 / 5.20  | 0.65 / 1.16 | -0.769  | 0.4465  | NS     |
| Ovarian Vol.- Rt | A / B | 20 / 20 | 2.76 / 2.21  | 2.01 / 1.64  | 0.45 / 0.37 | 0.957   | 0.3445  | NS     |
| Ovarian Vol.- Lt | A / B | 20 / 20 | 2.71 / 2.62  | 2.15 / 2.72  | 0.48 / 0.61 | 0.116   | 0.9083  | NS     |
| FSH              | A / B | 20 / 20 | 1.68 / 0.86  | 2.08 / 1.60  | 0.46 / 0.36 | 1.394   | 0.1716  | NS     |
| LH               | A / B | 20 / 20 | 2.14 / 0.19  | 2.40 / 1.95  | 0.54 / 0.44 | 2.836   | 0.0073  | Sig    |
| Testosterone     | A / B | 20 / 20 | 11.39 / 3.81 | 15.01 / 7.53 | 3.36 / 1.68 | 2.019   | 0.0506  | NS     |
| Serum Insulin    | A / B | 20 / 20 | 1.03 / 2.76  | 1.04 / 2.89  | 0.23 / 0.65 | -2.511  | 0.0164  | Sig    |
| Sr. TSH          | A / B | 20 / 20 | 0.01 / -0.11 | 0.26 / 0.28  | 0.06 / 0.06 | 1.471   | 0.1495  | NS     |

### Overall Effect of Therapy

Taking bleeding-pattern grade as the sole subjective parameter, the overall percentage effect was 92.00% in Group A against 83.72% in Group B. Across the objective parameters, the overall percentage effect was 15.50% in Group A and 11.24% in Group B.

On patient-wise global assessment, complete relief was recorded in 80% of patients in Group A and 85% in Group B, with the remainder showing marked to moderate improvement in both arms and no patient in either group left with no improvement.

**Table 12: Overall Effect (Patient-wise)**

| Response             | Group A (N) | Group A (%)   | Group B (N) | Group B (%)   |
|----------------------|-------------|---------------|-------------|---------------|
| Complete Relief      | 16          | 80.00         | 17          | 85.00         |
| Marked Improvement   | 2           | 10.00         | 2           | 10.00         |
| Moderate Improvement | 2           | 10.00         | 1           | 5.00          |
| Mild Improvement     | 0           | 0.00          | 0           | 0.00          |
| No Improvement       | 0           | 0.00          | 0           | 0.00          |
| <b>Total</b>         | <b>20</b>   | <b>100.00</b> | <b>20</b>   | <b>100.00</b> |

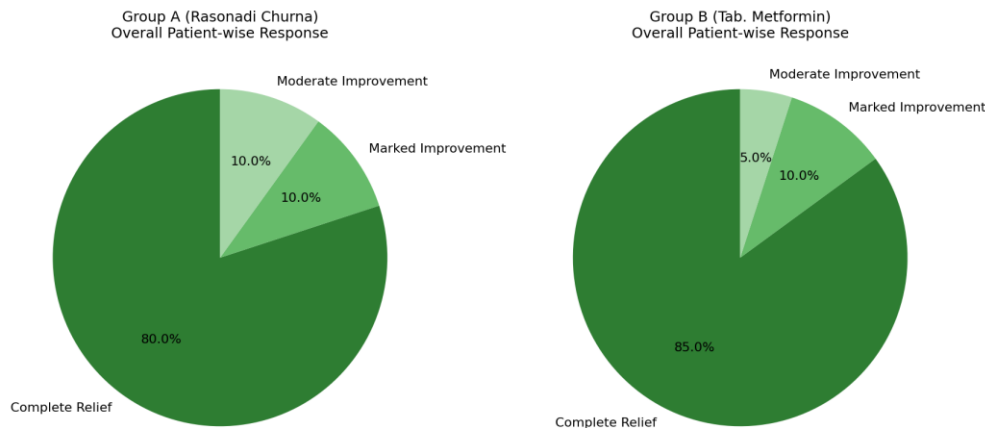


**Figure 2: Overall Patient-wise Response - Group A vs Group B**

### DISCUSSION

Both regimens produced a statistically significant intra-group improvement across virtually every parameter studied, confirming that *Rasonadi Churna* is an effective therapeutic option in PCOS, working comparably to Metformin, the current standard of care. Mechanistically, *Rasonadi Churna's* *Kapha-Vata Shamaka*, *Medohara* and *Artava Janaka* properties would be expected to correct the *Meda-Vata-Kapha* vitiation underlying *Nashtartava*, while *Rasona's* documented lipid-lowering and insulin-sensitising actions in modern pharmacology plausibly support the BMI and metabolic improvements observed.

The two significant inter-group findings merit particular attention. The markedly greater fall in LH with *Rasonadi Churna* suggests a more direct action on the hypothalamic-pituitary-ovarian axis and gonadotropin regulation, which may explain the correspondingly superior improvement in menstrual

bleeding pattern seen with this group on the Mann-Whitney comparison. Conversely, metformin's significantly greater reduction in serum insulin is consistent with its well-established role as an insulin-sensitising agent and was, if anything, the expected result. For all remaining parameters- BMI, bilateral ovarian volume, FSH, testosterone and TSH- the two treatments were statistically indistinguishable, meaning *Rasonadi Churna* matched metformin's benefit without evidence of any inter-group disadvantage.

Taken together, these results position *Rasonadi Churna* as a credible, and in respect of menstrual regularity and LH, possibly superior, alternative to Metformin for the Ayurvedic management of PCOS. Given its herbal origin, it may also offer a favourable long-term tolerability profile compared to Metformin, though this study did not formally record adverse

effects and that comparison would need to be addressed separately.

### CONCLUSION

*Rasonadi Churna* produced a statistically significant and clinically meaningful improvement in both the subjective and objective parameters of PCOS, and its overall efficacy was comparable to, and for menstrual regularity and LH reduction arguably better than, Tablet Metformin. These findings support *Rasonadi Churna* as a safe, effective and well-tolerated Ayurvedic alternative in the management of PCOS/*Nashtartava*, warranting confirmation in larger, multi-centric trials with longer follow-up.

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