



COMPARATIVE STUDY ON EFFECT OF TWO AYURVEDA FORMULAS ON UTERINE FIBROID: A Randomized Single-Blind Clinical Trial

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INTRODUCTION

Uterine fibroids are benign tumors common in reproductive-aged women, causing significant symptoms like menstrual irregularities, pelvic pain, and fertility issues. Current allopathic treatments have side effects. Ayurveda offers holistic alternatives like *Agraraja decoction* and *Tripal Gugul decoction*, whose scientific validation is limited. This study addresses this gap.

OBJECTIVE

To compare the efficacy and safety of *Agraraja decoction* and *Tripal Gugul decoction* in managing uterine fibroids, evaluating their impact on fibroid volume, symptom relief, and quality of life, alongside identifying adverse effects.

METHODS

- **Study Design:** Randomized (1:1), single-blind, Phase II clinical trial.
- **Setting:** National Ayurveda Teaching Hospital (NATH), Colombo, Sri Lanka.
- **Participants:** Female patients >20 years with USS-confirmed uterine fibroids (N=98, 49 per group).
 - **Exclusion:** Pregnancy, breastfeeding, severe bleeding, other chronic systemic diseases.
- **Intervention:**
 - **Group 1:** *Agraraja decoction* (30ml orally, BID)
 - **Group 2:** *Tripal Gugul decoction* (30ml orally, BID)
 - **Regimen:** 15 days on, 15 days off, for 3 cycles (3 months).

Outome Measures:

- **Efficacy:** Fibroid volume (USS), Symptom severity (UFS-QoL), Menstrual bleeding (PBAC), Dysmenorrhea (WaLIDD score) – all monitored monthly.
- **Safety:** Laboratory tests (FBS, LFT, Lipid Profile, S. Creatinine, FBC, Urine FR) – pre/post treatment. Adverse event reporting.
- **Statistical Analysis:** SPSS v30. Wilcoxon Signed-Rank Tests (within-group), Mann-Whitney U tests (between-group), Regression analysis. p<0.05 considered significant.
- **Ethics:** Approved by ERC, Institute of Indigenous Medicine, University of Colombo (ERC No. 21/128).

RESULTS

1. Within-Group Efficacy (Wilcoxon Signed-Rank Test):

Both *Agraraja decoction* and *Tripal Gugul decoction* significantly improved:

- Symptom Severity (p<0.001)
- Health-Related Quality of Life (HRQL) (p<0.001)
- Fibroid Volume Reduction (p<0.001)
- Menstrual Bleeding Volume Reduction (p<0.001)
- Dysmenorrhea Reduction (p<0.001) (*E.g., At follow-up, 74/86 participants showed symptom improvement; 84/86 showed fibroid volume decrease*).

2. Between-Group Efficacy (Mann-Whitney U Test):

- No statistically significant differences were observed between *Agraraja decoction* and *Tripal Gugul decoction* groups for any efficacy outcome at any time point (p>0.05). Both treatments offered comparable benefits.

3. Safety Analysis:

Both formulations demonstrated favourable safety profiles with no severe adverse effects.

- ***Agraraja Decoction*** : Significant reductions in total cholesterol, triglycerides, LDL, SGPT, SGOT, and alkaline phosphatase (p<0.05).

Tripal Gugul Decoction : Significant reductions in total cholesterol, triglycerides, SGPT, SGOT, Gamma GT, and alkaline phosphatase (p<0.05). Also, significant reduction in Fasting Blood Sugar (p=0.021).

4. Regression Analysis:

- Baseline symptom severity and HRQL were significant predictors of fibroid volume at follow-up.
- Baseline symptom severity and fibroid volume predicted HRQL at the third month.

CONCLUSION

Both *Agraraja decoction* and *Tripal Gugul decoction* are promising Ayurvedic treatments for managing uterine fibroids, offering significant symptom relief, improved quality of life, and reduced fibroid volume. They exhibit favourable safety profiles and positive impacts on metabolic and liver parameters. While individual responses may vary, no significant differences in efficacy were found between the two interventions.

RECOMMENDATIONS FOR FUTURE RESEARCH

- Larger sample sizes and diverse populations.
- Extended treatment and follow-up durations.
- Inclusion of a placebo or standard-of-care control group.
- More objective clinical measures (e.g., hormonal assays).
- Exploration of personalized medicine approaches based on Prakruti.

