The Review Of
DIABETIC
STUDIES OPEN ACCESS

Evaluation Of The Efficacy Of Shivlingi Beej Churna In The Management Of Infertility Due To Anovulation: A Randomized Clinical Trial

Dr. Moushami Kulhare[1] Dr. Nisha Bhalerao[2]

[1]Co-PI, Assistant Professor, PG Dept. of Prasuti tantra evum Stri roga, Pt. Khushilal Sharma Government (Autonomous) Ayurveda College & Institute, Bhopal. ORCID Id- 0009-0002-6862-5384
[2]PI, Associate Professor, PG Dept. of Rachna Sharir, Pt. Khushilal Sharma Government (Autonomous) Ayurveda College & Institute, Bhopal. ORCID ID : 0000-0001-7611-9348.
Corresponding author- Dr. Moushami Kulhare

Abstract

Background: Infertility is a growing reproductive health concern, with anovulation being one of the major contributing factors in female infertility. In Ayurveda, anovulatory infertility can be correlated with conditions involving Artava Kshaya and Beej Dushti, predominantly caused by vitiation of Vata and Kapha dosha along with impairment of Agni. Shivlingi Beej (Bryonia laciniosa Linn.) is a well-known Ayurvedic drug traditionally indicated in the management of infertility due to its Deepana, Pachana, Balya, and Garbhasthapana properties. The present study aims to evaluate the efficacy of Shivlingi Beej Churna in the management of infertility associated with anovulation. Assessment was carried out on the basis of associated hormonal parameters and folliculometry. The outcomes demonstrated improvement in follicular size and timely ovulation, indicating the therapeutic potential of Shivlingi Beej Churna. The study suggests that Shivlingi Beej Churna may be an effective, safe, and economical Ayurvedic intervention for managing infertility due to anovulation, delayed ovulation, PCOS with follicular arrest and Poor follicular growth.
Material and methods: Women diagnosed with infertility due to anovulation, were selected from the OPD of Prasuti Tantra Evum Striroga department of Pt. Khushilal Sharma Government (Autonomous) Ayurveda College & Institute, Bhopal, after obtaining written informed consent from the patients. The selected patients were randomly divided into two groups.
Dose and Duration:
Group- A: Placebo (Roasted Wheat flour) in the dose of 3gms twice daily with warm water for 08 weeks.
Group B: Shivlingi Beej churna in dose of 3 gms twice daily with warm water for 08 weeks.
Results: Group - B has shown better results as compared to group- A in all parameters.
Discussion: Shivlingi Beej Churna appears to be a safe, economical, and effective Ayurvedic intervention for anovulatory infertility.

Keywords- Infertility, Folliculometry, Anovulation, Shivlingi Beej, Artava Kshaya, Beej Dushti, Vandhyatva.

Introduction:

Infertility is a global health issue which affects millions of people of reproductive age worldwide. As per data, one in four couple experiences infertility i.e., 8-12% couples of reproductive age worldwide & 15-20 million people of reproductive age in India.[1] Infertility is inability to achieve pregnancy after 1 year or more of regular unprotected sexual intercourse.[2] Infertility is a multi-factorial condition influenced by a wide range of biological, environmental, and behavioral factors. In the present era, lifestyle-related factors such as unhealthy dietary habits, lack of physical activity, obesity, chronic psychological stress, disturbed sleep patterns, and exposure to environmental pollutants have significantly increased and adversely affected reproductive health. These factors alter metabolic

functions and interfere with the normal hormonal cascade required for optimal reproductive functioning, thereby contributing to declining fertility rates worldwide.[3]
In Ayurveda classics, Acharya Sushruta mentioned that natural conception occurs only when Garbhasambhava Samagri i.e. Ritu, Kshetra, Ambu and Beej remains in healthy & normal condition, when there is abnormality in any of them, it hinders the process of conception and causes infertility.[4] Among these factors Beej can be considered as ovum in females and sperm in males.

ध्रुवं चतुर्णां सान्निध्याद्गर्भः स्याद्विधिपूर्वकम् | ऋतुक्षेत्राम्बुबीजानां सामग्र्यादङ्कुरो यथा |Su.Sha. 2/33

Absence of this Beej in women is termed as anovulation. The main reason for anovulatory cycles is vitiation of Artava. Irregular dietetic and behavioural habits results into Dosha vitiation and mal-absorption which lead to Margasya Avarana (obstruction) and causes anovulation i.e. abeejotsarga or pushpa asamjanana.[5] Acharya Sushruta has quoted Vandhya under Vataja Yonivyapada. It indicates the condition where there is destruction of Artava. The word Artava can be used for either menstrual blood or ovum. So Nashtartava can be taken as condition of amenorrhoea or anovulation.[6]
According to Acharya Charaka, Mithya Ahara, Vihara, Artava Dushti and Daiv (destiny) are the main cause of Beejdosha (Abnormalities of Ovum).

मिथ्याचारेण ताः स्त्रीणां प्रदुष्टेनार्तवेन च| जायन्ते बीजदोषाच्च दैवाच्च शृणु ताः पृथक्|(Ch.chi.30/8)

Ovum carries Matraja Bhawas. Artava vitiated by different Doshas produces abnormality in ovum, ultimate result is that the ovum loses its capacity of fertilization and causes infertility.

Prevalence:
According to WHO one in every four couples in developing country is affected by infertility. 17.5% of adult population almost 1 in 6 worldwide experience infertility. Lifetime prevalence is 17.8% in high-income countries and 16.5% in low and middle income countries. Male is responsible in about 30-40% cases, female is responsible in about 40-55% of cases and both are responsible in about 10% of cases of infertility. Ovarian factors are responsible in 30-40% of female infertility.[7]

Rationale:
Conventional system offers ovulation induction to achieve pregnancy. Drugs like Clomiphene citrate, Letrozole, Metformin, Gonadotropins, Hormone replacement therapy (HRT). It often causes side effects like ; mood swings, thinning of endometrium, resistance towards these therapy, reduced ovarian reserve, multiple pregnancies, obesity, other menstrual issues. Surgical management done by Laparoscopic Ovarian Drilling. Assisted Reproductive Technologies (ART) - Intrauterine Insemination (IUI) or In Vitro Fertilization (IVF) are invasive procedures.[8]
Modern medicine only focuses on follicle stimulation overlooking overall reproductive environment. Hence, an accessible, holistic, natural, low cost, non-invasive, effective and safe alternative treatment protocol or medicine is needed.
Shivalingi beej churna is having properties like Putrajanana (responsible for reproduction), Yonishodhana (regulate female reproductive system), Rutupravartana (inducer of menstruation) and Prajasthapana (promotes conception), hence it is considered highly esteemed and has shown encouraging results in the management of infertility.[9]

Material and methods:
Women diagnosed with infertility due to anovulation, were selected from the OPD of Dept. of Prasuti Tantra Evum Striroga, Pt. Khushilal Sharma Government (Autonomous) Ayurveda College & Institute, Bhopal, after obtaining written informed consent from the patients. The selected patients were randomly divided into two groups. Before enrolling patients, male factor was excluded after evaluation of the semen morphology report. Couples were counselled regarding lifestyle modification, focusing on dietary habits, sleep patterns and phsical activity (Ahara and Vihara) to improve reproductive outcome.

Ethical Approval:

Grant-in-aid by: Madhya pradesh council of science and technology, Bhopal (MPCST) dated: 31/03/2023. Project presented to Institutional ethical committee for the approval and was approved on 29/09/2023.
After IEC clearance project forwarded to CTRI for registration and thus project registered on 30/10/2023.
CTRI Registration no. - CTRI/2023/10/059259.

Aims and objectives:
1. To evaluate the clinical efficacy of Shivlingi Beej churna in inducing ovulation for the management of anovulatory infertility.
2. To access follicular growth and changes in hormonal levels.
3. To achieve conception.

Diagnostic criteria:
Primary complaint: Inability to conceive after 1-2 years of regular, unprotected intercourse.
1. Menstrual irregularities: Oligomenorrhea (infrequent periods) or amenorrhea (absence of periods).
2. Ovulatory dysfunction: Confirmed anovulation or oligo-ovulation via: - Folliculometry.
3. Hormonal evaluation: Abnormal Serum levels of FSH, LH and Prolactin.

Inclusion criteria:
1. Married females having age between 20 to 40 years and having active married life of minimum 1 year having history of oligomenorrhoea/ hypomenorrhoea or irregular menstrual cycle.
2. Females with primary or secondary types of infertility due to anovulatory cycle or with immature ovarian follicle or Luteinised unruptured follicle.
3. Patient willing to participate in the study.

Exclusion Criteria:
1. Patients age less than 20 year and more than 40 years.
2. Patients suffering from systemic disorders like; tuberculosis, cardiovascular diseases, diabetes, hypertensions, hypo or hyperthyroidism, severe anaemia, congenital anomalies, sexually transmitted diseases, malignancy etc.
3. Patients having mental disorders like depression, anxiety etc.
4. Patients having any structural gynaecological disorders.
5. Patient not willing to participate in the study.

Investigations:
A. **General investigations –**
1) Haematological (Haemoglobin, TLC, DLC, PCV, ESR, RBS)- done before and after treatment.
2) Urine- routine and microscopic- done before and after treatment.
2) Serological (HIV, HBsAg, VDRL)- done before treatment.

B. **Specific investigations-**
1) TVS (Trans vaginal sonography)- for the diagnosis of anovulatory cycle was done on 12^{th} ,14^{th} ,16^{th} and 18^{th} day of menstruation or on days depending on menstrual cycle - done before and after treatment.
3) Test for serum FSH, serum LH, serum Prolactin, TSH - done before and after treatment on 3^{rd} day of menstrual cycle.

Grouping and Dosage of drugs:
The selected patients were randomly divided into two groups, A and B. Medicine was provided to patients in container of 100gm with a 3gm measuring spoon.
Group A (n = 28): Placebo (roasted Wheat flour) in the dose of 3gms twice daily with warm water for 08 weeks.
Group B (n = 28): Trial- (Shivlingi Beej Churna) in dose of 3 gms twice daily with warm water for 08 weeks.

- 2-2 patients were dropped out in both groups due to discontinuation of treatment protocol.

Shivlingi Beej was procured from authenticated source. To authenticate and standardize the raw material, the pharmacognostical analysis of Shivlingi seeds (Bryonia laciniosa) was conducted at the Central Research Laboratory, of Pt. Khushilal Sharma Govt. Ayurvedic College to evaluate macroscopic, microscopic, and physicochemical properties of Shivlingi Beej.

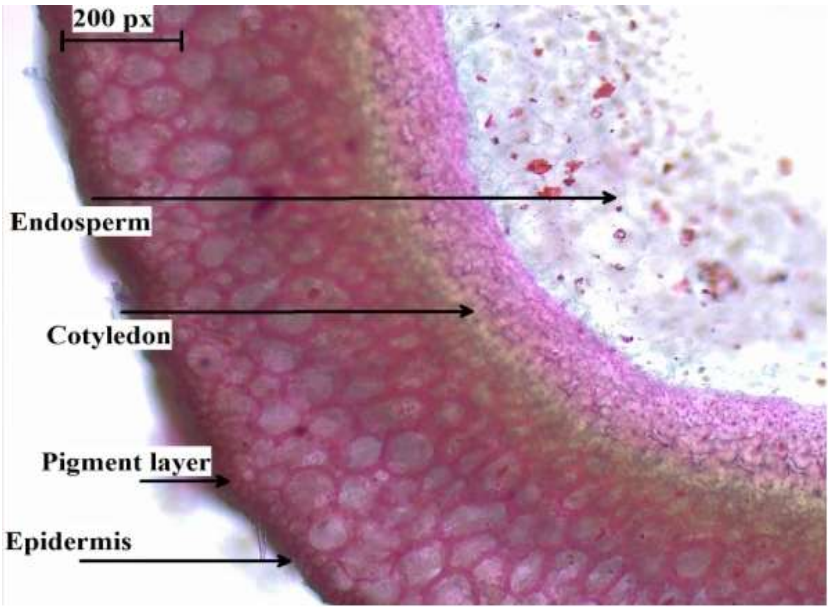
MACROSCOPIC EXAMINATION:

Figure 01. Seeds of Bryonia laciniosa Linn.

The seed appear to be approximately 5-6mm long. The surface is uneven and has a textured appearance with raised projections. Color is greyish-brown and yellowish-brown tones. Odor is faint. Shape is flattened, oval or slightly irregular. Taste is likely bitter or acrid.

MICROSCOPIC EXAMINATION:

Figure 02. T.S. of Bryonia laciniosa Linn. Seed



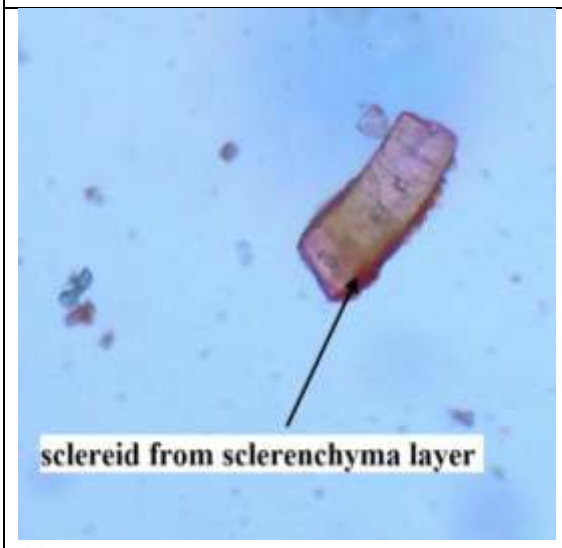
The transverse section of seeds shows the following-
1. Endosperm; 2. Cotyledon; 3. Pigment layer; 4. Epidermis.

POWDER MICROSCOPY EXAMINATION:

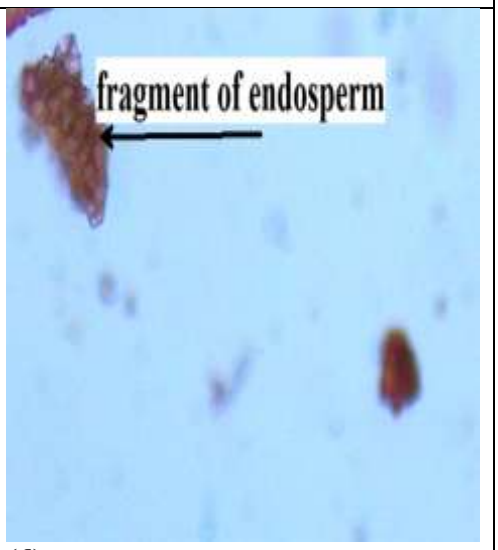
Figure 03. Powder Microscopy of Bryonia laciniosa Linn. Seed

(a)

(b)



(c)



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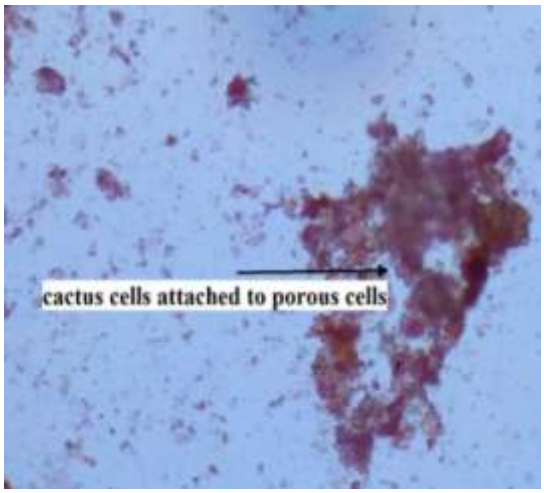
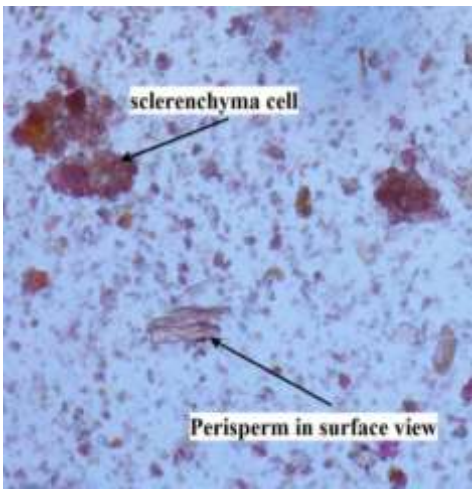


(e)



(f)

The powder characteristics of shivling seeds shows (a) Oxalate crystal; (b) Fragment of epidermal cell; (c) Sclereid from sclerenchyma layer; (d) Fragment of endosperm; (d) Cactus cells attached to porous cells; (f) Perisperm in surface view.

Table no. 1: Physiochemical evaluation of Shivlingi Beej-

S. No.	Name of Tests	Results
1	Foreign Matters	The Sample was free from visible signs of mold growth sliminess, stones, rodent extracts and insects.
2	Loss on Drying (at 105^0 C)	3.23%
3	Total Ash Value (% w/w)	4.952%
4	Acid Insoluble Ash (% w/w)	0.33%
5	Alcohol Soluble Extract (% w/w)	10.395%
6	Water Soluble Extract (% w/w)	13.84 %
7	pH	6.40

Drug Review:

Traditional knowledge regarding Shivlingi Beej:

In India, it's called as "Shivlingi" and "Gargumaru," and it's an annual climber with brilliant red fruits that's said to be very medicinal. its seeds are being used to help women become more fertile. Gond and Bharia tribes of Patalkot valley venerate this plant, they have a faith that this plant is also boon for issueless individuals. In Gailduba, customary healers make a mix of Shivlingi Beej with Tulsi (Ocimum basilicum) leaves and blend it in Jaggery. Furthermore, give it to a lady who is unable to imagine a child for whatever reason.[10]

Ayurvedic texts advocates the use of Shivlingi Beej for the treatment of infertility since ancient times. Numerous Ayurvedic references establish the use of these seeds to restore fertility in both men and women, such as Raja Nighaṇṭu and Saligrama-Nighaṇṭu in Guduchyadi Varga. However, its most recognized use, as orally consumed whole seeds, is in the improvement of sexual behaviour and treating infertility.[11]

Shivlingi Beej Churna is having properties like Balya (giving strength), Brihaniya (nourshing/increasing body strength), Deepana (appetizer), Pachana (digestive), Putrajanana (responsible for reproduction), Yonishodhana (regulate female reproductive system), Rutupravartana

(induce menstruation) and Prajasthapana (promotes conception). It also has hepato-protective and anti-oxidant properties, which ultimately helps in regulation of ovarian cycle.[12]

Table no.2: Description of Drug-

	Sanskrit synonyms	Lingini, Bahupatra, Ishwari, Shaivamallika, Swayambhu, Amruta, Pandoli, Lingasambhuta, Lingi, Chitraphala, Lingaja, Devi, Chanda, Apstambhini, Shivaja, Shivavalli, Sutbandhini.[13]
	Morphology[14]	It is Annual climbing herb. 1. **Stem:** Enormously expanded, thin, scored, labrous. Rings are Slender, striate, glabrous. 2. **Leaves:** Membraneous, 10-15 cm long and expansive, green and scabrid above, paler, and smooth or almost so underneath. Profoundly cordate at base. 5-lobed, processes elongated, lanceolate, midrib sometimes serrated. Petioles are 2.5-7.5 cm long, striate, slim. 3. **flower:** With little fascicles of 3-6, peduncle 5-20 mm long, filiform, glabrous. Calyx is glabrous with longer about 205 mm, teeth is subulate. Corolla 3–5 mm long. 4. **Fruit:** The fruits are Subsessile, with about 1.3-205 cm in breadth, smooth, globose, pale blue green, streaked with wide vertical lines and having seeds longer about 5-6 mm with yellowish cocoa.
	Latin name	Bryonia Laciniosa /Bryonopsis Laciniosa Naud.[(8)]
	Family	Cucurbitaceae[15]
	Genus	Bryonia
	Rasa (Taste)	Katu, Tikta
	Virya (Potency)	Ushna
	Vipaka (Resultant)	Katu
	Guna (Quality)	Laghu, Ruksha, Tikshna
	Dosha Karma (Effect on humors)	Pacifies Kapha dosha and increases Pitta dosha
	Parts Used	Seeds
	Karma	Rasayana[16]
	Medicinal properties	Uterine tonic, Fertility booster, Aphrodisiac, Spermatogenic, Antioxidant, Antioxident, Anti-inflammatory, Carminative Antimicrobial etc.[17]
	Chemical Composition	Saponins, flavonoids, phenolic acids, sugars, punicic acid, goniothalamin, and glucomannan.[18]

Assessment criteria:
Final treatment outcome was assessed on the basis of hormonal levels (S. FSH and S.LH) and confirmation of ovulation on TVS folliculometry before and after the treatment or confirmation of conception by a positive urine pregnancy test (UPT)
Objective parameters: Serum FSH, Serum LH and follicular size/ ovulation
Statistical analysis: All the Results are calculated by using Software: InStat GraphPad 3. Student‘s t‘ Paired and unpaired Test were used for parametric data, results calculated in each group.

Safety profile:
Shivlingi Beej has no known adverse effects when used correctly according to Dosha and recommendation.[19]

Factors responsible for Female infertility:

According to FIGO manual (1990) ovulatory factor are 30–40% responsible for infertility. Ovarian dysfunction is likely to be linked with disturbed hypothalamo-pituitary-ovarian (HPO) axis either primary or secondary from thyroid or adrenal dysfunction. It encompass:

- Anovulation or oligo-ovulation
- Decreased ovarian reserve (DOR)
- Luteal phase defect (LPD)
- Luteinized unruptured follicle (LUF)[20]

Causes of Anovulation in Ayurveda:

Ayurveda states that reproductive health is governed by balanced Vata, Pitta, and Kapha. From Ayurveda point of view, anovulation correlates with Artava Kshaya and Beej Dushti, caused by Kapha-Vata vitiation and Agnimandya.[21]

1. Kapha Dosha Imbalance- Acharya Charaka has mentioned Upachya as one of the important Karma of Kapha, moreover Kapha and Rasa have Ashrayasharyi Bhava. Rasa Dushti can cause further Dhatus to become vitiated and hence leads to formation of vikrut artava . Hence vitiation of Kapha can cause anovulation by disturbing the Beej formation or by causing Marga avarodha.

2. Vata Dosha Imbalance- Without Vata Yoni never gets vitiated. Vata Dosha is the governing factor of the whole reproductive physiology; ovulation is also under the control of Vata. Therefore any vitiation of Vata will certainly affect the ovulation.

3. Pitta Dosha Imbalance- Pitta and Rakta are Ashrayashrayi, hence vitiated Pitta can vitiate Rakta Dhatu. Thus can result in Vikrut Aartava formation or Anartava or anovulation.

Classification:

According to modern science, infertility is of two types, viz - Primary and Secondary. Primary infertility denotes those patients who have never conceived while Secondary infertility indicates previous pregnancy but failure to conceive subsequently.[22]

According to Acharya Charak, Vandhya is of three types, viz- Vandhya, Apraja and Sapraja. Vandhya refers to inability to conceive due to congenital malformation or genetical disorders. Apraja refers to a lady who can conceive after taking some treatment. Sapraja refers to a lady who has previous pregnancies but is not able to conceive subsequently. [23]

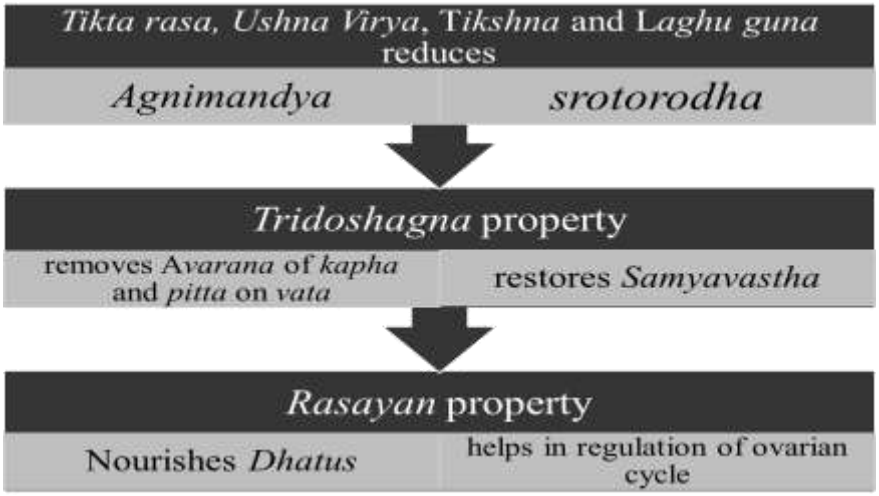
Probable mode of action of Shivlingi Beej on Ovulation:

Shivlingi Beej is known for its androgenic properties. It also helps patients who have ovulation problems common in diseases such as diminished ovarian reserve (DOR). Rasayana action of Shivlingi Beej helps to synthesize purest Rasa dhatu. subsequently, Upadhatu Artava is formed having required quality for fertilization. Hypothetically the Rasayana karma in this regard may act through androgenic effect via DHEA.[24]

DHEA (Dehydrepiendosterone) is a natural existing hormone in female body which converts into androgens and are essential for production and development of healthy eggs. It Improves ovarian responsiveness to FSH and thus foliculogenesis. Shivlingi Beej helps normalize Apana Vayu, promoting proper follicular maturation and rupture. Thus useful in anovulation and delayed ovulation. Shivlingi Beej have phyto-estrogenic modulation which supports to increase endometrial receptibility.[25]

Shivlingi Beej contains bioactive constituents such as punicic acid, goniothalamin, glucomannan and flavonoids. These compounds exhibit antioxidant, anti-inflammatory and reproductive tonic activities, which may improve ovarian function, promote follicular maturation and help in the management of anovulation.[26]

Mode of Action[27]

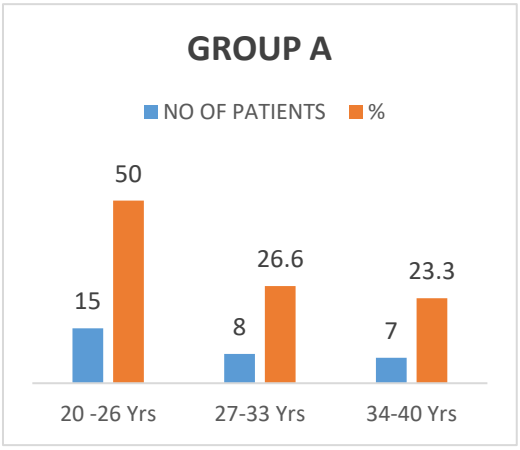


DEMOGRAPHIC DATA:

Table no. 3: Age wise distribution

S.NO.	AGE	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	20-26 Yrs	15	50%	7	23.3%
2.	27-33 Yrs	08	26.6%	14	46.6%
3.	34-40 Yrs	07	23.3%	09	30%

Graph 01: Age-wise distribution- Group A



Graph 02: Age-wise distribution-Group B

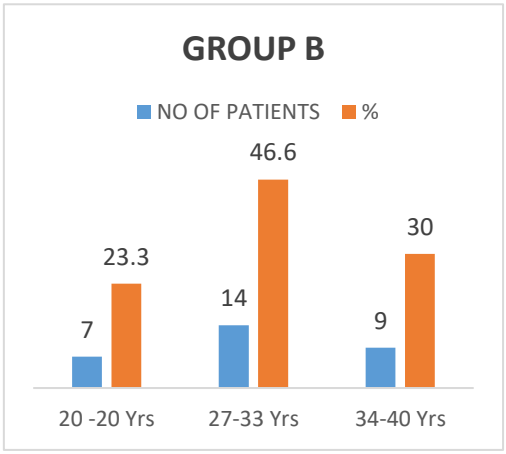
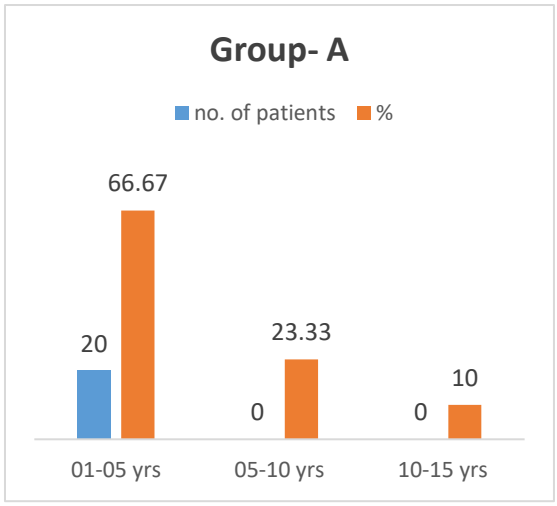


Table no. 4:Active Married life wise distribution

S.NO.	ACTIVE MARRIED LIFE	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	01-05 Yrs	20	66.67%	17	56.66%
2.	05-10 Yrs	07	23.33%	08	26.67%
3.	10-15 Yrs	03	10%	05	16.67%

Graph 03: Active married life Wise distribution- Group A

Graph 04: Active married life wise distribution-Group B



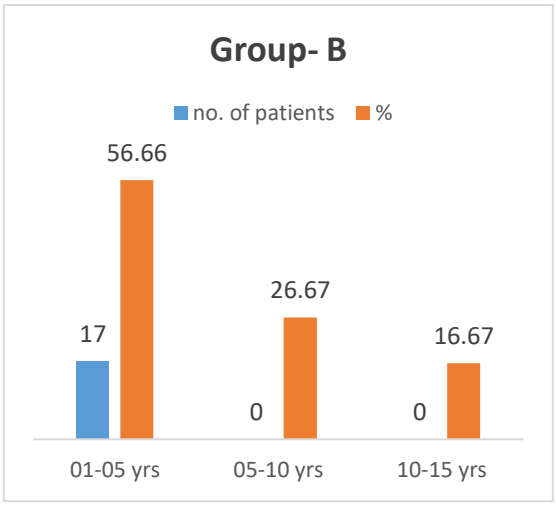
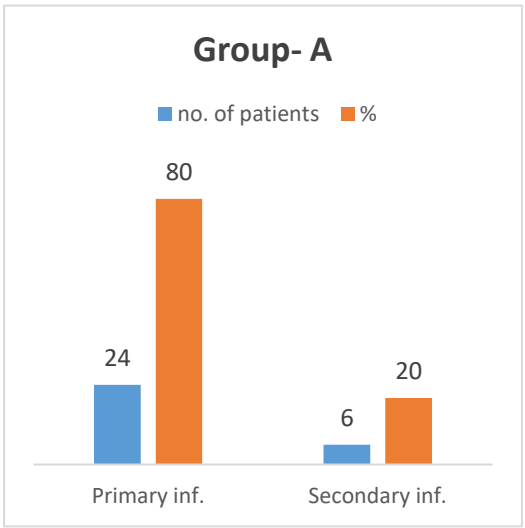


Table no. 5: Type of infertility wise distribution

S.NO.	INFERTILITY	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	Primary (Apraja)	24	80%	23	76.7%
2.	Secondary (Sapraja)	06	6.6%	07	23.3%

Graph 05: Type of infertility wise distribution-wise Group A

Graph 06: Type of infertility distribution- Group B



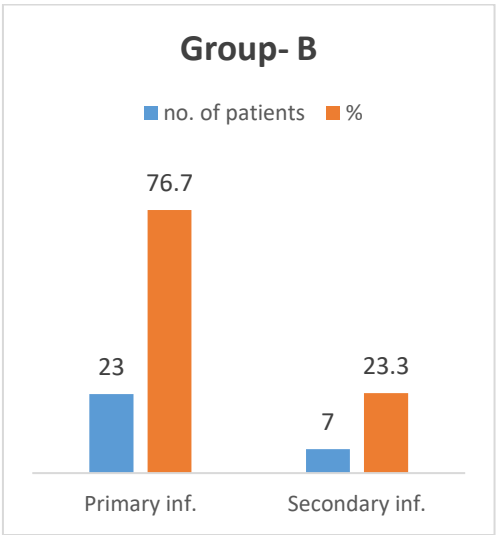
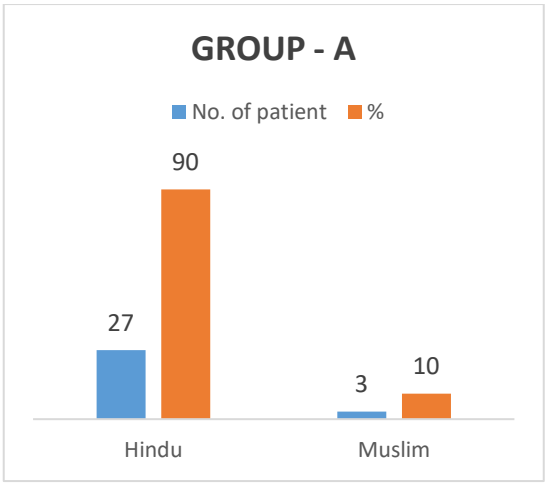


Table no. 6: Religion wise distribution:

S.NO.	RELIGION	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	Hindu	27	90%	28	93.3%
2.	Muslim	3	10%	2	6.7%

Graph 07:Religion wise distribution- Group

Graph 08:Religion-wise distribution- Group B



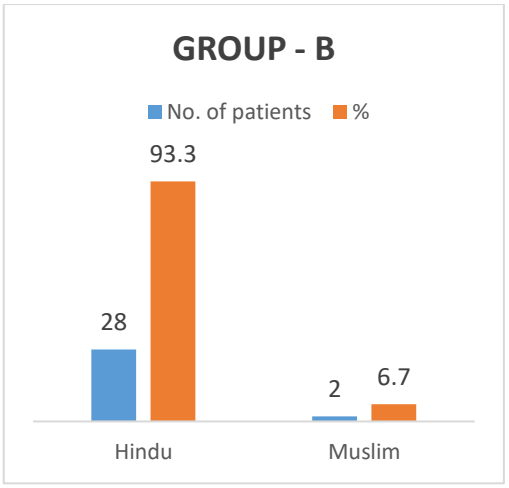
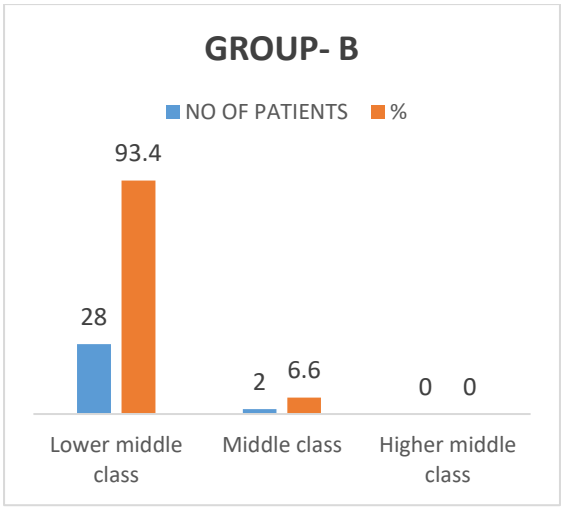


Table no. 7: Socio-Economic status wise distribution

S.NO.	SOCIO-ECONOMIC STATUS	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	Lower middle class	28	93.4%	02	6.6%
2.	Middle class	02	6.6%	27	90%
3.	Upper middle class	00	00%	01	3.4%

Graph 09:
Socio- Economic status wise distribution- Group A

Graph 10:
Socio-Economic status wise distribution - GroupB



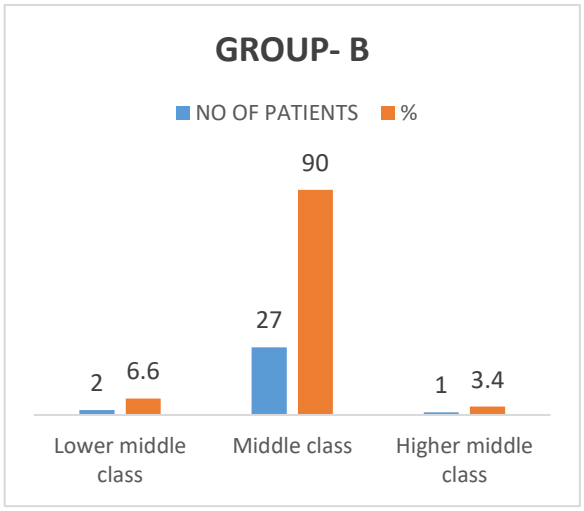


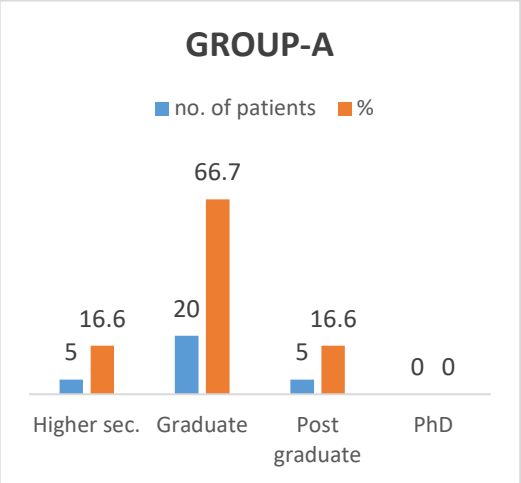
Table no.8: Education wise distribution

S.NO.	EDUCATION	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
	Higher Secondary	05	16.6%	02	6.6%
	Graduation	20	66.7%	15	50%
	Post graduation	05	16.6%	11	36.7%
	PhD	00	0%	02	6.6%

Graph 11: Group A

Graph 12: Group B

Education wise distribution



Education wise distribution

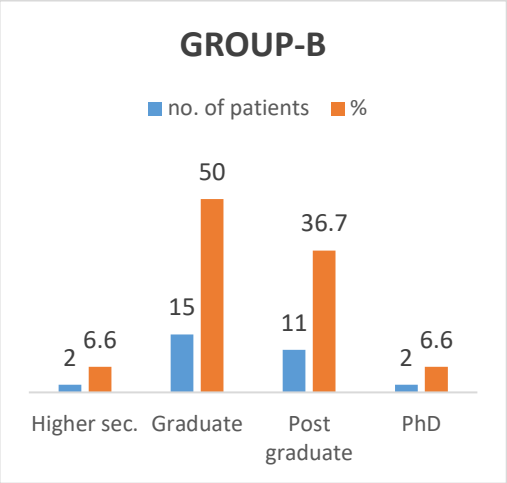
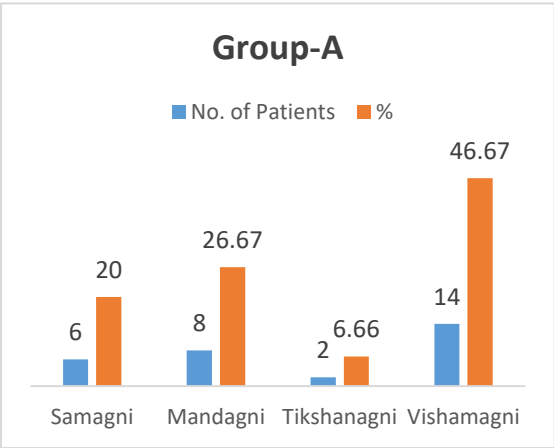


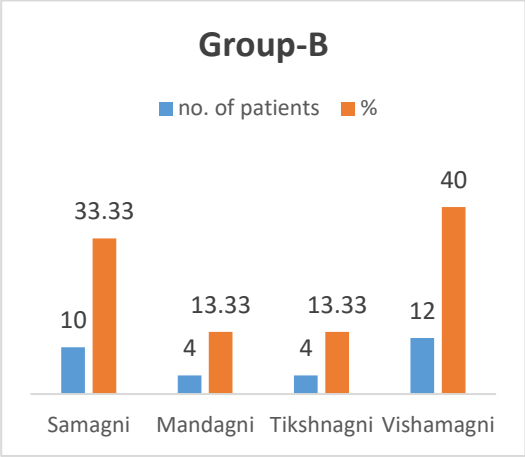
Table no.9: Agni wise distribution:

S.NO.	AGNI	GROUP A		GROUP B	
		No. of patients	%	No. of patients	%
1.	Samagni	06	20%	10	33.33%
2.	Mandagni	08	26.67%	04	13.33%
3.	Tikshanagni	02	6.66%	04	13.33%
4.	Vishamagni	14	46.67%	12	40%

Graph 13:Agni wise distribution- Group A



Graph 14:Agni wise distribution- Group B



Observation on Demographic data

- Age wise distribution revealed that 36.7 % patients were of 20-26 years and 27-33 years age group and 26.6% fall under 34-40 years of age group.
- Active Married life wise distribution revealed that 61.66 % couples had AML 01-05 years, 25% of couples had AML 05-10 years and 13.33% had AML 10-15 years.
- Type of Infertility wise distribution revealed 78.33% were of primary and 21.67% suffered from secondary infertility.
- Religion wise data states that 91.7% patients enrolled in study were of Hindu religion.

- Economic status revealed 50% patients were of middle class, 48% were of lower middle class and only 2% patients were of Higher middle class.
- Education wise data revealed that 11.7% studied up to secondary education, 58.3 were graduates, 26.7% were post graduates and only 3.3% attained higher education.
- Agni wise distribution revealed that 26.66% patients were of Samagni, 20% were of Mandagni, 10% of Tikshanagni and 43.33% had Vishamagni.

Effect of therapy on objective parameters

Table no. 10: Effect of therapy on objective parameters in Group- A (n=28) (Student's Paired- t test)

Variable	Mean		Mean diff.	Correlation coefficient	T value	p value	Result
	B.T.	A.T.					
S. FSH	3.571	3.143	0.4286	0.4914	1.759	0.0449	S
S. LH	1.929	1.464	0.4643	0.2488	2.100	0.226	S
Follicular size/ Ovulation	1.536	2.179	-0.6429	0.1018	2.540	0.0086	VS

Placebo group showed significant results on serum FSH and serum LH but very significant result on Follicular size/ Ovulation [Table no. 10]
***S** - Significant, ***VS** - Very significant

Table no. 11: Effect of therapy on objective parameters in Group-B (n=28) (Student's Paired- t test)

Variable	Mean		Mean diff.	Correlation coefficient	T value	p value	Result
	B.T.	A.T.					
S. FSH	3.536	2.393	1.143	0.4288	3.400	0.0011	VS
S. LH	1.714	1.143	0.5714	0.1414	2.458	0.0103	S
Follicular size/ Ovulation	1.643	2.750	-1.107	0.2557	4.117	0.0002	ES

@ **S**- Significant, **VS**- Very Significant, **ES-** Extremely Significant

- ❖ Trial group showed very significant results on serum FSH, significant result on serum LH and extremely significant result on Follicular size/ Ovulation [Table no. 11]

Intergroup comparison between Group-A and Group-B on all objective parameters by students unpaired 't' test [Table no. 12]

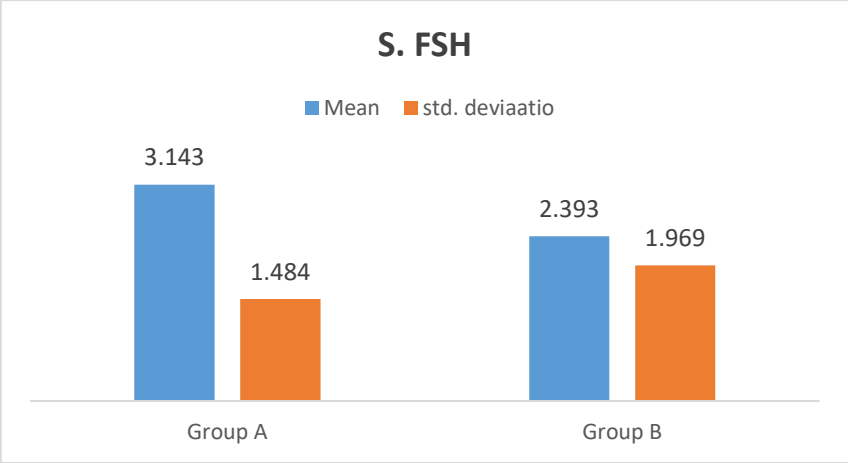
Table no. 12: Effect of therapy on objective parameters in Group-A and Group-B (n=56)

Variable	Group	Mean	SD	SE	Mean Diff.	t value	p value	Result
S. FSH	Group- A	3.143	1.484	0.2804	-0.7143	1.610	0.1133	NS
	Group- B	2.393	1.969	0.3721				

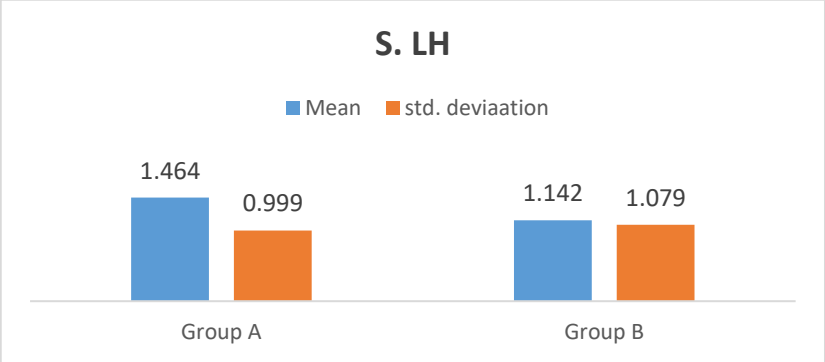
S. LH	Group- A	1.464	0.9993	0.1889	-0.3929	1.157	0.2525	NS
	Group- B	1.142	1.079	0.2039				
Follicular size/ Ovulation	Group- A	2.179	1.219	0.2303	0.5714	1.662	0.1023	NS
	Group- B	2.750	1.351	0.2552				

@ **NS**- Not Significant

Graph 15: Mean and Standard deviation on S. FSH in Groups A and Group B



Graph 16: Mean and Standard deviation on S. LH in Groups A and Group B



Graph 17: Mean and Standard deviation on Follicular size/ ovulation in Groups A and Group B

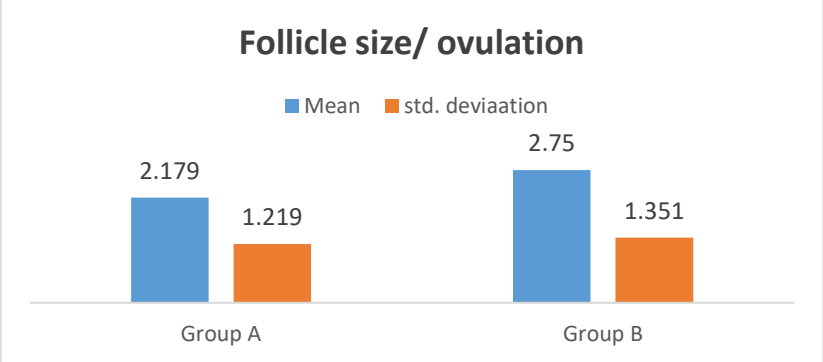
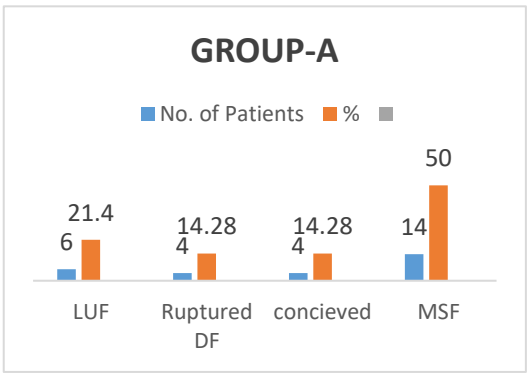


Table no. 13: Effect on ovulation (n=56)

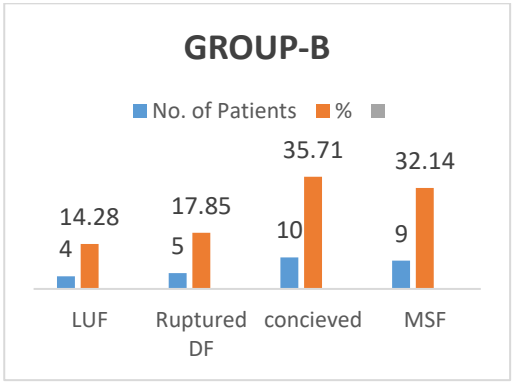
SNo.	State of follicle	Group A		Group B	
		No. of Patients	%	No. of Patients	%
1.	LUF	06	21.4	04	14.28
2	Ruptured DF	04	14.28	05	17.85
3	Conception	04	14.28	10	35.71
4	MSF	14	50	09	32.14

*LUF- Luteinized unruptured follicle
*DF- Dominant follicle
*MSF- Multiple small follicles

Graph 18: State of Follicle -Group A



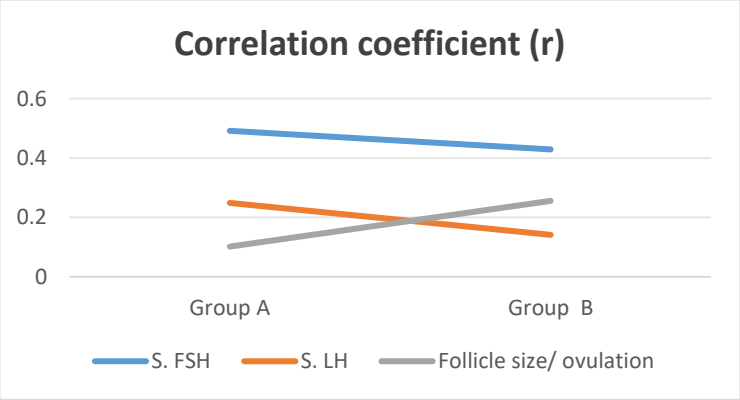
Graph 19: State of Follicle -Group B



- On assessing Effect on ovulation in both groups, ovulation occurred in 14.28% patients and 14.28 % of patients concieved in Placebo and in Trial group ovulation occurred in 17.85% and 35.71% patients concieved in trial group.
- Even a patient with active married life of 12 years and previous IVF failure, conceived during the course of this clinical trial in trial group, and delivered successfully a live child by LSCS on 7th May 2025. This outcome highlights the potential effectiveness of the intervention.

DISCUSSION:

Graph no. 20: Comparison of all objective parameters before and after treatment



- According to the two cell-two gonadotrophin theory (Fevold, 1941, Greep et al., 1942), both FSH are LH are necessary for ovarian follicular maturation and the production of ovarian

steroids.[28] When Gonadotropins (FSH and LH) levels are abnormally high, it usually indicates that the ovaries are not responding properly to hormonal signals. The pituitary gland increases secretion of FSH and LH in an attempt to stimulate the ovaries. Despite high hormone levels, follicular maturation and ovulation may not occur, resulting in anovulation. Normal level of serum FSH and LH on Baseline hormonal analysis on third day of menstrual cycle is responsible for normal growth and maturation of ovarian follicles and indicates normal ovarian function. Correlation coefficient graph shows normalization of Gonadotropins improves follicular growth.

- Anovulatory infertility is a major cause of female infertility and is closely associated with hormonal imbalance, metabolic disturbances, and lifestyle factors. The Deepana, Pachana, Kaphaghna, and Garbhasthapana properties of Shivlingi Beej helps to promote normal folliculogenesis and timely ovulation. The drug's uterine tonic and antioxidant actions may also support hormonal balance and endometrial receptivity.
- On study of Demographic data, present study can not establish relation of progressing age with anovulation, as patients in both groups fall almost equal in age ranging between 20-40 years. According to Global and india data anovulation due to DOR ranges between 3-5% and keeps increasing with advancing age and anovulation due to PCOS is about 10-20% in early reproductive age.[29]
- Married life wise data states that now a days couples are becoming aware of increasing infertility issues and side effects of contemporary treatments of infertility. As, 61.66% couples approached to Ayurveda as early as 5 years of active married life.
- High percentage of Primary infertility in present study can conclude that incidence of Primary infertility is rising concern as compared to secondary infertility and favors the study performed by Naina Purkayastha et.al. According to this study, prevalence of women experiencing primary infertility has shown a remarkable increase during the most recent decade. In India, the overall prevalence of primary infertility lies in between 3.9% and 16.8%, as per WHO estimates.[30]
- Agni wise distribution in present study establishes, relation of Agni Vaishamya with anovulation. As, 73.33% had Agni impairement. According to Acharya Charak, all diseases originates due to the Vaishamya of Agni.
- Due to small sample size, we can not conclude that anovulatory infertility is linked with particular religion, class or eduacation factor. As, Pandit Khushilal Sharma Ayurveda College and Institute is located in an urban area, the patients who came to us are mostly from urban areas and are also well educated. Therefore, we cannot conclude that anovulatory infertility occurs in urban areas and educated people and not in rural area and uneducated people.

Conclusion:

Effect of therapy on objective parameters in Group-A (n=28) and Group-B (n=28) by Student's Paired-t test showed significant results in hormonal levels normalization and very significant and extremely significant results on ovulation/ conception. It indicates statistically significant difference in group before and after treatment.

But, Intergroup comparison between Group-A and Group-B (n=56) on all objective parameters by students unpaired 't' test showed Not significant results. Which indicates that there is no statistically significant difference between the mean values of both groups.

The present randomized clinical study evaluated the efficacy of Shivlingi Beej Churna in improving ovulation and conception in women with anovulatory infertility. Better outcomes in the treatment group compared to placebo indicate its positive role in restoring ovulatory function. Patients receiving Shivlingi Beej Churna showed normalization in Gonadotropins level and improved follicular maturation, follicular rupture, and higher conception rates.

Overall, this clinical study concluded that the Shivlingi Beej churna is a promising , safe, economical, and effective Ayurveda intervention for future practices of Ayurveda gynaecologists for managing female infertility due to anovulation, though larger studies are required to confirm these findings.

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