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EFFICACY EVALUTION OF STANDARDIZED FENUGREEK SEEDS EXTRACT AS FUROSTANOLIC SAPONINS & MYO-INOSITAL (NUTRICYST-M) IN MANAGEMENT OF INSULIN RESISTANCE (IR) & OVARY VOLUME IN PCOS SUBJECTS

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ABSTRACT

Objective: Polycystic ovarian syndrome is affecting nearly 6-10% of women of reproductive age. A frequent feature of women with PCOS is insulin resistance accompanied by compensatory hyperinsulinemia, and increasing evidence suggests that hyperinsulinemia plays an important role in the pathogenesis of PCOS, pointing the way to new and novel therapy for PCOS. The study was planned with one natural alternative remedy Standardized Fenugreek seeds extract as Furostanolic saponins and Myo-inositol. Standardized Fenugreek seeds extract as Furostanolic saponins which contains bioactive components Saponins extracted from Fenugreek seeds improves insulin sensitivity and, in turn, may regulate circulating androgen levels. It improves insulin-mediated glucose disposal in women with PCOS. It also decrease in LH/FSH ratio observed in my last study. Myo-inositol improves fertility by lowering male sex hormones in both women with and without PCOS. But it could also improve ovulation in women with PCOS. Myo-inositol also reduces insulin resistance and increases estrogen levels. Myo-inositol reduced testosterone, luteinizing hormone (LH), and insulin levels. Present observation study is to establish efficacy and safety in management of IR and ovarian volume. **Methodology:** Our specific objective was to establish the correlation of reduction in ovary volume and insulin resistance in obese women with PCOS, treated with Standardized Fenugreek seeds extract as Furostanolic Saponins and Myo-inositol (Nutricyst-M). **Material & Method:-** An open labeled, single armed and non comparative observation study conducted in 30 female patients suffering from PCOS with high insulin resistance and acanthosis nigricans. The subjects were screened for the enrolment on the basis of following

inclusion & exclusion criteria:

Inclusion criteria

- The premenopausal women having age between 18-45 years.
- The patient having BMI less than 42.
- The patient diagnosed with PCOS.
- The patient having adequate hepatic, renal and haematological functions.
- Patient willing to give informed consent in writing.

Exclusion criteria

- Males
- Women with post menopausal.
- Women with hysterectomy.
- Patients with congenital adrenal hyperplasia.
- Patients suffering from Cushing's syndrome.
- Patients diagnosed with androgen secreting tumor.
- Patients with thyroid dysfunction
- Patients with Hypogonadism.
- Pregnant or lactating mothers.

The allocation of the product was done after screening. Investigational product was consumed by the patients for three months during which capsules of Nutricyst-M BD were given orally to the enrolled subjects.

Efficacy evaluation:- The efficacy of investigational product Nutricyst-M in PCOS patients was evaluated by the laboratory investigations. The following investigations were done at baseline, follow-up month (4 weeks and 8 weeks) and end of the study (12 weeks) for efficacy analysis:

Baseline & at the end of the study (after 12 weeks)

1- USG of lower abdomen/TVS 2- Menstrual cycle,

3- Body weight, BMI, Height. Blood pressure, Waist Circumference, 4- LH, FSH

5- LH/FSH ratio

6- TSH

7- Fasting insulin

8- Fasting glucose,

9- HOMA index

Visit 1 (after 4 weeks) & Visit 2 (after 8 weeks)

1- LH, FSH

2- LH/FSH ratio

Nutricyst-M was orally consumed by the patients as BD dosage in the form of 500 mg capsule for 12 weeks The data was complied and analysed.

RESULTS

Demographic data of study population

Mean Age of Patients 27.13±6.74 years, the average height, weight, and waist size of study population were 157.01 cm, 58.50 Kg and 54.42 cm, respectively.

PARAMETER	Mean	Standard Deviation	Minimum	Maximum
Age (years)	27.13	6.74	20	34
Pulse (per Minute)	74.10	4.06	70	95
Height (cm)	157.01	5.74	140	168

Blood pressure Systolic blood pressure

SBP (mmH)	Mean	Std. Deviation	t-value	p-value
Baseline	116.21	6.016		
Visit	116.02	4.745	.320	0.750
Visit	116.21	4.272	.627	0.533
Visit	116.39	4.078	.629	0.531

Diastolic blood pressure (DBP)

DBP (mmHg)	Mean	Std. Deviation	t-value	p-value
Baseline	76.5	5.053		
Visit 1	76.3	4.726	.216	.829
Visit 2	76.7	4.237	.938	.351
Visit 3	76.3	4.359	.158	.875

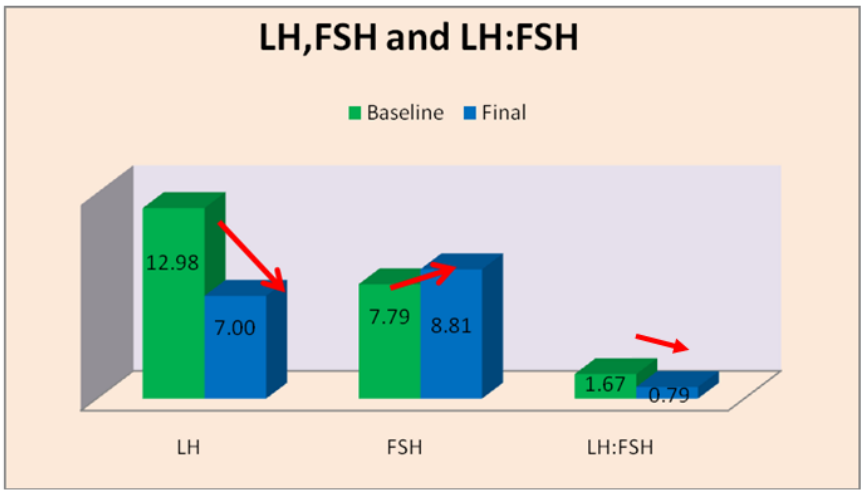
Body mass index (BMI)(Kg/m^2)

BMI	Mean	Std. Deviation	t-value	p-value
Baseline	24.58	5.349		
Visit	24.53	5.296	1.150	0.253
Visit	24.44	5.422	2.015	0.047*
Visit	24.16	5.285	2.445	0.017*

Out of 30 subjects, 15 of these patients were hirsute and the remaining 15 were not and eight women with chronic anovulation.

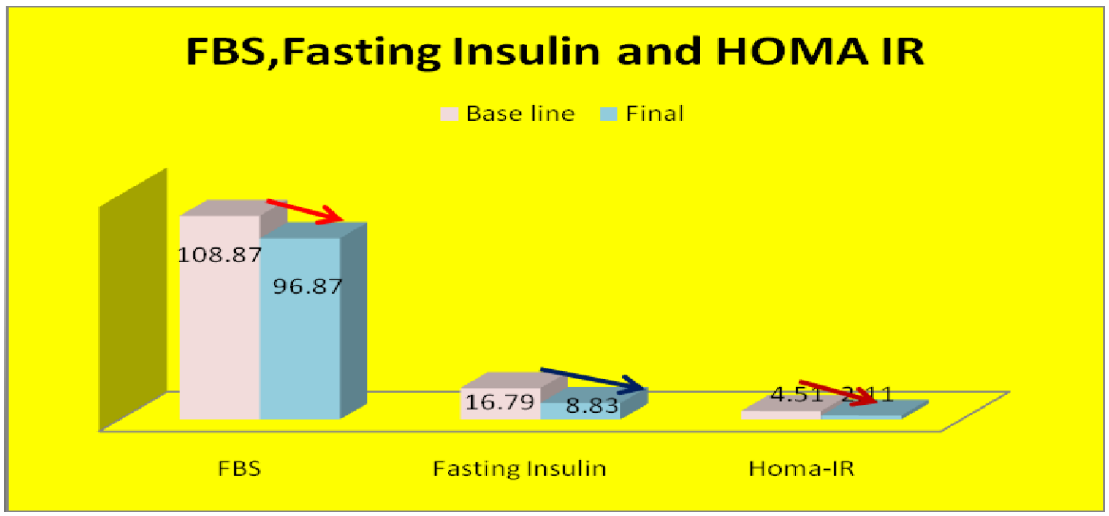
LH and FSH: Mean LH: FSH baseline was 1.67 and at completion is 0.79 LH was found to be highly significant (p<.001). A significant reduction was found in FSH (p=.019).

Test		Baseline	Final	% Change	t-value	p-value
LH	Mean	12.98	7	43.4	9.477	<.001
	SD	4.55	1.89	12.86		
FSH	Mean	7.79	8.81	19.7	-2.487	0.019
	SD	2.39	1.95	31.79		



MENSTRUAL

CYCLE After giving the Nutricyst-M the irregularity of menstrual cycle was significantly reduced and the proportion of subjects having regular menstrual cycle which was 1.1% at baseline increased to 79.5% at final observations.



Fasting Blood Sugar, Fasting insulin and Homa IR

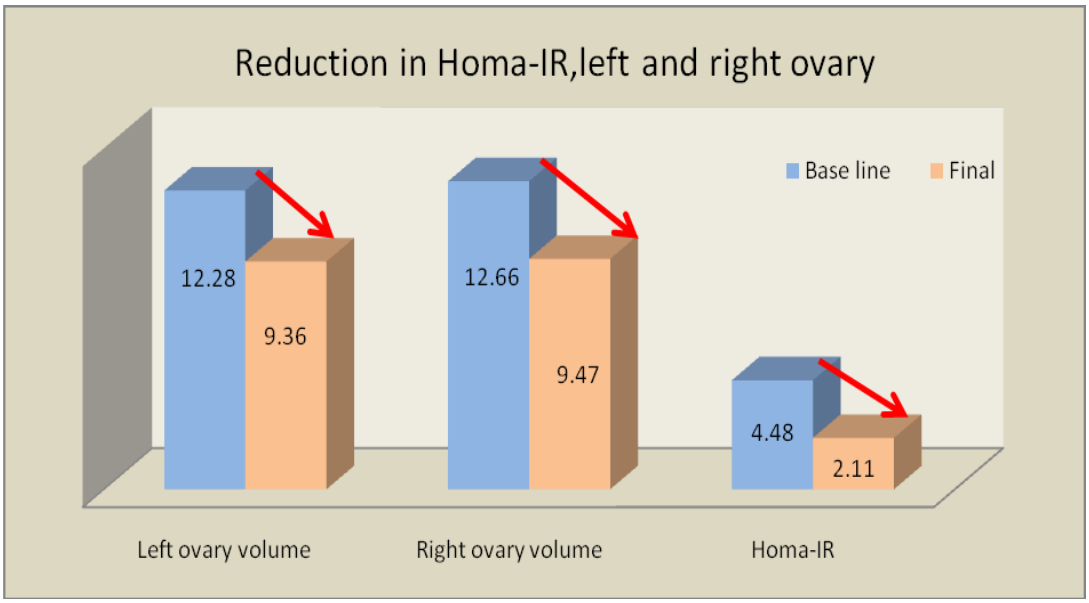
The reduction in FBS found to be highly significant (p<.001).

Test	Parameter	Baseline	Final	% Change	t-value	p-value
FBS	Mean	108.87	96.87	10.75	10.831	<.001
	SD	8.119	4.066	4.68		
Fasting Insulin	Mean	16.79	8.83	32.12	2.923	0.007
	SD	14.99	3.46	29.79		
Homa-IR	Mean	4.48	2.11	39.67	3.442	0.002
	SD	3.82	0.82	26.43		

Ovary Volome Reduction

After 12 weeks of Nutricyst-M intake, a significant reduction in rightovary 25.97% and left ovary volume 24.35%, with reduction in Homa-IR 39.67%.

Test	Parameter	Base line	Final	% Change	t-value	p-value
Left ovary volume	Mean	12.28	9.36	24.35	7.344	<.001
	SD	3.31	3.5	15.7		
Right ovary volume	Mean	12.66	9.47	25.97	5.912	<.001
	SD	3.16	3.91	22.24		
Homa-IR	Mean	4.48	2.11	39.67	3.442	0.002



Safety conclusion

No significant changes in liver function test and renal function test were observed concluding the safety of this molecule.

CONCLUSION

The consumption of Standardized Fenugreek seeds extract as Furostanolic Saponins & Myo-Inosital (Nutricyst-M) was found to reduce HOMA-IR, significantly improved insulin sensitivity resulting reduction in ovary volume & was effective as well as safe in the management of PCOS. There is need to have bigger study as the sample size of current study was small.

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