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Research Article

EFFICACY OF BALADI CHURNA IN MANAGEMENT OF FEMALE INFERTILITY WITH SPECIAL REFERENCE TO ENDOMETRIAL FACTOR

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ABSTRACT

Endometrial factor comes under the umbrella of *Kshetra*, which is one of the important factor for conception described in *Ayurveda i.e Rutu, Kshetra , Ambu , Beej***.** Decreased endometrial receptivity is the major cause of implantation failure, Therefore the present study was carried out for the clinical evaluation of efficacy of *Baladi Churna* in female infertility w**.**s**.**r to endometrial factor**.** Total 15 patients were registered and 11 completed the study. Assessment of results was done on the basis of Appelbaum's USSR by the tool of Transvaginal colour doppler sonography, shows 58.24% upgrading in score of Appelbaum's USSR. Trial drug contents having *Vata Pitta Shamak* properties which are assumed to be as main factor for infertility due to endometrial factor. This hypothesis was acceptable with the highly significant results of treatment regimen. The results revealed that, *Baladi churna* is a potent *Ayurvedic* regimen to increase endometrial receptivity.

Keywords: Appelbaum**'**s USSR, *Baladi Churna,* Endometrial factor, *Stree Vandhayatva***.**

INTRODUCTION

A woman hood is never considered complete without achievement of motherhood. Infertility is defined as failure to achieve a conception after 12 months or more having regular unprotected sexual intercourse[1]. 20-35% of Females are directly responsible for infertility[2]. Among various causes of infertility uterine factor as-endometrial abnormalities play an important role in the causation of infertility. Inadequate uterine receptivity is responsible for approximately two-thirds of implantation failures[3] IVF Success rate was only 35%, rest 65% cases of IVF failed because of implantation failure in which decreased endometrial receptivity is commonest cause of implantation failure[4]. Today's latest techniques like In-Vitro Fertilization (IVF), Embryo Transfer (ET), and Gamete Intra Fallopian Transfer (GIFT) all become failed due to decreased endometrial receptivity. The whole world see towards us with sight of hope where, research works on endometrial factor is negligible in Ayurveda research field**.** Thus, the need of the hour today is in findings means to improve the implantation rates. Here a preliminary effort has been made to provide simple and effective management of decreased endometrial receptivity which can be practiced regularly for the achieving and preserving conception by increase implantation rates.

MATERIALS AND METHODS

Source of Data: Patients attending the Outdoor Patients Department of Stree Roga & Prasooti Tantra fulfilling the criteria for selection was incorporated into the study. A special research Performa was prepared. Total 15 patients were registered, out of them 11 patients completed the course of treatment.

Ethics

Study started only after obtaining Ethical clearance from the Institutional Ethics Committee. Ref**.**PGT/7-A/Ethics/2012-13/1964 **(**dated 21/9/12**)**

CTRI Registration

Study registered in CTRI as REF/2013/07/005300.

Criteria for Selection of Cases

Inclusion Criteria

Patient of child bearing age of 20 to 40 year with active marital life of 1 year, having endometrial thickness ≤ 7mm, on the diagnostic basis of Trans vaginal sonography.

Exclusion Criteria

Patients having age less than 19 years and more than 40 years, with any possibility of active pelvic infection, sexually transmitted disease or any debilitating systemic diseases were excluded from the study.

Investigations

1. Routine haematological and urine investigations were done before and after treatment.
2. Serological tests for HIV (Human Immunodeficiency Virus), HBsAg (Australia antigen for hepatitis B) & VDRL (Venereal Disease Research Laboratory) were carried out in all the patients before starting the course of treatment.

3. Transvaginal colour Doppler sonography for diagnosis and assessment of result.

Selection of Drug

Infertility due to endometrial Factor has been considered as the Vata predominant Tridoshaja condition, with Pitta as being the next Dosha, as Vata was responsible for Dhatu vhuhan and Pravartan[5] and vata is causative factor for Parmanu (cell) sanyog (union) and Vibhag (division)[6],so new cell regeneration from basal layer may be assumed by proper Vata function. Pitta is responsible for conversion of one Dhatu into another Dhatu in adequate amount by its Pakti property[7], hence it is responsible for production of adequate level of hormonal support by aromatization of androgen into estrogen. Kapha by its Upachaya guna responsible for proliferative and secretory changes in endometrium for further development of cells, these three Dosha contributed in the different stages of receptive endometrium formation by their normal function. Any vitiation in the three Dosha was collectively responsible for the defective endometrial formation. The drug assumed as effective for healthy endometrial formation was considered to have Tridoshaghna properties mainly Vatapittashamaka. Baladi Churna[8] mentioned by Acharya Bhavaprakasha containing medicine with Balya, Punsavan and Vrishya properties were selected for the study. The ingredients of Baladi churna are 66.67% ingredients having Vatapitta shamak property, while 33.33% have Kaphapitta shamaka property.

Treatment Protocol

In the present study, before starting the treatment Deepana, Pachana by Amapachan vati-2 tablets B.D with Luke warm water for 3 days, from the hospital supply was given to the patients as Deepana; Pachan followed by Koshtha Shuddhi was done in all patients Koshtha Shuddhi with Erandbristh haritaki with Luke warm water before bed time for 2 days. Than Baladi churna was given in dose of 3gm B.D with milk before meal for 2 consecutive menstrual cycles.

Method for Assessment

For the evaluation of result, the Appelbaum's Uterine scoring system for reproduction was adopted (Table 1).

According to Applebaum, certain sonographic qualities of the uterus are noted during the normal mid-cycle *(*day 11- till ovulation*).* These include:

Endometrial Thickness > 7 mm in greatest anterior-posterior (A-P) dimension (full thickness measured from the myometrial-endometrial junction to the endometrial-myometrial junction).

Triple-Layered ('5-line') endometrial appearance.

Homogeneous Myometrial Echogenicity.

Uterine Artery Blood Flow < 3, as measured by pulsatility index (PI) on Doppler.

Blood Flow Within Zone 3 (hypoechoic inner layer) of the endometrium on colour Doppler.

Myometrial Blood Flow -internal to the arcuate vessels (seen on Gray-scale

Statistical Estimation of Results

The obtained data was analyzed for statistically significance by using student 't' test. The level of 'P' between 0.05 to 0.01, and P<0.001 was considered as statistically significant and highly significant respectively. The level of significance was noted and interpreted accordingly. If the calculated 't' value was more than 0.05 (P>0.05) results were taken as insignificant.

Insignificant $P > 0.05$

Significant $P < 0.05$

Highly Significant $P < 0.01$ & 0.001

Follow Up Study

Follow up study was conducted for two cycles after completion of the treatment.

Table 1: Appelbaum's USSR

Appelbaum's uterine scoring system for reproduction (USSR)		
Parameter	**Determination**	**Score**
Endometrial Thickness (mm)	<7	0
	7-9	2
	10-14	3
	>14	1
Endometrial layering	No layering	0
	Hazy 5-line appearance	1
	Distinct 5-line appearance	3
Myometrial echogenicity	Course, inhomogenous	1
	Relatively homogenous	2
Uterine artery Doppler flow (PI)	2.99-3.0	0
	2.49	1
	<2	2
Endometrial blood flow in zone 3	Absent	0
	Present, but sparse	2
	Present multifocally	5
Myometrial blood flow (Gray-scale)	Absent,	0
	Present	2

Table 2- Status of Patients

Total Registered	15
Completed	11
Drop out	04

Table 3: General observations on demographics of 15 patients

Observations	Number of Patients	%
Age group 26-35 years	10	66.7%
Occupation as house wife	13	86.67%
History of Abortion	06	40%
Primary infertility	08	53.3%
Secondary infertility	07	46.7%

Table 4: General observations on dietary habits of 15 patients

Observations	Number of Patients	%
Vishamasan	09	60%
Adhyashan	06	40%
Vishamagni	07	46.7%
Mandaagni	08	53.3%

Table 5: General observation Rasa dominancy in diet:

Lavan	13	86.7%
Amla	07	46.7%
Katu	09	60%

Table 6: General observation on Past T/T history (n=15)

Observations	Number of Patients	%
History of Hormonal treatment	14	93.7%

Table 7: General observation on Manasik bhav (n=15)

Observations	Number of Patients	%
Chinta	15	100%
Shoka	04	26.7%

Table 8: Effect of therapy on Appelbaum's USSR (n=11)

Parameter	Mean Score		% of relief	S.D. (±)	S.E. (±)	"t" (paired)	P
	B.T.	A.T.					
Endometrial Thickness	0.2	2.2	66.7%	0.471	0.14	13.41	p<0.001
Endometrial Layering	0.0	1.8	60%	1.03	0.33	5.57	p<0.001
Mayometrial ecogenicity	1.2	1.7	25%	0.53	0.17	3	p<0.05
Uterine Artery Doppler Flow	0.4	1.5	55%	0.74	0.23	4.71	p<0.001
Endometrial Blood Flow Zone 3	0.8	3.5	54%	1.49	0.47	5.71	p<0.001
Mayometrial Blood Flow	0.2	1.6	50%	0.97	0.31	4.58	p<0.001

Table 9: Total effect on upgrading of Appelbaum's USSR (n=11)

Parameter	Mean Score (A.T- B.T) of d	% of relief	S.D. (±)	S.E. (±)	"t" (paired)	P
Appelbaum's USSR	9.09	58.29%	3.01	0.90	10.9	<0.001

Table 10: Effect Of Baladi Churna On Menstrual Cycle (n=11)

	B.T.		A.T.		% Relief
	No. of patients	%	No. of patients	%	
Regularity	07	63.63%	10	90.9%	27.27%
Amount Moderate	04	36.36%	05	45.45%	9.09%
Duration 5-6 days	05	45.45%	06	54.54%	9.09%

Table 11: Effect of therapy on ovulation (n=11)

Effect of Baladi churna	B.T.		A.T.		% Relief
	No. of patients	%	No. of patients	%	
Ovulation	03	27.27%	08	72.72%	45.45%

Table 12: Effect of therapy on conception rate (n=11)

Total No. of patients	No. of Conceived patients	%
11	03	33.33%

RESULTS AND DISCUSSION

General Observations

Maximum patients i.e. 66.67% were between the age group of 25 to 35 years. The findings are very close to the figures of most studies because it is the most favorable period of reproductive life. 86.7% patients were housewife. Due to responsibility of her kids, husband and other family members, female always ignore their disease so disease turned into chronic phase which leads to bad prognosis and fertility also hampered. 40% patients had history of abortion figures suggests that endometrium was not supportive for continuation of pregnancy. 53.3% patients had primary infertility and 46.7% had secondary infertility [Table 3]. Most of the patients had defective dietary habits i.e. 60% patients had habit of Vishamasan and 40% had habit of Adhyasan cause Jatharagni dusti, consequence in Dhatvagni dusti leads to Rasa dhatu dusti and its Updhatu artava. Due to faulty dietary and life style most digestive power affected i.e. 53.3% were suffering from Mandaagni, while rest 46.7% suffered by Vishamagni. [Table 4] 86.7% patients use excessive lavan rasa, 46.7% patients Amla, 60 % Katu rasa in routine diet became the Aharaj nidan of Pitta dusti.[Table no.5] Chinta was present in all patients while and Shoka was found in 26.7% of patients [Table 6] . Manasika Bhavas leads to Vata-Pitta Prakopa which again leads to vitiation of Dosha, Dhatu, and Mala. Ultimately it hampers the proper formation of Rasa Dhatu and its Upadhatu. The modern research reveals that stress disturbs the normal hormonal regulation[9]. In present study, 93.3% of patients had history of taking hormonal treatment. [Table 7] Among which most used Clomiphene citrate for induction of ovulation. A direct adverse effect of Clomiphene citrate on endometrium has been presumed[10]. It is estrogen antagonist[11], that's why it inhibits the process of endometrium proliferation so, due exposure of Clomiphene citrate endometrial receptivity decreases gradually. Therefore, after the presence of ovum conception not occur because of implantation failure.

Discussion on Effect of Therapy

Effect of Therapy on Appelbaum's USSR [Table 8-9]

Endometrial Thickness- Before treatment, mean score of Grade for E.T was 0.2 which was upgrade up to 2.2 after treatment, showing a relief of 66.7%. The result is statistically significant (p<0.001).

Endometrial Layering- Before treatment, mean score of Grade for E.L was 0.0 which was upgrade up to 1.8 after treatment, showing a relief of 60%. The result is statistically significant (p<0.001).

Myometrial Ecogenicity- Before treatment, mean score of Grade for M.E was 1.2 which was upgrade up to 1.7 after treatment, showing a relief of 25%. The result is statistically significant (p<0.05).

Uterine Artery Doppler Flow- Before treatment, mean score of Grade for it was 0.4 which was upgrade up to 1.5 after treatment, showing a relief of 55%. The result is statistically significant (p<0.001).

Endometrial Blood Flow In zone 3 - Before treatment, mean score of Grade for E.B.F.Z3 was 0.8 which was upgrade up to 3.5 after treatment, showing a relief of 5.4%. The result is statistically significant (p<0.001).

Myometrial Blood Flow- Before treatment, mean score of Grade for M.B.F was 0.2 which was upgrade up to 1.6 after treatment, showing a relief of 70%. The result is statistically significant (p<0.001).

This total effect of therapy was very encouraging and highly significant to increase endometrial receptivity assessed on the basis of Appelbaum's USSR.It shows the potency of the drugs used in present study.

Effect of Therapy on Menstrual Cycle [Table 10]

Regularity of Cycle Before treatment 63.63% patients had regular menstrual cycle and after treatment Cycle was regular in 90.9% of patients so 27.27% relief was found.

Amount Of Menses- B.T 36.36% patients had moderate amount of menses come, and A.T. 45.45% of patients got moderate quantity of menses; so 9.09% improvement found in amount of menses A.T

Duration Of Menses- B.T 45.45% patients had 5-6 days duration of menses and A.T in 54.54% patients had 5-6 days duration of menses.

Effect of Therapy on Ovulation [Table 11]

Results show 45.45 % improvement found in process of ovulation.

Effect of Therapy on Conception [Table 12]

33.33% patients achieved conception by effect of therapy.

Probable Mode of Action of Drug

Baladi churna having Madhura vipaka, Sheet virya, Madhura, Tikta and Kshaya rasa so, the combined effect of all ingredients having Vatapitta shamak property. The root cause of implantation failure due to endometrial factor is due to vitiation of vata and pitta dosha.

Drug by its Vata Pittashamak property, Vata performed its proper function by its appropriate regulation and initiation of normal reproductive physiology. Hypothalmo Pitutatry Ovarian axis works normally subsequently the process of cell regeneration beginning from basal layer of endometrium by proper function of Vata. Beside it Pitta also act properly by its Paka action so, the conversion of all hormones from their subsequent in sufficient level was achieved and when the adequate level of hormones presents during follicular and luteal phase then the Kapha performs its proper function by proliferation and secretary changes in endometrium to make it receptive for implantation. We can understand it in a different manner also as when vata and Pitta comes in its equilibrium stage the Kapha also perform its proper function due to Tridoshasamya. Ahara rasa converted into Prasad and Kitta bhag under the influence of Jatharagni. Prasad bhag converted into Rasa dhatu by proper function of Rasa dhatvagni though which, proper formation of its Updhatu named as Artava (dhatu roop Artava /endometrium).

CONCLUSION

The results suggest that Baladi Churna is a potent drug to increase endometrial receptivity. On other hand our hypothesis that Vata Pitta are root factor for etiopathogenesis of decreased endometrial receptivity is accepted because drug has VataPitta Shamak property and it has efficacy to improve conception rate by increasing endometrial receptivity.

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