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# CLINICAL STUDY ON VANDHYATVA (FEMALE INFERTILITY) W.S.R. TO ANOVULATION AND ITS MANAGEMENT BY MAHARASNADI KWATHA

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## ABSTRACT

Reproduction is the noblest and should be the most reverent of all human powers. God has given this precious gift to the woman. Four essential factors for conception mentioned by ancient Ayurveda scholar *Sushruta* are as imperative today as they were. Ovum is one among these essential factors as far as female aspect is concerned. Vitiation of ovum reflects ovulatory dysfunction which contributes about 40% of female infertility in present era. numerous classical formulations are mentioned by Ayurveda scholars for the management of infertility however it is not evidently mentioned that which formulation acts upon which particular factor. *Maharasnadi kwatha* is mentioned by *Sharangdhara Samhita* while quoting treatment of infertility. Hence, the present study was undertaken to explore the effect of *Maharasnadi Kwatha* upon anovulatory factor of infertility. 18 Patients presenting with complaint of failure to conceive for minimum one year with two consecutive anovulatory cycles in serial trans-vaginal sonography were included in the study. Out of them 16 completed the treatment. Before starting treatment, *AmapachanaVati* was given for three days to improve digestion after that bio-purification was done with *ErandabrishtaHaritaki*. *Maharasnadi Kwatha orally with 5ml Eranda Taila* was given for befor meal at morning for 2 months after stoppage of menstruation. The Statistical significance of results on selected criteria established that *Maharasnadi Kwatha* mentioned in the management of infertility is effective treatment modality in Anovulation.

**KEYWORDS:** Infertility; Anovulation, *Maharasnadi Kwatha*, Reproductive system, Ovulation.

## INTRODUCTION

Every creature in this Universe tries to keep up its progeny. For this purpose, each creature has been given reproduction by the God. Reproduction is the noblest and should be the most reverent of all human powers. God has given this precious gift to the woman. *Acharya Charaka* has mentioned that the woman is the origin of progeny. Means, one who lodges foetus (*Garbha*) is known as *Stree*. Motherhood is the cherished desire deep down in the heart of every woman.

Infertility is one of the major concerns for the upcoming generation because busy with carrier making. Now a day's male and female both are competent in almost all the field from Driver to doctor, but they are not concerning about the features of the offspring. The World Health Organization (WHO) estimates that 60 to 80 million couples worldwide currently suffer from infertility. (NICE-fertility guidance 2004, www.nice.org,in).

Infertility by itself does not threaten physical health but has a strong impact on the psychological and social wellbeing of the couples. Couples often describe the "hope and despair" cycle, as they hope each month that they will finally conceive and then despair when once again it does not happen.

Proper functioning of four factors viz. *Ritu, Kshetra, Ambu* and *Beeja* is the prime requisites for *Garbha* (conception).[1] *Beeja*, most essential part among the four has been considered as *Antahpushpa*, i.e. ovum.[2] Ovulation refers to the physical act of rupture of the follicle with the extrusion of the oocyte. When the follicle does not rupture then ovulation fails, and it is called anovulation. There are many reasons both which can be solved, and which cannot be behind anovulation.

Considering these inconveniencies, the population is turning towards traditional modalities like Ayurveda. *Tridoshas* have an impact over all the process involved in ovulation. *Vata* stands for proliferation and division of cells (granulosa and theca cells), rupture of the follicle, etc.[3] *Pitta* is associated with its conversion power, like conversion of androgen to estrogen in Graffian follicle maturity of follicle by its function of *Paka Karma*.[4] *Kapha*

stands as a building and nutritive factor. It binds all the cells together and gives nutrition for growth and development of the cells.

So, anovulation can be included under *Beeja Dushti*. Ovarian factor contributes 15-25% and is the second common cause of infertility.[5] Ovulatory factor is an important subset in infertility among women, accounting about 40% cases.[6] Over the past few decades, modern medical field developed modalities like hormonal therapy, in‑vitro fertilization, embryo transfer, gamete intrafallopian transfer, etc. but with minimal success rate. Additionally, these procedures are associated with adverse effects and are not affordable to all.

Keeping this in mind a study was carried out to validate ayurvedic therapy in anovulation. *Maharasnadi Kwatha a*mentioned by *Aacharya Sharangdhara* in the management of infertility.[7]

**Aims and objectives**

**Primary objective**

- To evaluate the effect of selected *Ayurvedic* drugs and procedure on ovulation and to compare their efficacy (Based on TVS USG).

**Secondary objective**

- a. To evaluate the effect on menstrual abnormalities, dysmenorrhoea, etc. if any.
- b. To evaluate the role of *Deha Prakruti* in manifestation of a disease and treatment effect.

**MATERIALS AND METHODS**

**Patients Source**

- Patients The patients were selected from outpatient department of *StreeRoga and PrasootiTantra* Department, Institute of Post Graduate Teaching & Research in Ayurveda, Jamnagar for the present study.
- Patients fulfilling the criteria for selection were integrated into the study irrespective of caste, religion etc. A detailed history was filled up in specially prepared proforma on Ayurvedic guidelines.

**Ethical Clearance**

The study was stared after the clearance from the Institutional Ethics Committee. (Ref. PGT/7-A/Ethics/2014-15/1538 (dated 2/9/14).

Written consent was taken from each patient before starting of administration of trial drug.

**CTRI registration**

CTRI/2016/02/006630.

**Drug Source**

The drug *Maharasnadi Kwatha* for the study was prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar.

**Criteria for selection of patients**

**Inclusion criteria**

- Patients having age between 20 years to 40 years.
- Patients having active married life of (minimum 1 year).
- Married female patients of reproductive age group with at least 2 or more consecutive anovulatory cycles.
- Primary and secondary both types of infertile patients having anovulatory cycle or with immature ovarian follicle.

**Exclusion criteria**

- Patients having age less than 20 years and more than 40 years.
- Patients suffering from Systematic Disorders like HT, DM, Thyroid, Sever anaemia, Reproductive tract disorders like tuberculosis, carcinoma, and congenital deformities, Sexually transmitted diseases were excluded.

**INVESTIGATION**

**General investigations**

- Haematological- Hb%, TC, DC, ESR, PCV
- Biochemical- RBS
- Serological- HIV, VDRL, HBsAg
- Urine (Routine - Microscopic)

**Specific investigation**

- Transvaginalsonography (TVS): - For the diagnosis of anovulation.
- Hormonal assay-Serum FSH, LH, Prolactin, TSH. (B.T.&A. T)

**Plan of study**

**Study design**

| | |
|---|---|
| Study type | Interventional |
| Allocation | Randomized |
| Purpose | Treatment |
| Masking | Open label |
| Timing | Prospective |
| End point | Efficacy and safety |

**Criteria for diagnosis**

Trans Vaginal Sonography (TVS) is basic and primary investigation for this study. It was done from day 9$^{th}$of menstrual cycle up to at least 22$^{nd}$day of cycle to diagnose anovulation. In each patient, TVS was carried out for consecutive 2 cycles to diagnose appropriately.

Trans Vaginal Sonography was done before treatment (B.T.) for 2 months and after treatment (A.T.) for 2 months.

| **Treatment Modality** | **Dose** | **Duration** |
|---|---|---|
| *Deepana- Pachana* with *Aamapachana Vati* | 2 Tablets b.i.d., with luke warm water after meal | 3 days |
| *Koshtha Shuddhi* with *Erandabhrishta Haritaki* | 5 gm. or as per *Koshtha* with warm water at H.S. | 3 days |

| **Drug** | **Dose** | **Route** | **Time of Administration** | **Duration** |
|---|---|---|---|---|
| *Maharasnadi Kwatha* | 20ml B.D. | Orally with 5ml *Eranda* Taila | *Abhukta* | 2 months |

**Criteria for assessment**

The result was assessed on the basis of follicular study (ovulation study). To assess the overall effects of therapies, a special scoring method was adopted as follows.

Scoring pattern of follicle

0=0-12 mm

1=12-19 mm

2=19-23mm-cystic

3=Ovulated (For this scoring method, consecutive two cycles serial TVS was carried out to diagnose anovulation.)

## RESULTS

### Overall effect of treatment

| | | |
|---|---|---|
| | **Complete remission** | Ovulation occurred |
| | **Markedly Improved** | Ovulation not occurred improvement in the size of follicles up to fully maturation i.e.>19 mm. |
| | **Moderately Improved** | Improvement in size of follicles i.e.12-19 mm |
| | **Secondary outcome-Conceived** | Number of patients who conceived during or follow up period. |

### Statistical estimation of results

The obtained data was analyzed for statically significance by using paired 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.

Insignificant >0.05

Significant $p < 0.05$

Highly significant $p < 0.001$

Very highly significant $p < 0.0001$

### Follow up study

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

Total 18 patients were registered in present clinical study. So, observation of 18 patients and 2 patients, shifted to another city because of transfer of their husband’s job. effect of therapy of 16 patients who had completed the treatment were described.

### General observations (n=18)

In this study maximum number of patients (47.36%) belonged to age group of 26 - 30 years, which is the most fertile period of women 78.94% patients had primary infertility and 23.31% patients had secondary infertility.89.47% patients had 6 - 10 years chronicity and 68.00% had taken hormonal treatment for infertility. Mass Index (BMI) of 25-29 was found in 21.05% of theshows that maximum had anovulation. Maximum number of patients (57.89%) had irregular menstrual history while 47.36% had regular menses. Nearly 73.68% patients had moderate quantity of menses. 94.97% patients had painless menses. 63.15% patients had 2-5

days duration of menstrual period. While 57.89% had an interval of >35 days. *Chinta* (worry) was present in all registered patients while *Tanava* (stress) was found in 83.33% followed by *Bhaya*(fear) in 57.00%, *Krodha*(anger) in 78.81%, *Dainya* and *Shoka* in 94.26%. It shows that stress was present in all the patients, which is one of the causes of anovulation.

**RESULTS**

In (*Maharasnadi Kwatha*) before treatment size of follicle was 0-12 mm in 16 patients (88.89%) and 1 patient with follicular size 12-19 mm (5.56%) 5 patients (27.78) had follicular size 19-23mm. During treatment 1$^{st}$ cycle.4 patient had follicular size 0-12 mm (25.00%). (18.75%) had follicular size 12-19 mm while ovulation occurred in 08 patients (50.00). During treatment 2nd cycle.4 patient had follicular size 0-12 mm (25.00%). (50.00%) had follicular size 12-19 mm while ovulation occurred in 10 patients (62.50) After treatment, 4 patients with follicular size 0-12 mm (25.00%), 02 patients (50.00%) had follicle size 12-19mm and 02 patient (50.00%) had follicle size >19mm or Cystic. 8 patients (50.00%) had ovulated. (Table-1, Chart-1).

Due to Vatakaphashamaka, Vrishya, Artavajanana, Garbhashayashodhaka, Vajikara, Deepana, Pachana, Anulomana, Medohara, Lekaniya, Bhedana properties were not only effective on ovulation but also substantially reduced multiple cystic lesions of ovaries.

Non-significant change was observed in, S.FSH S. LH S.PRL, S.TSH (Table 2).

100% of patient of *Vatapitta Prakriti* had ovulated, 33.33% of patient of *Vatakapha Prakriti* had ovulated and 100% of patient of *Pittakapha Prakriti* had ovulated. These observations showed that *Maharasnadi Kwatha* had good effect on *Vatapitta Prakriti* and *Pittakapha Prakriti*. (Table- 4 Chart-2).

08 patients i.e. 44.45% had irregular menses while before treatment. While after treatment 5 patients i.e. 27.78% had irregular menses. And 03 patients i.e. 16.67% had Scanty menses before treatment, after treatment 01 patients i.e. 11.11% had Scanty menses. (Table 5, Chart-3).

While 08 patients (50.00%) had ovulated and 08 (50.00%) had unruptured or immature follicle after treatment. (Table 6).

In 1$^{st}$ month follow up 04 patients (25.00%) had follicular size 0-12 mm, and 02 patients

(12.5%) had 12-19 mm size follicle. 02 patients (12.5%) had follicular size 19-23 mm or Cystic formation. 50.00% of patients i.e. 08 patients had ovulation. In 2nd month follow up 04 patients (25.00%) had follicular size 0-12 mm, and none of the patient had 12-19 mm size follicle. 02 patients (12.50%) had follicular size 19-23 mm or Cystic formation and 62.50% of patients i.e. 10 patients had ovulation which was Statistically significant (P<0.05) (Table 8, Chart-4).

Conception rate was achieved in 12.50% of patients. (Table 9).

Data reveals that *Maharasnadi Kwatha with 5ml Erand Taila* 12.50 % of the patients had conceived Complete remission i.e. (Ovulation) was found in 43.75% of the patients. 25.00% of patients had no response to the treatment. ((Table 10, Chart-5).

No adverse drug reaction and no side effect were reported with the prescribed dose of the drug during treatment and in follow up period.

## DISCUSSION

Ovulatory cause is an important subset in infertility among women, accounting about 40% of cases. Anovulatory or inability to produce to fertile ovum is growing problem due to change in lifestyle, faulty food habits, environments, stress, etc. In the present study, maximum number of patients (47.36%) belonged to age group of 26-30 years, which is the most fertile period of women. The trend of late marriage is also increasing now a day because of higher education and social awareness of women. So, this may be probable causative factor and it is also because patients with infertility come to *Ayurvedic* line of treatment after trying modern medicine for a long time. Age related decline in female infertility can be attributed largely to progressive follicular depletion and a high incidence of abnormality in aging oocytes.[9] Nearly 89.47% patients had 6-10 years chronicity and 68.00% had taken hormonal treatment for infertility. It shows that patients approach modern science and after failure or huge expenses they prefer to Ayurveda as their last hope, which will lead to chronicity of the disease. All registered patients were found to be under psychological stress, which has a direct impact over fertility.[10] Catecholamines, prolactin, adrenal steroids, endorphins, and serotonin all affect ovulation and in turn are all affected by stress. Possibly this can be explained by a reduction in stress, and subsequently, alterations in the neuroendocrinologic characteristics of the infertile couple.[11] In the present study, total 73.68% of male partners were detected with abnormal semen reports that affect the overall effect of therapy.

**Probable Mode of action drug**

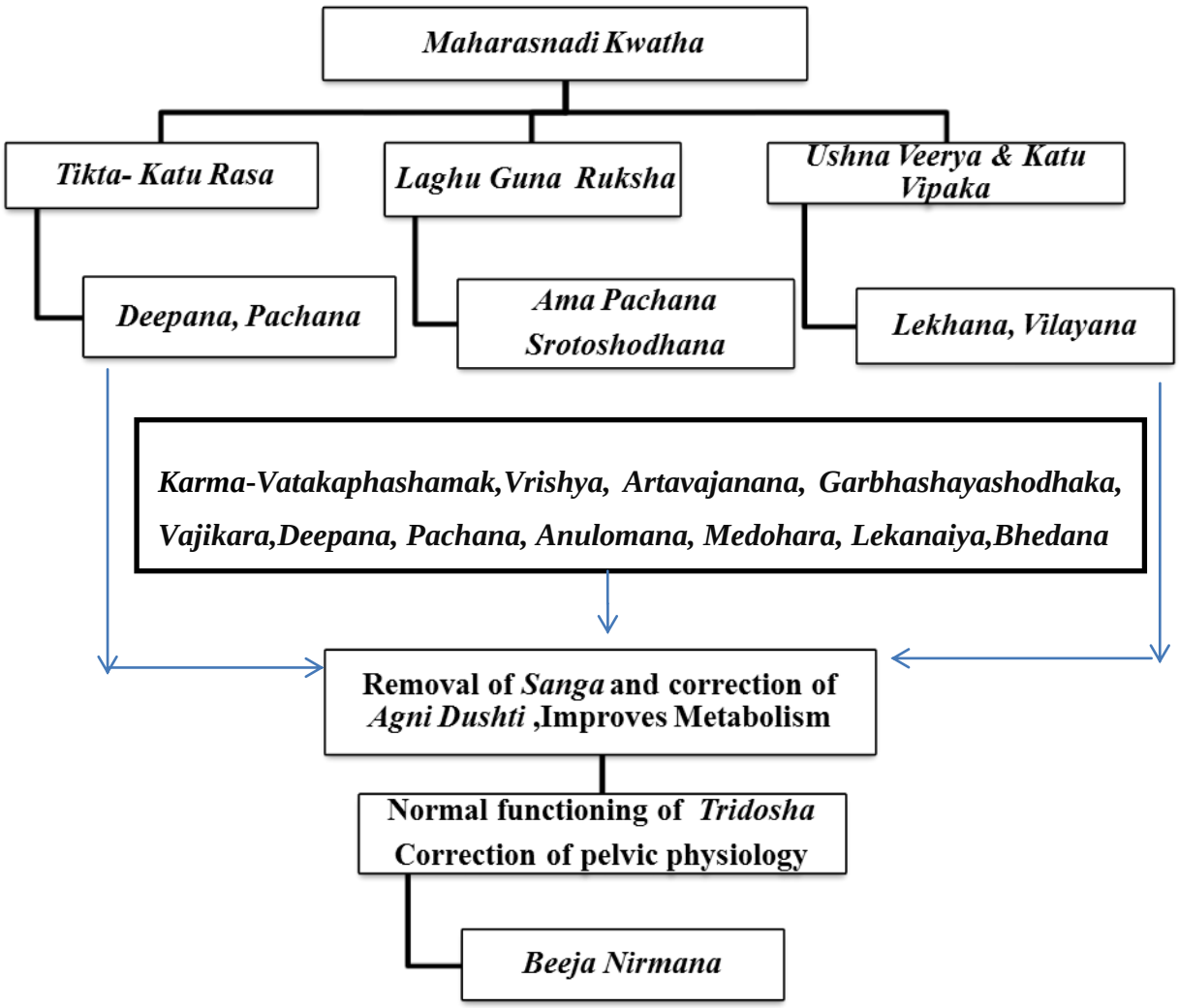



**Table 1: Effect of *maharasnadi kwatha* on follicular growth.**

| Size of follicle (in mm.) | B.T. | | D.T. (1st Cycle) | | DT (2nd Cycle) | | A.T. | |
|---|---|---|---|---|---|---|---|---|
| | No. of patients | % | No. of patients | % | No. of patients | % | No. of patients | % |
| 0-12 | 16 | 88.89 | 04 | 25.00 | 04 | 25.00 | 04 | 25.00 |
| 12-19 | 01 | 5.56 | 03 | 18.75 | 02 | 50.00 | 02 | 50.00 |
| 19-23-Cystic | 05 | 27.78 | 02 | 12.5 | 00 | 00.00 | 02 | 50.00 |
| Ovulation | 00 | 00.00 | 08 | 50.00 | 10 | 62.50 | 08 | 50.00 |

**Table 2: Effect of *maharasnadi kwatha* on hormonal level.**

| 'n' | Investigation | Mean Score | | S.D. (±) | S.E. (±) | 't' | P |
|---|---|---|---|---|---|---|---|
| | | B.T. | A.T. | | | | |
| 16 | **S. FSH** | 10.91 | 11.38 | 6.6933 | 1.6733 | 0.2763 | 0.768 |
| 16 | **S. LH** | 5.08 | 6.47 | 3.625 | 0.9064 | 1.5320 | 0.146 |
| 16 | **S.PRL** | 18.35 | 11.30 | 23.336 | 5.833 | -1.0208 | 0.246 |
| 16 | **S.TSH** | 3.019 | 2.92 | 1.3197 | 0.2579 | -0.3627 | 0.722 |

**EFFECT OF *MAHARASNADI KWATHA* ON GRADATION OF BMI**

Before treatment 7 patients i.e. 43.75% had Grade 2(21-25) BMI, after treatment 50% improvement was found because 1 patient had increase their BMI change grade 3 to grade 2.

Before treatment 4 patients i.e. 21.05% had Grade 3 (26-30) BMI, after treatment 43.75% improvement was found because 3 patients had decrease their BMI from grade 4 to grade Before treatment 4 patients i.e. 25.00% had Grade 4(>30) BMI, after treatment improvement was found because 3 patients had decrease their BMI from grade 4 to grade 3. They shifted in grade 3.

**Table 3: Effect of test drug on bmi.**

| n' | BMI | Mean Score | | S.D. (±) | S.E. (±) | 't' | P |
|---|---|---|---|---|---|---|---|
| | | B.T. | A.T. | | | | |
| 16 | ***Maharasnadi Kwatha*** | 27.21 | 25.76 | 5.6303 | 1.401 | 6.347 | <0.001 |

Data shows that **Highly Significant Effect** was found in **this therapy**

**Table 4: Effect of therapy on *prakriti* wise distribution of 16 patients.**

| ***Prakriti*** | **No of patients** | **Ovulation** | **%** |
|---|---|---|---|
| ***Vata pitta*** | 05 | 05 | 100 |
| ***vatakapha*** | 09 | 03 | 33.33 |
| ***Pittakapha*** | 02 | 02 | 100 |

**Table 5: Effect of therapy on menstrual irregularity.**

| MENSTRUAL HISTORY | *Maharasnadi Kwatha* | | | | |
|---|---|---|---|---|---|
| | B.T. | | A.T. | | |
| | No. of patients | % | No. of patients | % | % relief |
| Irregular | 08 | 44.45 | 03 | 27.78 | 16.67 |
| Scanty | 03 | 16.67 | 01 | 11.11 | 5.56 |

**Table 6: Total effect of therapy on ovulation.**

| Status of follicle | No of Patients | |
|---|---|---|
| Ruptured | 08 | 50.00 |
| Unruptured | 08 | 50.00 |

**Table 7: Follow up of growth of follicular size.**

| Size of follicle (in mm.) | 1st month | | 2nd month | |
|---|---|---|---|---|
| | No. of patients | % | No. of patients | % |
| 0-12 | 04 | 25.00 | 04 | 25.00 |
| 12-19 | 02 | 12.5 | 00 | 00.00 |
| 19-23-Cystic | 02 | 12.5 | 02 | 12.5 |
| Ovulation | 08 | 50.00 | 10 | 62.5 |

**Table 8: Effect Of Therapy On Follicular Size.**

| N | Mean | | X (AT-BT) | % | S.D. | S.E. | T | P |
|---|---|---|---|---|---|---|---|---|
| | B.T. | A.T. | | | | | | |
| 16 | 0.25 | 1.87 | -1.625 | 65 | 1.78 | 0.44 | -3.64 | <0.05 |

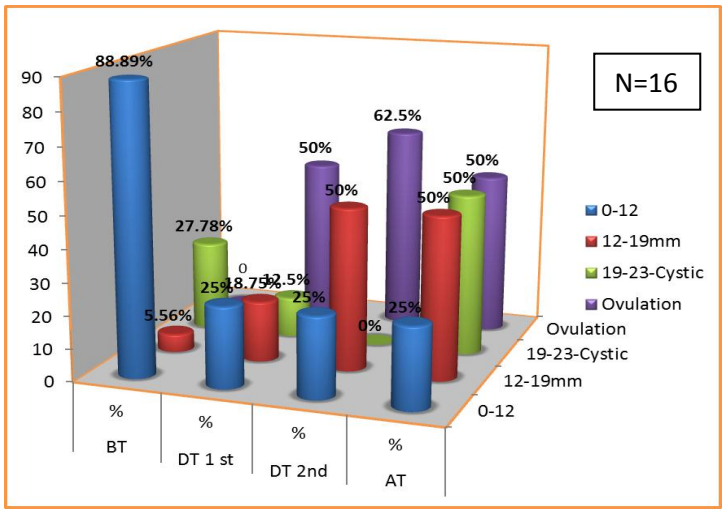
**Table 9: Total effect of therapy on conception.**

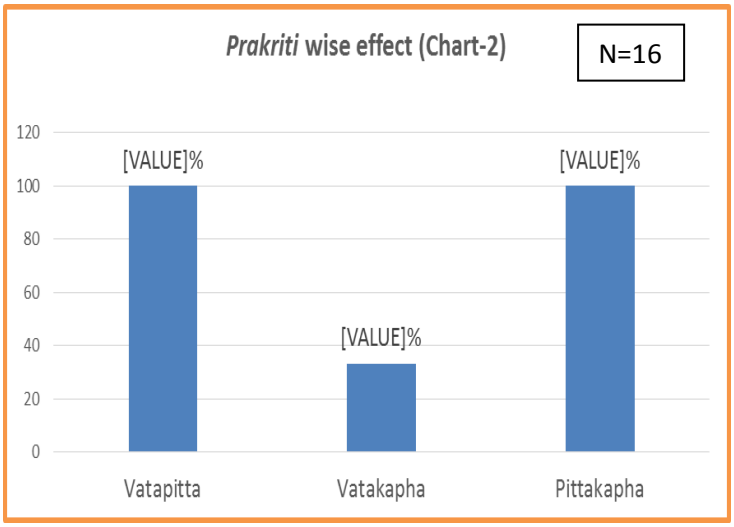
| No of Patients | Conception Rate | % |
|---|---|---|
| 16 | 02 | 12.50 |

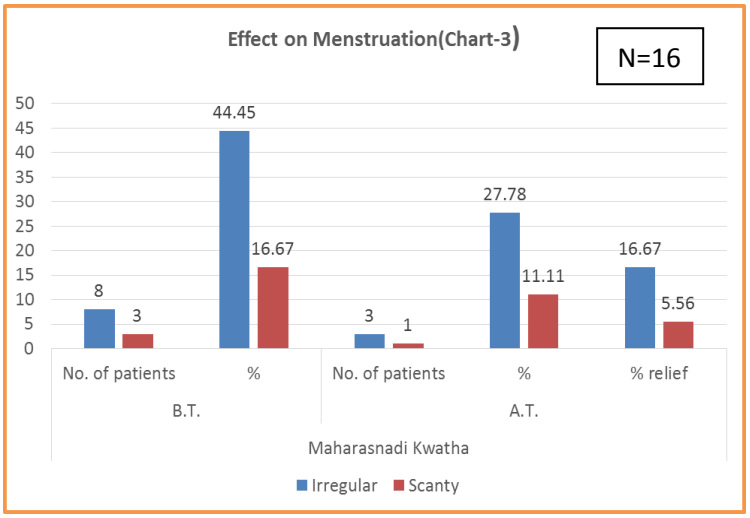
**Table 10: Over all effect of therapies.**

| *Maharasnadi Kwatha* | No. of patients | % |
|---|---|---|
| **Conceived** | **02** | **12.50** |
| Complete remission | 07 | 43.75 |
| Markedly Improved | 03 | 18.75 |
| Moderately Improved | 02 | 12.50 |
| Unchanged | 04 | 25.00 |

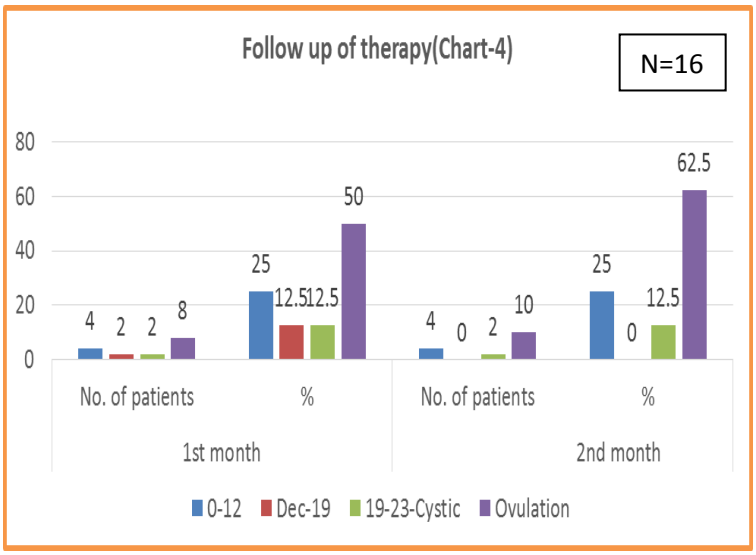
**Effect of *Maharasnadi Kwatha* on follicular Growth (Chart-1).**

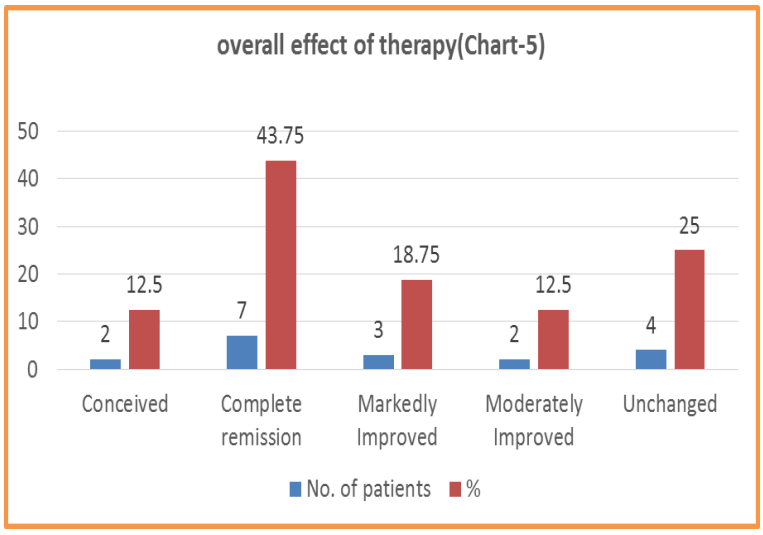



Effect on Menstruation(Chart-3)
N=16
50
45
40
35
30
25
20
15
10
5
0
8
3
44.45
16.67
3
1
27.78
11.11
16.67
5.56
No. of patients
%
No. of patients
%
% relief
B.T.
A.T.
Maharasnadi Kwatha
Irregular
Scanty

**(Chart-4)**


Follow up of therapy(Chart-4)
N=16
80
60
40
20
0
4
2
2
8
25
12.5
12.5
50
4
0
2
10
25
0
12.5
62.5
No. of patients
%
No. of patients
%
1st month
2nd month
0-12
Dec-19
19-23-Cystic
Ovulation


overall effect of therapy(Chart-5)
50
40
30
20
10
0
2
12.5
7
43.75
3
18.75
2
12.5
4
25
Conceived
Complete remission
Markedly Improved
Moderately Improved
Unchanged
No. of patients
%

## CONCLUSION

*Maharasnadi Kwatha*, is mainly having *Ushna Veerya, Tikshna, Deepana, Pachana, Vatanulomana, Artavajanana, Garbhashaya Shodhaka,* etc. properties. By Help of *Anupana* of *Eranda Taila*, it helps in removal of *Sanga* and so as to proper functioning of *Apana Vata*. It possesses antioxidant, hepatoprotective properties which ultimately help in regulation of ovarian cycle. Antioxidant drugs are supposed to remove free radicals which are like *Ama*.

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