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SHIVSHANKAR RAJPUT, PROF.L.P.DEI, PROF. NALINI ANAND

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A RANDOMIZED CLINICAL TRIAL ON VANDHYATVA W.S.R. TO TUBAL BLOCKAGE AND ITS AYURVEDIC MANAGEMENT

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ABSTRACT:

Acharya Harita has described six types of Vandhyatva with special clinical features. Kaka Vandhya, Anapatya, Garbhasravi, Mritvatsa, Balakshaya, *Unexplained. In* 6th type of Infertility given by Acharya Harita seems to be nearer to Tubal Infertility. According to Acharya Sushruta, tubal blockage can be considered as the deformity of Kshetra i.e. the female reproductive system. The management of infertility due to tubal factor in modern includes Tubal microsurgery, In vitro fertilization, Tubal cannulation etc. Depending upon the site of blockage, these methods are successful in 27% cases of fimbrial block and 50-60% cases of isthmic block. The chief among the adverse effects are anesthetic complications, failure of surgery and high incidence of ectopic pregnancy in post treatment cases etc. The treatment is very expensive also. It is the need of the time that a safer, more cost effective and complete cure of this sensitive problem should be developed. Uttarabasti is a unique procedure mentioned in Ayurvedic classics especially for the treatment of Vandhyatva and other gynecological disorders. For the present study it was planned to evaluate the efficacy of Kumari Taila & Apamarga Kshar Taila Uttarbasti in tubal blockage in the management of tubal blockage. A total number of 36 patients were registered and were randomly distributed into two groups, 18 in each group. c The effect of therapy in both the groups on tubal blockage was compared and analyzed statistically with unpaired 't' test. It showed the probability >0.05 and hence, the comparative effect of therapy in both the groups was found insignificant. The effect of therapy on conception is equivalent in both the groups.

Key Words: Apamargakshara Taila, Kumari Taila, Phalakalyana Ghrita,

INTRODUCTION

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Acharya Harita has described six types of Vandhyatva with special clinical features.1 Kakavandhya, Anapatya, Garbhasravi. Mritvatsa, Balakshaya, Unexplained. In 6th type of Infertility given by Acharya Harita seems to be nearer to Tubal Infertility. The word Yoni refers to entire reproductive system, thus under this heading congenital or acquired diseases of anatomic components of reproductive organs i.e. vagina, uterus. endometrium, and fallopian tube can be included. In 'Ayurveda', this condition is termed as "Vandhyatva". According to Acharya Sushruta,² tubal blockage can be considered as the deformity of Kshetra i.e. the female reproductive system. The management of infertility due to tubal factor in modern includes Tubal microsurgery, Laparoscopic tubal adhesiolysis, Fimbrioplasty and Tubal vitro fertilization, surgery, In Tubal cannulation etc. Depending upon the site of blockage, these methods are successful in 27% cases of fimbrial block and 5060% cases of isthmic block.³ But these modalities have their own demerits. The chief among the adverse effects are anesthetic complications, post operative wound infection, chest infection, embolism, failure of surgery and high incidence of ectopic pregnancy in post treatment cases. The treatment is very expensive also. Moreover, these methods attempt to tackle only the anatomical aspect of the problem. It is the need of the time that a safer, more cost effective and complete cure of this sensitive problem should be developed. Uttarabasti is a unique procedure mentioned in Ayurvedic classics especially for the treatment of Vandhyatva and other gynecological disorders⁴.

For the present study it was planned to evaluate the efficacy of *Kumari Taila & Apamarga Kshar Taila Uttarbasti* in tubal blockage in the management of tubal blockage.

AIMS AND OBJECTIVES

The present study was based on following aims and objects:

- ➤ To evaluate and compare the efficacy of trial drugs i.e. *Kumari Taila & Apamarga Kshar Taila Uttarabasti* in tubal blockage.
- ➤ To evaluate the efficacy of

 Phalakalyana Gritha orally in

 promoting conception rate after

opening the tube by intrauterine *uttarbasti*.

Materials and methods:

This study was a Simple Random Sampling Method Open clinical trial. The study was approved by Institutional Ethics Committee (No.PGT/7/A/Ethics/2013-14/1767 dated on 10/09/2013). Patients were selected from the O.P.D. of Dept. of Stree roga & Prasuti tantra and referred from other dept. of I.P.G.T. & R.A., G.A.U. Jamnagar. Patients' written informed consent was taken before starting the treatment. Patients were selected using 'Simple random sampling method'. The study has been registered in Clinical Trial Registry of India, CTRI/2015/06/005921.

DIAGNOSTIC CRITERIA:

CRITERIA FOR INCLUSION:

Patients of child bearing age group (20-40 years) with active marital life of 1 year or more having complaint of failure to conceive with at least one fallopian tube blocked diagnosed by H.S.G or S.S.G. Both the patients, having primary and secondary infertility were included.

CRITERIA FOR EXCLUSION

Patients having any active pelvic infection, hypersensitivity to chemical dye, congenital anomalies of vulva & vagina, CA cervix, sexually transmitted diseases or any debilitating disease like T.B. were excluded from the study. All the patients confirming the above said criteria were included in the study and subjected to thorough interrogation, physical and radiological

examinations. In both the groups patients were also subjected to other investigations.

Grouping:

Group A- Kumari Taila Uttarbasti: Uttarbasti was done in the dose of 5 ml after cessation of menstruation, once daily for 3 days; repeat same after an interval of 3 days for two consecutive menstrual cycles.

Group B- Apamargakshara Taila Uttarbasti: Uttarbasti was done in the dose of 5 ml after cessation of menstruation, once daily for 3 days; repeat same after an interval of 3 days for two consecutive menstrual cycles.

Common for both groups: If tubal patency was achieved, immediately *Phalakayana Ghrita* was gave in the dose of 10 ml orally once in a day with lukewarm water empty stomach for one month.

FOLLOW UP PERIOD: 2 MONTHS

INVESTIGATIONS

Patients were selected on the basis of Hysterosalpingography (HSG) with the report of unilateral or bilateral tubal blockage. No patient was incorporated for study with the report of laparoscopic chromopertubation, as the chances of false reports are there.

SCORING PATTERN: SUBJECTIVE SYMPTOMS

Yathochitakala Adarshana(Oligomenorrhoea)

0 - 22-35 days

1 - 36-45 days

2 - > 45 days

■ *Alpata* (Hypomenorrhoea)

- 0 3-5 days
- 1 2days
- 2 < 2 days
- 3 Spotting

• Yoni Vedana (Dysmenorrhoea)

- 0 No pain
- 1 Bearable pain
- 2 Requirement of oral analgesic
- 3 -Requirement of injectable analgesic

OTHER INVESTIGATIONS

- before starting the course of treatment every patients were screened out by Biochemical screening tests for HIV (Human Immunodeficiency Virus), HBsAg (Australia Antigen for Hepatitis B)

 WDRL (Venereal Disease Research Laboratory).
- ➤ Routine haematological & urinary investigations were done before and after treatment to rule out any type of infection.

STATISTICAL ESTIMATION OF RESULTS

The obtained data were analyzed statistically. The values were expressed as percentage of relief and Standard Error Mean. The data were analyzed by paired 't' test. Unpaired 't' test was applied for comparative study. i.e., P > 0.05 =

Insignificant, P < 0.05 and 0.01 = Significant, P < 0.001 = Highly significant

OBSERVATIONS AND RESULTS

In this clinical trial of tubal blockage, a total number of 36 patients were registered and were randomly distributed into two groups, 18 in each group. 17 patients in group A and 16 patients in group B were completed the course of treatment while 1 patient in group A and 2 patients in group B discontinued respectively. The general observations are shown in FIGURE NO. 1

Observation reveals that, Primary infertility was found in majority of cases i.e. 63.89% whereas 36.11% patients were secondary infertile. Maximum patients i.e. 77.78% registered patients had regular menstrual history while 22.22% patients had irregular menstrual history. 88.89% patients had normal menstruation, 2.78% had scanty menstruation while 8.33% of patients were found with history of excessive menstruation.

Among 36 registered patients, 36.11% gave the history of Pelvic Inflammatory disease (PID), followed by 2.78 % with history of Tuberculosis. Among 36 patients registered, 38.46% were having *Yoni Vedana* (Dysmenorrhoea), *Alpartava* (Hypomenorrhoea) was found in 11.54% patients while *Yathochitakale Adarshana* was found in 26.92% of patients. Findings of Hysterosalpingography (HSG) in 36

registered patients are shown in FIGURE NO. 2. Sites in Unilateral Tubal Blockage of 22 patients are shown in FIGURE NO. 3. Sites in Bilateral Tubal Blockage of 14 patients are shown in FIGURE NO. 4. Distribution of 36 patients on the basis of other uterine abnormalities showed that 16.67% patients had elongated cervix and 2.78% patients had adhesion. Observations of pain during and after procedure are shown in TABLE NO. 1. Total effect on tubal blockage is shown in TABLE NO. 2 and comparative effect of therapy in both the groups is shown in TABLE NO. 3. Effect therapy on Artavakshaya Lakshana (Oligohypomenorrhoea) in both the groups is shown in FIGURE NO. 5. Patients in which block could not be opened is shown in TABLE NO.4. Effect

of therapy on Artavakshaya (oligohypomenorrhoea) Lakshana in 12 patients of group A (Paired t- test) is shown in TABLE NO. 5. Effect of therapy on Artavakshaya (oligohypomenorrhoea) Lakshana in 12 patients of group B (Paired t- test) is shown in TABLE NO. 6. Effect of therapy on conception is shown in FIGURE NO. 6. Evaluation of patients who could not conceive within follow up period after removal of block is shown in TBLE NO. 7. Evaluation of other factors of infertility in patients in whom block was opened but no conception occurred within follow up period of 2 months is shown in TABLE NO. 8. Evaluation of primary and secondary infertility in the results of 24 patients is shown in TABLE NO. 9.

DISCUSSION

It is a trend in many gynecology clinics that tubal blockage is evaluated at last after long term of ovulation induction and other treatment. But, this data shows the change in trend, it also disproves the general belief that some infection during previous labour or abortion is the major cause of tubal blockage. Since tubal blockage is quite prevalent even in patients with primary infertility, it should not be neglected and must be evaluated after some cycles of treatment before allowing the condition to get much complicated due to several inductions. History of abortion was noted in 13.89% patients and 11.11%

patients gave the history of have undergone D & E/D & C in past, as abortion is one of the primary cause for Tubal Blockage. It supports the belief that the first pregnancy should be welcome and must not be terminated, until it is really essential.

All the registered patients had normal (88.89%) menstruation. Besides this, such infertile patients having scanty or excessive menses already treated before treatment. It is established that in only 36.11% cases of tubal blockage, history of pelvic inflammatory disease is found, though PID is the most important

etiological factor for it.⁵ This may be because generally chronic PID is more prevalent and its symptoms like dull abdominal pain or vaginal discharge are so mild and vague that patient feels it to be the discomfort normally associated with menstruation. PID can damage the tube at multiple sites and also predispose to ectopic pregnancy. Another very common factor, pelvic inflammatory disease is generally treated by the gynaecologists before investigating tubal factor.

History of tuberculosis was found in 2.78% patients. Tuberculosis is still responsible for several health hazards in Indian population. Infertility is no exception to this. It suggests that these diseases have become less prevalent in population than previously. It is because of the increasing use of antibiotics. The total history of reproductive tract infection in study sample was not more than 40%. It suggests that tubal blockage should be evaluated even if there are no apparent features or history of infection.

The observations regarding various complaints during and after procedure were supportive of the hypothesis that Intra uterine *Uttarbasti* with *Ushna-Tikshna* drug acts on tubal blockage by removing the whole inner lining and by mechanical effect by stimulating contractions of uterus. The lower abdominal pain was found as a post-procedural complaint in 30.56% patients

within their tolerance which lasted for less than 1 hour. Hot water bag was given as a post procedural measurement to all the patients and it relieved the pain properly. In case of intolerable abdominal pain, *Shamkha Vati*⁶, 2 tablets of 500 mg can be given. The lower abdominal pain was not taken as a bad sign, when it was within tolerance, because it denotes the contractile response of the uterus & Fallopian Tubes to remove the obstruction from the blockage site.

While analyzing the mode of of *Uttarbasti* on all the three features of Artavakshaya, its local & systemic both the effects can be considered responsible, as; i) Uttarbasti with Ushna-Tikshna drugs help to remove fibrosis (due to Khara & Daruna Guna of Vata) of endometrium, thus, helps in its rejuvenation, ii) after stimulating endometrial receptors, it stimulates the Hypothalamus-Pituitary-Ovarian-Uterine axis to restore the normal physiological neuroendocrine state & iii) after peritoneal spillage, it can also directly stimulate the dysfunctioning ovary with its potential drugs.

The effect of therapy in both the groups on tubal blockage was compared and analyzed statistically with unpaired t test. It showed the probability >0.05 and hence, the comparative effect of therapy in both the groups was found insignificant. Thus, *Kumari Taila* and *Apamarga*-

Kshara Taila Uttarbasti, both are equally effective to remove the blockage in fallopian tubes.

Among 33 completed patients, Secondary infertile patients got maximum positive results i.e. 75.00% (9 patients out of 12 patients), where as 71.43% positive results were achieved in primarily infertile patients (15 patients out of 21 patients). Maximum i.e. 28.57% (06 patients out of 21 patients) negative result was found in primarily infertile patients, while 25% secondary infertile patients got negative results (03 patient out of 12). Here it is noticeable that there is no major difference between primary as well as secondary infertility to treat.

EVALUATION OF THE FACTORS BEHIND NO CONCEPTION AFTER BLOCK REMOVAL

In order to assess the effect of *Phalakalyana Ghrita* on conception, a study is needed in the patients with no factor other than tubal blockage involved, and it is really difficult to find such patients.

On evaluation of the cases in which the conception did not occur even after the block was removed, it was found that out of the 09 patients in Group A, all patients had some other potent factor accounting for infertility. In Group B, out of the 09 patients who failed to conceive within follow up period, 07 patients were discovered to have causes other than tubal factor responsible for infertility positive. Thus only 02 patients in Group B were found in whom no other factor responsible for infertility could be detected. In Group A, out of 09 patients, anovulation was found in 04 patients, PCOD was found in 5 patients, and male factor was found unsatisfactory in 03 patients. In Group B, out of 12 patients, 03 had anovulation, 02 had bilateral PCOD, 01 had thyroid dysfunction and male factor was found abnormal in 05 patients.

It is not only the patency of tubal lumen, what is needed for the treatment of tubal infertility. Normalization of the actions of fallopian tube is also another very important objective of the study. It can be achieved by pacifying the vitiation of Vata. Snigdha Guna of Ghrita is definitely helpful relieve the to abnormality generated by the Ruksha, Daruna & Khara Guna of Vata. It restores the tonic phasic contractions of tube and movement of cilia. It is supported by the results of Uttarbasti and Phalakalyana Ghrita in study, because 25% patients in group A and B conceived, but no ectopic pregnancy was reported. Another supporting fact is that all these patients conceived within the two months follow up period, most of them in the very next cycle after treatment.

PROBABLE MODE OF ACTION OF PHALKALYAN GHRITA (BY ORAL ROUTE)

Ghrita is one of the main ingredients in the Phalkalyan Ghrita. GoGhrita is used in the preparation of Phalkalyan Ghrita. Ghrita is Vata Pittashamaka, and Hitakara for Rasa, Shukra and Oja.

Phalkalyan Ghrita also has Tikta
Rasa. Tikta Rasa has Deepana and
Pachana properties, helps in proper
functions of Agni and Samyaka Pachana
Kriya ultimately leads to Samyaka Rasa
Raktadi Dhatu and Upadhatu Artava
Utpatti.

Both Guru and Snigdha Guna of drug produce the Brimhana effect, Snigdha Guna also remove the Ruksha Guna and Shoshana Karma of Vata. Ushna Virya of drugs is Vatakapha Shamaka.

Rasayana property of Ghrita favors
Samyaka Rasaraktadi Dhatu and
Upadhatu Nirmana. To understand the
possible mode of action of Phalkalyan
Ghrita, we should consider Concept of
lipids, Concept of Phytoestrogen and
Estrogen metabolism.

Concept of lipids: Lipids in *Ghrita* are a source of energy and essential structural component for the cell membrane. Production of oestrogen is also increased by use of fatty articles in diet. Fatty

articles (*Ghrita*) increase the cholesterol in the blood circulation. Cholesterol is precursor of all steroidal hormones; especially in female it is responsible for production of oestrogen.

The main content of this Ghrita is *Shatavari*. So detail description of *Shatavari* mentioned as below:

Adaptogenic action of *Shatavari*⁶:

Shatavari has shown to protect the body from stressor. Shatavari may very helpful with women who have stress or immune mediated fertility issues. Shatavari has shown to increase the phagocytic activity of macrophages in turn reducing intra peritonial adhesions. If Shatavari can increase phagocytic activity of macrophages there is hope for it in reducing adhesion in the entire body and this may be great news for women suffering from fertility issue like fallopian tube blockage, endometriosis, uterine fibroids, damage from c- section and ovarian cyst. Supports mucous membrane herbs that have a demulcent action contain mucilage. Mucilage lines the mucous membrane and acts as a protector and tonic for those membranes. Shatavari contains mucilage this may be helpful to women with low cervical mucous.

Anti-Oxytocic Effect

In case where the uterus is contracting due to oxytocin release the

saponin rich *Shatavari* has shown to have an anti-oxytocin effect that may help the uterine contraction to subside and helpful in Threatened mis-carriage.

(ii) Concept of Phytoestrogen:

In Phalkalyan Ghrita majority of drugs like Shatavari, Bala, Haridra etc. have Phytoestrogenic properties Phytoestrogens have mixed estrogenic and antiestrogenic action, depending on target tissue. Phytoestrogens may be either able to affect the endogenous production of estrogens. The pituitary gland releases gonadotropins that stimulate estrogen synthesis in the Recent report indicate that ovaries. phytoestrogen exert their effect in a selective estrogen receptor modulators (SERM). Through this SERM like action they act as both oestrogen agonists and antagonists. They inhibit the enzymatic conversion of endogenous oestrone to oestradiol and also possess intrinsic oestrogen activity.

(iii) Estrogen Metabolism: Three natural estrogens in the human are estradiol (17 β -Estradiol – E 2), Estrone (E 1) and Estriol (E 3). Estrogens may circulate in three forms (1) Free, (2) Conjugated and (3) Protein bound. Free estrogens are lipophilic, freely traverse cell membrane and are thus biologically active. Estrogens are conjugated in the liver as sulphates or glucuronates, conjugated estrogens are water soluble biologically inactive, and

excreted into the urine or bile. Protein bound presumably estrogens are biologically inactive under most circumstances. All hormones act through receptors on the cell surface. In the case of estrogen, two receptors have been identified

- (1) Oestrogen receptor Alpha, (ER-α) and
- (2) Oestrogen receptor Beta (ER-β) ER α is the predominant subtype in the uterus and pituitary. ER β is present in ovary, testis, prostate and also in brain, bone and blood vessels. Estrogen metabolism is by 2 hydroxylation in the hypothalamus, which is rich in 2 hydroxylase activity. The enzymatic addition of a hydroxyl group at the 2nd position of the steroid nucleus converts estradiol to catecholestrogens which has structural similarity to the neurotransmitters, nor epinephrine and dopamine. By inducing transient elevation of the catecholamine content of the hypothalamus (because catecholestrogens are a competitive and more preferred substrate from the enzyme catechol o methyl transferase (COMT), and hence the catecholamines are spread) the catecholestrogens could influence GnRH neuronal activity and modulate gonadotropin secretion.

Considering all the above factors we can summarize the following points.

- **1.** Lipids are essential structural component for the cell membrane.
- **2.** Phytoestrogens may have ability to effect the endogenous production of estrogens. The pituitary

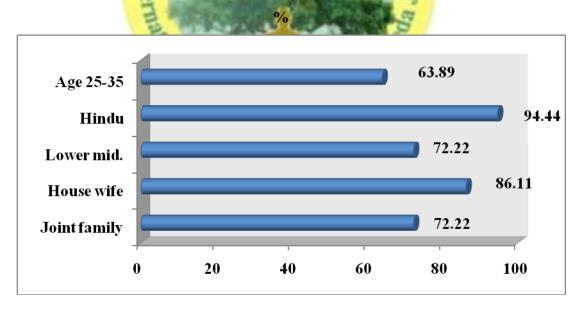
gonadotropin that stimulate estrogen synthesis in the ovaries. They exert their effect in selective estrogen receptor modulators (SERM).

CONCLUSION

Apamarga Kshara Taila & Kumari Taila, both are equally effective to achieve the patency of fallopian tubes. It can be established that *Uttarbasti* is an *Ayurvedic* procedure which has the prospective to replace microsurgeries for management of Tubal infertility in near future. After the tubal opening by above treatment protocol, orally introducing *Phalakalyan Ghrita* for one month increased the conception rate. Rate of conception within

follow up period i.e. 25% in each Group; shows chances of pregnancy, if other factors are normal. Hence, it can be said that *Uttarbasti* procedure along with the internal use of *Phalakalyana Ghrita* can be a standard treatment for management of female Infertility w.s.r. tubal blockage in future in routine *Ayurvedic* Gynecological practice.

FIGURE NO. 1: GENERAL OBSERVATIONS (n=36):



 $\begin{array}{c} FIGURE\\ NO.2\ Findings\ of\ Hysterosalping ography\ (HSG)\ in\ 36\ registered\ patients\\ N=36 \end{array}$

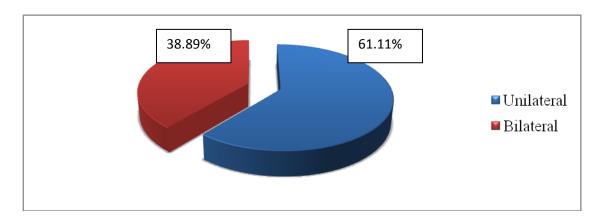


FIGURE NO. 3 Sites in Unilateral Tubal Blockage of 22 patients

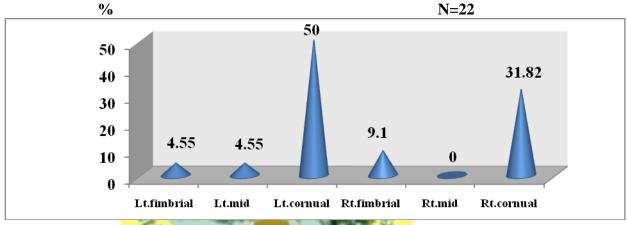


FIGURE NO. 4: Sites in Bilmeral Tubal Blockage of 14 patients % N=14

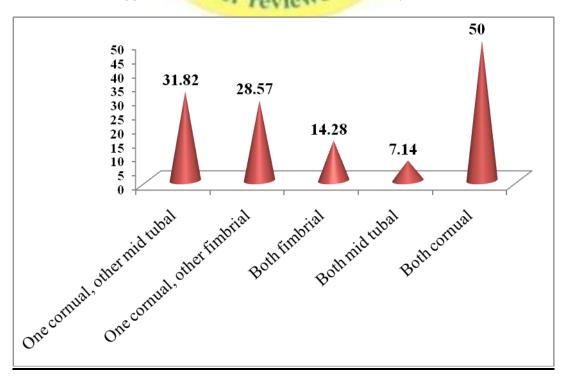


FIGURE NO. 05: Effect of therapy on *Artavakshaya Lakshana* (Oligohypomenorrhoea) in both the groups

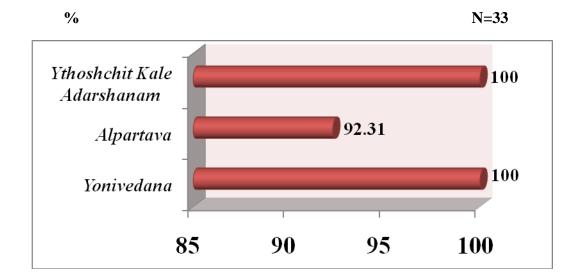


FIGURE NO. 06: Effect of therapy on conception

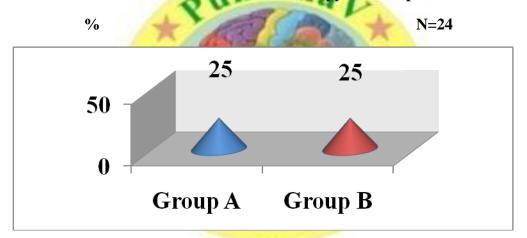


TABLE – 01: Observations of pain during and after procedure

Observation		Group A	Group B	Total	%
Abdominal Pain					
Severity	Tolerable	03	06	09	25.00
	Intolerable	00	04	04	11.11
Duration	<1 hour	03	08	11	30.56
	>1 hour	00	02	02	05.56

TABLE 02: Comparative effect of therapy in both the groups

Group	Tube opened	Tube can't opened	Total	't'	'P'
A	12	05	17	278.00	>0.05
В	12	04	16		
Total	24	09	33		

TABLE 03: Patients in which block could not be opened.

Case	Group	Type of Block	Abnormalities related to tube	History of other disease	Other
1 st case	Group A	Rt. Cornual	-	-	Acutely retroverted uterus
2 nd case	Group A	Both cornual	-	PID	Chronic & Acutely retroverted uterus
3 rd case	Group A	Rt. Cornual	-	-	
4 th case	Group A	Both mid tubal	-	-	Chronic & elderly age
5 th case	Group A	Both cornual	-	-	Acutely retroverted & small uterus
6 th case	Group B	Right cornual	Very narrow tube	History of PID	-
7 th case	Group B	Both cornual	-	-	Chronic & elderly age
8 th case	Group B	Right Cornual, Left Fimbrial	-	History of PID	-
9 th case	Group B	Both cornual	-	-	Adhesion

TABLE 04: Evaluation of patients who could not conceive within follow up period after removal of block

Group	No. of patients in whom block was opened but no conception occurred	for infortility was	Patients in whom other factors were involved
Group A	09	00	09
Group B	09	02	07

TABLE 05: Evaluation of other factors of infertility in patients in whom, block was opened but no conception occurred within follow up period of 2 months

			PCOD		Irregular	Thyroid	Male
No. of patie	nts	Anovulation	U/L	B/L	uterine cavity	dysfunction	factor
Group A	09	04	03	02	00	00	03
Group B	07	03	02	00	00	01	05
Total	16	07	05	02	00	01	08

TABLE 06: Evaluation of primary and secondary infertility in the results of 24 patients

Infertility	Total no. of patients	Open	Can't open
Primary infertility	21	15	06
		[71.43%]	[28.57%]
Secondary	12	09	03
infertility		[75.00%]	[25.00%]
Total	33	24	09

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