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# Management of Infertility in Endometriosis by Operative Laparoscopy and Medical Therapy—Practiced at 3 Different Centres, from September 2005 to October 2007

**Pratibha Devabhaktuni[1], Swathi Gogineni[1], Savitha Devi Yalamanchi[2], Anuradha Katragadda[3]**

[1]Government Maternity Hospital, Nayapul, Institute of Obstetrics and Gynaecology, Osmania Medical College, Hyderabad, India
[2]Swapna Health Care, Hyderabad, India
[3]Anu Infertility Centre, Hyderabad, India
Email: dpdnk@yahoo.com

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## Abstract

This is a prospective study conducted over a period of 2 years and 1 month (from September 2005 to October 2007). 60/117 (52.17%) patients who had laparoscopy for infertility at GMH had endometriosis. 60 patients operated for endometriosis at SHC and 40 patients managed at Anu Infertility Centre during the same period are also included in this study. All the 60 patients underwent operative laparoscopy for endometriosis. Adhesiolysis, electrocautery of surface endometriosis of the ovary, enucleation of endometriotic cyst, mobilization of ovary from uterus and pouch of Douglas and restoration of normal anatomy were carried out. Treatment interventions: Therapeutic hysteroscopy and laparoscopy, medical treatment by various ovulation induction protocols, monitoring by follicular sonography followed by pregnancy management were done in these women. **Results:** GMH—Seventeen 17 out of 18 coming for follow up conceived, 14 following ovulation induction and 3 after COH + IUI, by one year at GMH. SHC—14 out of 18 patients coming for follow up at the end of one year conceived, following ovulation induction 6, COH + IUI-3, IVF-3 and spontaneous 2. ANU—Out of 11 conceptions, COH + IUI resulted in 6, IVF in 4, spontaneous in 1—by one year. Pregnancy outcome: GMH: Ten delivered, Triplets in one, missed abortion two, emergency laparotomy in one. Pregnancy is continuing in 4. SHC: Eight patients delivered. Pregnancy is continuing in 4 patients. Ectopic-1, missed abortion-1. ANU: Five patients delivered. Pregnancy is continuing in 3 women, missed abortion-2, second trimester abruption-1. **Discussion:** The conception rate was 50% at the end of 6 months follow up (15 patients conceived out of the 30 who were coming for follow up at the end of 6 months). Fourteen

(14) out of the 17 conceptions (82.35%) occurred following the use of ovulation induction drugs alone. Especially in stages I and II, if ovulation induction can yield conceptions, there is no need to refer to health centres for COH and IUI as the first option. **Conclusions:** Operative Hysterolaparoscopy at the same sitting would enable correction of uterine lesions to improve conception rates. From our study at GMH, we conclude that after surgery, simple treatment by ovulation induction alone can result in a high percentage of conceptions within a six-month period.

## Keywords

Endometriosis, Infertility, Conceptions, Ovulation Induction

## 1. Introduction

Endometriosis fertility index (EFI) predicts live births following surgical resection of moderate and severe endometriosis. Live births can accurately be predicted with the endometriosis fertility index (EFI), with adnexal function being the most important factor to predict non-assisted reproductive technology (non-ART) fertility or the requirement for ART. A total of 147 women (63%) had a live birth following surgery, 94 of them (64%) without ART [1]. Women with a high EFI score have excellent fertility prognosis and may be advised to try to become pregnant with timed intercourse compared to women with a low score, for which prompt referral to ART seems more reasonable [1].

The Endometriosis Fertility Index takes into account surgical findings both pre-surgery (ASRM scores, essentially amount of disease) and post-surgery (least function score, essentially functional capacity post-resection), and also well known historical factors [2] including age, duration of infertility, and pregnancy history [2].

Ninety-six women of reproductive age who underwent operative laparoscopy to treat endometriosis-related infertility (endometriosis stage I/II n = 67; stage III/IV n = 29) from 2001 to 2011 at the Cleveland Clinic Foundation, to determine the fertility benefit of controlled ovarian hyperstimulation (COH) and intrauterine insemination (IUI) in surgically treated endometriosis, COH + IUI, did not improve pregnancy rates in any stage of endometriosis. In stage III/IV they recommend postoperative *in vitro* fertilization. Twelve-month cumulative pregnancy rates in stage I/II were 45% for spontaneous attempts and 42% for COH + IUI, and in stage III/IV were 20% for spontaneous attempts and 10% for COH + IUI [3].

However, for women with a poor EFI score (≤2) the chance of pregnancy with expectant management is very low (0% - 10%) and it is most appropriate to refer these women for ART early in the post-operative course to optimize their chance of pregnancy [4] [5]. For women with Stage III-IV endometriosis and an EFI score of >7, the chance of non-ART live birth after surgery is ~60% at 3 years,

rising to 75% at 5 years [1].

The endometriosis fertility index (EFI) has been externally validated for prediction of non-ART as well as ART outcomes [5]-[11].

The EFI was the first validated classification to predict spontaneous pregnancy after surgery in endometriotic, infertile, and operated-on patients. It may be a useful new tool to counsel couples for personalized management [5].

In a retrospective study by Nezhat *et al.* [12] at Stanford University, California, 29 patients with multiple IVF failures underwent laparoscopic treatment for endometriosis. 22 of the 29 patients conceived after laparoscopic treatment. 12 patients conceived spontaneously which included 4 patients with stage IV endometriosis. The high pregnancy rates were attributed to the thorough surgical technique. They have concluded that in the absence of tubal occlusion or severe male factor infertility, laparoscopy may still be considered for the treatment of endometriosis even after multiple IVF failures.

The Eva Littman Study [12] proves that spontaneous conceptions can occur after operative laparoscopy for stage IV endometriosis also without resorting to GnRH analogues. This has prompted us to conduct the following study and prove that the management of infertility in endometriosis must be individualized.

The question uppermost in mind is: what is the best treatment so that the patients conceive. In this publication, we present our data and suggest some conclusions.

## 2. Aims and Objectives

To study the various modalities of treatment of different stages of endometriosis practiced at 3 different centres—Government Maternity Hospital, Nayapul, (GMH) Hyderabad, Swapna Health Care (SHC) and Anu Infertility Centre, (ANU IC) and to document the conception rates.

We do not have an ART Centre in our hospital. Patients with tubal factor or male factor responsible for their infertility and therefore needing ART were referred to an ART centre.

We have studied the conception rates in endometriosis in an Assisted Reproductive Techniques centre (ART) during our study period which included cases referred from our institute also in addition to others.

## 3. Material, Treatment and Observations

**This is a prospective study** conducted over a period of 2 years and 1 month (from September 2005 to October 2007. 60/117 (52.17%) patients operated for infertility at GMH had endometriosis. 60 patients operated for endometriosis at SNH and 40 patients managed at ANUIC during the same period are also included in this study.

### 3.1. Data of Women Managed at GMH

Total Number of cases 60. Primary infertility-44, Secondary infertility with no

live child-11, Secondary infertility with one live child-5 (Table 1 & Table 2).

### 3.2. Infertility Treatment Prior to Laparoscopy at GMH

18 patients took some treatment for infertility [ovulation induction, IUI, IVF].

### 3.3. Surgical History

1) One patient underwent laparotomy and bilateral wedge resection of ovaries for endometriotic cysts in 1996. 2) Staging laparotomy was done for bilateral ovarian cysts in one patient. 3) Left ovarian cystectomy and wedge resection of left ovary was done in one patient for haemorrhagic corpus luteal cyst. 4) In one left ovarian cystectomy was done for twisted ovarian cyst. 5) ASD closure was done in one woman at the age of 18 years. 6) And another underwent thyroid surgery 3 years ago.

### 3.4. Medical History

Two patients were treated for tuberculosis—one for pulmonary TB and the other for tuberculous lymphadenitis. Hypothyroidism was present in two, treated, Epilepsy-2, Diabetes-1, Hypertension-1, Heart disease (ASD closure)-1, Previous cytomegalovirus infection-1.

### 3.5. Menstrual History

Menstrual cycles were regular in 46 patients and irregular in fourteen. 15 patients had dysmenorrhoea.

### 3.6. Gynae Examination

Eight patients had adnexal masses on per vaginal examination. (5 were chocolate

Table 1. Age wise distribution of patients in GMH, SNH, ANU IC.

| Age in years | GMH N = 60 | SHC N = 60 | ANU N = 40 |
|---|---|---|---|
| Less than 20 | 2 | - | - |
| 21 - 25 | 22 | 10 | 6 |
| 26 - 30 | 25 | 33 | 23 |
| 31 - 35 | 7 | 14 | 10 |
| 36 - 39 | 4 | 3 | 1 |

GMH—Government Maternity Hospital, SHC—Swapna Health Care, ANU IC—Anu Infertility Centre.

Table 2. Duration of infertility.

| Duration of infertility in years | GMH, N = 60 | SHC, N = 60 | ANU, N = 40 |
|---|---|---|---|
| Less than 5 years | 26 | 36 | 21 |
| 6 - 10 years | 25 | 18 | 16 |
| More than 11 years | 9 | 6 | 3 |

cysts at the time of laparoscopy, one was a dermoid cyst, one—a para-ovarian cyst and one was a fibroid). Examination findings were normal in the rest of the patients.

### 3.7. Other Salient Investigations

Hysterosalpingography (HSG) was done in 22 women. Both tubes were patent on HSG in 14 women and unilateral/bilateral tubal blockage was present in eight. CA 125 was done in 8 patients. It was normal in all of them. Four women had hyperprolactinaemia but repeat prolactin levels were normal in two of them. Endometriotic cysts were reported on USG in 8 patients and polycystic ovaries were present in 13.

**Treatment interventions:** Therapeutic hysteroscopy and laparoscopy, medical treatment by various ovulation induction protocols, monitoring by follicular sonography followed by pregnancy management were done in these women.

### 3.8. Hysteroscopy and Operative Laparoscopy

Hysteroscopy and operative laparoscopy were done in all infertile patients at the same sitting. Abnormal hysteroscopic findings are shown in Table 3. An endometrial curettage was done at the same sitting to detect endometrial hyperplasia, tuberculosis, abnormalities detected on hysteroscopy would be managed at the same time. Polyp removal, septal resection, synaechiaelysis were done at that time.

Table 3. Endometriosis, in addition, associated factors compromising fertility GMH, SHC, ANU.

| Sl. No | In addition to endometriosis Associated Factors Compromising fertility | GMH N = 60 | SHC N = 60 | ANU IC N = 40 |
|---|---|---|---|---|
| 1. | Hypothyroidism | 2 | 7 | 3 |
| 2. | PCO | 13 | 11 | 18 |
| 3. | Hyperprolactinemia | 2 | 2 | 3 |
| 4. | Tuberculosis endometrium | 2 | 1 | - |
| 5. | Diabetes | - | - | 1 |
| 6. | Abnormal hysteroscopic findings | 25 | 12 | 14 |
| 7. | Polyps | 14 | 3 | 5 |
| 8. | Synaechiae | 8 | 1 | 1 |
| 9. | Submucous fibroid | 1 | | |
| 10. | Blocked ostium | 1 | | 2 |
| 11. | Partial uterine septum | 1 | | |
| 12. | Septum uterus | | 5 | 3 |
| 13. | Uterus Duplex + vagina Duplex | | 1 | |
| 14. | Cervical stenosis | | | 2 |
| 15. | Adenomyosis indenting cavity | | 1 | |
| 16. | Pinpoint os | | 1 | 1 |

### 3.9. Histopathological Examination

Histopathological examination of the endometrial curettings revealed proliferative endometrium in 50 patients, secretory endometrium in 8 and simple cystic hyperplasia in 2.

### 3.10. Staging of Endometriosis at the Time of Laparoscopy

Accuracy of reporting stage I-IV endometriosis depends also on the subjective assessment. All the patients from three centres underwent operative laparoscopy for endometriosis [N = 160]. Adhesiolysis, electrocautery of surface endometriosis of the ovary, enucleation of endometriotic cyst, mobilization of ovary from uterus and poch of Douglas and restoration of normal anatomy were carried out. Methylene blue chromo perturbation was performed in all the cases.

They were advised to come for regular follow up. Those who came for follow up were started on ovulation induction drugs (clomiphene citrate 50 mg OD) from the 2$^{nd}$ day of their cycle for 7 days. Follicular growth was monitored on ultrasonography from the 11$^{th}$ day. Patients were called for post coital test around the time of ovulation (Table 4 & Table 5).

Table 4. Staging of endometriosis at the time of laparoscopy.

| Stage of endometriosis | GMH N = 60 | SHC N = 60 | ANU N = 40 |
|---|---|---|---|
| Stage I | 29 | 16 | 15 |
| Stage II | 20 | 7 | 12 |
| Stage III | 9 | 5 | 5 |
| Stage IV | 2 | 32 | 8 |

Table 5. Pregnancy rates after laparoscopic management of endometriosis GMH, SHC, ANU.

| No. of months of follow up | | No of conceptions | No. of patients coming for follow up | % of conceptions |
|---|---|---|---|---|
| 3 months | GMH | 7 | 41 | 17.07 |
| | SHC | 3 | 32 | 9.37 |
| | ANU | 3 | 37 | 8.1 |
| 6 months | GMH | 15 | 30 | 50 |
| | SHC | 10 | 25 | 40 |
| | ANU | 9 | 29 | 31.03 |
| 9 months | GMH | 16 | 20 | 80 |
| | SHC | 12 | 20 | 60 |
| | ANU | 9 | 24 | 37.50 |
| 1 year | GMH | 17 | 18 | 94.44 |
| | SHC | 14 | 18 | 77.77 |
| | ANU | 11 | 15 | 73.33 |

## 4. Treatment Outcomes

### 4.1. Post Operative Treatment

Post operative hormonal treatment has no beneficial effect on pregnancy rates after surgery.

Only one dose of GnRH analogue was given to two patients. (both of them had stage III endometriosis). One of them conceived. Tab. Danazol 200 mg BD was given for 6 weeks to a patient with stage IV endometriosis as she could not afford GnRH analogues (Table 6).

### 4.2. Conceptions with Ovulation Induction [OI], Spontaneous, COH + IUI and IVF

Conceptions in patients coming follow up at the end of one year: Figure 1.

GMH—Seventeen (17) out of 18 coming for follow up conceived, 14 following ovulation induction and 3 after COH + IUI.

SHC—14 out of 18 patients conceived. Following ovulation induction 6, COH + IUI-3, IVF-3 and spontaneous 2.

Table 6. Method of treatment given after operative laparoscopy for endometriosis. Stage wise conception rates in GMH, SHC, ANU infertility centre—2006-2008, Hyderabad.

| .No. | Method | | Stage I | | Stage II | | Stage III | | Stage IV | |
|---|---|---|---|---|---|---|---|---|---|---|
| | GMH—N = 60 | | GMH 29 | | GMH 20 | | GMH 9 | | GMH 2 | |
| | SHC—N = 60 | | SHC 16 | Conceptions | SHC 7 | Conceptions | SHC 5 | Conceptions | SHC 32 | Conceptions |
| | ANU—N =40 | | ANU 15 | | ANU 12 | | ANU 5 | | ANU 8 | |
| 1 | Ovulation induction | GMH | 23 | 7 | 16 | 5 | 7 | 2 | 2 | - |
| | | SHC | 12 | 4 | 3 | - | 3 | 1 | 5 | 1 |
| | | ANU | 1 | - | 2 | - | - | - | - | - |
| 2 | COH + IUI | GMH | 4 | 3 | 1 | - | - | - | - | - |
| | | SHC | 3 | 2 | - | - | 1 | - | 3 | 1 |
| | | ANU | 13 | 6 | 8 | - | 4 | - | 1 | - |
| 3 | IVF | GMH | - | | - | | - | | - | |
| | | SHC | 2 | | - | | - | | 8 | 3 |
| | | ANU | 3 | | 2 | 2 | 1 | | 8 | 2 |
| 4 | ICSI | ANU | - | | 1 | | - | | - | |
| 5. | DIPI | ANU | 1 | | 2 | | | | | |
| 5. | Spontaneous | GMH | | | | | | | | |
| | | SHC | | | | | | | | 2 |
| | | ANU | | | | | | | | 1 |
| 5 | Post Operative GnRH analogues | GMH | - | | - | | 2 | | - | |
| | | SHC | 3 | | 3 | | 2 | | 10 | |
| | | ANU | | | | | | | | |

Danazol was given to one patient (GMH), Novelon OC pill and Depoprovera (depot medroxy progesterone acetate) were given to one patient each (SHC).

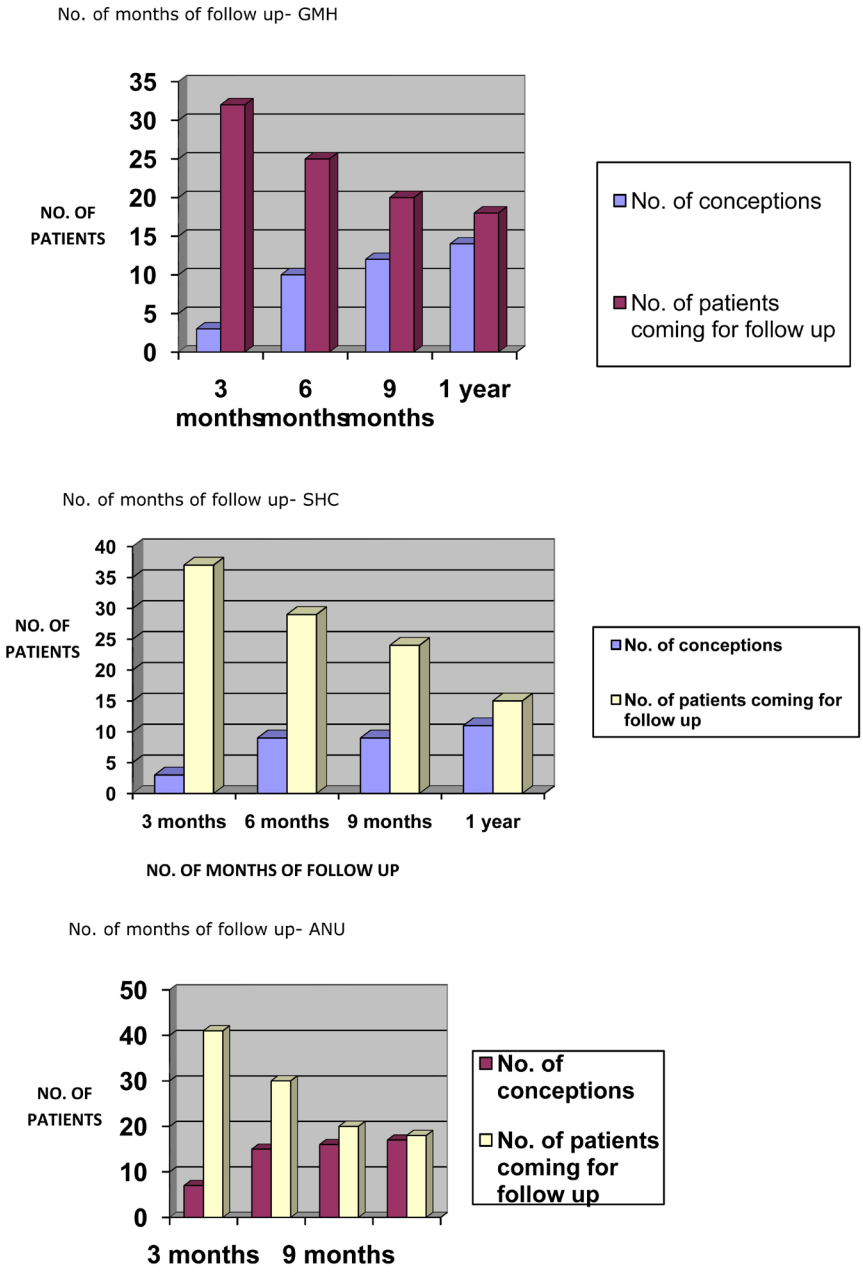


**Figure 1.** Pregnancy rates after laparoscopic management of endometriosis GMH, SHC, ANU IC.

ANU—Out of 11 conceptions, COH + IUI resulted in 6, IVF in 4 and spontaneous in 1 (Table 7 & Table 8).

Patients with male factor as a cause of their infertility, those with tubal factor and those who did not respond to clomiphene citrate were advised to attend ART centre for further management. Most of them could not afford and only 6 went to the ART centre.

### 4.3. Endometriosis and ART

Out of those who came for follow up and did not conceive, only one tube was

**Table 7.** Pregnancy rates after laparoscopic treatment of endometriosis [13]. Number of pregnancies/number treated (%).

| S.No. | Investigator | Stage I | Stage II | Stage III | Stage IV | Combined | Length of follow up (months) |
|---|---|---|---|---|---|---|---|
| 1 | Eward [14] | 4/7 (57) | 10/18 (56) | - | - | 14/25 (56) | 13 |
| 2 | Hasson [15] | 0/1 (0) | - | 2/2 (100) | 4/5 (80) | 6/8 (75) | 7 |
| 3 | Sulewski *et al.* [16] | - | 20/42 (48) | 20/58 (35) | - | 40/100 (40) | 37 |
| 4 | Seiler *et al.* [17] | - | 20/45 (44) | - | - | 20/45 (44) | 7 |
| 5 | Nowroozi *et al.* [18] | - | 42/69 (61) | - | - | 42/69 (61) | 8 |
| 6 | Daniell & Pittaway [19] | - | - | - | - | 33/60 (55) | - |
| 7 | Reich & Mc Glynn [20] | - | - | - | - | 15/23 (65) | 18 |
| 8 | Murphy *et al.* [21] | 24/36 (67) | 18/36 (50) | 2/7 (29) | 0/3 (0) | 44/82 (54) | 8 |
| 9 | Candiani *et al.* [22] | - | - | - | 98/206 (47.6) | 98/206 (47.6) | - |
| 10 | Luciano *et al.* [23] | - | - | 70% | - | - | - |
| 11 | Busacca *et al.* [24] | - | - | 57.5% | - | - | 24 |
| 12 | GMH Study Dr. D. Pratibha Dr. G. Swathi | 9/17 (52.94) | 5/8 (62.5) | 1/4 (25) | 0/1 (0) | 15/30 (50) | 6 |
| 13 | Swapna nursing home | 4/10 (40) | 0/1 (0) | 1/3 (33.33) | 5/11 (45.45) | 10/25 (40) | 6 |
| 14 | Anu infertility centre | 5/13 (38.46) | 2/8 (25) | 0/3 (0) | 2/5 (40) | 9/29 (31.03) | 6 |

**Table 8.** Method of conception GMH—(n = 17), SHC (n = 14), ANU—(n = 11).

| S.No. | Method | | Total | Stage I | Stage II | Stage III | Stage IV |
|---|---|---|---|---|---|---|---|
| 1 | Ovulation Induction OI | GMH | 14 | 7 | 5 | 2 | - |
| | | SHC | 6 | 4 | - | 1 | 1 |
| | | ANU IC | - | | | | - |
| 2 | COH + IUI | GMH | 3 | 3 | - | - | - |
| | | SHC | 3 | 2 | - | - | 1 |
| | | ANU IC | 6 | 6 | | | |
| 3 | IVF | SHC | 3 | - | - | - | 3 |
| | | ANU | 4 | - | 2 | - | 2 |
| 4 | Spontaneous | SHC | 2 | - | - | - | 2 |
| | | ANU | 1 | | | | 1 |

patent in 7 women, both tubes were blocked in 3, oligospermia was present in 4 (two of them had grade iii varicocele and one was a known diabetic) and asthenospermia was present in three. Patients with bilateral tubal blockage (3) and those with male factor contributing to infertility (7) were referred to infertility clinic for assisted reproductive techniques. Seven out of these 10 women could not afford and only 3 took treatment at the ART centre (**Figure 2**).

### 4.4. Pregnancy Outcome: Table 9

GMH: Ten out of the 17 patients delivered. One of them has triplets. All the babies

**Table 9.** Endometriosis—pregnancy outcome

| Centre | Total conceptions | Delivered | Pregnancy continuing | Abortion/Ectopic | Pregnancy outcome |
|---|---|---|---|---|---|
| GMH | 17 | 10 | 4 | Missed Abortion-2 | Emergency hysterotomy-1 |
| SHC | 14 | 8 | 4 | Ectopic-1, Abortion-1 | |
| ANU IC | 11 | 5 | 3 | Missed abortion-2 | |

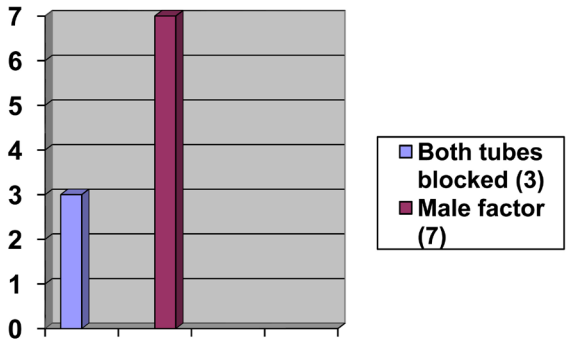


**Figure 2.** Reason for referral to ART—GMH.

survived. Two patients had missed abortion. The abortion rate in our study was 2/17 (11.76%) which is the same as in the general population (12% - 15%). Emergency hysterotomy was done for a patient in the 6$^{th}$ month for severe preeclampsia and abruption with failure to progress. Pregnancy is continuing in 4 cases.

SHC: Eight patients delivered. One patient had an ectopic pregnancy. Following surgery for ectopic, she conceived spontaneously and had a missed abortion. Pregnancy is continuing in 4 patients.

ANU: Five patients delivered. Two patients had missed abortion. Second trimester pregnancy loss occurred in one. Pregnancy is continuing in 3 women.

## 5. Discussion

The gold standard in the diagnosis of endometriosis is by laparoscopy. The diagnosis of endometriosis—minimal and mild, by USG is difficult and may be missed in the majority of cases.

Operative Hysteroscopy and laparoscopy at the same sitting would enable correction of uterine lesions improving conception rates. Diagnosis of endometriosis as well as management has to be planned at the first laparoscopy to give the maximum benefit to the patient.

Expectant management was not given to any of the patients managed at our institute. All the 60 patients who were diagnosed to have endometriosis at the time of laparoscopy had operative procedure by laparoscopy.

The Canadian Collaborative Group [25] [26] on Endometriosis evaluated the effect of surgical treatment of early stage endometriosis on subsequent fertility. Cumulative pregnancy rates were significantly higher in the group that had un-

dergone surgical treatment (30.7% vs 17.7%).

In another randomized study, Nowroozi [18] and colleagues evaluated the effect of surgical treatment in 123 women with mild endometriosis. Of the patients in the surgical treatment group, 61% achieved pregnancy whereas 18.5% of women who did not receive treatment achieved pregnancy. This difference was significant ($P < 0.001$).

Post operative hormonal treatment has no beneficial effect on pregnancy rates after surgery. By the time patient resumes normal ovulatory patterns, which may be months after completion of therapy, the deleterious effects of the disease process on fertility that were suppressed initially by medications recur even if the patient remains asymptomatic (RCOG) [27]. GnRH agonists after laparoscopic surgery would delay conception.

Out of 392 analyzed patients, after surgery, 146 couples conceived without ART and 164 with ART (*in vitro* fertilization [IVF]—intracytoplasmic sperm injection [ICSI]) [5].

A take home baby rate of 59.9% in ART population, compared with 76% among patients who obtained an ongoing pregnancy without ART has been reported [5].

After operative laparoscopic surgery for endometriosis, expectant management in cases with high EFI (from 7 to 10), spontaneous pregnancy could be favored [5] [28].

An average pregnancy rate of 41.9%, (18/43 patients) through natural conception has been reported during the first year after laparoscopic surgery in infertile women with endometriosis and no other factors, without ART or hormone treatment (stage I, 35.7%; stage II, 44.4%; stage III, 53.3%; and stage IV 20.0%) [29].

Seventy-eight women diagnosed with severe endometriosis during surgery (AFS 3 - 4) with multiple failed IVF treatments before surgery, had (42.3%) 33 conceptions after surgical treatment, following ART and delivered [30].

The success rates following ART and spontaneous conceptions after laparoscopic surgery signal that there is light at the end of the tunnel.

In our study from GMH, the conception rate was 50% at the end of 6 months follow up (15 patients conceived out of the 30 who were coming for follow up at the end of 6 months).

Fourteen (14) out of the 17 conceptions (82.35%) occurred following the use of ovulation induction drugs alone.

From all three centres, by the end of 6 months, 34/84 patients, 40.47% conceived, 42 out of 50 coming for follow up [84%] conceived by one year.

IVF is the appropriate treatment especially if tubal function is compromised, if there is also male factor infertility and/or other treatments have failed [27].

## 6. Conclusions

Hysteroscopy and laparoscopy (hysterolap.) at the same sitting would enable

correction of uterine lesions, to improve conception rates.

Adequate surgical treatment by laparoscopy would improve conception rates. Diagnosis of endometriosis as well as management has to be planned at the first laparoscopy to give the maximum benefit to the patient.

From our study at GMH, we conclude that after surgery, simple treatment by ovulation induction alone can result in a high percentage of conceptions within a six-month period. The longer the interval to conception, dropout rate would increase, especially in the Indian scenario where family pressure to consult another doctor would be more.

Especially in stages I and II, if ovulation induction can yield conceptions, there is no need to refer to health centres for COH and IUI as the first option.

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## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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