



Effect of Myomectomy on IVF outcomes, among women presenting at Infertility Clinic at SPHMMC.

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Summary

Background: The impact of myomas on fertility outcomes has long been debated. A number of studies have examined the effect of myomas in women undergoing In Vitro fertilization and have suggested that myomas have a significant effect on IVF outcomes. Uterine myomas affect 20-50% of women of reproductive age and are present in approximately 5-10% of patients presenting with infertility; however, they are found to be a sole factor identified in only 1-2% of infertile patients. At the fertility Clinic of SPHMMC, myomectomy is being done prior to IVF. However, the exact effect of myomectomy on IVF outcome has not yet been studied in our set up.

Objective: The objective of this study is to determine the effect of myoma removal, on IVF outcome.

Methods: Hospital based retrospective review of infertile women who underwent myomectomy prior to invitro fertilization between APRIL2011 to DECEMBER 2023 E.C . Data will be collected retrospectively from electronic medical record at CFRM of SPHMMC and through phone interview. Data will be entered into Epi-data Version 3.1 and analyzed using SPSS 20.0 version. Categorical factors will be summarized using frequencies and percentages. Statistical significance will be assessed using, fischer exact test and p values less than 0.05 will be used as cut off point for statistical significance.

Work plan and budget: The total duration of the research from its inception to its completion will be from APRIL2019-DECEMBER 2022 . A total of 30,500 ETB budget is proposed to conduct the research& the source of the budget will be St. Paul's hospital.

Key words: myomas, myomectomy, Invitro fertilization, CFRM, infertility clinic, St. Paul hospital

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LIST OF ABBREVIATIONS

IVF- Invitro fertilization

ICSI- Intra cytoplasmic sperm injection

ART-assisted reproductive technologies

CFRM-center of fertility and reproductive medicine

GA- Gestational age

CPR- clinical pregnancy rate

OBGYN- Obstetrics and Gynecology

SPHMMC- Saint Paul's Hospital Millennium Medical College

1. INTRODUCTION

1.1 BACKGROUND

Uterine myomas are benign smooth muscle neoplasms arising from smooth muscle of the uterus (1). It occurs in 10-20% of women. The most common clinical presentation is abnormal uterine bleeding and pelvic pain. It is clear that fibroids can adversely affect reproductive outcome, these adverse outcomes both include impaired fertility and adverse obstetric outcomes. (2) The incidence of fibroids in infertile women with no obvious cause of infertility is estimated to be between 1 and 2.4% (3) Two important considerations involved in the decision to undertake surgery are the location of the fibroid, and whether or not the uterine cavity is obliterated increase the risk of miscarriage, and so should be removed (4,5). Submucous fibroids. A recent meta-analysis showed that submucous fibroids significantly reduced the implantation rate, clinical pregnancy rate and live birth rate and significantly increased the miscarriage rate (6). The presence of a submucous fibroid in women with RIF, regardless of the size, should be removed as it was shown in the meta-analysis that removal of submucous fibroids improves clinical pregnancy rates (6). Patients having subserosal or intramural leiomyomas of 6 cm not

encroaching on the uterine cavity have IVF-ICSI outcomes comparable to those of patients without such leiomyomas. Therefore, they might not require myomectomy before being scheduled for assisted reproduction cycles. However, we recommend caution for patients with fibroids 6 cm and that such patients be subjected to surgery before they are enrolled in IVF-ICSI cycles. Whether or not women with fibroids 6 cm would benefit from fibroid treatment remains to be determined. (7,8) When women with SS fibroids were examined in comparison with women without fibroids, no difference was observed for any outcome measure. In contrast, women with IM fibroids produced significantly lower clinical pregnancy rates, implantation rates, and ongoing pregnancy/live birth rates and significantly higher spontaneous abortion rates. No difference was seen in the rate of preterm delivery. When the analysis is restricted to prospective studies, only the clinical pregnancy rate loses statistical significance; all other effects remain unchanged. When the analysis is limited to those studies using a high-quality method to assess the uterine cavity in all subjects, only implantation rate maintains statistical significance. No changes in results are seen by elimination of studies involving subjects with earlier surgery or restricting inclusion to assisted reproduction studies. (6)

Despite numerous publications and years of research, the relationship between uterine fibroids and infertility is still unsettled. The exact mechanism by which fibroids may affect infertility is not certain and includes: blockage of the fallopian tubes; alterations of tubal motility and prevention of sperm-egg assembly; prevention of proper sperm migration through the cervical canal; dyspareunia; and thin, vascularized endometrium (3) and abnormal uterine peristalsis. (8) Only the last two can directly affect implantation and assisted reproductive technologies (ART)/IVF results.

In fertility treatment, it is generally accepted that the anatomical location of a uterine fibroid (submucosal, intramural or subserosal), is an important factor in determining the treatment plan (9).

Myomectomy is found to significantly increase conception rate in women with myomas as a sole factor of infertility. The conception rate following myomectomy ranged from 25 to 77% in available retrospective studies (18)

If the fibroids are of the submucosal type, they can be effectively resected with a hysteroscope, which is a less invasive surgical technique. On the contrary, intramural or subserosal lesions should be treated by laparotomy or laparoscopy (9). However, in some cases myomectomy leads to surgical complications and adhesion formation. In the case of intramural fibroids, patients are required to cease fertility

treatment for several months following surgery to allow the uterine scars to heal. However, even with these precautions, scarring has been known to cause uterine rupture during labor or pregnancy (10) Moreover, whereas meta-analyses consistently showed a detrimental effect of submucosal but not subserosal fibroids on treatment outcomes, conclusions regarding intramural lesions have been conflicting (9,10)

2 statement of the problem

The conception rate following myomectomy has been examined in a number of studies and ranged from 25-75%. The presence of other infertility factors appears to have an important effect on the conception rate. In a recent meta-analysis(4) the conception rate following myomectomy in a women with other wise unexplained infertility 61% was higher than in those with other infertility factors 38%. However, few studies have considered the reproductive performance prior to myomectomy, including the presence of infertility and miscarriage, and hence have not examined how myomectomy alters the reproductive performance.(11)

A few studies have evaluated the impact of uterine fibroids on the results of assisted reproductive technology (ART) treatment. (12)showed that the PR after IVF-ET treatment was impaired only when the fibroids caused deformation of the uterine cavity.(13) Showed that even after excluding patients with submucosal fibroids, the presence of fibroids reduced the efficacy of ART treatment.

one study found that the treatment outcome after ART was not influenced by the presence of subserosal fibroids but was considerably impaired in patients with either intramural or submucosal fibroids, even when there was no deformation of the uterine cavity. Surgical or medical treatment should be considered for these patients.(14)

There is evidence to suggest that submucosal and intramural fibroids that distort the endometrial cavity are associated with decreased pregnancy and implantation rates in women who attempt to conceive spontaneously or who are proceeding with IVF treatment (15)

Several studies suggest that pregnancy rates improve following the resection of fibroids distorting the uterine cavity (19,20,21) conducted a systematic literature review and meta-analysis of existing

controlled studies and concluded that women with submucosal fibroids have decreased clinical pregnancy and implantation rates compared with infertile control subjects (19). The authors concluded that removal of submucous myomas appeared to improve outcome (19)

IVF outcomes appear to be improved by judicious removal of clinically significant fibroids. Further prospective studies are required to confirm the role of fibroids, and their removal, on ART outcomes before advocating for routine myomectomy amongst women with fibroids undergoing ART.(16) SPHMMS is one of the hospitals which provide infertility treatment service; and myomectomy is one of the modality of treatment given for infertility. However, the exact effect of myomectomy on ivf outcome is not known. Thus, the purpose of the study will be to determine the effect of myomectomy on ivf outcome.

3. Literature review

Uterine myomata may act as a deterrent to conception and successful culmination of pregnancy. It has been stated that 40% of women undergoing myomectomy are infertile (22) and that 5% of infertile women have uterine myomata (23).

A Systematic literature review and meta-analysis of existing controlled studies were done at Private center for Reproductive endocrinology and infertility to investigate the effect of fibroids on fertility and of myomectomy in improving outcomes in women with fibroids and infertility. The main Outcome Measure(s) were Clinical pregnancy rate, spontaneous abortion rate, ongoing pregnancy/live birth rate, implantation rate, and preterm delivery rate in women with and without fibroids, and in women who underwent myomectomy. And the result(s) showed that Women with subserosal fibroids had no differences in their fertility outcomes compared with infertile controls with no myomas, and myomectomy did not change these outcomes compared with women with fibroids in situ. Women with intramural fibroids appear to have decreased fertility and increased pregnancy loss compared with women without such tumors, but study quality is poor. Myomectomy does not significantly increase the clinical pregnancy and live birth rates, but the data are scarce. Fibroids with a submucosal component led to decreased clinical pregnancy and implantation rates compared with infertile control subjects.

Removal of submucous myomas appears likely to improve fertility. Finally they reached on Conclusion(s) that Fertility outcomes are decreased in women with submucosal fibroids, and removal seems to confer benefit. Subserosal fibroids do not affect fertility outcomes, and removal does not confer benefit. Intramural fibroids appear to decrease fertility, but the results of therapy are unclear. More high-quality studies need to be directed toward the value of myomectomy for intramural fibroids, focusing on issues such as size, number, and proximity to the endometrium. © 2009 American Society for Reproductive Medicine.(6)

A matched follow-up study design was used to test the hypothesis that pregnancy rates following assisted reproduction procedures do not differ between women with or without intramural or sub-serosal uterine leiomyomas. Women undergoing their first in-vitro fertilization (IVF)– embryo transfer or zygote intra-Fallopian transfer (ZIFT) cycle between January 1993 and June 1995 were included. Cases (women with leiomyomas) were matched 1:1 with the next consecutive control (women without leiomyomas) according to age, number of embryos transferred, embryo grade, and the route of embryo transfer (uterine or Fallopian). Assisted reproduction cycles were performed in an identical manner, independent of the presence or absence of uterine leiomyomas. The main outcomes measured were clinical pregnancy and delivery rates. A total of 182 cycles was evaluated. Of the 91 assisted reproduction cycles performed in the leiomyoma group, there were 34 clinical pregnancies (37%) and 30 deliveries (33%). Of the 91 assisted reproduction cycles in the control group, there were 48 clinical pregnancies (53%) and 44 deliveries (48%). The Mantel–Haenszel estimate of relative risk indicated that the presence of a uterine leiomyoma significantly reduced the chance for a clinical pregnancy or delivery. These findings suggest that leiomyomas are associated with a reduction in the efficacy of assisted reproduction cycles.(13)

Another study was conducted in Melbourne, Victoria, Australia To investigate the effect of subserosal, intramural, and submucosal fibroids on the outcome of assisted reproductive technology (ART) treatment By using A retrospective comparative study at a tertiary referral center for infertility: Treatment outcome of 106 ART cycles in 88 patients with uterine fibroids (33 subserosal, 46 intramural without cavity distortion, and 9 submucosal) was compared with that of 318 ART cycles in age-matched patients without fibroids.The Intervention(s) taken was Controlled ovarian hyperstimulation and ART. By using Main Outcome Measure(s): Findings on transvaginal uterine ultrasonography performed before the initiation of treatment and pregnancy and implantation rates. and the Result(s) shows the

pregnancy rates per transfer were 34.1%, 16.4%, 10%, and 30.1% in the patients with subserosal fibroids, intramural fibroids, submucosal fibroids and no fibroids, respectively. The implantation rates were 15.1%, 6.4%, 4.3%, and 15.7%, respectively. Both rates were significantly lower in patients with intramural fibroids than in those with subserosal fibroids or no fibroids. And the study Conclusion(s) was Pregnancy and implantation rates were significantly lower in the groups of patients with intramural and submucosal fibroids, even when there was no deformation of the uterine cavity. Pregnancy and implantation rates were not influenced by the presence of subserosal fibroids. Surgical or medical treatment should be considered in infertile patients who have intramural and/or submucosal fibroids before resorting to ART treatment.(14)

In the united states of America, in cleaveland, Single institution retrospective cohort study of infertility patients who underwent myomectomy prior to either in vitro fertilization (IVF) or intrauterine insemination (IUI) between August 2006 and October 2015 (N = 49) was made and two separate control groups were established: 1) women with fibroids left in situ during the ART process (N = 76), and 2) women with no fibroids (N = 103). The study was powered to detect a difference between a 42%, 11%, and 25% live birth (LB) rate in the myomectomy, fibroids in situ, and no fibroids groups at $P < 0.05$. Results: There were no significant differences in IVF cycle parameters between groups. Fibroids that were either submucosal or intramural with associated cavity distortion were significantly more likely to be removed. Amongst women undergoing IVF, the cumulative incidence of clinical pregnancy (CP) was significantly higher in the myomectomy group than the in situ or no fibroids groups. Women who underwent pre-IVF myomectomy also achieved CP more quickly. Cumulative LB rates did not differ significantly amongst women undergoing IVF. CP and LB rates per cycle were similar between myomectomy, in situ, and no fibroids groups (CP 49% vs. 37.5% vs. 54.4%, $P = 0.21$; LB 41.7% vs. 27.1% vs. 43.9%, $P = 0.17$). Discussion: IVF outcomes appear to be improved by judicious removal of clinically significant fibroids. Further prospective studies are required to confirm the role of fibroids, and their removal, on ART outcomes before advocating for routine myomectomy amongst women with fibroids undergoing ART.(16)

Study made in cairo Egypt The aim of this work was to study the effect of uterine myomata on the implantation rate and outcome in in-vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI). Among 406 patients, 51 (12.6%) were found to have uterine corporeal myomata. Twelve patients were excluded from the study as they had large myomata, submucous myomata or intramural myomata

encroaching on the cavity. These patients were advised to have myomectomy before being enrolled in the IVF/ICSI programme. The remaining patients (n J 39) were sorted according to the number, site and size of the myomata as assessed by transvaginal sonography. Three patients had more than one myoma. Most of the myomata were subserous (72.7%) and the mean diameter of the myomata was 3.5 K 0.9 cm. A control group (n J 367) was chosen with normal uteri and no history of uterine reconstruction surgery. The mean age of myoma patients was 34.7 K 3.6 years as compared to 34.0 6 4.4 years in the control group. The age, period of infertility, body mass index, duration and number of human menopausal gonadotrophin ampoules needed for stimulation, oestradiol levels, number of oocytes retrieved and the fertilization rate were not significantly different in the myoma patients compared to the control group. Fifteen myoma patients (38.5%) subsequently showed one or more pregnancy sacs on ultrasonography of which three (20%) spontaneously aborted during the first trimester and two (13.3%) had preterm labour, as compared to 123 (33.5%), 19 (15.5%) and nine (7.3%) respectively, among the control group (P J 0.27, 0.33 and 0.21). In conclusion, uterine corporeal myomata, not encroaching on the cavity < 7cm in mean diameter, don't affect the implantation or miscarriage rate in ivf or ic si (17)

Study done in Ethiopia at Addis abeba, St. Paul's Hospital Millennium Medical College, A Hospital-based retrospective cross-sectional study was conducted to determine pregnancy rate after myomectomy and its associated factors. On Patients who had myomectomy in SPHMMC from September 2012 to September 2017 were enrolled. Information was retrieved from hospital records and phone interviews with the patients. The strength of statistical association was measured by adjusted odds ratios and 9 5% confidence intervals. Statistical significance was declared at p value < 0.05. Among 180 females participated in this study, 52.2% got pregnant after myomectomy. The result showed that females with age > 35 years were 0.31 times less likely to get pregnant after surgery than those ages 20-25 years [AOR = 0.31 (95% CI: 0.29-0.54)]. People with no infertility before surgery were 1.19 times more likely to be pregnant after surgery than those with unexplained infertility before the surgery [AOR = 1.19 (95% CI: 1.06-1.57)]. People with two uterine incisions were 0.06 times less likely [AOR = 0.06 (95% CI: 0.043-0.51)] while those with three or more than three incisions were 0.02 times less likely [AOR = 0.02 (95% CI: 0.002-0.22)] to get pregnant compared with those with one incision on uterine wall. so they Concluded that age, number of incision, and infertility before surgery were significantly associated with rate of pregnancy after myomectomy.(2)

4. SIGNIFICANCE OF THE STUDY

The cause–effect relationship of myomata with infertility has not been clearly established, the inconclusive data evidence regarding the association between fibroids and fertility had made it difficult for clinicians to interpret the existing data and emphasize the need for high quality appropriately controlled studies. Thus, the primary aim of this study is to determine the effect of fibroid removal on clinical pregnancy (CP) and biochemical pregnancy rate, in women undergoing in vitro fertilization.

Furthermore the study will serve as a base line for those who want to do further research on the same topic

5. OBJECTIVE

5.1 general objective

- The main aim of the study is to describe the pregnancy outcome of patients in those who underwent myomectomy among women's seeking infertility service at center for fertility and reproductive medicine of Saint Paul's hospital millennium medical college, Addis Ababa, Ethiopia

5.2 specific objective

- To describe the pregnancy outcome of IVF after myomectomy.

6. METHODOLOGY

6.1 study area

The study will be undertaken at the fertility clinic, in Saint Paul's Hospital Millennium Medical College in Addis Ababa, capital city of Ethiopia. Saint Paul's hospital is one of the teaching and tertiary referral hospitals directly under the federal ministry of health. The hospital gives service to 200,000 people annually, who are referred from all corners of the country. It has a total bed of 360, and on average 650 patients visit the hospital as outpatient and emergency daily. It gives service under different clinical disciplines which include obstetrics and gynecology. Fertility clinic is under OBGYN department located around haya hulet which gives infertility related services. Around 1,800 women receive infertility care in the hospital annually (Statistics office of the hospital).

6.2 study design and period

A retrospective electronic medical record review will be conducted during the study period at the CFRM of SPHMMC.

6.3 Populations

6.3.1 Source population

All women who came to the fertility center for infertility workup and management within the study period.

6.3.2 Study population

The study population will be all women presented with myoma and infertility in fertility clinic at SPHMMC with in the study period.

6.4 Inclusion and exclusion criteria

6.4.1 Inclusion criteria

- Include all women for whom IVF was done after myomectomy.

6.4.2 Exclusion criteria

- Women who previously underwent myomectomy.
- Incomplete medical records.

6.5 Sample size and sampling procedure

Purposive sampling will be used and all women who had myomectomy and ivf recorded in the log book of the CFRM within the study period that are eligible according to the inclusion criteria's will be reviewed.

6.6 study variables

6.6.1 Dependent variables

Clinical pregnancy

6.6.2 Independent variables

- I. Socio Demographic Characteristics
 - Age
 - Place of residency
- II. Reproductive Characteristics
 - Gravidity
 - Parity
 - Abortion history
- III. Mode of myomectomy
 - Laparoscopic
 - Laparotomy
 - hysteroscopic
- IV. Location of the myoma
 - Subserosal
 - Submucosal
 - Intramural
 - Submucosal and intramural

6.6.3 Operational definition

myomectomy: A procedure done to remove myoma

Invitro fertilization: a procedure in which eggs are removed from a women's ovary and combined with the sperm outside the body to form embryos

Clinical pregnancy rate; cases of sonographic fetal cardiac activity/ total# ART cycle

Abortion is the process of pregnancy termination before the gestational age of viability (28 weeks/07months).

Infertility is one year unprotected sexual intercourse without conception.

6.7 DATA COLLECTION

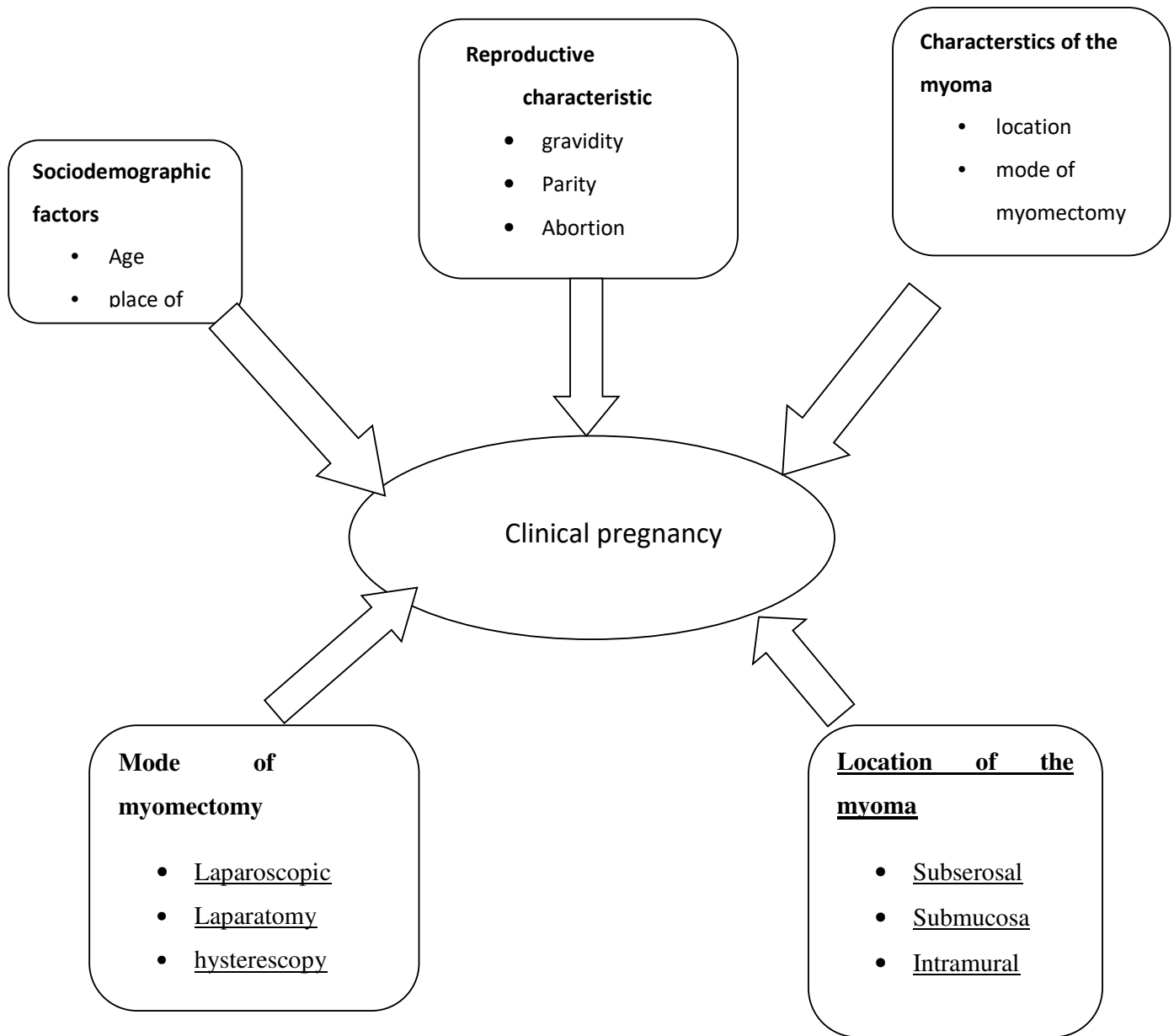
After clearly defining the Objectives of the Study, data will be collected with a check list through electronic medical record reviewing at fertility center in SPHMMC . All data will be collected and stored anonymously. .

6.8 DATA QUALITY ASSURANCES

Pretesting of the check list will be conducted on ten electronic medical records of women who underwent IVF with myomectomy procedure done at fertility center in SPHMMC in the study period, and appropriate modification will be applied if there is. Data collectors will be trained at fertility Center for 02 consecutive days by the principal investigator in pre-tested check lists.

All filled check lists will be checked on daily basis for completeness, accuracy, and consistency by the principal investigator. Supervision will be carried out by the principal investigator throughout the data collection.

7) Conceptual framework



8. DATA PROCESSING AND ANALYSIS

After data collection, each check list will be checked for completeness before entering to software. Data will be entered in to SPSS version 20 statistical package. Coding of individual check

list will be checked before data entry in to the software. Further, data cleaning will be performed to check for outliers, missed values and any inconsistencies before the data analysis.

Data will be analyzed using SPSS 20.0 version. Bilvariate and Multivariate logistic regression will be used to identify independent factors associated with effect of myomectomy on ivf outcome.

9. RESULT DISSEMINATION PLAN

The final result of this paper will be submitted to SPHMMC department of obstetrics and gynecology and public health department. There will be presentation of the research outputs to the college community and other concerned stakeholders. Manuscript will also be prepared and sent for publication to reliable journals.

10. ETHICAL CONSIDERATION

Ethical clearance will be obtained from the Institutional Review Board (IRB) of SPHMMC. Permission to conduct the study will be taken from the hospital administration. Confidentiality will be maintained during data collection, analysis and interpretation. To ensure confidentiality of participants, we will not collect or store any identifying information about participants.

11)Result

There were around 85 myomectomy done prior to IVF at center of fertility in SPHMMC during the study period from (April 1, 2019 – December 30, 2022)

11.1) Sociodemographic characteristics of respondents

Around 53(62.4%) of participants age were ≤ 35 years while 32 of the participants were >35 , from the participants 82(96.5%) were from urban area

Table1. Sociodemographic factors

		Ferquency	Percent
Age	≤ 35	53	62.4
	>35	32	37.6
Place of residency	Urban	82	96.5
	Rural	3	3.5

11.2) Obstetric characteristics of the respondent

Sixty-two (72.9%) of respondents were nuligravids and 21.2% of the respondents has history of previous pregnancy loss.

Table2. Obstetric characteristics

		Frequency	Percent
Gravidity	Nuligravid	62	72.9
	Primigravid	18	21.2
	Multigravid	5	5.9
Parity	Nuliparous	78	91.8
	Primiparous	6	7.1
	Multiparous	1	1.2
Previous pregnancy loss	Yes	18	21.2
	No	67	78.8

11.3) Characteristics of the myoma

Fourty-six (54.1%) of respondents had intramural and 23 of them had both intramural and sub mucosal myoma prior to myomectomy and 71 of the myoma were removed with laparatomy.

Table3. characterstics of the myoma

		Frequency	Percent
Location of myoma	Intramural	46	54.1

	Submucosal	16	18.8
	Both intramural and submucosal	23	27.1
Type of myomectomy done	Hysteroscopy	14	16.5
	Laparotomy	71	83.5

11.4) Type of IVF protocol used

From 85 of the participants 60 (70.6%) of them used minimal stimulation protocol during IVF followed by long protocol with a frequency of 18 (21.2%)

Table4. Type of IVF protocol

IVF PROTOCOL	Frequency	Percent
Antagonist	18	21.2
Long	7	8.2
Mildstimulation	60	70.6

11.5) clinical pregnancy

From 85 of the participants 31(36.5%) achieved clinical pregnancy after myomectomy was done prior to IVF.

Table5. Clinical pregnancy

Clinical pregnancy	Frequency	Percent
Yes	31	36.5
No	54	63.5

11.6) Age of patient * clinical pregnancy

Chi-square statistics were used to examine the association between age and clinical pregnancy. The analysis indicates that there is association (1 degree of freedom, p-value (0.03)

Table6. cross tab of age * clinical pregnancy

Clinical pregnancy	<=35	>35
Yes	24	7
No	29	25

11.7) type of IVF protocol * clinical pregnancy

Chi-square statistics were used to examine the association between type of ivf protocol and clinical pregnancy. The analysis indicates that there is association (1 degree of freedom, p-value 0.15)

Table7. crosstab of type of IVF protocol * clinical pregnancy

		Antagonist protocol	Long protocol	Mild stimulation protocol
Clinical pregnancy	Yes	7	6	18
	No	11	1	42

12) Discussion

IVF outcomes appear to be improved by judicious removal of clinically significant fibroids (16). Myomectomy is found to significantly increase conception rate in women with myomas as a sole factor of infertility. The conception rate following myomectomy ranged from 25 to 77% in available retrospective studies (18)

It is our policy, not to allow patients with myomata which distort uterine cavity or large in size to undergone IVF prior to myomectomy, which is similar to Egypt (7)

In this study, there were 85 womens who undergone myomectomy prior to IVF from those participants 31(36.5%) Of them achived clinical pregnancy,this result is comparable with those done at pennsylvania with outcome of 34 clinical pregnancies (37%) (13) also in resarch done at cleaviland with clinical pregnancy rate of (49%) (16)

In this study, a significant proportion (28.2%) of the participants who achieved clinical pregnancy were ≤ 35 years (p -value=0.03) this association might be due to a large proportion of the participants (62.4%) were age ≤ 35 . And participants with age of >35 were 37.6% which is similar with study done in Egypt where (25%) of the participants were above age 35 and this might be due to low socioeconomic status, tradition, delay in seeking medical attention or preference to exhaust means of spontaneous pregnancy, whether medical or surgical, before resorting to assisted reproduction.(7)

In this study a significant higher proportion of (21.1%) of the participants who achieved clinical pregnancy used the mild stimulation protocol (p -value=0.015), this association may be due enrollment of a large number of participants in this IVF protocol (70.6%)

13) Conclusion

This study showed that clinical pregnancy after myomectomy was 36.5% and age ≤ 35 and mild stimulation IVF protocol were associated with the clinical pregnancy.

14) Limitation

- The limitation of the study is data collection was from secondary source and being retrospective made it difficult to get all the information needed.

15) Recommendations

For researchers

- Recommended to conduct further prospective comparative studies with a larger sample size to confirm the role of myomas, and their removal ,on IVF outcomes before advocating for routine myomectomy amongst women undergoing IVF treatment.

16. Budget

- Table 8

Description	No. of participant	N. of days	Total cost (ETB)
Data entry clerk	6	10	9,000
Supervisor	3	10	9,000
Secretarial work	1	20	4,000
Statistician	1	10	4,000
Sub total	11		26,000

➤ Table 3

Item	Unit cost (ETB)	Multiplying factor	Total cost (ETB)
Office supplies	1000	3	3,000
Transportation	40	30	1,200
Photo copy and print for Proposal	1	100	100
Photo copy and print for final Research paper	1	100	100
Sub total			4,500

Grand total = personal budget + stationary budget
26,000 + 4,500 = 30,500 ETB

Person to contact

This research project was reviewed and approved by the IRB SPHMMC. If you have any question you can contact the following individual and you may ask any time you want.

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ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research proposal and for provision of required progress reports as per terms and conditions of the St. Paul's Hospital and Millennium Medical College in effect at the time of grant is forward as the result of this application.

Name of student_____

Date_____

signature_____

APPROVAL OF THE FIRST ADVISOR

Name of first advisor_____

Date_____

signature_____

17. Check List

Part 1.Demographic characteristics

1. Patient ID no.....
- 2 . Age a)<=35 b)>35
3. Parity.... a)nulli parous b)primiparous c)multiparous
- 4) Gravidity A)nulli gravid B)primigravid c)multigravid
- 5) previous pregnancy loss a)yes b)no
- 6) prior myomectomy a)yes b)no

Parts 2 state of pregnancy (clinical pregnancy)...

- .
- 1) yes 2] No

Part 3-characterstics of the myoma

- 1) Location of myoma
 - 1, subserosal
 - 2, submucosal
 - 3, intramural
 - 4, both intramural and submucosal
- 2) Type of myomectomy done
 1. Laparatomy
 2. Laparoscopic
 3. HYSTEROSCOPIC
- 3) Type of infertility a. Primary b. secondary

18. REFERENCE

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