PREGNANCY OUTCOMES AFTER MYOMECTOMY IN INFERTILE WOMEN WITH FIBROIDS:

A SYSTEMATIC REVIEW OF THE LITERATURE

A THESIS

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Abstract

Objectives: To analyze the impact of abdominal myomectomy on pregnancy outcomes of infertile women with fibroids, and to conduct a comparative effectiveness study of abdominal and laparoscopic myomectomy.

Study design: A systematic review of all relevant literature in MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) from inception to November 2015 respectively. English language restriction was applied to searches.

Results: Out of 352 articles identified by literature search, and subsequently reviewed, six articles met the study inclusion criteria, three case series on effectiveness studies and three studies (one RCT, one cohort, one case series) on comparativeness effectiveness studies. There was a very low quality of strength of evidence for effectiveness studies though they support the hypothesis that pregnancy outcomes are improved after abdominal myomectomy. Furthermore, the comparative effectiveness studies showed no statistical significant difference in pregnancy outcomes.

Conclusion: There is need for further research to be conducted.

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CHAPTER ONE

INTRODUCTION

Fibroids are benign non-cancerous growths of the uterine muscle with zero potential of a malignant transformation (Mayo Clinic, 2014). Fibroids are seen in about 25% of women of reproductive ages (Gale Encyclopedia, 2008). They are the most common benign tumors in the genital tracts of adult females; 3 out of 4 women have fibroids at some point in time in their lifetime (Mayo Clinic, 2014). Fibroids develop in women between the ages of 30-50years and are unlikely to occur in women in their 20's (Gale, 2008). Overall, fibroids are an incidental finding during a pelvic examination or ultrasound (Mayo Clinic, 2014).

In addition to other symptoms caused by fibroids, depending on their size, number and location, such as heavy menstrual difficulties, frequent urination, constipation, pain, difficulty emptying the bladder and leg pain, there is a 3% risk of infertility associated with fibroids (Gale Encyclopedia, 2008).

Fibroids may affect different parts of the uterus and they pose different problems for pregnancy. Subserosal fibroids grow outwards into the serosa and may cause pelvic pressure effects and pain; intramural fibroids grow within the uterine muscle, and may distort the shape of the uterus if large enough, and may cause prolonged heavy menstruations, pain and pressure; and submucosal fibroids grow into the uterine cavity distorting the shape of the cavity, and also cause heavy menstruations and problems for women trying to become pregnant (Mayo Clinic, 2014). Fibroids that are intramural or submucosal have been associated with higher risks of infertility compared to fibroids located elsewhere (Mayo Clinic, 2014).

Infertility is defined as the failure to achieve a clinical pregnancy after 12 months or more of regular (at least 3 times during ovulation week) unprotected sexual intercourse (WHO, 2014). Infertility is described as primary infertility if the couple has no existing children and secondary infertility if they have children already that were conceived naturally

(WHO, 2014). Infertility is a common medical condition with psychological, economic, cultural and medical consequences (Kuohung, et al, 2014). One in four couples in the developing world suffers from infertility (WHO, 2017). Because infertility involves a couple and not just an individual (Kuohung, et al, 2014), it is important for male factor related causes of infertility to be excluded before fibroids can be attributed as the only plausible cause of infertility in a woman without other explainable causes of infertility. Uterine factors that cause implantation difficulties such as uterine leiomyomas (fibroids) or uterine anatomic abnormalities could result in infertility, and should also be ruled out before attributing infertility to fibroids.

The treatment of symptomatic fibroids ranges from watchful waiting for small fibroids, to drug therapy (Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), Gonadotrophin Releasing Hormone (GnRH), Intra-Uterine Device (IUD)) and newer non-invasive procedures such as focused ultrasound therapy (FUS), and finally to the invasive procedures (Mayo Clinic, 2014) for bigger and more problematic fibroids. Invasive procedures for the treatment of fibroids for women who want to preserve their uterus are either the minimally invasive procedures, which includes the laparoscopic myomectomy, or the more invasive traditional surgical procedure, which includes the abdominal myomectomy for women wishing to preserve their uterus (Mayo Clinic, 2014). The effectiveness of myomectomy, on subsequent desired pregnancy outcomes, after the surgery for infertile women with fibroids, is controversial.

Definition of Terms

Myomectomy: the surgical removal of a fibroid without removing the uterus.

Abdominal myomectomy: a myomectomy performed by opening up the abdominal wall with a wide incision and having direct visualization of the uterus, also known as open myomectomy.

Laparoscopic myomectomy: a minimally invasive procedure performed by inserting a laparoscope through a small incision on the abdomen.

Purpose of Literature Review

The purpose of this literature review is to analyze the impact of myomectomy on pregnancy outcomes of infertile women with fibroids. This literature review seeks to ascertain the role of myomectomy among infertile women identified as having a coexisting fibroid. This analysis will help to understand the outcomes associated with a myomectomy surgery for the treatment of infertility in women with fibroids. In addition, a comparative effectiveness study of two procedures for performing myomectomy, abdominal and laparoscopic, will be conducted in order to appreciate the impact of the newer laparoscopic technological procedure on pregnancy outcomes.

Research Questions

1) What is the impact of abdominal myomectomy on pregnancy outcomes?
- What is the pregnancy rate before and after abdominal myomectomy in infertile women with fibroids who wish to conceive?
- What is the live birth rate before and after abdominal myomectomy in infertile women with fibroids who wish to conceive?
- What is the miscarriage rate before and after abdominal myomectomy in infertile women with fibroids who wish to conceive?

2) How does abdominal myomectomy compare to laparoscopic myomectomy for pregnancy rates, miscarriage rates and live birth rates after myomectomy?

CHAPTER TWO

METHODS

Eligibility criteria

The study characteristics with reference to participants, interventions, comparisons, outcomes, and study design (PICOS) are-

- Participants: Infertile women with fibroids
- Intervention: Abdominal Myomectomy
- Comparison: No treatment for fibroids; Laparoscopic myomectomy
- Outcomes: Pregnancy (Pregnancy rate, Live birth rate, Miscarriage rate)
- Study designs: All studies

Only records published in English were included in the literature review.

Inclusion criteria for systematic review

1). Unexplainable infertility in reproductive aged women with fibroids

2). Elective myomectomy for infertility: abdominal or laparoscopic

3). Desire to conceive

Exclusion criteria for systematic review

1). Explainable cause of infertility other than fibroids

2). Intrapartum myomectomies

3). Caesarian section myomectomies

Information sources

Ovid Medline, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL) databases were used as information sources. Publications from inception to date of final search 11/6/2015 identified using the search strategy were used.

Search strategy

Figure 1: Ovid Medline ®, Embase Search Strategy

Ovid MEDLINE(R), Embase		
#	**Search Statement**	**Results**
1	*myomectomy/	1766
2	*leiomyoma/su [Surgery]	5755
3	uterine myomectom*.mp.	386
4	(uterine adj3 (fibro* or myoma*) adj3 surg*).mp.	520
5	1 or 2 or 3 or 4	7822
6	*pregnancy/	194984
7	*pregnancy outcome/	25342
8	live birth*.mp.	40388
9	*infertility/	20498
10	*fertility/	38116
11	*infertility, female/	30606
12	6 or 7 or 8 or 9 or 10 or 11	337108
13	5 and 12	454
14	limit 13 to English language	363
15	limit 14 to human	335
16	remove duplicates from 15	269

Figure 2: CENTRAL Search Strategy

Search Name:
Date Run: 06/11/15 19:04:43.593
Description:

ID Search Hits
#1 MeSH descriptor: [Uterine Myomectomy] explode all trees 20
#2 MeSH descriptor: [Leiomyoma] explode all trees and with qualifier(s): [Surgery - SU] 235
#3 leiomyoma surg* 314
#4 uterine myomectom* 274
#5 uterine adj3 (fibro* or myoma*) adj3 surg* 38
#6 {or #1-#5} 483
#7 MeSH descriptor: [Pregnancy] this term only 63
#8 live birth* 1853
#9 MeSH descriptor: [Infertility] explode all trees 2006
#10 MeSH descriptor: [Infertility, Female] this term only 1116
#11 MeSH descriptor: [Fertility] this term only 161
#12 {or #7-#11} 3811
#13 #6 and #12 46

Study selection

The articles identified by the search of Medline, Embase and CENTRAL databases were screened in an initial phase using the titles of the articles. This was followed by a screening using the abstracts of the articles. Subsequently, full text eligibility of the remaining articles was conducted using the eligibility criteria to select studies for the review and exclude others.

Data Collection Process

Each of the paper that was selected for this review was read and analyzed for its content on pregnancy outcomes following myomectomy. The following data were extracted and presented in tables: authors, year of publication, study design, purpose of study, sample

size, age range in years of participants, instrument used to collect information, setting of study and type of myomectomy, follow-up period following myomectomy, pregnancy rate, time to pregnancy, live birth rate and miscarriage rate.

Definition of Data Items

Pregnancy rate: percentage of women at the end of the follow-up period who achieve pregnancy.

Live birth rate: percentage of women at the end of the follow-up period who achieve a live birth.

Miscarriage rate: percentage of women at the end of the follow-up period who suffer a pregnancy loss.

Quality assessment

For each study, the retrieval of records, the inclusion and exclusion of patients from the study, the follow-up of patients and the outcome measures used were all critically appraised to ensure that they are appropriate for the study. Finally, the data analysis methods were critically appraised for appropriateness. Selection bias, Performance bias, Attrition bias and Detection bias were assessed for all the observational studies.

Using the domain-based evaluation for randomized controlled studies from Cochrane, the randomized controlled trial between abdominal myomectomy's and laparoscopic myomectomy's impact on pregnancy outcomes was assessed for risk of bias. The domain-based evaluation consists of the following domains: Random sequence generation (selection bias); Allocation concealment (selection bias); Blinding of participants and personnel (performance bias); Blinding of outcome assessment (detection bias); Incomplete outcome data addressed (attrition bias).

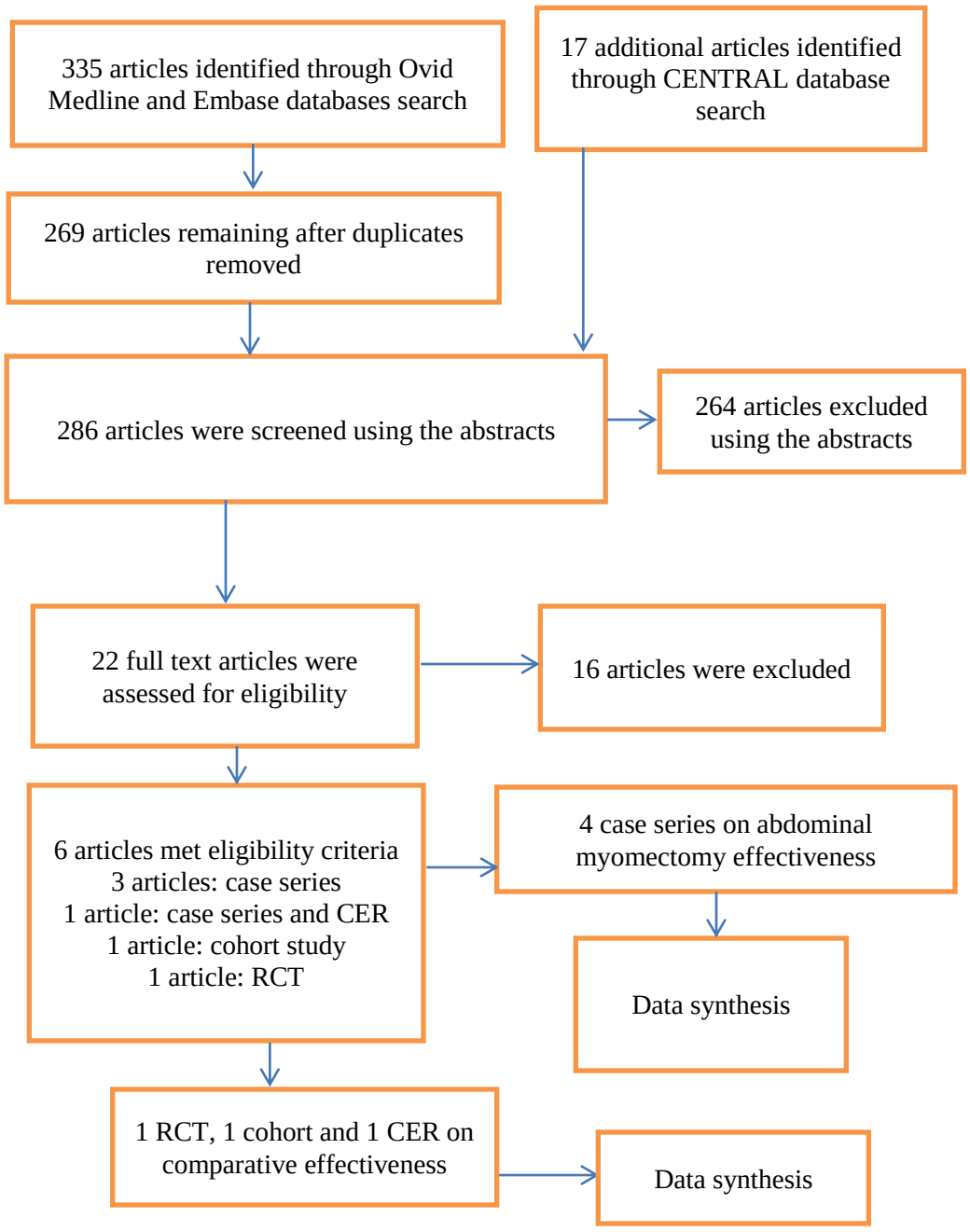
The strength of evidence across all studies was assessed with the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) Working group scoring system. It was conducted separately for the observational studies addressing the impact of

abdominal myomectomy, and for the randomized controlled study addressing the comparative effectiveness of abdominal and laparoscopic myomectomy.

CHAPTER THREE

RESULTS

Figure 3: Study Selection Flow Charts



Study characteristics for abdominal myomectomy effectiveness studies

For each study identified as eligible for the review, the authors, study design and year of publication of the study were noted. There were three case series addressing the effectiveness of abdominal myomectomy. These case series studies can be useful for developing hypothesis for future research on the role of abdominal myomectomy on pregnancy outcomes.

Li et al, 1999 study is a retrospective case series study of infertile women with fibroids that was performed at the Jessop Hospital for Women in Sheffield, UK. It examined the medical records of the Jessop Hospital to identify cases of myomectomy performed in women less than 45 years of age between May 1991 and December 1996. A total of 113 cases of myomectomies were identified by computer search and manual search of theatre operating records. 51 of these 113 cases were eligible for the Li et al study on the basis of the following inclusion criteria: "(i) they had laparotomy and myomectomy for intramural or sub-serosal fibroid(s); (ii) they wished to conceive shortly after surgery; (iii) they had no other significant infertility factors, i.e. tubal disease, abnormal semen analysis of the partner." No exclusion criteria were provided. Of the eligible 51 patients, 19 had primary infertility, 11 had secondary infertility and 21 had no infertility. The study examined the pregnancy outcomes before and after myomectomy collectively for the 51 patients and separately in a sub-analysis for the 11 patients with secondary infertility and recurrent pregnancy losses. Unfortunately, the authors did not provide a sub-analysis for women with only primary infertility. There was a wide range of duration of follow-up post-myomectomy (3-60 months) with an average of 12.6 months. No clarifying information was provided by the authors on the wide range of duration of follow-up.

The Marchionni et al, 2004 study is a retrospective case series. It was conducted in an academic setting specializing in gynecologic surgeries, in Florence, Italy. 284 records of myomectomies performed between January 1996 and December 1998 were identified via a manual search of theatre operating records. Of these 284 records, 72 were considered

eligible for the study by the authors on the basis that they underwent myomectomy for intramural or sub-serosal uterine fibroids and the women desired to have a pregnancy after myomectomy surgery. The 212 records excluded were for the following reasons such as not seeking to have a pregnancy after the myomectomy or not being able to attend follow-up because they lived far away from the hospital in other parts of the country. All 72 patients gave informed consent to be followed up and for data collection. The 72 patients' records reviewed were followed up by collecting pregnancy outcomes from the theatre operating records. They were followed up regularly and usually seen twice a year when they came back to the hospital for their follow-up visits. The remaining patients not returning for follow-up visits were followed up by telephone. The duration of follow-up ranged from 48-83 months and no further information was provided by the authors on their reasons for wide range of follow-up.

The Vercellini, et al, 1999 study is a case series study that was conducted at the Department of Obstetrics and Gynecology, University of Milan, Italy. The study period under review was between 1990 and 1997. Using clinical records, 466 patient records were identified to have had abdominal myomectomy surgery within the study period. Of these 466 patient records, 138 were eligible for the study using the inclusion criteria identifying only abdominal myomectomies performed for intramural or sub-serosal uterine fibroids in patients with no other explainable causes of infertility. Post-myomectomy pregnancy outcomes were assessed for the impact of myomectomy during the follow-up period. Informed consent was obtained from all the patients to participate in follow up and collection of data on pregnancy outcomes. The patients were followed up regularly, at least twice a year, at their follow-up clinic visits, and for those who were not visiting by telephone and subsequent mailed questionnaire. The mean follow-up period was 41 months (9-103 months) and there was no loss to follow-up. The very wide range of follow-up was not explained by the authors.

Study characteristics for comparative effectiveness studies

There was one randomized comparison, one cohort study and one comparative effectiveness research study/case series study addressing the comparative effectiveness of the two procedures, abdominal and laparoscopic myomectomy. Seracchioli, et al, 2000 study is a randomized comparison of pregnancy outcomes after abdominal myomectomy versus laparoscopic myomectomy that was conducted at the Reproductive Medicine Unit, University of Bologna, Italy. This randomized comparison study involved 131 patients who had myomectomies between January 1993 and January 1998. After the informed consents were obtained, random digits were used to allocate the patients to either laparoscopic or abdominal myomectomy the day prior to surgery. Following the random allocation, 65 patients underwent laparotomy while 66 patients underwent laparoscopy. The same two investigating surgeons operated on all the patients. Post-myomectomy, the patients were followed up for pregnancy outcomes by using the hospital records, physicians' reports and direct reports from the patients. The follow-up period commenced after the 6 months waiting period for uterine scar repair and the mean follow-up was 32 months for the abdominal myomectomy group and 31 months for the laparoscopic myomectomy group. Only patients with a minimum follow-up period of 12 months were included in the study. 6/65 (0.09%) of women in the abdominal myomectomy group and 7/66 (0.11%) of women in the laparoscopic myomectomy group were lost to follow up. An additional 3 women in the laparoscopic group were excluded in the analysis because they had a laparoconversion which involved techniques for both abdominal and laparoscopic myomectomy. The pregnancy outcomes analysis was adjusted for attrition. The remaining 59 women in the abdominal group and 56 women in the laparoscopic group were analyzed for pregnancy outcomes.

The Tian, et al, 2015 study compared the pregnancy outcomes between abdominal and laparoscopic myomectomy. The study was a mixed cohort study that retrospectively and prospectively collected data for the purpose of identifying patients who underwent myomectomy for fertility requirement at the Beijing Obstetrics and Gynecology Hospital, China. Between, January 2005 to January 2013, a total of 268 records of myomectomies

were collected. Of these 268, 157 were retrospectively collected between January 2005 and December 2010, and 111 were prospectively collected between January 2011 and January 2013. Abdominal myomectomy surgery was conducted in 89 patients and laparoscopic myomectomy was conducted in 179 patients. Post-myomectomy follow-up pregnancy outcomes were obtained from medical records and by telephone contact. The mean follow-up time was 32.54 months and follow-up ended in December, 2013.

Campo et al, 2003 study is a comparativeness effectiveness research study and a case series study of women wishing to conceive with no other plausible infertility factors other than fibroids. The comparative effectiveness of abdominal and laparoscopic myomectomy was conducted alongside the before and after pregnancy outcomes rates for myomectomy. The authors used the medical records in this hospital-based study to retrospectively identify all cases of myomectomy within the study period, January 1990 to December 1996. A total of 128 patients were identified to have had a myomectomy within this study period. Of these 128, only 41 of these cases of myomectomy were eligible for the Campo et al study based on the inclusion and exclusion criteria for their study. All patients with tubal disorders; patients who had other surgeries during myomectomy (adhesiolysis, ovarian cyst excision, tubal surgery, endometriosis) and patients with partners with severe oligoastenospermia were excluded. Their study looked at the pregnancy and miscarriage rates before and after myomectomy in these 41 patients. 19 of these 41 patients had abdominal myomectomy (Group A) and the remaining 22 had laparoscopic myomectomy (Group B). In addition to comparing the before and after rates within each group for the case series, the Campo et al study also compared the rates between the groups submitted to abdominal or laparoscopic myomectomy respectively. Written informed consent was obtained from all the patients for the surgery and the patients were followed up post-myomectomy for fertility and pregnancy outcomes by telephone interview and questionnaires posted directly to the patients or their primary care physicians. Patients in group A were followed up for a mean length of 65 months (range 31-108) and those in group B for 45 months (range 27-106). The follow-up for a

patient was concluded when the patient either conceived or lost the desire to conceive. All follow-up was concluded in December 2000.

Patient and fibroid characteristics for abdominal myomectomy effectiveness study

For the three case series on pregnancy outcomes following abdominal myomectomy, patient and fibroid characteristics provided in the studies are described in Table 1 below. The table shows that Vercellini, et al study is the only study of the three case series in which 100% of the women had infertility as the primary indication for myomectomy compared to the Li, et al study (45%) and Marchionni, et al study (43%). The Li, et al and Vercellini, et al studies provided sub-classifications of primary and secondary infertility and Marchionni, et al study did not.

The table shows similarities in distribution of fibroid characteristics in all three case series for fibroid size, number and location. In all three studies, most women had only 1 or 2 fibroids, more than 50% of these fibroids were >5cm in diameter and about two thirds of the fibroids were intramural fibroids.

Table 1: Characteristics of study participants in effectiveness study

Characteristics	Li, et al	Marchionni, et al	Vercellini, et al
Primary indication Infertility Miscarriage Menorrhagia/pelvic mass	 45% 22% 33%	 43.0% 8.4% 48.6%	 100%
% with Primary Infertility % with Secondary infertility % with no infertility	37% 22% 41%		66% 34%
Parity			

0 1 2 3	80% 12% 4% 4%	72.2% 19.5% 8.3%	
Pregnancy loss 0 1 2 ≥3	 72% 16% 8% 4%	 77.8% 19.4% 2.8%	
Number of fibroids 1 2-3 ≥4 Unspecified	 43% 39% 12% 6%	 45.8% 29.2% 25.0%	 44% 27% 29%
Size of largest fibroid (cm) <5 ≥5 Unknown	 20% 78% 2%	 38.8% 58.4% 2.8%	 27% 73%
Location of largest fibroid with respect to uterine wall Intramural Subserosal Unknown	 80% 20%	 65.3% 29.2% 5.5%	 78% 22%
Location of largest fibroid with respect to uterine body Fundal Anterior Posterior Lateral Unknown		 33.3% 16.7% 26.4% 20.8% 2.8%	 35% 24% 30% 11%

Patient and fibroid characteristics for comparative effectiveness study

For each of the articles on studies that compared abdominal myomectomy to laparoscopic myomectomy with regard to their pregnancy outcome subsequent to the surgery, information provided by the authors on patient and fibroid characteristics for each intervention group are described in the table below. The table shows that the fibroid characteristics have similar distributions across the studies.

Table 2: Patient and fibroid characteristics for comparative effectiveness study

Characteristics	Campo, et al	Seracchioli, et al	Tian, et al
Percentage of patients AM LM	 46% 54%	 49.6% 50.4%	 33% 67%
Age (years)[a] AM LM	 33.1 ± 4.8 34.3 ± 3.7	 33.97 ± 4.79 34.00 ± 4.11	 30.87 ± 3.97 30.28 ± 3.99
Number of myoma per patient[a] AM LM	 2.95 ± 2.6 2.9 ± 2.0	 2.75 ± 1.98 2.94 ± 1.53	
Diameter of largest myoma (cm)[a] AM LM	 6.13 ± 2.76 4.41 ± 1.76	 7.47 ± 2.60 7.07 ± 2.54	 6.37 ± 1.30 6.20 ± 1.23
Location of myomas (AM; LM) Subserosal Intramural Reaching uterine cavity		 44.2%; 55.8% 52.9%; 47.1% 9.2%; 4.1%	 15.73%; 26.26% 84.27%; 73.74%

Parity before surgery AM; LM 0 1			 91.01%; 89.39% 8.99%; 10.62%

AM: abdominal myomectomy LM: laparoscopic myomectomy [a]mean ± standard deviation

Risk of bias

Table 3: Risk of bias: abdominal myomectomy effectiveness study

Entry	Study	Judgement	Support of Judgement
Selection bias	Li, et al	High risk	Quote: "Patients were identified by computer search and by manually going through the operating theatre records." Comment: There is insufficient information on the selection process and no identified control group.
	Marchionni, et al	High risk	Quote: "Patients were identified by a manual search of the operating theatre records" Comment: There is insufficient information on the selection process and no identified control group.

	Vercellini, et al	High risk	Quote: "Clinical records were retrieved for women who underwent first-line conservative surgical treatment..." Comment: The manner in which the clinical records were retrieved is not provided and there is no identified control group.
Instrumentation bias for the diagnosis of fibroids	Li, et al	High risk	Quote: "The information retrieved included… the location, number and size of the fibroid(s)." Comments: There is no specific mention of a preoperative sonographic diagnosis of fibroids.
	Marchionni, et al	High risk	Quote: "recent preoperative transvaginal ultrasound scans with surgical descriptions and pathologic reports" Comments: Pathologic reports occur after myomectomy and not with ultrasound scans.
	Vercellini, et al	High risk	Quote: "Data were

			collected on…number, size and location of the fibroids." Comment: No information on how the preoperative diagnosis of fibroids was made.
Performance bias (Data collection)	Li, et al	High risk	Quote: " The information retrieved included details and outcome of any pregnancy, either before or after surgery" Comment: There is no information on who conducted the data collection and if the process was standardized.
	Marchionni, et al	High risk	Quote: "Data were collected for demographic characteristics, number and outcome of pregnancies before and after surgery" Comment: There is no information on who conducted the data collection process and if the process was standardized.
	Vercellini, et al	High risk	Quote: "Data were collected on outcome of

			pregnancies" Comment: No information on who conducted the data collection process and if the process was standardized.
Attrition bias	Li, et al	High risk	Quote: "The duration of follow-up ranged from 3-60 months, and averaged 12.6 months." Comments: There is no information on loss to follow up. There is a very wide range of duration of follow up with no explanation for it. Pregnancy outcomes were only reported in 29 of the 51 patients.
	Marchionni, et al	High risk	Quote: "After surgery, most of the 72 patients were seen regularly, usually twice per year." "Follow-up information for the remaining patients not attending regular visits was obtained by telephone." Comments: Information on follow-up lacks clarity and is insufficient. Authors did not provide specific

			numbers for patients seen regularly and for those lost to follow up. It is not clear what the authors mean by "most of the 72".
	Vercellini, et al	High risk	Quote: "after a mean follow-up of 41 months (range, 9-103 months), 76 (55%) of 138 infertile women became pregnant" Comments: There was no information on the reason for the wide range of follow-up for women in the study. It is unclear if all the women in the study had an equal opportunity of follow-up to achieve pregnancy outcomes.

Table 4a: Risk of bias: Comparative effectiveness studies

Entry	Study	Judgement	Support for Judgement
Selection bias	Campo, et al	High risk	Quote: "From January 1990 through December 1996, 128 patients under 42 years underwent myomectomy" Comment: There is no information on how they searched the medical records and how the treatment groups

			were assigned.
	Tian, et al	High risk	Quote: "268 patients who had fertility requirements following myomectomy" Comment: There is insufficient information on the sample selection process from the medical records and on how the treatment groups were assigned.
Instrumentation bias for the diagnosis of fibroids	Campo, et al	Moderate risk	Quote: "All patients had been submitted to preoperative sonography" Comments: There is lack of information on the expertise of the personnel who conducted the sonography.
	Tian, et al	Moderate risk	Quote: "pelvic examination or transvaginal ultrasound or transabdominal ultrasound" Comments: Different methods were applied to diagnose fibroids rather than one standardized procedure.
Performance bias (Data collection)	Campo, et al	Moderate risk	Quote: "Follow-up data regarding fertility and pregnancy outcomes were collected by telephone

			interview or a questionnaire posted to the patients or to their primary care physician." Comment: The study did not tell if this was conducted by the authors or other persons.
	Tian, et al	Moderate risk	Quote: "we collected the data regarding the obstetric characteristics from the hospital medical records" and "through the phone directly." Comment: Insufficient details on who conducted the data collection and the number of patients whose data were collected from medical records or by phone.
Attrition bias	Campo, et al	High risk	Quote: "The follow-up was concluded in December 2000." "The follow-up has been considered concluded when the patient has lost her wish to conceive" Comments: There is no information on why they lost their wish to conceive. There is no information on the attrition rate.
	Tian, et al	High risk	Quote: "The follow-up work

			was carried out until the patients had pregnancy outcomes." "The follow-up work was finished on December 2013". Comment: Not all patients had pregnancy outcomes. Only 138/268 women had pregnancy outcomes. The follow-up ended less than a year after the study period. Pregnancy outcome analysis was only conducted for 138 women.

Table 4b: Risk of bias for Randomized Controlled Study

Entry	Study	Judgement	Support for Judgement
Random sequence generation (selection bias)	Seracchioli, et al	Low risk	Quote: "by means of random selection" Comment: Probably done.
Allocation concealment (selection bias)	Seracchioli, et al	Moderate risk	Quote: "by use of total random digits" Comment: Probably done.
Blinding of participants and personnel (performance bias)	Seracchioli, et al	Moderate risk	Quote: "Assignment to laparotomy or laparoscopy took place after the patients had consented to surgery"

			Comment: Blinding of patients and surgeons could only occur before consent to surgery.
Blinding of outcome assessment (detection bias)	Seracchioli, et al	Moderate risk	Quote: "obtained from hospital records, physicians and direct reports from the patients" Comment: No information on who collected the data and on blinding of assessment.
Incomplete outcome data addressed (attrition bias)	Seracchioli, et al	High risk	Quote: "followed up for almost one year" "Six patients in group 1 (0.09%) and seven in group 2 (0.11%) were lost from our study" Comment: The follow-up period was for less than a year.

Table 5: Strength of Evidence for Observational Studies

	Score	Basis
Initial score	+2	Observational studies
Quality	-1	Follow-up and withdrawals
Consistency	-1	Lack of agreement between studies
Directness	-1	Population from case series are not broadly generalizable to our population of interest

Effect size	0	Outcome rates mostly not significant
Final GRADE score	-1	Very low strength of evidence

Table 6: Strength of Evidence for RCT

	Score	Basis
Initial score	+4	RCT
Quality	-1	Sparse data. Less than 200 women (131) were included in the study analysis.
Consistency	-1	There is only one RCT study.
Directness	0	Population and outcomes from the RCT is broadly generalizable to our population of interest.
Effect size	0	There was no significant difference between abdominal and laparoscopic myomectomy for pregnancy outcomes.
Final GRADE score	+2	Low strength of evidence

Table 7: Quality assessment for incomplete data reporting/analysis: effectiveness studies

Study	Assessment
Li, et al	There was no sub-analysis for the impact of primary infertility versus secondary infertility on pregnancy outcomes following myomectomy.
Marchionni, et al	There was a sub-analysis for the role of primary versus secondary infertility on pregnancy rates following myomectomy. "Patients with primary infertility had a pregnancy rate of 67.7% (21 of 31) compared with 73.2% (30 of 41) for patients with secondary infertility (difference not significant)."

Vercellini, et al	There was no sub-analysis for the impact of primary infertility versus secondary infertility on pregnancy outcomes following myomectomy.

Table 8: Quality assessment for incomplete data reporting/analysis: comparative effectiveness studies

Study	Assessment
Campo, et al	The sub-analysis to assess the impact of previous pregnancies on conception after myomectomy showed no statistical significant difference (p=0.176) in conception rates of those previously pregnant and those not previously pregnant.
Seracchioli, et al	There was no sub-analysis for the role of primary and secondary infertility on pregnancy outcomes following myomectomy.
Tian, et al	The sub-analysis for demographics and leiomyoma characteristics show no statistically significant difference in parity before surgery for women with transabdominal myomectomy versus laparoscopic myomectomy (p=0.677).

Study Outcomes: Abdominal Myomectomy Effectiveness

Table 9a: Campo, et al Pregnancy outcomes before and after myomectomy

Study Group	Variable	Before Myomectomy	After Myomectomy
Abdominal myomectomy (n=19)	Number of pregnancies	17	15
	Proportion of women who became pregnant	7/19	11/19
	Delivery rate	40%	80%
Laparoscopic myomectomy (n=22)	Number of pregnancies	11	14
	Proportion of women who became pregnant	7/22	14/22

	Delivery rate	36.4%	93%
	Total number of pregnancies	28 (14/41 women)	29 (29/41 women)

Table 9a shows that out of the 19 infertile women who submitted to abdominal myomectomy, 7 infertile women had previously been pregnant (secondary infertility) and consequently, 12 infertile women had not been previously pregnant (primary infertility). No information was provided by the authors on the individual parities of these 19 infertile women. After abdominal myomectomy for these 19 infertile women, over a 10 year period of follow-up post-abdominal myomectomy, a total of 11 women achieved pregnancy. The authors did not provide information on the subgroup pregnancy outcomes after abdominal myomectomy for primary and secondary infertility. However, the authors conducted a sub-analysis which showed that there was no impact on pregnancy rates following myomectomy by previous pregnancies (p=0.176).

The authors reported the delivery rate as 40% of 17 pregnancies achieved before abdominal myomectomy (Table 9a) with a corresponding 60% miscarriage rate (Table 9b). After abdominal myomectomy, the delivery rate increased to 80% of the 15 pregnancies achieved (Table 9a) with a corresponding decrease in miscarriage rate to 20%. The difference in pregnancy loss was not statistically significantly different (p=0.06).

Table 9b: Campo et al, Pregnancy loss before and after myomectomy

Study	Group	Before Myomectomy	After Myomectomy	P-value
Campo, et al 2003	Abdominal myomectomy	9/15 (60%)	3/15 (20%)	0.060
	Laparoscopic myomectomy	7/11 (63%)	1/14 (7.1%)	0.007
	Total	16/26 (61.5%)	4/29 (13.8)	<0.001

In the Li, et al study, of the 51 women in the study, 19 women had pregnancies before the myomectomy surgery and 29 women had pregnancies after the myomectomy surgery. There were a total of 40 pregnancies before myomectomy and 33 pregnancies after myomectomy (Table 10). Of the 40 pregnancies that occurred before myomectomy, 24 pregnancies (60%) were lost in miscarriages and 16 pregnancies (40%) resulted in live births. On the other hand, of the 33 pregnancies after myomectomy, there were 8 pregnancies (34%) lost after myomectomy and 25 live births (76%) achieved. The pregnancy losses and live births before and after myomectomy were significantly different ($p<0.001$) in the Li, et al study.

Table 10: Li, et al outcomes

Variable	Before myomectomy n (%)	After myomectomy n (%)
Subjects in the study	51	51
Subjects who became pregnant	19	29
Total number of pregnancies	40	33
Pregnancy loss		
First trimester	16 (40)	8 (24)
Second trimester	7 (17)	0 (0)
Third trimester	1 (3)	0 (0)
Total[a]	24 (60)	8 (24)
Live birth[a]	16 (40)	25 (76)

[a]Results before and after myomectomy are significantly different ($P < 0.001$).

Table 11: Marchionni, et al outcomes

Variable	Before myomectomy n (%)	After myomectomy n (%)
Subjects in the study	72	72
Subjects who became pregnant	20	51
Total number of pregnancies	26	68

Pregnancy loss		
First trimester	14 (54)	15 (22)
Second trimester	3 (11)	—
Third trimester	1 (4)	—
Ectopic	_	2 (3)
Total[a]	18 (69)	17 (25)
Live birth[a]	8 (31)	51 (75)

[a]Results before and after myomectomy are significantly different (P < .001)

Table 11 shows the pregnancy outcomes in the Marchionni, et al study. There were statistically significantly different pregnancy losses and live births rates before and after myomectomy ($p<0.001$). The total number of pregnancies before and after myomectomy was 26 and 68 respectively. Pregnancy losses reduced from 69% of pregnancies before myomectomy to 25% of pregnancies after myomectomy while the live birth rates increased from 31% to 75%.

The Vercellini, et al outcomes is outlined in Table 12 below. Percentage of women who became pregnant increased from 34% before myomectomy to 55% after myomectomy. No information was provided for live births and miscarriage rates before myomectomy for the 138 women who had infertility as the main or only indication for myomectomy.

Table 12: Vercellini, et al outcomes

Variable	Before myomectomy	After myomectomy
Number of women	138	138
Number of women who became pregnant	47 (34%)	76 (55%)
Number of live births	No information	68
Number of first semester abortions	No information	2
Number of voluntary termination of pregnancy	No information	2

Study Outcomes: Comparative Effectiveness

The randomized comparison by Seracchioli, et al did not reveal any statistically significant differences between the pregnancy outcomes of women who had abdominal myomectomy and those with laparoscopic myomectomy (Table 13). Likewise, the pregnancy outcomes from the Tian, et al study outlined in Table 14 did not show any statistically significant difference in number of conceptions, miscarriage rates and live birth rates for abdominal and laparoscopic myomectomy. Lastly, the Campo, et al study showed no statistically significant difference in pregnancy outcome for type of surgery (p=0.707). No information was provided by the Campo et al study on comparativeness effectiveness for miscarriage and live birth rates.

Table 13: Seracchioli, et al outcomes

Pregnancy outcome	Abdominal myomectomy	Laparoscopic myomectomy
Pregnancy rate (%)	33/59 (55.9)	30/56 (53.6)
Abortion rate (%)	4 (12.1)	6 (20)
Ongoing pregnancy	2	3
Ectopic pregnancy	0	1
Deliveries (%)	27/59 (48)	20/56 (36)
Preterm deliveries (%)	2 (7.4)	1 (5)
Vaginal deliveries	6 (22.2)	7 (35)
Caesarian sections (%)	21 (77.8)	13 (65)
Uterine rupture	0	0

There were no significant differences between the groups.

Table 14: Tian, et al outcomes

Pregnancy outcome	TAM (n=57)	LAM (n=81)	P-value
Pregnancy number (%)[a]	59	82	0.694
Pregnancy mode			1.000
Spontaneous pregnancies	54 (91.53)	76 (92.68)	
Assisted reproductive pregnancies	5 (8.48)	6 (7.32)	

Miscarriage (%)[a]	5 (8.48)	9 (10.98)	0.624
Induced abortion (%)[a]	3 (5.09)	3 (3.66)	1.000
Ectopic pregnancy (%)[a]	4 (6.78)	2 (2.44)	0.403
Ongoing pregnancy (%)[a]	1 (1.70)	7 (8.54)	0.173
Live birth (%)[a]	45 (76.27)	61 (74.39)	0.799
Preterm birth (%)[a]	5 (11.11)	3 (4.92)	0.412
Term birth (%)[a]	40 (88.89)	58 (95.08)	0.412
Caesarian section (%)[a]	24 (53.33)	20 (32.79)	0.034
Obstetric complications			
Fetal distress (%)[a]	2 (4.44)	2 (3.28)	1.000
Placenta previa (%)[a]	3 (6.67)	2 (3.28)	0.727
Postpartum hemorrhage (%)[a]	4 (8.89)	7 (11.48)	0.913
PROM	2 (4.44)	2 (3.28)	1.000
Uterine dehiscence (%)[a]	0	4 (4.94)	0.235
Fetal weight[b]	3164.11 ± 397.25	3240.79 ± 594.52	0.205

[a]Values are expressed by mean ± SD. [b]Values are expressed by relative frequency.

Table 15: Campo, et al comparative effectiveness outcomes

Type of surgery	Pregnant (%)	Not pregnant (%)
Laparotomy	11 (44.00)	8 (50.00)
Laparoscopy	14 (56.00)	8 (50.00)

There were no statistical significant difference for type of surgery (p=0.707).

CHAPTER FOUR

Discussion (1): abdominal myomectomy effectiveness

The place of myomectomy in improving fertility and pregnancy outcomes in infertile women with fibroids is still controversial. The review on the effectiveness of abdominal myomectomy on pregnancy outcomes yielded four case series studies. Collectively, these case series studies had a very low quality of strength of evidence using the GRADE scoring system with a total score of -1. The case series studied groups of infertile women with fibroids, including women with primary infertility (no previous pregnancy), and those with secondary infertility (have previous pregnancies). The impact of abdominal myomectomy in each of these case series studies was studied by assessing the pregnancy outcome rates before and after myomectomy collectively for all women in each study. Two of the case series studies, Marchionni, et al and Campo, et al, conducted a sub-analysis for the role of primary versus secondary infertility on pregnancy rates after abdominal myomectomy. Both studies found no statistically significant difference in pregnancy rates after myomectomy for the groups of women with primary versus secondary infertility (Campo, et al $p=0.176$). The Li, et al and Vercellini, at al studies did not conduct sub-analyses to assess the role of primary versus secondary infertility in the pregnancy outcomes after myomectomy.

For the pregnancy outcomes after abdominal myomectomy, two of the case series showed a statistically significant difference for pregnancy outcomes before and after abdominal myomectomy. The other two case series studies both showed an improved pregnancy outcome after abdominal myomectomy compared to before abdominal myomectomy, with no statistical significance reported or present. The Marchionni, et al and Li, et al studies both show a statistical significant ($p<0.0001$) increase in live birth rates after abdominal myomectomy compared to before abdominal myomectomy, with a corresponding statistically significant decrease in the pregnancy loss rates for both studies ($p<0.0001$). The Vercellini, et al study reported an increase percentage of women who became pregnant after abdominal myomectomy (55%) compared to before

abdominal myomectomy (34%) with no report on its statistical significance. The Campo, et al study showed an increased proportion of women got pregnant after abdominal myomectomy (11/19) compared to before abdominal myomectomy (7/19) with delivery rates increased from 40% before abdominal myomectomy to 80% after abdominal myomectomy with no report on the statistical significance of the difference in pregnancy outcomes. The Campo, et al study also reported a reduction in pregnancy loss after abdominal myomectomy (20%) compared to before the surgery (60%) with the difference not statistically significant (p=0.060).

Although, there were overall increased pregnancies, reductions in miscarriages and increased live births after abdominal myomectomy in infertile women with fibroids, the reviewed effectiveness studies are weak case series studies with a lot of missing information. With their no comparator groups, very low strength of evidence, high selection bias and high attrition bias, the findings of these medical case series are poorly generalizable to the population of infertile women with fibroids seeking to become pregnant.

In conclusion, no conclusions can be drawn from this set of case series reviewed. The effectiveness of abdominal myomectomy on pregnancy outcomes still remains controversial. There is a need for stronger studies (RCT) to be conducted to assess the effectiveness of abdominal myomectomy.

Discussion (2): comparative effectiveness study

Although, there are now newer minimally invasive technologies engaged in performing myomectomies, such as laparoscopic myomectomy, abdominal myomectomy, the traditional form of myomectomy, is still the main type of myomectomy in most developing countries of the world. Abdominal myomectomy is not without risk. It is a major surgery with risks that include bleeding, infection and uterine rupture which could necessitate a hysterectomy. Nevertheless, the benefits of an abdominal surgery seem to outweigh the risks of the surgery, especially so for communities in developing countries where infertility has enormous socioeconomic burden and implications. Since

laparoscopic myomectomy is a safer surgery compared to abdominal myomectomy the comparative effectiveness of both procedures were also reviewed and did not show any statistical significant difference for pregnancy outcomes. In this review, in addition to the Campo, et al case series study, with no reported statistically significant difference for the pregnancy outcomes after abdominal myomectomy compared to after laparoscopic myomectomy, there were a cohort study and a randomized study included in the review. Both the cohort study (Tian, et al) and the randomized study (Seracchioli, et al) showed no statistically significant difference in pregnancy outcomes for abdominal myomectomy compared to laparoscopic myomectomy.

In the Tian, et al cohort study, the number of pregnancies following myomectomy were 59 (transabdominal myomectomy group) and 82 (laparoscopic myomectomy group) with a difference of no statistical significance (0.694); the miscarriage rates were 8.48% (TAM) and 10.98% (LM) with a difference of no statistical significance (0.624); and the live birth rates were 76.27% (TAM) and (74.39%) with no statistically significant difference (p=0.799). In the Seracchioli, et al RCT, the pregnancy rates following myomectomy were 55.9% (abdominal myomectomy) and 53.6% (laparoscopic myomectomy); miscarriage rates were 12.1% (AM) and 20% (LM); and deliveries were 48% (AM) and 36% (LM). All differences had no statistical significance respectively.

It is noteworthy that in the Seracchioli, et al study, which is the only RCT study in this review, that the differences in rates of pregnancy outcomes, although not statistically significant, are markedly different for deliveries (+12%) and miscarriage rates (-7.9%) for abdominal myomectomy compared to laparoscopic myomectomy. Obviously, the increased delivery rate and decreased miscarriage rate following abdominal myomectomy compared to laparoscopic myomectomy should have a clinical significance. Perhaps with a better power of at least 80% and better sample size calculation before conducting the RCT, the trial may have been able to detect a true difference.

The review finding of no statistically significant difference, in comparative effectiveness for abdominal and laparoscopic myomectomy, in achieving pregnancy outcomes makes

either of the surgeries adequate for infertile women with fibroids opting for an elective myomectomy. But the higher delivery rate and lower miscarriage rate following abdominal myomectomy, compared to laparoscopic myomectomy, may still make abdominal myomectomy the preferred choice among surgeons. However, given the Tian, et al study finding of a lower caesarian delivery rate after laparoscopic myomectomy (32.79%) compared to abdominal myomectomy (53.33%) with p=0.034, it strongly suggests that laparoscopic myomectomy may be better than abdominal myomectomy for achieving natural spontaneous deliveries and avoiding caesarian section deliveries.

Obviously, the results of this review show a paucity of information and the need for more research to be done. Primary weaknesses in existing evidence that should be addressed in future studies are (a). There should be more detailed information on the methods to avoid missing information, (b). There should be a better sample size calculation with power set at least at 80% to be able to detect true differences and minimize Type II errors, and (c). There should be sub-analysis for primary and secondary infertility to be able to accurately look at the two groups of infertility separately since they do not bear the same psychological burden or implications.

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Chapter Three

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APPENDICES

Appendix 1: Summary of Study Characteristics

For each of the eligible full text review article identified, the study characteristics were summarized in the table below.

A. Author, Year	B. Type of study C. Purpose of study D. Setting of study	E. Study participants recruitment F. Eligible Study Sample size G. Age Range in Years; Mean Age (±S.D.)	H. Ethnicity I. Instrument Used for Data collection
A. Campo, S., Campo, V., & Gambadauro, P. 2003	B. Retrospective case series C. To analyze the reproductive outcome before and after myomectomy in patients with subserous or intramural myomas, and to assess the factors influencing pregnancy rate after myomectomy D. Department of	E. 128 patients between January 1990 and December 1996 who underwent myomectomy F. 41 were eligible for study G. 22-42; 33.7 ± 4.2	H. Information not provided on ethnicity I. Telephone interview/ Questionnaire sent by post to patient or primary care physician

	Obstetrics and Gynecology of the Catholic University of the Sacred Heart in Rome		
A. Author, Year	B. Type of study C. Purpose of study D. Setting of study	E. Study participants recruitment F. Eligible Study Sample size G. Age Range in Years; Mean Age (±S.D.)	H. Ethnicity I. Instrument Used for Data collection
A. Li, T.C., Mortimer, R., & Cooke, I.D. 1999	B. Retrospective case series C. To establish the impact of myomectomy on pregnancy outcome D. Jessop Hospital for Women, Sheffield, UK	E. 113 records of myomectomies performed between May 1991 and December 1996 were retrieved. F. 51 were eligible for study G. 25-44; 33.7 ± 0.7	H. I. Computer search and manual search of the operating theatre records.
A. Marchionni, M., Fambrini, M., Zambelli, V., Scarselli, G., & Susini, T. 2004	B. Retrospective analysis of a case series C. To evaluate the results of abdominal myomectomy for intramural and subserosal fibroids and to identify factors that	E. Manual search of the operating theatre records between January 1996 and December 1998 yielded 284 records of abdominal myomectomies	H. I. Manual search of the operating theatre records

	influence the reproductive outcome after surgery D. Obstetrics and Gynecology Department, University of Florence, Italy	F. 72 were eligible for study G. 22-35; 31 ± 3.1	
A. Seracchioli, R., Rossi, S., Govoni, F., Rossi, E., Venturoli, S., Bulletti, C. & Flamigni, C. 2000	B. Randomized comparison of laparoscopic and abdominal myomectomy C. To compare in infertile patients, the efficacy of laparoscopic myomectomy versus abdominal myomectomy D. Reproductive Medicine Unit, University of Bologna, Italy	E. Participants were recruited from the 744 patients between 1991 and 1998 who had myomectomy F. 131 were eligible for study G. 21-42	H. Information not provided I. Hospital records, physicians and direct reports from patients.
A. Tian, Y., Long, T., & Dai, Y. 2015	B. Mixed cohort study C. To compare the effectiveness of transabdominal myomectomy and laparoscopic myomectomy on women who want to have a baby but suffer from	E. Between January 2005 and January 2013, data were collected on 268 patients who had fertility requirements following myomectomy (retrospectively on 157 patients and prospectively on 111 patients).	H. Information not provided. I. Hospital medical records and phone contact.

	leiomyomas. D. Beijing Obstetrics and Gynecology Hospital	F. 268 G. 20-45	
A. Author, Year	B. Type of study C. Purpose of study D. Setting of study	E. Study participants recruitment F. Eligible Study Sample size G. Age Range in Years; Mean Age (±S.D.)	H. Ethnicity I. Instrument Used for Data collection
A. Versillini, P., Maddalena, S., De Giorgi, O., Pesole, A., Ferrari, L., & Crosignani, P.G. 1999	B. Retrospective Study of a Case series C. To determine the effect of myomectomy as a therapy for infertility and to define the factors that influence reproductive outcome D. First Department of Obstetrics and Gynecology, University of Milan, Italy	E. Clinical records were retrieved for 466 women who had abdominal myomectomies between 1990 and 1997. F. 138 G. 31 (± 6)	H. Information not provided I. Clinical records, telephone contact and mail questionnaire

Appendix 2: Excluded records after full text assessment for eligibility

Author, Year	Reasons for exclusion
Berkeley, A.S., Decherney, A.H, & Polan,	Small sample size for patients with infertility

M.L. 1983	as only indication for myomectomy.
Dahlman, M., Palmer, M., Havstad, S., Wegienka, G., Eisenstein, D., Bagaria, M., et al. 2012	Insufficient information on methods.
Fauconnier, A., Dubuisson, J.B., Ancel, P.Y. & Chapron, C. 2000	Participants with other major causes of infertility (male, tubal pathology and ovulatory functions) were included in the study. Study design not for impact of myomectomy on infertility.
Fukuda M, Tanaka T, Kamada M, Hayashi A, Yamashita Y, Terai Y, et al. 2013	No explicit exclusion criteria. All patients identified to have had a myomectomy in this retrospective case series were included in the studies.
Gatti, D., Falsetti, L., Viani, A., & Gastaldi, A. 1989.	Outcome analysis not specific for impact of myomectomy.
Gehlbach, D.L., Sousa, R.C., Carpenter, S.E., Rock, J.A.1993	Majority of patients included in study had other explainable causes of infertility. There was no sub-analysis for the impact of myomectomy in patients with only fibroids as explainable cause of infertility.
Kasum, M. 2009	Study design issues. Questionnaires were sent to all identified 236 patients with myomectomies within study periods with no exceptions. All 78 who responded were included in the study without excluding responders with other causes of infertility.
Kinugasa-Taniguchi, Y., Ueda, Y, Hara-Ohyagi, C., Enomoto, T., Kanagawa, T., Kimura, T. 2011.	Study is about myomectomy for asymptomatic fibroids. No infertility component.

Orazulike, N., & Uzoigwe, S. 2014.	Insufficient information.
Palomba, S., Zupi, E., Falbo, A., Russo, T., Marconi, D., Tolino, A., Manguso, F., Mattei, A., & Zullo, F. 2007.	Myomectomies not specific for infertility associated fibroids.
Ramavath, K. K., & Pasumarthy, S.M. 2011.	No exclusion criteria for all patients identified to have had myomectomy within study period.. Some patients had explainable causes of infertility with no outcome subgroup analysis exclusive to only those with fibroids.
Sinclair, D., Gaither, K., & Mason TC. 2005.	Small sample size (8 Participants). Did not achieve statistical significance.
Sirjusingh, A, Bassaw, B., & Roopnarinesingh, S. 1994.	Patients with other major causes of infertility were included in the study.
Yao, S. 2010.	Insufficient information on methods (inclusion/exclusion criteria, follow up and data analysis).
Zare, F. 2013	Study design issues. Insufficient information on methods. Outcome measures used number of years of infertility before myomectomy as reference point.