

Welcome to Presentation of Thesis Proposal

Title

Laparoscopic Findings of Subfertile Women at
Rajshahi Medical College Hospital

Submitted by

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INTRODUCTION

Introduction

- ✓ Subfertility is a common medical problem and significant reproductive health concern in Bangladesh.
- ✓ Subfertility is a disease of reproductive age and affects 10–15% of couples (Kumar and Singh, 2015).
- ✓ Worldwide, approximately one in every six individuals of reproductive age experience Subfertility during their lifetime which has a significant impact on families and communities.
- ✓ Many couples who are unable to conceive are subjected to social stigma and discrimination which has a detrimental effect on their quality of life.

Introduction Cont..

- ✓ Subfertility is most frequently caused by issues with the ejection of semen, the absence or low levels of sperm, or the aberrant shape (morphology) and movement (motility) of the sperm in the male reproductive system.
- ✓ A variety of abnormalities of the endocrine system, ovaries, uterus and fallopian tubes may result in Subfertility in the female reproductive system (Segal and Giudice, 2019).
- ✓ Most common causes responsible for primary Subfertility in women were ovulatory disorders-25%, endometriosis-15%, pelvic adhesions-12%, tubal blockage-11%, other tubal/uterine abnormalities-11% and hyperprolactinemia-7%.

Introduction Cont..

- ✓ Subfertility evaluation is done in women with unsuccessful pregnancies after 12 months of unprotected regular intercourse or 6 months if they are more than 35 years.
- ✓ Any well-defined cause leading to Subfertility needs instant diagnosis and treatment (Wilkosz et al., 2014).
- ✓ Among the many investigations available to evaluate the female partner of the subfertile couples, laparoscopy is relatively recent and considered standard for pelvis evaluation.
- ✓ It is indicated as a diagnostic test for suspected pelvic adhesions, endometriosis, or other pelvic pathologies.

Introduction Cont..

- ✓ Much pathology undetected by ultrasound can be seen with naked eyes and can be cured like minimal endometriosis (Agarwal et al., 2019).
- ✓ Though it is an invasive procedure, complications are minimal with an experienced hand.
- ✓ Becoming invasive and expensive, the necessity of laparoscopy in a Subfertility work up is thought controversial specially in developing countries like Bangladesh.
- ✓ The study will be done to confirm the suspected causes of Subfertility among the women attending in infertility center of Rajshahi Medical College Hospital.

RATIONALE

Rationale

- ✓ Parenthood is considered as the most desired goal in adulthood by the majority of world population.
- ✓ There are various factors behind Subfertility in female. For couples, the treatment of Subfertility and the subsequent distress on their interpersonal relationship result in emotional breakdowns.
- ✓ It is essential to find out the main causes of Subfertility as long term Subfertility becomes tedious to treat.
- ✓ In modern days, many diagnostic modalities are available for assessment of Subfertility.

Rationale Cont..

- ✓ In a country with limited resources, it is not feasible to mandate all Subfertility investigations on subfertile couples.
- ✓ Despite the numerous investigations that are available to assess the female companion of subfertile couples, laparoscopy is a relatively recent development and is now regarded as the standard for pelvic evaluation.
- ✓ Although laparoscopy is not indicated in routine evaluation of Subfertility but some diseases especially mild to moderate endometriosis, mild to moderate pelvic inflammatory disease or tubal factors leading to subfertility needs to be evaluated early by laparoscopy.

Rationale Cont..

- ✓ Laparoscopy is minimally invasive, more convenient, safe and economic procedure for diagnosis of pelvic pathologies.
- ✓ Diagnostic laparoscopy offers a direct visual view of the interior pelvic anatomy, enabling the examination of the ovaries, fallopian tubes and uterus as well as the more detailed examination of its pathology.
- ✓ Laparoscopy not only increases pregnancy rate, it also modifies the line of treatment.

Rationale Cont..

- ✓ Laparoscopy is considered as an important procedure to diagnose certain causes like endometriosis, mild PID, peri-tubal blockage which cannot be diagnosed on transvaginal ultrasound and hysterosalpingograph (HSG).
- ✓ Though it is an important topics but there are very limited studies in Bangladesh specially in North Bengal Region of Bangladesh.
- ✓ This study will be conducted to highlight the role of laparoscopy for instant diagnosis of the causes leading to primary and secondary Subfertility.

Research Question

✓What is the role of diagnostic laparoscopy in the evaluation of female Subfertility?

OBJECTIVES

General Objective

- ✓ To determine the proportion of different types of pelvic pathologies and conditions in women of Subfertility in Rajshahi Medical College Hospital.

Specific objectives

- i. To find out the pathologies in terms of tubal patency with or without adhesions, tubal patency with or without cystic ovaries, genital tuberculosis, endometriosis with uterine leiomyoma and hypoplastic uterus responsible for subfertility in women.
- ii. To determine the socio-demographic characteristics of the respondents.
- iii. To see the relationship of pathologies of subfertility with socio-demographic variables, duration and kind of subfertility.

METHODS AND MATERIALS

✓ **Study design:** The present study will be a cross-sectional type of descriptive study.

✓ **Place of study:** This study will be conducted in the Department of Obstetrics & Gynaecology, Rajshahi Medical College Hospital, Rajshahi.

✓ **Period of study:** The study will be done in a one and half years from January 2025 to July 2026.

- ✓ **Data collection place:** Data will be collected from the outpatient Department of Obstetrics & Gynaecology, Rajshahi medical college hospital, Rajshahi.
- ✓ **Study population:** Study population will be primary and secondary subfertile women who will be undergone diagnostic laparoscopy at the time of data collection period. The following eligibility criteria will be employed to select the required number of subfertile women.

Inclusion criteria

- ✓ Women with one year unprotected intercourse who could not achieve pregnancy with regular coitus.
- ✓ Age 20-40 years
- ✓ Normal semen analysis of husband.
- ✓ Subfertile women who will give consent to participate in the study.

Exclusion criteria

- ✓ Couple who will not live together for at least previous one year.
- ✓ Male factor subfertility.
- ✓ Women having medical disorders like hypertension, cardiac disease, uncontrolled diabetes mellitus.
- ✓ Women with chronic respiratory disease, generalized peritonitis, intestinal obstruction and active foci of tuberculosis.
- ✓ Women with previous history of abdominal surgery.
- ✓ Women with medical disorders.
- ✓ Contraindications for laparoscopic surgery.

Sample size determination

- Sample size is determined using single proportion estimate formula Haque, (2021) as follows:
- It is expected from the findings of a previous study “Female infertility and laparoscopic surgery: A series of 415 operations at the Yaounde Gyneco-Obstetric and Pediatric Hospital, Cameroon” by Mboudou et al., (2013) that tubo-peritoneal adhesions was the responsible factor in 71.6% women with primary subfertility. So, the minimum sample size at 5% level of significance was calculated using the following formula,

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Sample size determination cont..

Here

- n =The desired sample size
- Z =Standard normal deviate for Z distribution which corresponds to 95% confidence interval in normal distribution = 1.96
- p = Anticipated prevalence of tubo-peritoneal adhesions due to primary Subfertility=71.60% = 0.716 = 0.72 (Mboudou et al., 2013).
- $q=1-0.72=0.28$
- d =Allowable error of anticipated prevalence =10% of the anticipated ‘ p ’=0.072

Sample size determination cont..

Therefore, the desired sample size

$$\begin{aligned} n &= \frac{(1.96)^2 \times 0.72 \times 0.28}{(0.072)^2} \\ &= \frac{3.84 \times 0.20}{0.005} \\ &= \frac{0.77}{0.005} = 154 \end{aligned}$$

The calculated sample size of this study is 154. So, 154 primary and secondary subfertile women will be included in the study.

Sampling technique

- ✓ Purposive sampling technique will be applied to select each woman in this study.

Variables will be used in the study

Independent variables

- ✓ Age
- ✓ Residence
- ✓ Educational status
- ✓ Occupational status
- ✓ Height, Weight
- ✓ BMI
- ✓ Monthly family income
- ✓ Subfertility

Dependent variables

- Probable pathologies behind Subfertility
- ✓ Endometriosis
- ✓ Polycystic ovaries
- ✓ Tubal block with adhesions (Unilateral)
- ✓ Tubal block with adhesions (Bilateral)
- ✓ Genital tuberculosis
- ✓ Tubal patency
- ✓ Uterine anomaly-Fibroid adenomyosis

OPERATIONAL DEFINITIONS

Operational definitions

- ✓ **Subfertility:** Subfertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse.
- ✓ **Primary Subfertility:** Primary Subfertility is defined as the failure to achieve a pregnancy after a year (or six months for those over 35) of regular, unprotected sexual intercourse, when a couple has never been pregnant before.

Operational definitions cont..

- ✓ **Secondary Subfertility:** Secondary Subfertility is defined as the inability to conceive or carry a baby to term after previously giving birth.
- ✓ **Laparoscopy:** Laparoscopy for Subfertility is a minimally invasive surgical procedure in which a telescope-like instrument (laparoscope) with light and small camera allows the surgeon to examine the pelvic anatomy for causes of female subfertility. Laparoscopy will be done in in premenstrual phase (7, 8, 9th day of menstrual cycle) after conducting thorough clinical and biochemical examinations.

Detailed study procedure

- ✓ This will be a cross-sectional type of descriptive study conducted in the Department of Obstetrics and Gynaecology, Rajshahi Medical College Hospital, Rajshahi after obtaining approval from the Ethical Review Committee, Rajshahi Medical College, Rajshahi.
- ✓ The study will be conducted on 154 subfertile women to detect the possible pathologies behind Subfertility.
- ✓ All subfertile women will be assessed and evaluated with history and clinical examination, as well as hormonal profiles and endocrinological examination.

Detailed study procedure cont..

- ✓ Full blood count, blood urea, blood sugar estimation, urine examination, ECG, Chest X-ray, ultrasonography and endometrial biopsy will be performed and selected as having suspected case of pelvic inflammatory disease, endometriosis, polycystic ovaries and abnormal findings with blocked tubes and fibroid uterus.
- ✓ Informed written consent will be taken after full explanation of risk, benefit of the study. A semi-structured questionnaire will be designed including all the variables of interest.

Detailed study procedure cont..

- ✓ Detailed socio-demographic data, family history and medical history will be recorded on a data sheet appropriately.
- ✓ Data will be collected through laparoscopy of the patients at the respective operation settings by the researcher.
- ✓ Laparoscopy will be scheduled in premenstrual phase and performed as day case procedure.

Detailed study procedure cont..

- ✓ The tubal patency will be tested by chromoperturbation using methylene blue dye.
- ✓ HSG will be done as preliminary test followed by diagnostic laparoscopy with instillation of using 10-15 ml of 0.5% autoclaved methylene blue dye for tubal patency test.
- ✓ Laparoscopy will be performed under general anesthesia. Just below the umbilicus a small incision along the langers line will be made.

Detailed study procedure cont..

- ✓ Through that incision carbon dioxide gas insufflation will be done and pneumo peritoneum will be created.
- ✓ Trochar will be inserted through the incision and through it laparoscope will be passed after withdrawing the canula.
- ✓ During the procedure, pelvis will be inspected along with the surfaces of the uterus, both the ovaries, fallopian tubes, uterosacral ligament and pouch of douglas.

Detailed study procedure cont..

- ✓ Fallopian tubes will be inspected for abnormality in length and shape. In ovaries, their size, shape, thickness of peripheral follicle will be done.
- ✓ Other pathologies like peritubal adhesions, omental adhesions, perifimbrial adhesions, fibroids, endometriosis, tubo ovarian mass, will be also noted if present.
- ✓ Tubal patency will be tested by injecting methylene blue dye through the uterine cavity and its spillage from the fimbrial end of the fallopian tube.

Data collection tools

- ✓ Data will be collected using a semi-structured questionnaire (research instrument) containing all the variables of interest, measuring tape, weight machine, with the help of laboratory and laparoscopy settings.

Statistical analysis

- ✓ All data will be analyzed by using the ‘Statistical Package for Social Sciences (SPSS)’ software, 26-version.
- ✓ Categorical variables will be summarized by using numbers and percentages while continuous variables will be summarized by means \pm standard deviation (SD).
- ✓ An independent sample t-test will be used to compare continuous variables with two categories and a chi-square test will be used to compare categorical variables. A p-value < 0.05 will be considered statistically significant for all tests.

Utilization of the study

- i) The study might be helpful in identifying the probable conditions of Subfertility in our settings.
- ii) The study also helpful for future treatment planning of Subfertility.

Ethical Implications

- Permission will be taken from the Institutional Review Board (IRB) of Rajshahi Medical College (RMC), Rajshahi before data collection. Keeping compliance with Helsinki Declaration for Medical Research Involving Human Subjects 1964, revised in 2013, all the study subjects will be informed verbally about the study design, the purpose of the study and potential benefits derived and risks involved from the study. They will also be assured that they will have full rights to withdraw themselves from the study at any time for any reasons what-so-ever. Patients who will give informed consent to participate in the study will be included as study sample.

References

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thank
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