A STUDY ON THE COMPARISON OF SAFETY AND EFFICACY OF POST PARTUM INTRAUTERINE CONTRACEPTIVE DEVICE (PIIUCD) WITH INTERVAL INTRAUTERINE CONTRACEPTIVE DEVICE

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ABSTRACT

Objective: To compare the safety and efficacy of post partum intrauterine contraceptive device with interval intrauterine contraceptive device, to avoid unplanned pregnancies.

Study Design: Quasi-experimental study.

Place and Duration of Study: Gynaecology and Obstetrics Department, Combined Military Hospital (CMH) Okara, from Aug 2019 to Jul 2020

Methodology: One hundred patients were included in the study. Divided in 2 groups, group A (post partum intrauterine contraceptive device, n=50) patients underwent cesarean section under spinal anesthesia, after removal of placenta and membranes contraceptive device was placed near fundus with fingers and incision was closed. In group B (interval intrauterine contraceptive device, n=50) and intrauterine contraceptive device was placed 6 weeks postpartum. Post insertion follow up was at 6 weeks and then 6 months. Efficacy was assessed by the continuation rate and safety, by presence or otherwise of heavy menstrual bleeding, lost threads, abnormal vaginal discharge and pain abdomen on follow up visits.

Results: Efficacy in group A was 46 (92%) and in group B 40 (80%). Safety that is heavy menstrual bleeding 3 (6%) and 5 (10%), lost threads 3 (6%) and 1 (2%), abnormal vaginal discharge 2 (4%), and 3 (6%), and pain abdomen 1 (2%) and 2 (4%) in groups A and B respectively.

Conclusion: Postpartum intrauterine contraceptive device insertion was found to be effective and safe method as compared to interval intrauterine contraceptive device. Successful placement, continuation and retention rate were significantly higher in post placental intra uterine contraceptive device insertion.

Keywords: Acceptability, Contraception, Efficacy, Intrauterine contraceptive device.

INTRODUCTION

Pakistan is 6th most populous country in the world. Population is inversely proportional to the economic growth of any country. Lesser the population more are the resources available for alleviation of living standards and development of country and vice versa. In the present scenario of global population explosion, the need for control of birth rate globally is not only discussed at the higher forums but also concrete steps are being taken at country level to keep the birth rate. To achieve the sustainable development goals (SDGs) and ensure prosperity for all by 2030, over the period of time Pakistan is trying to establish a mechanism for promotion and effective use of contraception. It has started with serious efforts for the family planning in 2012. Government of Pakistan along with help of provisional governments has drafted a consolidated plain for family planning which includes preparation of contraceptives and training of mid level service providers both in private and government sector to provide intrauterine contraceptive devices and implants. In addition to these efforts are being made to increase the social acceptability of family planning by involving the men and religious scholars as part of social mobilization.

Maternal and child health is one of the health indicators of the country. Fertility can return shortly after birth and in some non-lactating women it is reported as early as 3-4 weeks post-delivery. Fifty percent of women resume sexual activity 6 weeks postpartum. Therefore risk of
unplanned and unintended pregnancy, unless an effective contraception is used, is very high. Unplanned pregnancy is associated with poor maternal and fetal outcome. Short interpregnancy interval is associated with obstetric complications like preterm delivery, low birth weight infants, fetal growth restrictions and neonatal mortality. Provision of contraception during immediate postpartum period is most helpful to overcome the unmet need of contraception. Globally women are being encouraged to deliver in facilities providing immediate postpartum contraceptive device. According to World health organization (WHO) postpartum family planning (PPFP) is focusing on prevention of unplanned and closely spaced pregnancies. World health organization state that postpartum intra uterine contraceptive devices are cost effective, its advantages outweigh the disadvantages and can be inserted by a mid-level skilled birth attendant. Women are offered intrauterine contraceptive device (PPIUCD) placement at 3 points, postplacental: insertion within 10 minutes after placental expulsion, Intra-cesarean: Insertion before closing the uterine incision, Predischarge: insertion from 10 minutes up to 48 hours postpartum. While interval intrauterine contraceptive device can be placed any time four weeks or later after childbirth if patient is not pregnant.

In Pakistan the millennium development goal (MDG 5) could not be achieved despite multiple efforts from the government. The modern contraceptive prevalence is lagging behind and unmet need for contraception is on a rise. This study was done to compare the safety and efficacy of postpartum intrauterine contraceptive device insertion with interval intrauterine contraceptive device insertion. The evidence from the study will help to formulate recommendations and sensitize healthcare workers to implement certain interventions in our setup to fulfill the unmet need of contraception.

**METHODOLOGY**

After getting approval from institutional ethics review committee (IERC/OBS/2020/03) this quasi-experimental study was carried out in department of Obstetrics and Gynecology Combined Military Hospital Okara, from August 2019 to July 2020. Assuming 25% prevalence of intrauterine contraceptive device insertion rate with a 80% power and a 4% margin of error the sample size calculated was 100 cases 1 (50 patients in each group A and B) through non probability convenience sampling. It was calculated using WHO sample size calculator. Patients were counselled during antenatal period, during early labor and also at post natal visits for postpartum intrauterine contraceptive device and interval intrauterine contraceptive device insertion. The willing patients were explained the advantages, insertion technique, mode of action, potential complications and follow-up schedule. The Women were allocated to the post partum intrauterine contraceptive device insertion group (group A) and interval intrauterine contraceptive device insertion group (group B) by lottery method. Verbal informed consent was taken and documented in the patient’s record. All patients attending antenatal clinic with low risk pregnancies, multigravidas admitted in labor room with labor, patient shifted for emergency cesarean section from antenatal clinic, labor room or obstetrical ward were included in study. Patients with congenital uterine malformations, anemia with hemoglobin <10g/dl, premature rupture of membranes >12 hours, active genital tract infection were excluded from the study. In group A, (PPIUCD, n=50) patients underwent cesarean section under spinal anesthesia, after removal of placenta and membranes PPIUCD was placed near fundus with fingers and incision was closed (figure).

In group B (interval intrauterine contraceptive device, n=50) patients were called 6 weeks postpartum and intrauterine contraceptive device was placed under aseptic measures. Post insertion the patients were explained the possible complications like expulsion, excessive vaginal bleeding, uterine perforation and also how to feel the thread of intrauterine contraceptive device. In case thread was not felt they were told to report
immediately in outpatient department. Patients were called for follow up after 4-6 weeks and if everything remained satisfactory next follow up after 4-5 months was advised. At follow up visits patients were asked about any menstrual disturbances, vaginal discharge, lost strings or pain lower abdomen. Per speculum examination was done to look for vaginal discharge and also presence of thread was appreciated. Complications if any, were recorded on pre designed proforma and dealt accordingly. Patient who never reported back in outpatient department for follow-up and also did not responded on phone were excluded from the study. Demographic details like age, parity, educational status, socioeconomic class of both groups were recorded in performa. Efficacy was assessed by continuation rate of intrauterine contraceptive device by the patient at 6 months. Safety was evaluated by incidence of infection, perforation, lost thread, heavy menstrual bleeding and abnormal vaginal discharge.

Data was analyzed using SPSS-22. For qualitative variables frequency and percentages were calculated and for quantitative variables mean and standard deviation was calculated. For comparison of safety and efficacy between both groups chi square test was used.

RESULTS

The study comprised of 2 groups, according to the type of intrauterine contraceptive device insertions (post partumand interval). Fifty patients in each group. The study showed that both the groups were comparable regarding basic demographic features in them. Meanage of group A patients was 30.30 ± 4.59 years, while mean age of group B was 29.68 ± 3.65 years. Most of the patients were ranging in age group between 17-21 years.

The mean parity of the group A was 2.64 ± 1.1; while in group B it was 3.0 ± 1.32. Majority of the patients i.e. 26 (52%) in group A and 31 (62%) in group B belonged to middle socioeconomic class.

Efficacy assessed by the continuation rate at 6 months in group A was 46 (92%) and in group B it was 40 (80%). Retention rates of intrauterine contraceptive device was noted to be 48 (96%) in group A and 46 (92%) in group B.

Safety that is heavy menstrual bleeding 3 (6%) and 5 (10%) p-value 0.00, lost threads 3 (6%) and 1 (2%) p-value 0.00, abnormal vaginal discharge 2 (4%), and 3 (6%) p-value 0.00, and pain abdomen 1 (2%) and 2 (4%) p-value 0.001 in groups A and B respectively table.

Table: Comparison of safety factors among both groups.

<table>
<thead>
<tr>
<th></th>
<th>PPIUCD (Group A) n(%)</th>
<th>Interval (Group B) n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heavy Menstrual Bleeding</td>
<td>3 (6%)</td>
<td>5 (10%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lost Thread</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Abnormal vaginal Discharge</td>
<td>2 (4%)</td>
<td>3 (6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain abdomen</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
<td>&lt;0.001</td>
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</tbody>
</table>

DISCUSSION

The population of Pakistan is 212.2 million and growth rate is 5.8% the maternal mortality rate of Pakistan is 276/100,000 live births. Annual estimate of modern contraceptive prevalence rate (MCPR) is 35.8% in women 15-49 years of age. An unmet need for family planning of 20% with a high fertility rate of 3.8%, and it has made Pakistan 4th most populous country in Asia11. In a study conducted by Afshan and Asim no serious complications were associated with post-

Figure: Post partum insertion of intrauterine contraceptive device.
partum intrauterine contraceptive device insertion, continuation rate in the study was 90% at 6 weeks and 84% in interval intrauterine contraception device insertion, as compared to our study which is 96% and 92% respectively\textsuperscript{11}. Which is slightly higher.

According to a study conducted by Zafar and Habib 2.3% of married Pakistani women use post partum intrauterine contraceptive device for contraception, although intrauterine devices have been available in Pakistan for decades\textsuperscript{12}. Constricts in acceptance of modern family planning methods were illiteracy, myths like the belief that PPIUCD can cause cancer, can move freely out of the uterus, it can reach the heart and can cause death also the health concerns like excessive bleeding, abdominal pain etc\textsuperscript{13}.

In our study 3500 patients were counselled in outpatient department during antenatal visits, acceptance rate for interval IUCD was more 83% as compared to a study carried out by Nayak and Jain\textsuperscript{14}, where it was 42.8%. Efficacy of post partum intrauterine contraceptive device (PPIUCD) as contraceptive was assessed by removal or retention rate and expulsion rate. Expulsion rate in interval intrauterine contraceptive device was higher 4 (8%) as compared to 2 (4%) in post partum intrauterine contraceptive device (PPIUCD) group, same statistics were observed in in a study conducted by Banapurmath et al\textsuperscript{15}. While in a study conducted by Mohan et al, expulsion rate after post placental insertion was 5\%\textsuperscript{16}. Safety was assessed by side effects like pain abdomen, loss threads, heavy menstrual bleeding and abnormal vaginal discharge. Only few patients were reported with missing threads at 6 weeks, per speculum examination the curled up string in vaginal fornixes and cervical canal. If thread was not found the presence of IUCD was confirmed by trans abdominal ultrasound and patient were counselled. The frequency of lost thread was higher in PPIUCD group as compared to interval IUCD group i.e. 3 (6\%) as compared to 1 (2\%), this is comparable to study conducted by Mohan 2\% and 1\% respectively\textsuperscript{16}.

Study conducted by Nahar et al, 3.5\% and 10\% of patients complained of pain lower abdomen and abnormal vaginal discharge respectively, as compared to our study where pain lower abdomen was 2\% and excessive vaginal discharge was 4\%\textsuperscript{17}. All these patients were advised culture sensitivity, but none of the results revealed growth of any organisms. Heavy menstrual bleeding was 6\% in study by Nahar which is comparable to our results\textsuperscript{18}. No case of PID, endometritis or perforation was reported in our study, the decreased risk of uterine perforation may be because of thick uterine wall and also PPIUCD is placed higher near fundus\textsuperscript{19}.

CONCLUSION

It was concluded that PPIUCD (trans cesarean section) found to be effective and safe and reversible method as compared to interval IUCD. Successful placement, continuation and retention rate were significantly higher in PPIUCD. The propagating practice of PPIUCD can play a great role in accepting contraception in our country.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES


