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## SAFETY OF IUCD (COPPER -T<sub>380</sub>)

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### ABSTRACT

**T**he role of family planning in preventing maternal deaths and improving the quality of women's lives is one of the key strategies of the safe, motherhood initiative. **OBJECTIVES:** To study the safety and efficacy of IUCD (copper T<sub>380</sub>) as a contraceptive device. **DESIGN:** Prospective study. **PERIOD:** 18 months from 1<sup>st</sup> January 1994 to 31<sup>st</sup> June 1995. **SETTING:** DHQ Hospital Faisalabad. **PATIENTS & METHODS:** 500 women were selected for IUCD insertion. Insertions were performed on healthy sexually active women who had requested contraception and had no contraindication for the fitting of an IUCD. Clinical follow up was scheduled. **RESULTS:** IUCD especially the last generation of copper releasing device i.e. copper T<sub>380</sub>, seems to be one of the most appropriate contraceptive method for a developing country like Pakistan. **CONCLUSION:** IUCD is a highly effective method of contraception with patient acceptances as good as for other reversible methods such as the pill.

**KEY WORDS:** IUCD (Copper T<sub>380</sub> A) contraception.

### INTRODUCTION

Pakistan is amongst the countries which has the highest population rate in the world. The current estimates of annual growth rate range from 2.85% to 3.15%<sup>1</sup>. If this growth of population remains unchecked there would be a population explosion and the world run out of its food resources so a balance between population growth and economic development is essential to national progress.

Family planning contributes to safer motherhood by preventing too early, too close, too many or too late in-life pregnancies<sup>2</sup>. Many unwanted pregnancies are terminated by illegal septic abortions and family planning is an indispensable ingredient to prevent these complications<sup>3</sup>.

In spite of the efforts of the Government of Pakistan to provide family planning services to the masses, the programme has not met the same success as in some neighbouring countries. The overall contraceptive

prevalence in the country is only 14%<sup>4</sup> between 1975 - 1991 compared to this, the trend has changed from 33.6% to 57% in Dhaka, Bangladesh between 1989 to 1991<sup>5</sup>. The major causes of this lack of success may be unevenly and sparsely located family planning services, the lack of service accessibility to the majority of the population<sup>6</sup>. In our set up husbands are more interested in the birth of male children to continue the family line than in the reproductive health of their wives<sup>7</sup>. All these ideas originate from our culture and should be discouraged by educating the people particularly the youth, parents, teachers and religious leaders.

Contraception can be criticized on the grounds that it encourages promiscuity and extra marital sex but accepting the increasing permissiveness of the society and liberation of women, contraception is preferable to unwanted babies or termination of pregnancies.

There are many methods of contraception which have been used since ancient time. The IUCD is now the 2<sup>nd</sup>

most commonly used reversible and reliable method of contraception in developing countries<sup>8</sup> with more than 85 million users world wide<sup>9</sup>. IUCD has a unique quality among reversible methods of contraception in providing long term reduction in fertility by a single, safe and relatively simple procedure. In our set up especially in rural areas where most of the women are uneducated and illiterate, IUCD is one of the most acceptable method of contraception because it is safe, effective and easy for them.

### **TIME OF INSERTION OF AN IUCD**

**Intermenstrual:** The conventional time for IUCD insertion is during or immediately after menses, because the insertion is easier due to the natural dilatation of the Cx. Moreover at menstruation patient is known to be not pregnant. Insertion at other times during the cycle is feasible and has been investigated. There is now ample evidence that the IUCDs can be inserted immediately after a spontaneous miscarriage or after termination of pregnancy<sup>10</sup>.

The postpartum period is an ideal time to begin contraception as women are more highly motivated to adopt contraception at this time and it is convenient for both patients and service providers. This offers other advantages such as ease of insertion and minimal adverse impact on breast feeding<sup>11</sup>.

IUCD can also be inserted after caesarean section without risk of perforation<sup>12</sup>.

It can be inserted immediately after placental delivery (within 10 minutes of delivery of placenta) with low expulsion rate. The insertion of the IUCD during caesarean section is a secure and helpful method for fertility control for patients with high risk of reproduction<sup>13</sup>.

Copper device can also fitted within 5 days of unprotected intercourse to prevent implantation of the fertilized ovum.

### **COMPLICATIONS OF AN IUCD**

Highlighting the side effects of IUCD and the presence of the letter "P" in most of the headings to be covered when counseling a potential acceptor is a useful method

of remembering the key factors of pregnancy, periods, pain, pelvic infection, expulsion and perforation<sup>14</sup>.

Bleeding is mostly in the form of menorrhagia i.e. excessive vaginal bleeding for 6 days or more and containing a significant amount of blood clots<sup>15</sup>. The increased blood loss is known to be associated with a vascular reaction which is most pronounced in the endometrium adjacent to the IUCD<sup>16</sup>.

According to Pan IF et al 1994 the IUCD induced menorrhagia might be correlated with poor contractility of spiral arterioles in the spongy layer. Unbalance of PGI<sub>2</sub>/TXA<sub>2</sub> ratio (PGI<sub>2</sub>/TXA<sub>2</sub>) may be the direct cause of menorrhagia<sup>17</sup>.

Pain may be due to infection or partial perforation of IUCD. According to Far G, Amatya R et al 1999. Cu T380A IUD users were more likely to report experiencing increased dysmenorrhoea or intermenstrual pelvic pain than were MLCu 250 IUCD users. These complications can respond to medication and reassurance i.e. NSAID; and PG synthesis inhibitors.

### **INFECTION**

Infection as a complication of IUCD was recognised since their infancy as early as 1929 but with better sterilization procedures and favourable reports by Ishihama and Oppenheimer (1959) there was renewed interest in IUCD as a mean of contraception. These measures include antiseptic coated IUCDs, aseptic conditions during IUCD insertion, prophylactic antibiotics immediately prior to IUCD insertion e.g. a single dose of doxycycline 200 mg before insertion, follow up visits with short intervals to monitor health and treatment of opportunistic infection may have reduced the potential of PID within the population<sup>18</sup>.

According to Farley-TM et al (1992) PID risk was more than six times higher during the first 20 days after insertion than during later times (unadjusted rates, 9.7 vs 1.4/1000 women years respectively). The risk was low and constant for upto eight years of follow up so PID is an infrequent event beyond the first 20 days after insertion. As PID among IUCDs users is most strongly related to the insertion process and to background risk of STD. IUCDs should be left in place upto their

maximum life span and should not routinely be replaced earlier provided there are no contra indications to its continuous use and the woman wishes to continue with the device as well.

**PREGNANCY** with a well positioned IUCD is a clinically significant event and net pregnancy rate for T Cu 380 was 1 to 3/100 women a year<sup>15</sup> and the incidence decreases with succeeding years of use. Pregnancy when occurs is either intra uterine or ectopic.

**ECTOPIC PREGNANCY;** IUCDs provide less protection against ectopic pregnancy. The relationship between IUCD use, PID and the risk of ectopic pregnancy is not clear. Patients at high risk of ectopic pregnancy are those who have had PID, a previous ectopic pregnancy and/or previous tubal surgery and not really the ones who have an IUCD inserted in the absence of these conditions. Therefore, careful selection of patient with avoidance of risk factors for ectopic will reduce the risk still further<sup>18</sup>.

**INTRAUTERINE PREGNANCY** with an IUCD in Situ cannot be taken lightly as it is not an innocuous situation. Once the pregnancy is confirmed the visible thread should be removed. Leaving it in place during pregnancy results in higher miscarriage rate and incidence of pre-term birth<sup>19</sup>.

### **LOST OF THREAD OR LOST IUCD**

IUCDs are fitted with a thread which passes through the cervix into the vagina. Manual detection of this thread is the user's means of ensuring that the device remain in place. Once it is misplaced a correct and safe diagnostic technique is ultrasound especially vaginal probe. Plain x-ray with uterine sound in utero is a popular simple technique which does not require special skills<sup>21</sup> where facilities for ultrasound are not available.

The copper IUCD trans-located to peritoneal cavity may provoke peritoneal or omental adhesions, uterocutaneous fistula, bowel perforation and volvulus which involves a significant morbidity<sup>22</sup>, so once the diagnosis of ectopic IUCD was made, it justify, its immediate removal from the peritoneal cavity by laparoscopy or laparotomy. This complication can be prevented by

asking the women to self check the IUCD tail after every menstrual period<sup>23</sup>.

### **SPONTANEOUS EXPULSION**

Expulsion rates vary widely between the different devices and between different groups of women. The age, parity, timing of insertion and the skill of the inserter all have an effect. Expulsion is more common in the first three months of fitting.

According to Sivin-I and Sternj (1979) spontaneous expulsion occurred more with Lippe's loop than with T-Cu 380 A i.e. 7.8 to 13.0 per 100 women with lippes loop and 3.3-7.1/100 women with copper T 380A<sup>19</sup>. This is surprising because the size of lippes loop is larger than that of copper devices. It therefore, follows that the shape of the device rather than the size is more important factor in resisting spontaneous expulsion.

Timing of insertion is also very important and up-till now immediate post-placental insertion has not been widely accepted in clinics because its expulsion rate still appears to be higher than that of interval insertion<sup>11</sup>. So an easy insertion technique with fundal placement by a trained doctor or nurse gives the lowest expulsion rate.

### **PATIENTS & METHODS**

It included all the patients attending the family planning clinic in DHQ hospital Faisalabad from 01.01.1994 to 31.06.1995. A strict statistical record of all these patients using different types of contraceptives was kept in this clinic. All the women attending the family planning clinic were fully evaluated before giving the advice regarding the best suitable contraceptive method. The patients were selected for IUCD insertion after following parameters were evaluated.

Detailed history was obtained from each woman with special reference to any pregnancies, the menstrual cycle and past or present genital tract infections, or any systemic disease.

General physical, systemic and abdomino pelvic examination were done. At time of pelvic examination, the size, shape and position of the uterus was defined and conditions such as gynaecological infections were excluded.

There was a check list for both the history and the physical examination so that no contraindications were overlooked, this was especially important as personnel other than doctors e.g. LHV's were also providing the service.

A clinical assessment for the possible presence of severe anaemia was carried out if laboratory test for Hb% was not available.

Laboratory tests were not essential before an IUCD insertion but the service to the patient could be improved if Hb%, pregnancy test, microscopy of vaginal discharge and cervical cytology are available and therefore during my study above mentioned tests were also performed in selected cases including pap smear, before insertion of an IUCD.

### FOLLOW UP OF IUCD USER

Clinical follow up was scheduled at 6 weeks and 3 months after insertion and this was followed with checks at 6 monthly intervals for a year and then, if the patient is happy with her device, annual visits until renewal of the device is needed.

All those cases who reported with minor complications with IUCD were treated in family planning clinic while these few patients who had major complications e.g. perforation were admitted in the gynaecology ward where they were investigated and managed accordingly.

### RESULTS

A total of 20480 women attended the family planning clinic at DHQ Hospital Faisalabad during the 18 months period during which study was carried out. Out of these 500 women were selected for IUCD insertion. Insertions were performed on healthy sexually active women who had requested contraception and had no contraindication for the fitting of an IUCD.

All the patients who were selected for IUCD insertion, had Copper-T 380 inserted and no other type of IUCD (Lippe's loop or multiload ) was used during my study.

The age distribution of women who had IUCD insertion in our clinic is shown in Table-I.

**Table-I. Ages of women wearing IUCD**

Age in years	No of Pts	%age
15 years	0	0
16-20 years	2	0.4
21-25 years	60	12.0
26-30 years	200	40.0
31-35 years	208	41.6
36-40 years	20	4.0
Above 40 years	6	1.2

This table shows that peak age range for the IUCD insertion was 26-35 years (81.6%). No patient was aged less than 15 years. According to Skajaa K et al (1990) on account of a high frequency of infection, increased tendency to extrusion and poor effectivity, the use of IUCD in young nulliparous women are not recommended. The relationship between parity and IUCD insertion is shown in Table-II.

**Table-II. Parity and contraceptive use.**

Parity	No of Pts	%age
0	0	0
1	30	6.0
2-3	342	68.4
4-5	120	24.0
6 and above	8	1.6

This table shows that after 2<sup>nd</sup> and 3<sup>rd</sup> delivery. The IUCD insertion rate was highest i.e. (68.4%) substantiating the findings of Gu-J; Campbell M (1993). The time of insertion in various patients was analyzed as shown in Table-III.

This table shows that maximum insertion i.e. 70% was during and soon after menstruation and 25.6% cases were 4 – 6 weeks after delivery. Only one was in postcoital period which shows total unawareness of emergency contraception. This needs lot of more emphasis and projection.

**Table-III. Time of insertion**

Time of insertion	No of Pts	%age
Intermenstrual	350	70.0
Postnatal	100	20.0
Postabortion	21	4.2
Postcoital	1	0.2
Post caesarean	28	5.6

The complications encountered during insertion of IUCD are shown in Table-IV.

This table shows that pelvic pain (3%) was the commonest problem during insertion of IUCD and 1% cases required dilation while none of patient had syncope and cervical laceration.

The main complications associated with IUCD was shown in Table-V.

**Table-IV. Percentage of complications/complaints associated with IUCD insertion**

Insertion problems	No of Pts	%age
Failed insertion	2	0.4
Dilatation	5	1.0
Cervical laceration	0	0
Syncope	0	0
Pelvic pain	15	3.0

**Table-V. Complications associated with IUCD**

Complications	No of Pts	%age
Accidental pregnancy	5	1.0
Expulsion	3	0.6
Bleeding	27	5.4
Pain	28	5.6
Pelvic infection	10	2.0
Misplaced thread	9	1.8
Perforation	1	0.2

This table shows 1% pregnancy rate with IUCD, similar to the study of Reinprayoon-D (1992). The complications associated with pregnancy is shown in Table-VI.

**Table-VI. Outcome of pregnancy**

Outcome of pregnancy	No fo Pts	%age
Spontaneous abortion	1	0.2
Ectopic pregnancy	1	0.2
Septic abortion	-	-
Full term pregnancy	3	0.6

This table shows that 1 patient had spontaneous abortion while 3 patients had full term pregnancies. Table VII shows that most common reasons for discontinuing IUCDs use were planned pregnancy, husband or personal reasons (27%) similar to results of Petta CA; Amata R et al 1994 so effective and regular counseling about IUCD use, especially among illiterate women, may help to prevent IUD discontinuations related to personal reasons.

**Table-VII. Causes of removal of IUCD**

Causes of removal Cu-T	No of pts	%Age
Menorrhagia	16	3.2
Amenorrhoea (Pregnancy)	4	0.8
Pelvic infection	5	1
Planning pregnancy or personal reasons	135	27

Table-VIII, shows various ways of removal of misplaced IUCD.

**Table-VIII. Removal of misplaced thread.**

Procedure	No of Pts	%age
Dilatation	8	1.6
Laparotomy	1	0.2
Laparoscopy	0	0

This table shows that in 8 patients, the lost thread of

IUCD was removed by dilatation of cervical Os. One patient presented with post menopausal bleeding with formation of pyometra. On dilatation, a forgotten IUCD was removed.

**Table-IX. Follow up cases.**

Complaints on follow up	No of Pts	%age
No problems	312	62.4
Came with problems	83	16.6
Never come for follow up	105	21.0

Only one patient required laparotomy for lost IUCD. The Cu-T was embedded between omentum by perforating the fundus. However, there were 4 patients referred from outside with misplaced thread and laparotomy was done for removal of lippe's loop from peritoneal cavity.

This table shows that 62.4% patients had no problems associated with IUCD, only 16.6% patients had some problems i.e. bleeding, pain, pelvic infection etc. The follow up service is poor i.e. 21% patients had never come for follow up.

## DISCUSSION

In developing countries Copper-T 380 A. seems to be one of the most effective method of birth spacing because most of women are illiterate and worked up with house hold affairs as it provides effective contraception without paying much attention to the method e.g. having to attend the family planning clinic repeatedly or to remember taking a pill.

They have a significantly extended use effectiveness and are easy to insert, the useful life span probably can be prolonged to 6 – 8 years or more<sup>24</sup>.

There is no evidence of impairment in resumption of fertility in women who discontinue use. The net cumulative probability of pregnancy was three times higher in first three months and somewhat higher in the first 4 – 11 months after removal of IUCDs<sup>25</sup>.

In our study maximum age were between 26 – 35 years (81.6%) and parity was between 2 – 3 (68.4%).

Very few insertion problems were encountered in our study and this is very important psychologically for the clients who have developed absolute confidence in the services offered by the unit. The most common problem encountered was pelvic pain (3%) and 1% patients required dilatation due to cervical stenosis.

No analgesia or local anaesthesia was used during insertion. A modified paracervical block with lignocaine injection has been demonstrated to give excellent pain relief, although the injection themselves may offer some discomfort and risk<sup>26</sup>. More recently intracervical application of gel have offered significant reduction in patients pain perception and this seems to be simpler and less invasive than injections<sup>27</sup>.

In our study majority of insertions 70% were in intermenstrual phase, 25.6% was carried out 4 – 6 weeks after delivery. According to Blum-MN Kaplan-B (1992) 3 – 6 weeks post delivery IUCD insertion is the best method of choice for breast feeding mothers.

Post placental insertions and early puerperal insertion within 7 – 8 days from delivery were not carried out in our study. Perhaps insertion at this time could revolutionize the family planning practice in our country as patients are easier to convince at that time and later they usually never return to the hospital.

In our study main problems noted were bleeding (5.4%), pain (5.6%) pelvic infection (2%) accidental pregnancy (1%), misplaced thread (1.8%), spontaneous expulsion (0.6%) and perforation (0.2%).

According to Saeeda Majid (1993) the main problems noted were spontaneous expulsion (7.8%) followed by bleeding (5.5%), pain (7.2%) and infection (2.8%).

The only possible drawback of IUCD could be that on the whole, majority of our women are already anemic & IUCD increases the menstrual blood loss by about 40 – 50%. Severe menstrual blood loss mostly occurred in the first three months after insertion and then declined in the rest of the year<sup>25</sup>, similar to my study and majority of patients respond to medical treatment i.e. PG synthesis inhibitor and antifibrinolytic agents. This treatment is used only intermittently, has been well tolerated with no serious side effects<sup>28</sup>.

In our study the overall pregnancy rate was 1% (both ectopic & intrauterine). The high efficacy of Copper-T in preventing accidental pregnancies has been equated to that of oral contraceptives and even sterilization<sup>29</sup>.

In this study expulsion occurred in 3 patients (0.6%) within first 3 months of insertion. According to WHO (1987) Copper device is associated with low expulsion rates i.e. 3.3-7.1/100 women. In this study expulsion took place in young multiparous woman substantiating the findings of Zhang-J et al, 1992<sup>30</sup>.

Lastly perforation of the uterus by an IUCD is thankfully a rare but a recognised potentially fatal complication. In our study the incidence of perforation was 0.2% and this varies from 0.12 – 0.68/1000 insertion<sup>31</sup>. This occurred mainly during insertion and can be avoided by careful examination of the patient to determine the size and position of the uterus.

## CONCLUSION

It is concluded from this study that the IUCD is a highly effective method of contraception with patient acceptance as good as for other reversible methods such as the pill. The acceptability of IUCD can be increased by good clinical management, sympathetic counseling, careful client selection, proper device selection, careful insertion, timing and regular follow up with good access to medical care<sup>30</sup>.

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