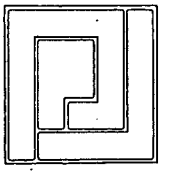
# A COMPARATIVE STUDY OF THE COPPER T 380 AG AND THE COPPER 7



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## ABSTRACT

**Two copper devices are compared in randomly selected 199 interval women in a big urban family planning center in Manila. Users of Cu 7 and Cu T 380 Ag were followed up for one year. No complications were encountered during insertion. Rates between the two groups did not show any statistical difference, with high continuation for both during the short observation period. Cu T 380 Ag contains silver which can possibly increase effectiveness.**

## INTRODUCTION

Most studies point to copper intrauterine devices (IUDs) as an improvement over the first generation nonmedicated IUDs because the pain, bleeding, and expulsion rates are relatively less. However, all these event rates are influenced not only by the shape and the size of the device but also by the amount of copper contained in the vertical or horizontal arm, as copper is thought to have a special contraceptive effect. It is for this reason that many types of copper devices have been designed and studied to find what might be an "ideal" IUD.

One such study was conducted at the Jose Fabella Memorial Hospital Comprehensive Family Planning Center in Manila for an 18-month period, from May 1981 to November 1983. A total of 200 women were enrolled in this study designed to compare two types of copper IUD – the Copper 7 (Cu 7) and the Copper T380 Ag (TCu 380 Ag).

The TCu 380 Ag is a polyethylene T-shaped device with two copper collars on its horizontal arm and tightly wound copper wire with a silver core on its vertical stem. The silver core prevents the wire from fragmenting as the copper dissolves. Total exposed copper surface area is 380 sq. mm. The TCu 380 Ag is manufactured with a polyethylene ball at the bottom of the vertical stem which helps prevent cervical injuries.

The Cu 7 IUD consists of 200 sq. mm. of copper wire wound on the longitudinal limb of a plastic carrier shaped like the number seven.

## METHODOLOGY

Data for this study were generated by recording information on the 200 sample women reporting at the Jose Fabella Memorial Hospital for IUD insertion and on their follow-up visits during the next 12 months. The devices were randomly allocated to these women according to sealed envelopes preprinted at Family Health International (FHI)[1] in the United States of America and opened at the time of insertion. All the devices were inserted by an obstetrician/gynecologist.

Following the random allocation, a total of 107 women were fitted with the Cu 7 and 93 women fitted with the TCu 380 Ag. They constituted the study group for comparative purposes in this study. The IUDs were inserted in the women at least 42 days after their last pregnancy termination. This study, however, focuses on only 199 interval women, i.e. women not pregnant within the last 42 days, and excludes one woman fitted with the Cu 7 device as she was already postpartum at the time of insertion.

Socio-demographic characteristics, past contraceptive history and medical conditions were recorded at insertion time. Results of medical examinations and complaints, on the other hand, were the focus of the follow-up visits. These data were recorded on standard forms designed by FHI. At the end of the data collection period, forms were sent to FHI for processing and analysis. A copy of the forms was retained and has been the data source for this paper.

## PATIENT CHARACTERISTICS

### *Socio-demographic Characteristics*

The socio-demographic characteristics of each study group of sample women are listed in Table 1.

*Age.* The mean age of the women in the TCu 380 Ag group was 25.9 years. For the Cu 7 group, the mean age of the women was 25.1 years. In both groups, the biggest number of women were to be found in the 20-24 age cohort; both groups had 46.2 percent of these women. The next biggest group was the 25-29 age cohort. But whereas the TCu 380 Ag group had 33 women (35.5 percent), the Cu 7 group had 27 women (25.5 percent). The latter group, however, had a far greater number of women in the below-20 age group – 11 women (10.4 percent) as against two women (2.2 percent) from the TCu 380 Ag group. This age distribution depicts a slightly younger Cu 7 group.

*Education.* The median number of years completed in school was 9.9 for the TCu 380 Ag group and 10.0 for the Cu 7 group. The majority of women in both groups had reached high school, i.e. had completed from seven to 12 years of schooling – 62 women (66.7 percent) of the TCu 380 Ag group and 75 women (70.7 percent) of the Cu 7 group.

*Live Births.* At the time of insertion, the mean number of live births was 2.4 for the TCu 380 Ag women and 2.3 for the Cu 7 women. The biggest number of women had had two live births (37 women or 39.8 percent among the TCu 380 Ag group and 48

Table 1. Socio-demographic Characteristics

| Characteristics | TCu 380 Ag (N = 93) No. | TCu 380 Ag (N = 93) Percent | Cu 7 (N = 106) No. | Cu 7 (N = 106) Percent |
|---|---|---|---|---|
| Age (in years) | | | | |
| 20 | 2 | 2.2 | 11 | 10.4 |
| 20–24 | 43 | 46.2 | 49 | 46.2 |
| 25–29 | 33 | 35.5 | 27 | 25.5 |
| 30–34 | 11 | 11.8 | 16 | 15.1 |
| 35+ | 4 | 4.3 | 3 | 2.8 |
| Mean | 25.9 | | 25.1 | |
| Education (years completed) | | | | |
| 1–6 | 26 | 28.0 | 20 | 18.8 |
| 7–12 | 62 | 66.7 | 75 | 70.7 |
| 13+ | 5 | 5.4 | 11 | 10.4 |
| Median | 9.9 | | 10.0 | |
| Live births | | | | |
| 1 | 16 | 17.2 | 20 | 18.9 |
| 2 | 37 | 39.8 | 48 | 45.3 |
| 3 | 30 | 32.3 | 29 | 27.4 |
| 4+ | 10 | 10.8 | 9 | 8.5 |
| Mean | 2.4 | | 2.3 | |

Table 2. Previous Contraceptive Use

| Contraceptive method used in past month | TCu 380 Ag (N = 93) No. | TCu 380 Ag (N = 93) Percent | Cu 7 (N = 106) No. | Cu 7 (N = 106) Percent |
|---|---|---|---|---|
| None | 78 | 83.9 | 94 | 88.7 |
| IUD | 0 | 0.0 | 1 | 0.9 |
| Orals | 10 | 10.8 | 7 | 6.6 |
| Condoms | 3 | 3.2 | 3 | 2.8 |
| Withdrawal/rhythm | 2 | 2.2 | 1 | 0.9 |

women or 45.3 percent among the Cu 7 group). This was followed by the women who had had three live births (30 women or 32.3 percent for the former and 20 women or 27.4 percent for the latter).

In other words, in terms of age, education and the number of live births, the women in the two groups were basically similar.

*Previous Contraceptive Use*

There was a high tendency in the sample to accept IUD as a first method inasmuch as 78 women (83.9 percent) in the TCu 380 Ag group and 94 women (88.7 percent) in the Cu 7 group were not using any form of contraception in the month prior to IUD insertion (Table 2). Among those who had previous contraceptive experience, the pill was the most popular followed by the traditional methods. The breakdown for the two groups is as follows. None of the TCU 380 Ag users and one Cu 7 user (0.9 percent) had previously worn an IUD. Oral contraceptives had been used by 10 women (10.8 percent) in the TCu 380 Ag group and by seven women (6.6 percent) in the Cu 7 group. Five of the women (5.4 percent) in the TCu 380 Ag group and four women in the Cu 7 group (3.7 percent) had been using more traditional methods of contraception such as condoms or withdrawal/rhythm.

*Medical History*

An examination of the medical history reports of the women reveals that only one woman (1.1 percent) in the TCu 380 Ag group had a previous episode of pelvic inflammatory disease (PID) four to six months prior to IUD insertion and another had a previous PID episode more than a year earlier. No other relevant medical problems prior to insertion were reported. Among the Cu7 group, there was no report of previous infection.

## RESULTS

*Complications and Complaints*

Complications and complaints recorded at insertion and follow-up are presented in Table 3.

At the time of insertion, no complications were reported for either group. None of the women in either group required cervical dilatation. There were no lacerations, perforations or other related problems reported at the time of insertion. All insertions were completed successfully.

There was, however, a small number in each group which reported mild pelvic pain at the time of insertion. Thirteen women or 14 percent of the TCu 380 Ag group and 11 women or 10.4 percent of the Cu 7 group recalled having some kind of mild pelvic pain.

Post-insertion data were obtained from a total of 91 women in the TCu 380 Ag group (97.8 percent) and 105 women in the Cu 7 group (99.1 percent) who returned for at least one follow-up visit. The following are the reports of these women.

Dysmenorrhea was the most com-

Table 3: Complications/complaints at Insertion and Follow-up*

| Complications | TCu 380 Ag (N = 93) No. | TCu 380 Ag (N = 93) Percent | Cu 7 (N = 106) No. | Cu 7 (N = 106) Percent |
|---|---|---|---|---|
| Insertion complications/complaints | | | | |
| Pelvic pain | | | | |
| None | 80 | 86.0 | 95 | 89.6 |
| Mild | 13 | 14.0 | 11 | 10. |
| Follow-up complications/complaints | 91** | | 105** | |
| Perforation | 0 | 0.0 | 1 | 0.9 |
| Dysmenorrhea | 28 | 30.8 | 36 | 34.3 |
| Intermenstrual | | | | |
| Bleeding | 0 | 0.0 | 1 | 0.9 |
| Spotting | 0 | 0.0 | 1 | 0.9 |
| Pelvic pain | 4 | 4.4 | 2 | 1.9 |
| Infection | 0 | 0.0 | 1 | 0.9 |
| Women with 1+ complications/complaints | 28 | 30.8 | 36 | 34.3 |

*More than one complication/complaint may be recorded for a woman.
**Women who came back for follow-up.

monly cited complaint in both groups. It was reported by 28 women (30.8 percent) in the TCu 380 Ag group and 36 women (34.3 percent) in the Cu 7 group.

There was relatively small proportions reporting other types of complaints. While none of the women in the TCu 380 Ag group reported intermenstrual bleeding or spotting, one woman in the Cu 7 group (0.9 percent) reported intermenstrual spotting.

Intermenstrual pelvic pain was reported by four women (4.4 percent) in the TCu 380 Ag group and two women (1.9 percent) in the Cu 7 group.

There were no other complications or complaints recorded for the women in the TCu 380 Ag group. For the Cu 7 group, however, two other complications or complaints were recorded. One woman (0.9 percent) was discovered to have a cervical perforation. The device was removed but no other treatment was required. Another woman had an unspecified infection diagnosed. This infection was diagnosed eight months after the insertion and the device was removed by a physician

In summary, the total number of women with at least one complication or complaint was 28 in the TCu 380 Ag group (30.8 percent) and 36 in the Cu 7 group (34.3 percent). It can, therefore, be argued that client satisfaction was greater among the former group.

Table 4. Gross Event and Continuation Rates per 100 Users

| Termination Type and Period | TCU 380 Ag | Cu 7 |
|---|---|---|
| Pregnancy | | |
| 3 months | 0.0 | 0.0 |
| 6 months | 0.0 | 1.1 ± 1.1 |
| 12 months | 0.0 | 4.5 ± 2.2 |
| Expulsion/displacement | | |
| 3 months | 6.5 ± 2.6 | 4.8 ± 2.1 |
| 6 months | 8.8 ± 3.0 | 7.8 ± 2.6 |
| 12 months | 9.9 ± 3.1 | 8.9 ± 2.8 |
| Removal for bleeding/pain | | |
| 3 months | 0.0 | 2.0 ± 1.4 |
| 6 months | 0.0 | 2.0 ± 1.4 |
| 12 months | 2.5 ± 1.8 | 2.0 ± 1.4 |
| Removal for other medical reasons | | |
| 3 months | 0.0 | 0.0 |
| 6 months | 0.0 | 1.1 ± 1.1 |
| 12 months | 0.0 | 2.2 ± 1.5 |
| Continuation rate | | |
| 3 months | 93.5 | 92.4 |
| 6 months | 89.1 | 87.6 |
| 12 months | 85.7 | 81.6 |
| Follow-up rate* | | |
| 3 months | 97.7 | 98.0 |
| 6 months | 97.6 | 97.8 |
| 12 months | 96.3 | 9 |

*Follow-up rate is defined as the percent of women who returned for follow-up who were not previously terminated.

*Termination and Event Rates*

Termination and event rates are shown on Table 4.

Termination rate, which is computed on the basis of the life table method, refers to discontinuation of use of the method by the women due to accidental pregnancy, expulsion, removal for bleeding/pain, planning for next pregnancy, medical, personal and other reasons. The above reasons for discontinued use of the method are called "events."

The follow-up rate (the percentage of women returning for follow-up who have not been previously terminated) at 12 months was excellent: 96.3 for the TCu 380 Ag users and 94.3 for the Cu 7 users.

Accidental pregnancies with the device in situ occurred only in the Cu 7 group. In this group, four pregnancies occurred at four, seven, eight and 12 months after the device had been inserted for a cumulative rate of 4.5 at 12 months. Three of these four pregnancies resulted in spontaneous abortions and the fourth resulted in a live birth. In spite of this, the pregnancy rate difference between the two groups, however, was not statistically significant.

At 12 months, the expulsion rate was 9.9 for the TCu 380 Ag group and 8.9 for the Cu 7 group.

The TCu 380 Ag group had a 12-month removal rate for bleeding/pain of 2.5, compared to a rate of 2.0 for the Cu 7 group.

There were no TCu 380 Ag devices removed for other medical reasons. On the other hand, two devices were removed for the Cu 7 group, one for perforation and one for infection, yielding a 12-month removal rate of 2.2.

It is important to note, however, that there were no statistically significant differences between the two groups for any of the termination rates. Likewise, complications and complaints were comparable for both groups.

At the end of the 12 months of follow-up, the continuation rate was 85.7 for the TCu 380 Ag group and 81.6 for the Cu 7 group.

## CONCLUSION

The findings of the study did not validate an expected advantage of the TCu 380 Ag which has longer effective life due to its silver content. This is not conclusive though, since the follow-up was done only for a period of one year. A longer follow-up may still demonstrate its prolonged effectiveness, in which case replacement may not be necessary for at least six years.

In conclusion, there seemed to be no important differences in the types and incidence of problems related to insertion of the two types of IUD. Likewise, there were no important differences in their failure rates as indexed by pregnancy rates, expulsion rate and removal rate. On the whole, the problems related to both IUD types were minimal.

## NOTE

[1]FHI partially supported this study, with funds from the United States Agency for International Development.