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PREGNANCIES WITH COPPER INTRAUTERINE DEVICES: HYSTEROSALPINGOGRAPHIC STUDIES

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I. INTRODUCTION

Although the addition of a small amount of copper has increased the effectiveness of small plastic intrauterine devices[16 19 23 24], the mechanism by which this effect is achieved has not been established. The copper content in the cervical mucus of T-Cu users is increased[5 6] and it has been suggested that copper ions may inhibit sperm motility and migration through cervical mucus[10 20]. Copper may also have an effect[2] on the endometrium, preventing implantation by humoral or cell-mediated reactions or through mobilization of leucocytes of various types in the lining or the lumen[21]. The copper does not appear to have a direct cytotoxic effect on the zygote[2].

In contrast to the T- and 7-shaped devices the effectiveness of the Lippes Loop has not been enhanced by the addition of copper[12 13]. This finding suggests that the mechanism by which copper enhances the effectiveness of the T- or 7-shaped devices may not be related to a chemical action, but perhaps to a local mechanical action resulting from the increased size and surface area of the smaller devices.

The present study was undertaken to investigate pregnancies that occurred with the two copper-bearing devices--the Cu-7 and Cu-T-200--to determine why contraceptive failures occur with these devices.

II. MATERIALS AND METHODS

The study population consisted of 155 multiparous, private patients of the Senior Authors who were followed up for at least 24 months after IUD insertion. In 75 women, the copper T (T-Cu 200) was inserted and in 80 the Cu-7-200 (gravigard) was used. IUD insertions were performed as described in a previous paper[8].

After 12 months of uninterrupted use, three women using the T-Cu device and five women using the Cu-7 became pregnant. When these women returned for follow-up visits after missing one or more menstrual periods, the suspected pregnancies were diagnosed clinically and by pregnancy tests.* The IUD was expelled in only one of the eight cases: this patient had a Cu-7.

Hysterosalpingograms using dilute Urographine[14] were performed on the eight patients who became pregnant during the first year. In four cases the devices were in situ (visible thread), and the pregnancies were confirmed (Figures 1, 2, 3, and 4). After x-ray diagnosis, dilatation and evacuation of the uterine contents were performed. Subsequent histological examinations of curetted material verified the diagnosis of pregnancy. In the one patient who had unknowingly expelled the device (Figure 5) and in two others (Figures 6 and 7), the hysterosalpingograms were performed after the uterine contents were evacuated. In these three cases, IUDs similar to those originally present (one T-Cu and two Cu-7s) were reinserted in order to study the configuration of the uterine

*Pregnosticon Plantotest, Organon, Inc., West Orange, New Jersey.

cavity in relation to the orientation and disposition of the device.

The eighth woman elected to continue the pregnancy. In order not to injure or disturb the conceptus, hysterosalpingography or removal of the device was not attempted during pregnancy. The pregnancy continued to full term and the patient gave birth to a normal baby.

III. RESULTS

Hysterographic findings from these eight cases are presented in Figures 1 through 8. Three patients had uterine anomalies: two had uteri biconis (Figures 1 and 2) and one had uterus arcuatus (Figure 3) In three patients (Figures 1, 4, and 5), the devices were located in the cervix. It cannot be determined from these hysterograms whether the devices were pushed down by the products of conception when pregnancy occurred or were placed low originally. In one case the device was anchored to the myometrium and, thus, could not be displaced downwards by pregnancy (Figure 6). In the patient who spontaneously expelled the Cu-7 (Figure 7), the uterine cavity had a normal triangular shape. One patient retained the T-Cu during pregnancy and labor. Four months after the delivery, hysterography showed that the IUD was still anchored to the myometrium in the middle of the uterine cavity away from the fundus (Figure 8).

During the second follow-up period, two more patients became pregnant (one T-Cu and one Cu-7). Hysterography revealed an arcuate uterus with the T-Cu, and with the Cu-7, the device was in the lower part of

the uterus. This patient had had a lower segment cesarean section two years before.

The one-year pregnancy rates per 100 woman years in the study population are given in Table I for copper-bearing devices. The table also includes the pregnancy rate for a group of the senior author's private patients who used the Lippes Loop C[9]. Age, parity, and socio-economic status of the groups of women were comparable. Pregnancy rates after one year were 4.1, 6.9, and 2.6 for the T-Cu, Cu-7, and Lippes Loop users, respectively. The differences in the pregnancy rates between the T-Cu and the Cu-7 were not significant ($p>.10$), but the rates for the two copper-bearing devices together were significantly greater than for the plastic Lippes Loop ($p<.10$). It is apparent, however, that because of the small number of subjects, a difference of only one or two pregnancies would significantly alter the rates.

Data for a substantially larger population provided by the Cooperative Statistical Program of the Population Council, New York[1], are given in Table II. These data show that the addition of copper wire to the T device did not lower the pregnancy rate to that of the plastic Lippes Loop. The gross cumulative pregnancy rates for the T-Cu and the Lippes Loop were identical in the first year of use (3.2) and the rate for the T-Cu was slightly higher after the second year (6.1 for the T-Cu and 5.5 for the Lippes Loop).

IV. COMMENTS

The T and 7 devices, which are smaller than the Lippes Loop D, are reported to be better tolerated and to cause fewer problems with bleeding and pain than the Lippes Loop[11 15]. The addition of copper wire around the stems of the plain T and 7 devices has also been reported to increase their contraceptive effectiveness. It was found that the pregnancy rate could be reduced from 18.3 to 4.9 per 100 woman years when 30 mm^2 of metallic copper was added to the T device[24]. Increasing the surface area of the copper wire to 200 mm^2 further reduced the pregnancy rate to 1.0 per 100 woman years[17].

It is not clear whether the effectiveness of the added copper is the result of a chemical action or simply the result of the increased surface area created by the wire added to the stems of the plain T and 7 devices. It is known that the smaller the size of a particular type of device, the higher the pregnancy rate[18]. It has also been reported that the total surface area of a plastic device is inversely correlated with its pregnancy rate (Table III)[3]. Pregnancy rates for the Birnberg bow (small) and the Lippes Loop A (14.5 and 9.7) were nearly double for the large bow and the Lippes Loop D (7.1 and 4.3). In contrast to the results obtained with the T- and 7-shaped devices, the addition of copper to the inert plastic Lippes Loop did not significantly alter its contraceptive effectiveness[19].

The one-year gross cumulative pregnancy rates in our population were 4.1, 6.9, and 2.6 for the T-Cu 200, the Cu-7, and the Lippes Loop,

respectively. These rates for the copper devices are slightly higher than the one-year pregnancy rate of 3.2 per 100 women-years associated with the T-Cu as reported by Tietze in the Cooperative Statistical Program[18].

In this study population, the pregnancy rates for the Cu-7 and the T-Cu were not significantly different. Among the eight cases of pregnancy occurring among patients with copper-bearing devices, three women had congenital uterine anomalies. Regardless of whether the patient has a plain or a copper-bearing device, abnormalities in uterine shape, such as a uterus bicornis, can disorient the device or displace the device away from the fundus leaving an area of the uterine cavity where pregnancy may occur. In this study population the T-Cu appeared to be better retained in the uterus than the Cu-7. While the Cu-7 has only one free tip, the T-Cu can anchor itself to the myometrium by the free tips of its two transverse arms[8].

In conclusion, the contraceptive action of an IUD appears to be primarily local, related to the area in contact with endometrium. The surface area of the device plays a major role, perhaps by increasing leucocytosis, phagocytosis, or other histochemical reactions. The presence of a congenital anomaly in the uterus or a disproportion between the uterine cavity's shape and size and that of the device leads to its disorientation or displacement; thus, it leaves part of the endometrium unprotected in which implantation can occur.

In order to achieve optimum contraceptive effectiveness, an IUD should come in contact with most of the uterine cavity and should be made of a pliable material which can adapt to minor abnormalities in the shape of the uterine cavity. It should be retained very near the fundus of the uterus and should have some mechanism to prevent its displacement. The mechanism of retention can vary from one device to another, but the contraceptive effect probably remains the same and is related to the amount of surface area in contact with the myometrium whether the IUD is a plain or a copper-bearing device.

LEGENDS TO FIGURES

Fig. 1. Uterus bicornis, pregnancy in right horn, Cu-7 displaced down into cervix.

Fig. 2. Uterus bicornis, T-Cu reinserted six months after evacuation.

Fig. 3. Uterus arcuate, Cu-7 reinserted three months after evacuation.

Fig. 4. Pregnant uterus, T-Cu pushed down into cervix.

Fig. 5. Pregnant uterus one year after cesarean section, Cu-7 displaced down into cervix.

Fig. 6. Pregnant uterus one year after cesarean section, Cu-7 in body of uterus anchored in myometrium.

Fig. 7. Spontaneous unnoticed expulsion, Cu-7 reinserted three months after evacuation. No anomalies could be detected.

Fig. 8. T-Cu retained during pregnancy and labor, hysterogram taken four months after labor.

Table 1

ONE-YEAR PREGNANCY RATES PER 100 WOMAN-YEARS

Device	No. of Insertions	Woman Months of Use	Pregnancies No.	Pregnancies Rate
T-Cu 200	75	868	3	4.1
Cu-7	80	875	5	6.9
Lippes Loop C	590	4584	10	2.6

Table II

ONE- AND TWO-YEAR PREGNANCY RATES PER 100 WOMEN*

Device	No. of Insertions	Woman Months of Use	Pregnancy Rate	
			1 year	2 years
T-Cu	6,801	52,133	3.2	6.1
Lippes Loop D	7,419	105,199	3.2	5.5

*Source: Data from the Cooperative Statistical Program, Reference 1.

Table III

TWO-YEAR PREGNANCY RATES BY SURFACE AREA OF DEVICE

Device	Surface Area by mm^2	Rate/ 100 Women
Birnberg bow (small)	390	14.5
Lippes Loop A	527	9.7
Birnberg bow (large)	730	7.1
Margulies (small)	960	3.6
Lippes Loop D	960	4.3
Margulies (large)	1200	2.5

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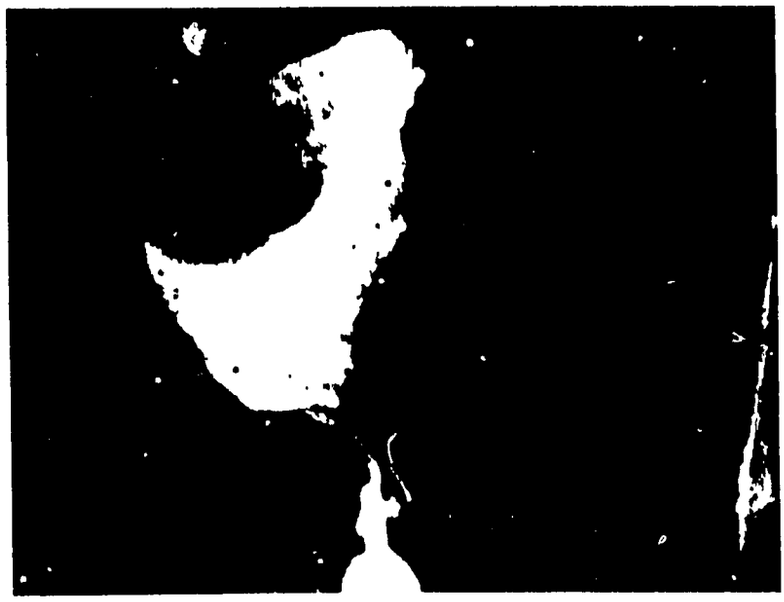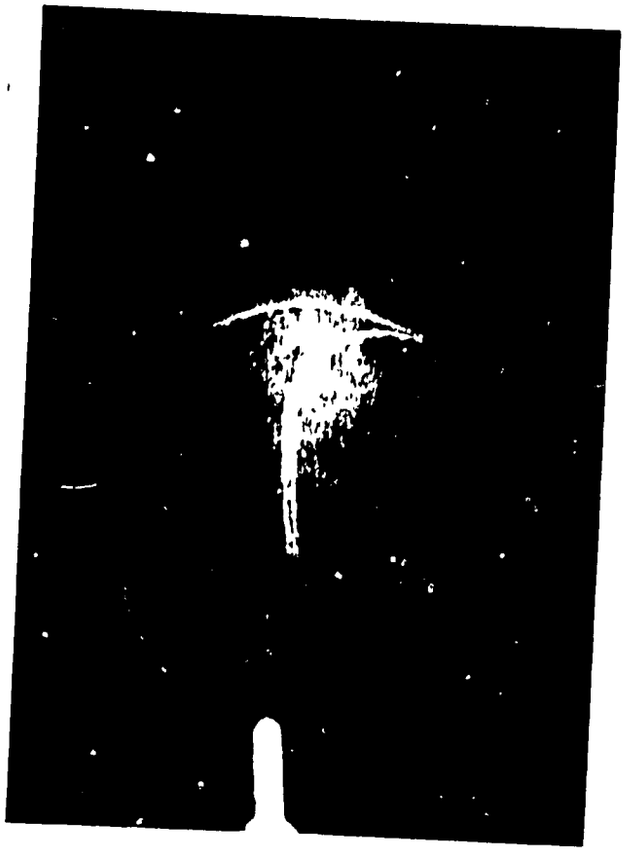
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