



## Clinicocytological study in copper-T users

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**OBJECTIVE(S) :** To study cervical changes in copper –T (Cu-T) users, along with effect of Cu-T on cervical exfoliative cytology by Pap test and to ascertain the safety of Cu-T with reference to cervical dysplasia.

**METHOD(S) :** Two hundred and eighty two women with Cu-T in situ were subjected to detailed history taking, clinical examination and Pap smear study. These women were compared with 100 asymptomatic women and having no Cu-T insitu matched for age, parity and socioeconomic status.

**RESULTS :** 47.6% of subjects had normal cytology as compared to 58% of the controls. Atypia of squamous cells of undetermined significance were seen in 1.4% of the subjects as compared to 2% of the controls. There was increased acceptance of Cu-T for family planning (73%), even though backache (44.6%) and menorrhagia (38.2%) occurred.

**CONCLUSION(S) :** There is no precipitous carcinogenicity of Cu-T but a long term follow up is needed. Subjects fitted with intrauterine devices deserve continuous surveillance but are not subjected to increased risk of malignancy because of their choice of birth control method.

**Key words :** copper T users, Pap test, dysplasia

### Introduction

About 106 million women throughout the world are using intrauterine contraceptive device (IUCD)<sup>1</sup>. At present Copper T – 200B (Cu-T) is the most widely used IUCD in India. It is a reliable, reversible, economic, and safe method for regulation of population<sup>2</sup>. The patients with intrauterine devices came for relatively frequent follow ups. This study deals with the changes in cervical cytology associated with Cu-T IUCD. The side effects with copper devices have also been studied.

### Methods

In the present study 290 women with Cu-T insitu were subjected to cytological examination of the cervix by Pap

test done by standard technique. In eight cases the smears were unsatisfactory (did not have endocervical and metaplastic cells). Hence these were excluded from the study. A total of 100 controls matched for age, parity and socioeconomic status were similarly studied. Subjects (282) and controls (100) were compared for cytological changes with special reference to dysplasia and malignancy. The smears were taken from the cervix by an Ayre's spatula fixed by standard method of fixation, and subjected to Pap staining. Cytology of the uterine cervix was reported according to the Bethesda classification<sup>3</sup>. The results were analysed using Z test for proportions.

### Results

47.5% (134/282) of the subjects showed normal cytology as compared to 58% (58/100) of the controls. 22.7% (64/282) of the subjects showed infection of various types compared to 18% of the controls. Trichomonal infection was the commonest one seen in 73.4%. Reactive and reparative changes were seen in 26.9% (76/282) of the subjects. Atypia of squamous cells of undetermined significance (ASCUS) was seen in 1.4% of the subjects as compared to 2% of the controls. No case of invasive cancer was seen.

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Maximum number of normal smears (61.5%; 64/104) were found when the duration of Cu-T was less than one year. As the duration of Cu-T increases, incidence of infection

increases reaching a maximum incidence of 35.4% with duration of Cu-T up to 3 years. Incidence of ASCUS and low grade intraepithelial lesion (LSIL) increases with the increase in duration of insertion (Table 1).

**Table 1. Cervical cytology in relation to duration of use of Cu-T (n=282).**

Cervical cytology	Duration of Cu-T use			
	Upto 1 year n=104	Upto 2 years n = 85	Upto 3 years n = 79	More than 3 years n=14
Normal	64	40	26	4
Infection	14	20	28	2
Reactive and reparative	26	24	22	4
ASCUS	-	-	2	2
LSIL	-	1	1	2

ASCUS - Atypia of squamous cells of underdetermined significance LSIL - low grade intra epithelial lesion

Maximum number of women with Cu-T insitu were in the age group of 21-25 years (39.8%) and among those having one child group (73.1%).

A total of 126 (44.6%) subjects had no complaints. The most common complaint was backache followed by menorrhagia. Yet the most common reason for the removal of Cu-T was for planning pregnancy (14.8%) followed by those undergoing sterilization (12%) (Table 2).

**Table 2. Complaints in Cu-T users (n=282).**

Complaint	Number (Percentage)
Backache	126 (44.6)
Menorrhagia	108 (38.2)
Lower abdominal pain	46 (16.3)
Excessive vaginal discharge	42 (14.8)
Pregnancy	
Intrauterine	6 (2.1)
Ectopic	2 (0.7)
Expulsion	4 (1.4)

**Table 3. Relative risk of dysplasia in Cu-T users.**

Copper-T usage	Relative Risk	95% Confidence Interval
1yr to 2 yrs	1.308	1.004-1.734
1 yr to 3 yrs	1.653	1.275-2.186
1 yr to >3 yrs	1.176	1.028-1.414
2 yrs to 3 yrs	1.319	0.983-1.764
2 yrs to > 3yrs	1.111	0.938-1.324
3 yrs to > 3 yrs	1.03	0.823 - 1.221

?<sup>2</sup> = 50.76, P<0.001 - Very highly significant

## Discussion

A number of reports suggest that copper devices are effective and safe but the effect of copper on cervical epithelium with regards to dysplasia has not been specifically reported. IUCD usage by a large number of women has caused concern about its safety especially regarding carcinogenicity. A total of 282 smears of Cu-T users failed to reveal any case of malignancy or severe dysplasia. ASCUS were seen in four subjects (1.4%) all were above the age of 30 years and having a duration of insertion of 2-3 years. LSIL in the present study was found in four subjects (1.4%) and all were above the age of 30 years. In two of these Cu-T was insitu for more than 3 years (12 and 8 years with intermittent insertion) and in two others it was for 2 years. Incidence of ASCUS and LSIL increases with the increase in duration of insertion being maximum when the duration of insertion is more than 3 years<sup>4</sup>. Incidence 1.4% of cervical dysplasia in subjects was comparable to 2% incidence in controls. There is no increase in incidence of cervical dysplasia among subjects in the present study. However a long term follow up is needed to rule out the possibility of any increased rate of dysplasia or carcinoma in women using Copper IUCD's. The copper in the device progressively diminishes, leaving a minimal amount of the metal on the device at the end of 3 years<sup>4</sup>. Hence no increase in incidence of dysplasia is noted in the first 3 years. But it may be possible that the constant release of the copper from the device in the first 3 years of insertion in some way initiates cellular changes in the cervical epithelium that promote the occurrence of dysplasia at a later date. Table 3 gives the statistical analysis of our findings. Based on this it can be concluded that women using copper containing intrauterine devices are not subjected to increased risk of cervical malignancy.

**Conclusion**

Women using CuT for contraception do not have increased risk of malignancy but need continuous surveillance and long term follow up.

**Reference**

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