

# CURRENT CONCEPTS ON THE USE OF IUDs

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## ABSTRACT

IUDs have been used in Singapore since the mid 1960's but acceptance of this contraceptive method has fluctuated widely as a result of misconceptions regarding possible complications. The current generation of copper bearing devices have pregnancy rates below 1 per 100 women per year and this rate falls further with continued use. New developments which hold promise include a device releasing 20mcg levonorgestrel per day and a copper device without a plastic frame which may reduce menstrual blood loss and dysmenorrhoea. In addition to the well established contra-indications to use, a past history of pelvic inflammatory disease or ectopic pregnancy, promiscuity, nulliparity and age less than 25 are now considered relative contraindications.

**Key Words:** IUDs, Efficacy, Contraindications

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## INTRODUCTION

Even though IUDs have been used worldwide for more than 25 years their exact mode of action is still not fully understood (1). In the human female, the changes occurring in the endometrial environment after IUD insertion are pronounced enough to suggest strongly that the viability and implantation of the embryo would be compromised. However, the copper ions or progestin released by bioactive devices appear to have a much wider range of influence, affecting sperm migration, sperm penetration and ovum transport in addition to any local endometrial effect. Though failure of implantation remains the most likely final factor in the high contraceptive efficacy of modern IUDs a significant but unknown percentage of conceptions appear to be blocked at an earlier stage (2).

In 1985/86 events occurred which had an adverse effect on IUD use. One was the publication in the *New England Journal of Medicine* (3) of the first prospective data linking IUD use with subsequent infertility (presumably though the pathway of pelvic inflammatory disease), and the other the decision by Ortho Pharmaceutical Co. and later GD Searle to cease production of their devices (4).

Though nulliparity, promiscuity and age less than 25 have now been added to the list of relative contraindications for IUD use the impact of the withdrawal of the Tatum T (TCu200) and the Gravigard (7Cu200) from the USA market was felt throughout the world. Even though the manufacturers specifically stated that their action was based on financial rather than medical grounds the medical press linked the withdrawal to the unfortunate Dalkon Shield affair and many women became worried about IUD safety. A copper bearing IUD (TCu380A) was reintroduced into the US market in mid 1988 but its continued production must be tenuous in view of the recent successful multimillion law suit against G D Searle including a substantial element of punitive damages for supposed suppression of adverse research data.

In Singapore the position is rather more straight forward. After the initial fall in use when the Family Planning Board dropped the IUD from its first 5 year plan in the mid 1960's most of the newer IUDs have been first tested in randomized prospective trials through the NUS Department of Obstetrics and Gynaecology, first at Kangang Kerbau Hospital and more recently at the National University Hospital (5). The MCHC clinics continued to provide the Lippes Loop and more recently the Multiload (MLCu250) to interested users and two firms Organon (MLCu250 and MLCu375) and Schering AG (NTCu200Ag) have actively promoted their products in the private sector. The action by A H Robins Co. in encouraging past users of the Dalkon Shield to take legal action against them in order to support their claim for insolvency under Chapter II of the US tort laws was luckily not taken up by the Singapore press in the same way as it was in Malaysia (6) and so many of the unnecessary panic removals have been avoided.

## EFFICACY

Five of the more recent copper bearing IUDs have failure rates significantly below 2 per hundred women years in multicentre trials and 3 (TCu380A, TCu220C, MLCu375) a point estimate below 1 per hundred women years (7).

There appears to be a general trend to increasing the exposed copper area from 200-250mm to 375-380mm (2) and it is claimed that this increases efficacy though this was not demonstrated in our Singapore prospective trial (8). It has been shown that significant concentrations of copper ions are found in the fluid of the Fallopian tubes so that fundal and lateral placement of copper, near the tubal ostia, may well play a significant effect in marginally increasing efficacy. The TCu380A which is the only copper device which has a failure rate significantly below 1 per 100 women years exhibits both these features (Fig 1). these features (Fig 1).

Another device, the LNg20 (Fig 2), shows even greater efficacy having a Pearl Index of only 0.12 per 100 in a large multicentre trial. This levonorgestrel releasing device also decreases total menstrual loss whereas copper devices in general increase loss by a factor of 2 when compared to pre-insertion levels. Unfortunately supplies of this device have been temporarily cut off due to the recent legal liability fears of the manufacturers with regard to medical grade elastomer 382 (9) (incidentally a product which has been used extensively and safely in many types of human implants, including heart valves, for many years).

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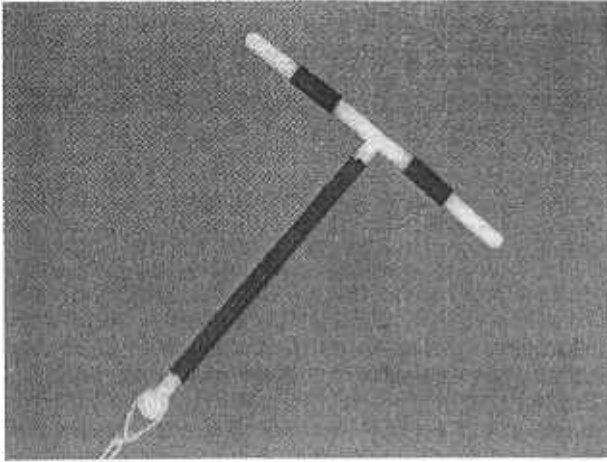


Figure 1: TCu380A

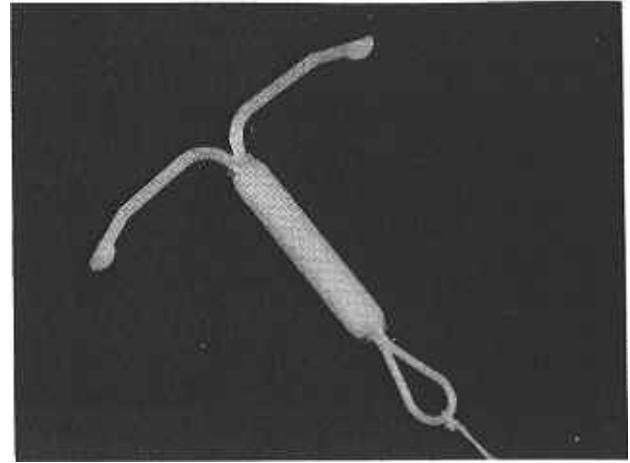


Figure 2: LNG20

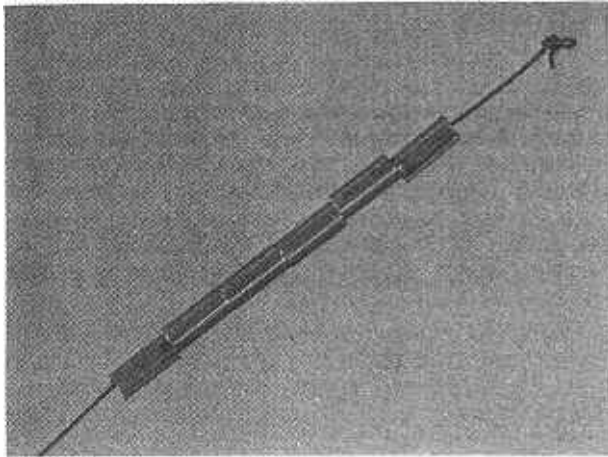


Figure 3: CuFix

### COMPLICATIONS OF IUDs

"There is no such thing as a wholly safe contraceptive" but all the currently available effective methods are associated with death rates well below the level of 10-20 per 100,000 births which is the maternal mortality even in the USA and in fact the risk of deaths is lower for IUD users than for any of the other contraceptive methods (10).

However, the risk of deaths for contraceptives is so low that this cannot usefully be used to compare methods. IUD complications can be divided into major, which result in permanent damage (e.g. ectopic pregnancy, perforation, PID) and minor, which are fully reversible when the IUD is removed (e.g. dysmenorrhoea, vaginal discharge, increased menstrual loss).

Ectopic pregnancy appears to be the most dangerous of these complications since it is potentially life threatening and also reduces the chance of future pregnancies even with modern conservative surgical management. Except for the very low dose progestin devices which have now been discontinued the current opinion is that IUDs do not increase ectopic pregnancy rates (11). However, it is true that when pregnancy occurs in IUD users it is at least 10 times (12) more likely to be ectopic than in a non user. This is explained by the concept that the IUD is much more effective in suppressing intrauterine rather than extrauterine pregnancies whereas most other contraceptive methods will affect both sites equally. Notwithstanding this theory, if IUDs are related to PID, no matter how small the incidence is there must be at least a potential for IUDs to cause ectopic pregnancy. Since the ectopic pregnancy risk appears to be least with copper bearing IUDs the

explanation perhaps lies with the significant part that copper ions play in reducing fertilization in the Fallopian tubes.

The most debated controversy about IUDs concerns the relative risk of PID. Current opinion is that IUDs are associated with PID though the relative risks (1.5 — 2.6) found in the most objective studies are well below those quoted a decade ago (13). Other contraceptive methods including oral contraceptives, spermicides and barriers give significant protection against infection and this appears to be the cause of the higher early estimations.

Most IUD related PID appears within 4 months of insertion and later presentations are usually associated with other factors, particularly sexually transmitted disease. Infection related to the Dalkon Shield also plays a significant role in all the large retrospective series from the USA but whether this is a real entity or an artifact caused by high publicity and the inherent difficulty in making a certain diagnosis of PID remains controversial.

The prospective infertility studies suggested that the PID associated with IUD use was more significant with inert devices and was not found with multiparous patients or one partner relationships. It is now therefore recommended that special care be taken to reduce infection at the time of insertion and that younger, nulliparous and promiscuous patients are generally unsuitable users. In contrast to previous teaching it is now believed that IUDs should be removed immediately on diagnosis of PID without waiting to see the results of a therapeutic trial of antibiotics.

There is no need to discuss the reversible complications in depth. Modern ultrasound techniques have proved very useful in assessing the site of an IUD even when the threads are not visible or if perforation has occurred. In some European centres an ultrasound scan is routinely performed after insertion ensuring good position of the device and thereby reducing complications such as implantation above the device (with low placement) or embedding of the device tip into the endometrial wall (which could proceed to full perforation).

### NEW IUD SYSTEMS

The combination of commercial pressures and enthusiasm from those that have designed new devices will always ensure that new IUD systems appear. However, since complication rates (particularly pregnancies) are now so low and the inter-clinic variability in results so high, the only effective way to assess new IUDs is in multicentre trials such as those sponsored by WHO and the Population Council.

It must also be remembered that it is not only the device itself but the whole system, including the insertion

mechanism which is important for correct placement. New designs currently under investigation in Singapore include the MLCu380 with its rather complicated insertion system and the CuFix (Fig 3) with its copper cylinders suspended on a nylon thread from the myometrium at the uterine fundus.

WHO has promised to reintroduce the LNG20 device once a manufacturer can be found for the plastic reservoir which releases the levonorgestrel and it is hoped this will be available for further trials within 2 years. Another current WHO multicentre trial is also assessing whether the silver cored copper wire used to prevent fragmentation (e.g. in the TCU380Ag and the NTCu200Ag) has any adverse effect on contraceptive efficacy.

International attempts are still being made to design a system for immediate post partum insertion which is not associated with a high expulsion rate. IUDs containing other bioactive elements such as prostaglandins or

antifibrinolytics have not even reached Phase 2 trials despite several years of experimentation.

## CONCLUSION

IUDs offer a safe and effective method for family planning. They are most suitable for older women who have either completed their family or want child spacing. They are least suitable for the young unmarried and promiscuous. Where IUDs were previously used following termination of pregnancy in younger women other methods such as the long acting progestin methods would now be preferred. IUDs can safely be used through the perimenopausal period unlike contraceptive pills and there have never been any substantiated suggestions of a cancer or teratogenic risk. The TCU380A (or the less tested TCU380Ag) is probably the best device currently on the market but the TCU220C and MLCu375 both have pregnancy rates below 1 per 100 women per year.

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