สารศิริราช
SIRIRAJ HOSPITAL GAZETTE
จัดพิมพ์โดยอนุมัติคณะกรรมการคณะแพทยศาสตร์ศิริราชพยาบาล
Published Under the Auspices of the Faculty of Medicine Siriraj Hospital

ปีที่ 40, ฉบับที่ 2, กุมภาพันธ์ 2531 | Volume 40, No. 2, February 1988

A Comparative Trial of the Three Copper IUDs in Nulliparous Women

Orwan Kiriwat, M.B.
Suwanee Srisupandit, M.B.
Nuanchan Patrasupapong, B.Sc.
Vannida Jirochkul, B.A.
Supanee J. Apimas, M.A.
Suratana Pibulmanee B.Sc.

Department of Obstetrics and Gynaecology
(Head of Dept.: Prof. Dr. Chalam Vardthananusara)

Abstract: **A comparative trial concerning the uses of the Nova T, Multiload short and Mini Cu-7 devices in nulliparous women with 30 in each group was carried on at the Family Planning Research Centre of the Department of Obstetrics and Gynaecology at Siriraj Hospital in Bangkok, Thailand. After a two-year experimental period, 50% Nova T users, 40% Multiload short users and 46.7% Mini Cu-7 users continued to use these IUDs; and 20% % Nova T users, 26.7% Multiload short, and 26.7% Mini Cu-7 discontinued their use as they wished to have babies for the first time.**

The study did not find pelvic inflammatory disease or sexually transmitted disease. At insertion time, no pain was so extensive that an analgesic tablet was needed. The study only found two women (6.7 pregnancies per 100 IUD users) become pregnant with the IUD in situ in the Mini Cu-7 group in the first 6 months of use and the net cumulative rate is still 6.7 pregnancies per 100 IUD users after the two-year period of use, and the rate of pregnancy with the IUD in situ of the other two groups was totally negative.

The results of the study show that there is no statistical significance in the rate of pregnancy, expulsion and bleeding or pain. In conclusion, these three kinds of Copper IUDs are equally effective and of the same favourable qualities. All three can be used in nulliparous women.

เรื่องย่อ : การศึกษาเปรียบเทียบการใช้ห่วงคุมกำเนิดชนิดทองแดง 3 ชนิด ในสตรีที่ยังไม่เคยมีบุตร.

อรวรรณ คีรีวัฒน์, สุวนีย์ ศรีสุพรรณดิฐ, นวลจันทร์ ภัทรสุภพงศ์, วนิดา จิโรจน์กุล
สุภาณี จิวาศักดิ์อภิมาส, สุรัตน์ พิบูลย์มณี.
ภาควิชาสูติศาสตร์-นรีเวชวิทยา, คณะแพทยศาสตร์ศิริราชพยาบาล, มหาวิทยาลัยมหิดล, กรุงเทพฯ 10700.
สารศิริราช 2531; 40: 55-60.

รายงานการศึกษาเปรียบเทียบการใช้ห่วงคุมกำเนิด โนวา ที (Nova T), มัลติโลด ช้อร์ต (Multiload Short) และ มินิ คอปเปอร์ 7. (Mini Cu 7) ในสตรีที่ยังไม่เคยคลอดบุตร กลุ่มละ 30 ราย เท่าๆ กันที่ศูนย์วิจัยการวางแผนครอบครัว, โรงพยาบาลศิริราช, ปรากฏว่าเมื่อศึกษาครบ 2 ปี, ร้อยละ 50.0 ของผู้ใช้ โนวา ที, ร้อยละ 40.0 ของผู้ใช้ มัลติโลด ช้อร์ต และร้อยละ 46.7 ของผู้ใช้ มินิ คอปเปอร์ 7. ที่ยังคงใช้ห่วงคุมกำเนิดต่อไป และร้อยละ 20.0 ของผู้ใช้ โนวา ที ร้อยละ 26.7 ของผู้ใช้ มัลติโลด ช้อร์ต และ มินิ คอปเปอร์ 7. ที่ขอเอาห่วงออกเพราะว่ายังไม่เคยมีบุตรและถึงเวลาที่สมควรจะมีบุตรได้แล้ว.

ไม่พบมีการอักเสบในอุ้งเชิงกรานหรือติดเชื้อใด ๆ และไม่มีความเจ็บปวดขณะใส่ห่วงคุมกำเนิดจนถึงกับต้องให้ยาแก้ปวดเลย. พบอุบัติการตั้งครรภ์พร้อมทั้งห่วงคุมกำเนิดในกลุ่มที่ใช้ มินิคอปเปอร์ 7 เพียง 2 ราย(ร้อยละ 6.7) ในช่วง 6 เดือนแรกเท่านั้น, เมื่อศึกษาครบ 2 ปี ก็ไม่มีเพิ่มขึ้นและไม่พบในอีก 2 กลุ่มเลย.

ไม่มีความแตกต่างโดยมีนัยสำคัญทางสถิติเกี่ยวกับอัตราการตั้งครรภ์, การหลุด, อาการเลือดออก หรือปวดท้องในห่วงทองแดงทั้งสามกลุ่ม.

ผลการศึกษานี้ แสดงว่าห่วงคุมกำเนิดทั้ง 3 ชนิดนี้มีประสิทธิภาพดีและมีคุณสมบัติต่าง ๆ ในทางที่ใกล้เคียงกันน่าจะสามารถนำไปใช้ในสตรีที่ยังไม่เคยมีบุตรได้.

Since IUD insertion is usually associated with considerable pain and a higher risk of expulsion in nulliparous women, other kinds of contraception were thought at one time to be preferrable for them. Certain of the newer devices notably the Copper 7 and the Copper T have been reported to be particularly satisfactory in nulliparous women.[1, 2] However, in the case of very young women, the benefit/risk ratio should be carefully appraised because of reports of higher failure rates and complications, and reliability is less than of combined oral contraception. But it is particularly recommended for women who for medical reasons cannot use hormonal contraceptions, who decline to use them or who cannot take these preparations regularly for one reason or another.

This is a randomized comparative trial of the three copper IUDs in nulliparous women to find which is a suitable IUD for nulliparous women who may have one of the condition as above.

MATERIAL AND METHOD

The three IUDs were Nova T, Multiload Short and Minigravigard (Cu-7 mini). All are copper IUD. The size and the surface area of copper of each IUD is shown in Table 1. The Nova T is the biggest in size and the multiload short is the smallest but highest in copper.

Table 1. Type of IUD.

IUD type	Width (mm.)	length (mm.)	Cu_2 (mm.)
Nova T (NT)	32	32	200
ML Short (ML)	20	25	257
Cu 7 mini (MG)	22	30	200

Subject selection:-

– Healthy informed female volunteers.

– Age less than 40 years and more than 16 years.

– Nulliparous women only, if, had pregnancy, have less than 20 weeks gestation or

a foetus less than 500 gm.

– Women with normal menstrual patterns.

– At least 1 month after OC/3 month after injectable.

– Willing to participate in the trial.

– Ability to attend follow up at required intervals.

Criteria for exclusion:-

– Routine complications with IUD, such as PID etc.

– Women discontinue IUD because of side effects.

Range of insertion dates: 15 June 1983 through 2 January 1985.

This study was performed with 90 cases consisting of 30 women who had the NT,ML and MG inserted. The percentage of the interval insertion was 97.8% and of post abortion insertion 2.2% (Table 2). Notice that the percentage of the women who had no pregnancy and had one abortion in each group was about 94% on the average (Table 3).

The age range of the cases was 20-29 years, with NT 86.6%, ML 89.9% and MG 90.0% (Table 4)

Mainly the contraceptives used in the past month in each group were oral pill, condom or nothing (Table 5).

We investigated the occurrence of bleeding, pain/dysmenorrhoea, PID and STD before insertion of all three kinds of devices in comparison with the after effects. There was only one case (3.3%) of preinsertion bleeding in ML group (Table 6) and PID and STD in women under study before insertion were not found (Table 7).

Table 2. Percentage of the interval insertion and post abortion insertion.

IUD type	Interval (%)	postabortion (%)	Total (%)
NT	(29) 33.0	(1) 50.0	(30) 33.3
ML	(30) 34.0	0.0	(30) 33.3
MG	(29) 33.0	(1) 50.0	(30) 33.3
Total	**(88) 97.8**	**(2) 2.2**	**(90) 100**

It can be emphasized that the socio-demographic and reproductive aspects of the women under study in all three groups especially in respect to the bleeding/pain PID and STD were in the normal and with the same conditions for the purpose of comparison.

Table 3. Previous abortions (less than 20 wks.).

Induced and Spontaneous abortion	NT (%)	ML (%)	MG (%)
0	(25) 83.3	(22) 73.3	(20) 66.7
1	(4) 13.3	(6) 20.0	(8) 26.7
2	(1) 3.3	(2) 6.7	(2) 6.7

Table 4. Age.

Age	NT % (n=30)	ML % (n=30)	MG % (n=30)
< 20	20.0	23.3	20.0
20 – 24	43.3	33.3	33.3
25 – 29	23.3	33.3	36.7
30 – 34	6.7	6.7	3.3
35 – 39	6.7	3.3	6.7

Table 5. Contraceptive method used in past month.

Method	NT % (N=30)	ML % (N=30)	MG % (N=30)
none	53.3	20.0	33.3
IUD	6.7	6.7	13.3
Orals	33.3	50.0	33.3
Injectables	3.3	3.3	0.0
Condom	3.3	13.3	16.7
Withdrawal/ rhythm	0.0	3.3	3.3

Table 6. Preinsertion Bleeding or Pain Complication.

	NT % (n=30)	ML % (n=30)	MG % (n=30)
None	100.0	(29) 96.7	100.0
Intermenstrual spoting	0.0	(1) 3.3	0.0
Dysmenorrhoea	0.0	0.0	0.0

Table 7. PID and STD.

PID AND STD	NT % (n=30)	ML % (n=30)	MG % (n=30)
Previous PID and STD - None	100.0	100.0	100.0
PID and STD after insertion none	100.0	100.0	100.0

RESULT

The following Tables are the results of the expected problems at insertion and after insertion time.

At insertion time: (Table 8 and Table 9)

No pain and mild pain at insertion were detected in 93.3%, 93.3% and 96.6% of women who had NT, ML and MG inserted respectively There were no complications or complaints at insertion.

After insertion time: (Table 7, Table 10 and Table 11)

After devices inserted for two-year period of trial, PID and STD were not found (Table 7). Table 10 shows that the abnormal bleeding experienced by women after the IUDs insertion of each group increased, ranging from 20.0% in MG group (the highest) and 10.3% in NT group (the lowest). But, detailed analysis showed that such bleeding was spotting occuring mostly in the first few months, similar to the bleeding case of multiparous women who had the IUD inserted. And, the percentage of occurrences of intermenstrual pain increased as well mostly in the first 3 months.

Table 11 gives the percentage of the events causing removal of IUDs during the two-year insertion. The events closely investigated were:- pregnancy, pain, displacement/expulsion and bleeding.

Removal of devices because of pregnancy occureed 6.7% (2 cases) in MG group and pregnancy with IUD insitu was not found in NT and ML group. Removal of IUDs because of displacement/expulsion occurred in MG group 6.7% NT and ML 10.0%, because of pain occurred in ML and NT group only 3.3% and

Table 8. Pelvic Pain at Insertion.

	NT % (n=30)	ML % (n=30)	MG % (n=30)
None	3.3	3.3	3.3
Mild	90.0	90.0	93.3
Moderate	6.7	6.7	3.3

Table 9. Management of Complications/Complaints At Insertion.

	NT % (n=30)	ML % (n=30)	MG % (n=30)
No Complications or complaints observed only	3.3	3.3	3.3
	96.7	96.7	96.7

Table 10. Bleeding or Pain Complication after insertion.

	NT % (n=30)	ML % (n=30)	MG % (n=30)
None	82.2	69.0	76.7
Intermenstrual			
– spotting	6.9	10.3	13.3
– bleeding	3.4	0.0	6.7
Menorrhagia	0.0	3.4	0.0
Dysmenorrhoea	3.4	0.0	0.0
Intermenstrual pain	3.4	13.8	3.3

Table 11. Reasons for removal of device.

Removal of Device	NT %	ML %	MG %
not remove	50.0	40.0	46.7
Suspected/confirmed pregnancy	0.0	0.0	6.7
Displacement	10.0	10.0	6.7
pain	3.3	3.3	0.0
Bleeding	6.7	10.0	6.7
Other medical reason	0.0	0.0	3.3
Planned pregnancy	20.0	26.7	26.7
Personal reason	10.0	10.0	3.3

Table 12. Net cumulative discontinuation rates at 6, 12, 18 and 24 months.

	Rates Per 100 IUD Users											
	6m.			12 m.			18 m.			24 m.		
	NT	ML	MG	NT	ML	MG	NT	ML	MG	NT	ML	MG
Pregnancy	0.0	0.0	6.7	0.0	0.0	6.7	0.0	0.0	6.7	0.0	0.0	6.7
Displacement	3.3	0.0	3.3	10.0	6.7	3.3	10.0	10.0	6.7	10.0	10.0	6.7
Pain	0.0	0.0	0.0	0.0	0.0	0.0	3.3	3.3	0.0	3.3	3.3	0.0
Bleeding	3.3	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	10.3	6.7
Other medical reason	0.0	0.0	3.3	0.0	0.0	0.0	0.0	0.0	3.3	0.0	0.0	3.3
Personal reason	3.3	3.3	3.3	6.7	3.3	3.3	10.0	6.7	3.3	10.0	10.0	3.3
Planned pregnancy	0.0	0.0	6.7	6.7	13.3	13.3	16.6	23.3	23.3	20.0	26.7	26.7
Continued using	90.0	90.0	70.0	70.0	70.0	63.3	53.3	50.0	50.0	50.0	40.0	46.7

NT = Nova T
ML = Multiload short
MG = Minigravigard (Cu 7 mini)

was not found in MG group, because of bleeding problem occurred in NT and MG group 6.7% and ML group 10.0%

It should be noticed that removal of IUDs because of planned pregnancy occurred in a rather high percentage. (from 20.0%-26.7%)

DISCUSSION

This study showed that at insertion time, no pain and mild pain were detected in nulliparous women who had one of the three copper IUDs inserted, and there was no need to take any analgesic tablet.

At the end of two-year period of study, there was no occurrence of PID or STD. The result is satisfactory because PID and STD are closely related to infertility. The reason for not finding the PID and STD cases might be that the profession of those nulliparous women is not related nor a risk to PID or STD. Every women in this study was married or monogamous as in the case with the report by Jane E.[3]

The Figures for reasons for removal of device (Table 11) in each group are small and stay within the normal range of removal of all IUDs as shown in Population Reports.[4]

The incidence of two women in MG group becoming pregnant with IUD insitu during the first six months period (6.7 pregnancies per 100 IUD users) might be the use of MG IUD which is small in size in comparison with NT and has less copper than ML according to Zipper[5] and Tietze.[3]

The reason of removal of NT and ML because of displacement, a rather high percentage, might be that ML is the smallest in size and NT has a more flexible wing.[6]

The removal of IUD because of pain was found with only one case in each NT and ML group and in no cases in MG group. This might be because NT and ML are bigger in size than MG.[7]

The cases of IUD removal becuase of bleeding was found more often in ML group than in the other two groups. As reported in Koetsawang S,[5] the amount of bleeding depends on the stiffness and flexibility of device. It should be noticed that the wing of NT is more flexible and MG is more adjustable.

In order to ensure the credibility of the study results of the comparative trial of the three IUDs in Nulliparous women; we also compared in quantitative terms for each reason of removal of IUD with each kind of device. Those are

pregnancy, displacement / expulsion, pain, bleeding and other medical reason. With statistical method, Chi-square test was calculated by a statistician.

The result showed no significance statistically.

This study as such revealed that the percentage of favourable effects were high while the percentage of problematic main effects of IUD after insertion were low. And it is widely accepted that to find the ideal IUD poses no problems at all is impossible.

To sum up: This result in making a comparative trial of the three copper devices in nulliparous women for two-year period, is that all three kinds of IUDs can be used in the nulliparous women and are of equal use. Further studies and investigations along with more selected cases and more follow up cases could give us more insights and be of more use in the future.

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