

Comparison of two copper IUDs: the MLCu375 and the Nova-T

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Abstract

A comparative randomized trial was carried out on two intrauterine contraceptive devices: the Nova-T and the MLCu375. The IUDs were used by 1116 and 1237 women respectively, over a period of 2 years. The reasons for IUD removal were analyzed after one and two years using the life-table method. Statistically significant differences were found in the rates for pregnancy, expulsion and removal for bleeding and/or pain favoring the MLCu375 IUD.

Introduction

Since the reintroduction of the intrauterine device (IUD) as a means of contraception more than two decades ago, important changes in the IUD have occurred. One of the most important is the increase in the amount of copper in the IUD itself. Since the late 1970s high-load copper IUDs have been available. The pregnancy rates with high-load IUDs are lower than with low-load IUDs [1-3].

The aim of the trial described in this paper was to compare a high-load copper IUD with a low-copper IUD to see if there were any differences in the IUD discontinuation rates for any reason.

Materials and methods

We compared two IUDs, the Nova-T (low-load copper IUD, 200 sq.mm) and the MLCu375 (high-load copper IUD, 375 sq.mm). These two IUDs were inserted in 2353 women requesting intrauterine contraception and having no contra-indications for use

of the method, who did not use any additional contraceptive method while under observation. All data regarding age and parity were comparable for both groups of users (Table 1).

Table 1 Data on the women included in the study

	<i>Nova-T IUD</i> (200 sq.mm copper)	<i>MLCu375 IUD</i> (375 sq.mm copper)
Mean age	36.8±0.24 years	37.5±0.23 years
Range	16-45 years	19-43 years
Mean parity	3.8±0.07	4.2±0.08
Range	0-14	0-16

All 2353 women were monitored for two years, unless the IUD was removed earlier. The resultant data were analyzed after one and two years of IUD use by the life-table method. The randomization was performed using a program specially designed for a personal computer; this explains the large difference between the number of users in each group.

Results

The Nova-T group

Among 1116 women wearing the Nova-T IUD, there were 22 pregnancies. One of them was an ectopic pregnancy and occurred in the sixth month; 50% of pregnancies occurred within the first 12 months post-insertion. There were 28 confirmed device expulsions; of these, 65% were partial expulsions and 50% occurred within the first three months of use. In five cases it was necessary to remove the IUD for bleeding complications by the eighth month. Nine women experienced PID, all later than the fifth month. Table 2 shows the gross cumulative rates.

The MLCu375 group

Among 1237 women wearing the MLCu375 IUD, there were nine pregnancies, 50% of them occurring within the first 12 months of use. No ectopic pregnancies occurred in this group. There were 13 expulsions; 61.5% occurred within the first three months and 80% were partial expulsions. In three cases it was necessary to remove the IUD for bleeding complications by the sixth month. Two women experienced PID, one in the eighth and the other in the ninth cycle post-insertion. The gross cumulative rates are given in Table 3.

Table 2 Gross cumulative rate per 100 women at 12 months

	<i>Nova-T</i>	<i>MLCu375</i>
Pregnancy	1.8	0.5*
Expulsion	3.5	1.2*
Removals		
Bleeding and/or pain	1.8	0.4*
Other medical reasons	0.1	0.0
Planned pregnancy	0.0	0.0
Other personal reasons	0.3	0.1
Lost to follow-up	3.3	0.4*

* $p < 0.01$ **Table 3 Gross cumulative rate per 100 women at 24 months**

	<i>Nova-T</i>	<i>MLCu375</i>
Pregnancy	3.9	1.3*
Expulsion	4.3	1.3*
Removals		
Bleeding and/or pain	2.1	0.4*
Other medical reasons	0.1	0.0
Planned pregnancy	0.0	0.0
Other personal reasons	2.1	0.1*
Lost to follow-up	3.5	0.4*

* $p < 0.01$

Comparing the IUDs, we found statistically significant differences in unwanted pregnancy, expulsion and bleeding/pain rates ($p < 0.01$) in favor of the MLCu375 IUD. Gross cumulative rates and statistical significances are shown in Tables 2 and 3.

Discussion

We found that in the first and second year of use the pregnancy rate was lower for the MLCu375 IUD. This fact could be related to hormonal endometrial receptor alterations [4,5] and changes in the cervical mucus. Also, the greater copper mass could release more copper ions influencing the cervical mucus so that sperm penetration was decreased [6].

Expulsion rates were lower for the MLCu375 IUD; this result is similar to that for the MLCu250. We attribute this finding to the special design of the Multiload IUDs. The shape and dimensions of the endometrial cavity could influence the high expulsion rate for the Nova-T [7,8]. Pregnancy rates were similar for Nova-T and MLCu250 [8].

In regard to IUD removal because of bleeding disturbances, a lower incidence of bleeding complications was seen in the high-load IUD (MLCu375) than in the low-load IUD (Nova-T).

We conclude that there is no advantage in using low-load IUDs. High-load IUDs (MLCu375, TCu380, etc) have produced lower pregnancy rates, while side-effects are similar.

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Resumé

Une étude comparative randomisée a été effectuée sur deux dispositifs contraceptifs intrautérins: le Nova-T et le MLCu375. Ces stérilets ont été utilisés respectivement par 1116 et 1237 femmes sur une période de deux ans. On a analysé après un an et après deux ans, par la méthode des tables de survie, les raisons pour lesquelles ces DIU avaient été abandonnés. Des différences significatives du point de vue statistique ont été constatées dans les taux de grossesse, d'expulsion et de retrait pour cause de saignement et/ou de douleurs, et ces différences étaient favorables au dispositif MLCu375.

Resumen

Se hizo una prueba comparativa al azar de dos dispositivos anticonceptivos intrauterinos: el Nova-T y el MLCu375. Los DIU fueron usados por 1116 y 1237 mujeres respectivamente, durante un período de 2 años. Las razones para quitar un DIU fueron analizadas después de uno y dos años de uso empleando el método de tabla de vida. Se encontraron diferencias estadísticas significativas en las tasas de embarazo, expulsión y remoción por sangrado y/o dolor, siendo favorables para el MLCu375.