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A randomized comparative trial of Nova-T and TCu200Ag in Yugoslavia

M. KOŽUH*, L. ANDOLSĚK* and H. ALLONEN†

*University Clinical Centre Ljubljana, Department of Obstetrics and Gynaecology, Šlajmerjeva 3, 61000 Ljubljana, Yugoslavia
†Leiras Research Laboratories, Box 415, 20101 Turku, Finland

Abstract

The contraceptive efficacy and clinical performance of Nova-T and TCu200Ag were studied in a randomized comparative study with 819 interval acceptors. The 1- and 2-year gross termination rates were evaluated by means of the life-table method. The 12-month pregnancy rates were 1.0 per 100 women with Nova-T and 3.0 per 100 women with TCu200Ag. The preliminary 2-year rates were 1.7 and 5.5 per 100 respectively ($p = 0.037$). Rates of expulsion, medical and personal removals were not significantly different for the two devices. Continuation rates for the first year were 89.4 and 90.5 per 100 respectively.

Introduction

The Nova-T was designed with several new features that promise to rank it among the best IUDs so far. Results of studies available at present confirm its efficient performance. In a randomized 5-year multi-center study with 1865 women made in Scandinavia by Luukkainen [1], Nova-T proved to be more efficient as a contraceptive than TCu200Ag. The findings of this study were confirmed by the preliminary results of Batár [2], who carried out a randomized comparative trial on 1738 women. Timonen [3] analyzed 1-year use of three IUDs – the MLCu375, Fincoid and Nova-T – in 1003 women. In that randomized study it was found that Nova-T had a higher pregnancy rate and a lower rate of removal than the other IUDs, but the differences between the devices were not significant.

In Slovenia, Yugoslavia (population 2 million), the IUD is one of the most widely used contraceptive methods. In 1982, IUDs were used by 19% of women of fertile age. Since we are interested in offering the female population a device most suitable for their use, a randomized clinical trial was carried out by the Department of Obstetrics and Gynaecology at Ljubljana with the object of determining the differences between the clinical performance of Nova-T and TCu200Ag.

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Materials and methods

The IUDs investigated were Nova-T and TCu200Ag (Leiras Pharmaceuticals, Turku, Finland). Both devices were copper-releasing IUDs with a surface area of 200 mm^2 of copper. They were both equipped with a silver-core copper wire [4] for the purpose of preventing fragmentation and thus prolonging the lifetime *in utero*. Nova-T has curved, flexible horizontal arms which bend upwards when loaded into the inserter tube. The insertion technique was therefore different for the two IUDs, and insertions were performed according to the manufacturer's instructions.

For our randomized study we fitted 410 consenting women with the Nova-T device and 409 consenting women with the TCu200Ag device. The IUDs were inserted during menstruation. The women in question were first encouraged to participate in the trial by a nurse, and the final decision was made by each individual in consultation with her gynecologist, who also inserted the IUD. The subjects were asked to return for a follow-up examination after 3, 6, 12 and 24 months. Those who did not return for a check-up on their own initiative were contacted by telephone.

The two groups did not differ in respect to age, number of abortions or contraceptive use. There was, however, some difference in the distribution of women into parities 1 and 2 (Table 1).

Pregnancy rates, expulsion rates and removals were analyzed by the life-table method of Tietze [5]. For significance testing, the log-rank-chi-square test of Azen [6] was used.

The effect of the difference between the two groups with respect to parity distribution was studied by standardizing for parity [7].

Results

For the 12-month analysis, 4.6% of Nova-T users and 3.2% of TCu200Ag users were lost to follow-up. The 24-month follow-up was completed by 223 Nova-T users and 215 TCu200Ag users respectively at the time of analysis, and the 2-year results must be regarded as preliminary. The number of events is given in Table 2.

The gross cumulative rate of unwanted pregnancy with Nova-T was one-third of that with TCu200Ag, at both the 1-year and 2-year follow-ups (see Table 3). The 1-year rates were 1.0 and 3.0 per 100 acceptors respectively. The preliminary 2-year rates, 1.7 and 5.5 respectively, were statistically significantly different ($p = 0.037$). An induced abortion was performed in all cases of unwanted pregnancy, except for one woman in each IUD group, both of whom were still pregnant at the time of last observation.

Expulsion and removal rates for various reasons are presented in Table 3. None of these rates was statistically significantly different for Nova-T as compared to TCu200Ag. The continuation rates at 1 year were 89.4 and 90.5 respectively.

The IUD was removed in 4 cases due to pelvic infection. In addition to the removal of the IUD, the patients received antimicrobial treatment. Two of them were hospitalized for diagnosis and medical treatment. There were no other

Table 1 Clinical characteristics of acceptors. Percentage distribution: *p* is the significance level of chi-square statistics

	Nova-T	*TCu200Ag*	*p*
Number of acceptors	410	409	
Age in years			0.9
–19	1.9	1.5	
20–24	14.8	16.5	
25–29	35.0	33.2	
30–34	29.2	28.3	
35+	19.0	20.6	
Parity			0.025
0	0.7	0.7	
1	28.0	38.1	
2	61.6	52.6	
3+	9.7	8.6	
No. of abortions			0.9
0	32.4	32.4	
1	32.8	35.6	
2	21.4	18.4	
3+	13.4	13.6	
Method of contraception prior to study			0.9
none	34.1	33.4	
IUD	10.2	10.1	
pill	23.1	22.6	
other	32.4	33.4	
unknown	0.2	0.5	

Table 2 Cumulative number of events

	12 months		*24 months*	
	Nova-T	*TCu200Ag*	*Nova-T*	*TCu200Ag*
No. of acceptors	410	409		
No. completing year	349	358	223	215
No. of incomplete observations	19	13	121	124
No. of discontinuations	42	38	66	70
Pregnancy	4	12	6	20
Expulsion	8	3	11	5
Bleeding/pain	24	15	33	23
Infection	1	1	2	2
Other medical	1	1	2	2
Planning pregnancy	3	5	11	16
Other personal	1	1	1	2
Woman-months of use	4532	4545	7617	7523

Table 3 Cumulative gross rates per 100 acceptors by device and year

Discontinuation categories	*12 months*				*24 months*			
	Nova-T		*TCu200Ag*		*Nova-T*		*TCu200Ag*	
	Rate	*SE*	*Rate*	*SE*	*Rate*	*SE*	*Rate*	*SE*
Pregnancy	1.0	0.5	3.0	0.9	1.7	0.7	5.5*	1.2
Expulsion	2.0	0.7	0.7	0.4	3.0	0.9	1.4	0.6
Bleeding and pain	6.0	1.2	3.8	1.0	9.2	1.5	6.3	1.3
Infection	0.2	0.2	0.3	0.3	0.6	0.4	0.5	0.4
Other medical	0.2	0.2	0.3	0.3	0.5	0.4	0.6	0.4
Planning pregnancy	0.8	0.4	1.3	0.6	3.5	1.1	4.9	1.2
Other personal	0.3	0.3	0.3	0.3	0.3	0.3	0.5	0.4
Continuation	89.4	1.5	90.5	1.5	81.2	2.1	80.2	2.2

SE = standard error

hospitalizations for any IUD-related complications. No uterine or cervical perforations occurred.

In 27 cases the IUD was removed for planned pregnancy. Two of the subjects changed their minds again and selected a method of contraception. Of the remaining 25 women, all except one have become pregnant; 22 (88%) conceived within 12 months of the removal of the IUD. Out of 24 pregnancies, 19 resulted in live births, one terminated in spontaneous abortion, one in missed abortion and one in induced abortion. Two pregnancies were still continuing at the time of last contact.

In order to determine whether the discontinuation rates for the two IUDs were biassed owing to the differences in parity, parity-adjusted termination rates were computed. There were no essential changes in the rates or significance levels. It was therefore concluded that the difference between the two IUD groups with respect to parity caused no bias in the results.

Discussion

In comparison with Luukkainen's Scandinavian study [4], tolerance of both IUDs by our study population is much better. In our trial fewer pregnancies were observed during the first twelve months, fewer removals for bleeding and/or pain, as well as fewer removals for infections and other medical reasons. As a result, our continuation rate is higher (Luukkainen 76.1 and 77.0; our study 90.4 and 91.4). The difference may be explained by the fact that the Scandinavian study included 28.4% nulliparae, and our study only 0.7%. Differences exist also in distribution by age. In the Scandinavian study the number of women under 25 years of age was 35%; in our study the corresponding figure was 17.3%.

With regard to side-effects, our findings are very similar to those of the Hungarian study by Batár *et al.* [2]. This may be because the age and parity of the acceptors in these two studies are very similar.

The most important finding for the evaluation of Nova-T performance is that in all three studies there were fewer pregnancies during the first twelve months than with TCu200Ag. As far as side-effects are concerned there was no significant difference between the three studies.

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Resumé

L'efficacité anticonceptionnelle et la performance clinique des stérilets Nova-T et TCu200Ag ont été évaluées dans le cadre d'une étude comparative randomisée portant sur 819 femmes ayant accepté des intervalles d'utilisation. On a évalué les taux de terminaison totaux sur 1 et 2 ans par la méthode des tables de survie. Dans une période de 12 mois, les taux de grossesse ont égalé 1% chez les femmes portant le Nova-T et 3% chez les femmes portant le TCu200Ag. Les taux préliminaires pour 2 ans ont respectivement atteint 1,7 et 5,5% ($p = 0{,}037$). Les taux d'expulsion, ou d'extraction pour motifs médicaux et personnels n'ont pas différé sensiblement pour les deux types de stérilets. Durant la première année, les taux de continuation d'emploi respectifs ont été de 89,4 et 90,5%.

Resumen

La eficacia anticonceptiva y los resultados clínicos del Nova-T y el TCu200Ag fueron estudiados en 810 aceptantes en un estudio comparativo randomizado. Las tasas brutas de terminación a uno y dos años fueron evaluadas por medio de la tabla de vida. La tasa de embarazos a 12 meses fue de 1,0 por cien mujeres con Nova-T y 3,0 con TCu200Ag. Las tasas

preliminares a dos años fueron 1,7 y 5,5 respectivamente ($p = 0,037$). Las tasas de expulsión y de remociones por razones médicas y personales no fueron significativamente diferentes para los dos dispositivos. Las tasas de continuación para el primer año fueron 89,4 y 90,5 por ciento respectivamente.