

The clinical performance of the Multiload IUD. II. The influence of age

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Abstract

Six thousand four hundred and sixty-two Multiload IUDs were inserted (3606 MLCu375 and 2856 MLCu250). In this study, we determined the acceptance and safety of Multiload IUD use in different age groups. Results were analyzed according to the usual life table method. The pregnancy rate was higher with the users of MLCu250 than with the MLCu375 in a clear relation to age group. Expulsion and bleeding and/or pain rates were higher with younger women in both IUD types.

Introduction

For the last thirty years the intrauterine device (IUD) has been used to prevent unwanted pregnancies. A number of clinical studies have been designed to establish the efficacy and clinical safety of this contraceptive method [1].

In the 1980s the technology of IUDs underwent an important change, with modification of the copper content of the devices [1-3]. The reduction in the pregnancy rate has been dramatic, reaching levels similar to that associated with hormonal methods, and even comparable to that of sterilization methods. Despite this, the data presented by the worldwide literature has always been concerned with the comparison between low- and high-load copper IUDs offering little information concerning the efficacy and problems of the IUD in relation to the age of the user.

The intention of the present study has been to determine the levels of efficacy, and secondary effects in women of different ages who use the high-load copper intrauterine device, and compare these results with similar groups of low-load IUD users.

Materials and methods

All those women who came to our family planning unit requesting intrauterine contraception were incorporated into a randomized study. The devices used were

Multiload Cu375 and Multiload Cu250.

In total 6462 IUDs were inserted: 2856 Multiload Cu250, and 3606 Multiload Cu375.

The difference in the number of users of each device is because the randomization was carried out in the first visit, and 750 of the MLCu250 users failed to appear for the insertion.

The patients were divided into six age groups:

- Group I: <25 years
- Group II: 26–30 years
- Group III: 31–35 years
- Group IV: 36–40 years
- Group V: 41–45 years
- Group VI: >45 years

The number of births are comparable between age groups.

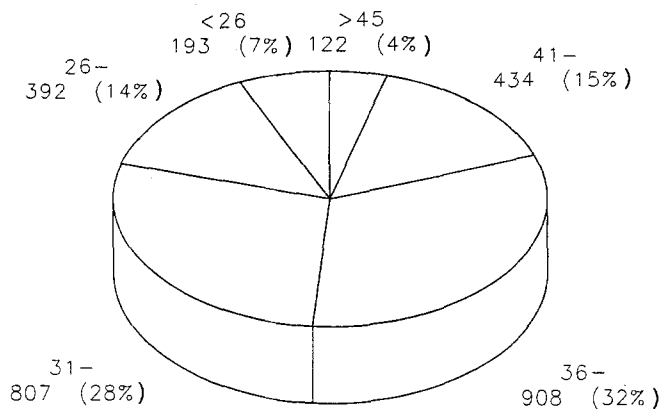


Figure 1. Age groups distribution – MLCu250

The insertion of the IUD was undertaken at the convenience of the patient, during her menstrual period, by the staff assigned to the Family Planning Section of the Hospital Materno Infantil 'La Paz' (La Paz Maternity and Children's Hospital).

Results were evaluated using the actuarial analysis of life tables according to Tietze and Lewit's model. Statistical significance was determined using Cramer's Z, presenting gross cumulative rates only.

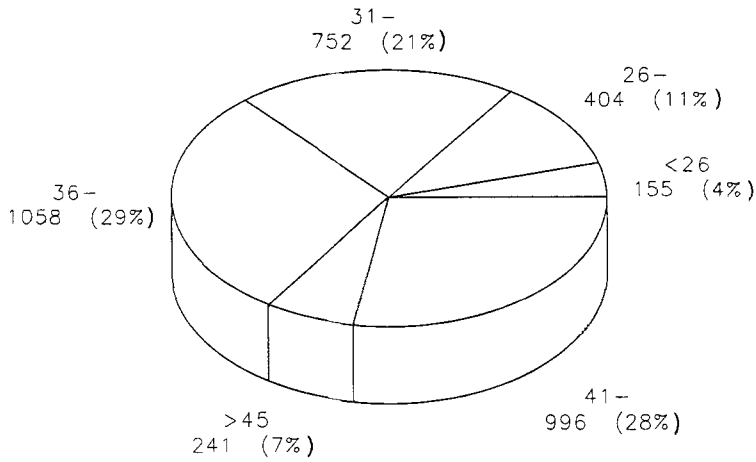


Figure 2. Age groups distribution - MLCu375

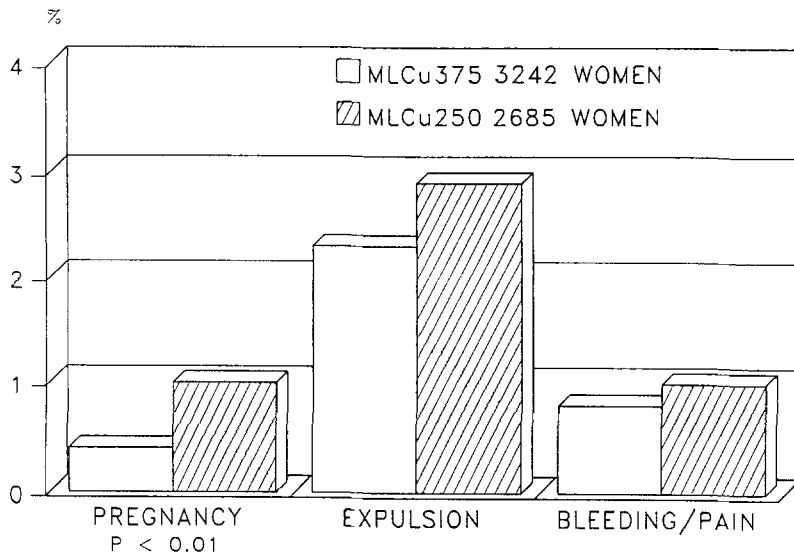


Figure 3. Gross cumulative rates - 1 year use

Results

We evaluated the efficacy and incidence of problems for the users of each type of IUD. Figure 3 presents the cumulative rates after a year of observation for MLCu250 and MLCu375. Some 2685 women completed a year of observation with MLCu250

and 3242 with MLCu375. The only statistically significant difference was observed in relation to the rates of undesired pregnancies. The data for expulsion, bleeding and pain were similar.

The results obtained during the second year of observation were similar to those obtained in the first year, the pregnancy rate doubling for users with a low-load copper device. Figure 4 presents these data.

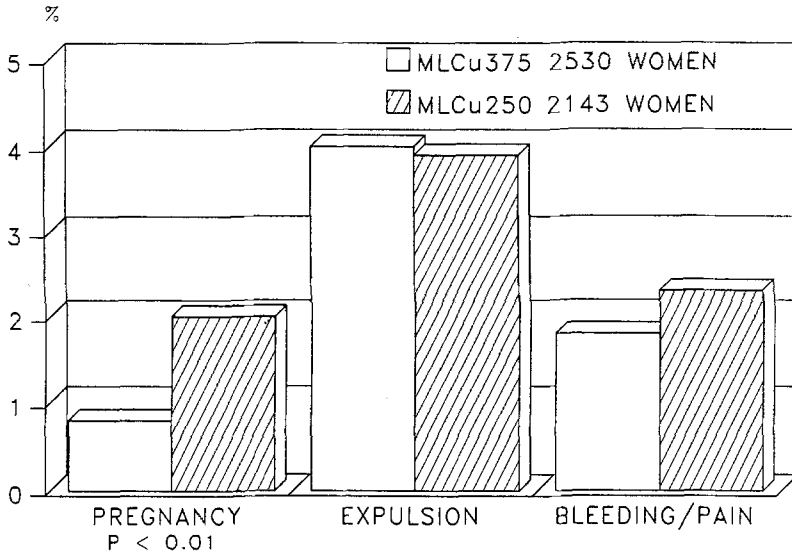


Figure 4. Gross cumulative rates - 2 years use

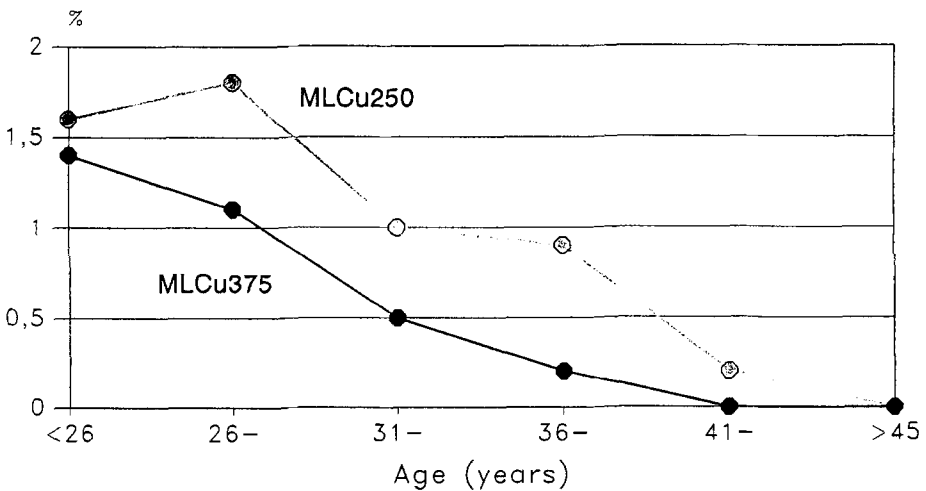


Figure 5. Pregnancy gross cumulative rate per 100 women - one year

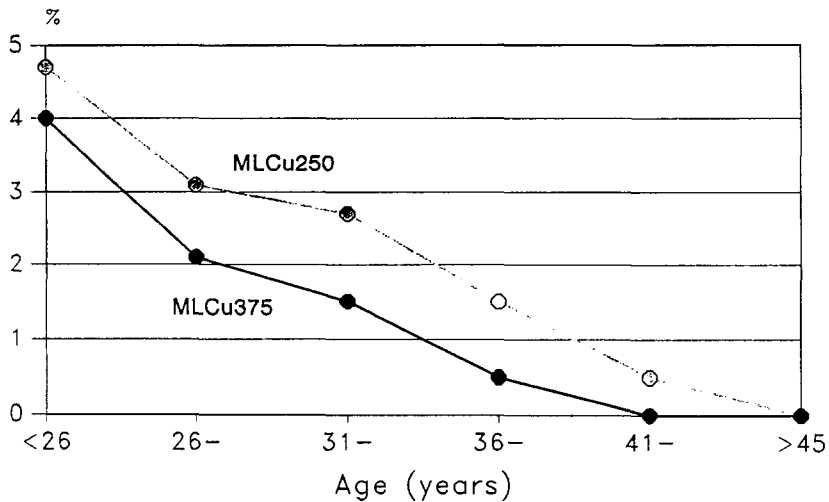


Figure 6. Pregnancy gross cumulative rate per 100 women - two years

When we evaluate the gross pregnancy rates in relation to age we find a very important decrease with increasing age of users.

A statistically significant difference ($p < 0.01$) was observed in all groups between users of low- and high-load IUDs, showing a displacement to the right among the carriers of the low-load device (Figures 5 and 6) [4].

It should be noted that users of MLCu375 reached a zero pregnancy rate around 40 years; those with MLCu250 reached this level beyond 45 years.

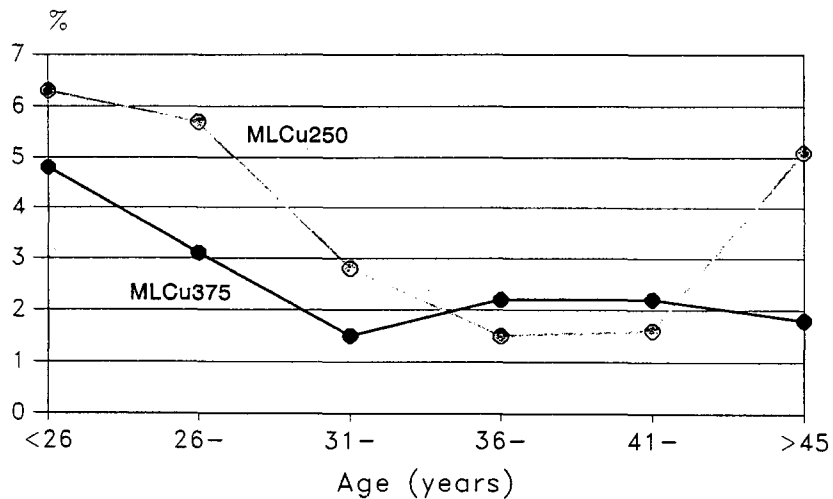


Figure 7. Expulsion gross cumulative rate per 100 women - one year

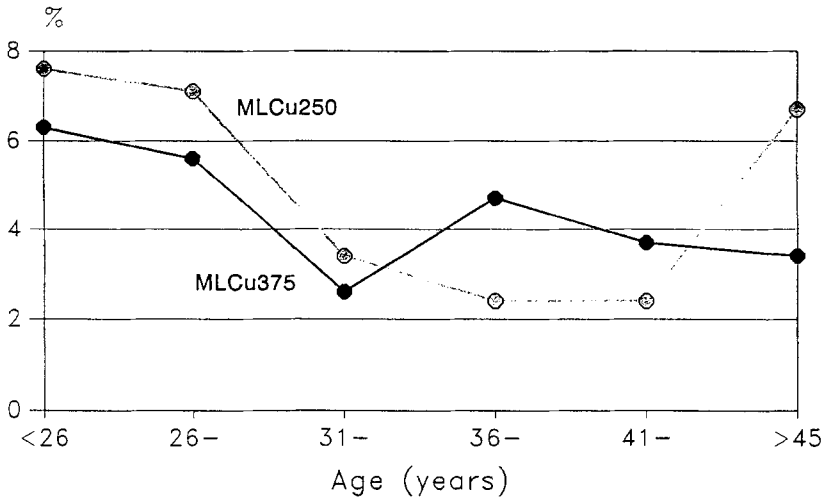


Figure 8. Expulsion gross cumulative rates per 100 women – two years

We note a similar, age-related decrease in expulsions in both groups. However, among older women there is a higher expulsion rate in the group with low-load devices, a difference that has not yet been explained (Figures 7 and 8).

We also note high expulsion rates among the youngest women, possibly related to their low number of childbirths. This suggests that women who have had few children have a more irritable uterus, a condition that would favor expulsion [5].

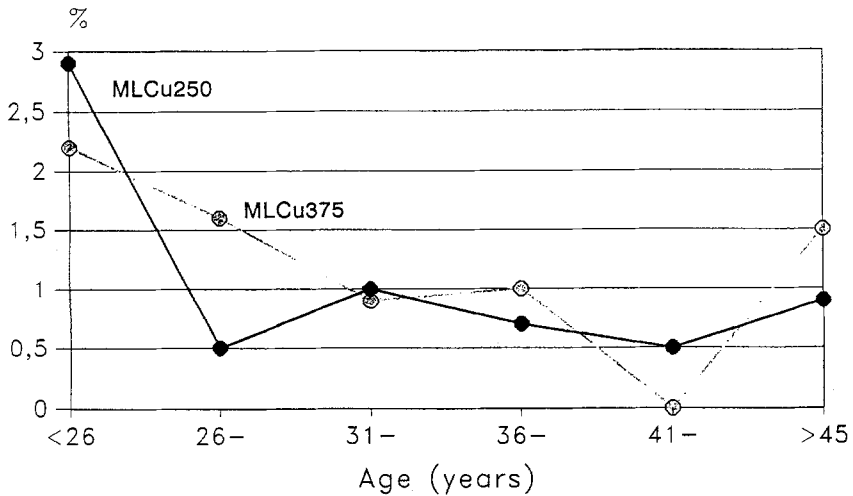


Figure 9. Bleeding/pain gross cumulative rate per 100 women – one year

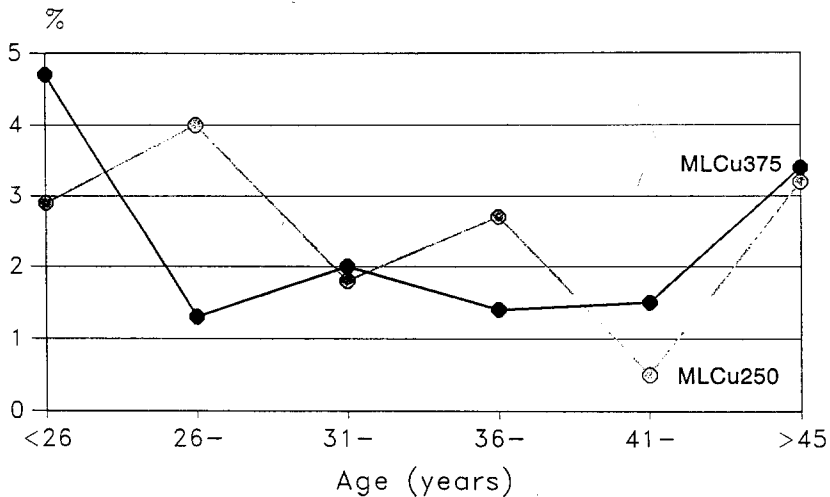


Figure 10. Bleeding/pain gross cumulative rate per 100 women – two years

The removal of the device due to bleeding and/or pain maintains a similar curve with both types of device. A greater number of removals are seen in the youngest and oldest women (Figures 9 and 10). The reason for removal of the device due to bleeding and/or pain in the youngest women may be similar to that given for expulsion: that the low number of births presupposes a more irritable myometrium, which would favor displacement of the device with resulting pain, bleeding and expulsion [5]. The bleeding observed in older women could be explained as a result of ovary failure, normal in perimenopausal women. Nevertheless, despite the general belief that bleeding incidence increases with a greater amount of copper, it is possible to show that those users with an IUD of 375 mm² surface area do not have a greater incidence of removal than those users with a device of 250 mm² surface area of Cu.

Conclusions

A careful analysis of the data presented above leads us to the following conclusions. The intrauterine device is not a good contraceptive method for younger women seeking to prevent pregnancy. It is preferable to recommend to these women hormonal methods (in the case of stable couples with frequent sexual intercourse) or barrier methods (in the case of women with a variety of sexual companions or with infrequent sexual intercourse).

Inserting an IUD in these women should be considered only when other methods have failed or at the insistence of the woman.

For perimenopausal women, the IUD is an excellent contraceptive option. In the majority of cases, acceptability permits its continued use until the menopause, without exposing the women to unnecessary medical risk. However, in those cases where

abnormal uterine bleeding is observed, it is essential to remove the IUD immediately and to determine the cause of the bleeding, as gynecologic cancer occurs more frequently in this period. In our experience it is not advisable to re-insert IUDs in these women; they should use barrier methods or sterilization.

The data presented in this study indicate that there are no scientifically valid reasons to support the use of low-load IUDs.

References

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Resumé

L'étude a porté sur 6462 insertions de DIU Multiload (3606 MLCu375 et 2856 MLCu250). Nous avons déterminé l'acceptation et la sécurité de l'utilisation des DIU Multiload dans différents groupes d'âge. Les résultats ont été analysés selon la méthode usuelle des tables de survie. Le taux de grossesses était plus élevé chez les utilisatrices de MLCu250 que chez celles qui portaient un MLCu375 et nettement en rapport avec le groupe d'âge. Les taux d'expulsion et de saignements et/ou de douleurs étaient plus élevés chez les femmes jeunes pour les deux types de DIU.

Resumen

Se insertaron 6462 DIU (3606 MLCu375 y 2856 MLCu250). En este estudio se determinó la aceptación y seguridad del uso del DIU Multiload en distintos grupos de edad. Los resultados se analizaron según el método habitual de tablas de vida. La proporción de embarazos fue superior entre las usuarias del MLCu250 que entre las del MLCu375 en una clara relación con el grupo de edad. Las proporciones de expulsión y sangrado y/o dolor fueron superiores entre las mujeres más jóvenes con ambos tipos de DIU.