Clinical study of Multiload Cu375 in Pakistan

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Abstract

Three hundred and sixty five volunteers were observed for a total of 4882 woman-months for the clinical evaluation of MLCu375. Data were analyzed by life-table method at 6, 12 and 18 months. Most women were 21–30 years old, and of parity 2–4. Continuation rates of 78.2 and 68.8 at 12 and 18 months, respectively, and a pregnancy rate of 0.3% proved the device to be highly effective and well tolerated.

Introduction

Research to design more effective and safer IUDs has been extensive. In the 1970s, this has led to the development of bioactive medicated devices bearing copper or hormones in the 1970s [1]. Many modifications in shape and design have been attempted to reduce rates of expulsion and pregnancy. Multiload devices belong to this generation or IUDs. Most studies showed the device to be highly effective and safe, having low expulsion rates [2–5]. Since a consensus had emerged that additional copper not only enhances contraceptive effectiveness but also the life-span of IUDs, MLCu375 was produced by increasing the surface area of copper to 375 mm$^2$. This device showed even lower failure rates (less than 1.0% pregnancy) with other events remaining the same [3,4,6].

Pakistan, with a population growth rate of 3% [7], has a very pressing population problem indeed. The choice of suitable contraceptives for the National Population Planning Programme is an important issue. The IUD is the most popular clinical method in this country at present; 15.5% ever users cited the IUD as their method of choice in a national survey in 1983 [8]. Since then, many investigators have reported that MLCu375 has lower pregnancy rates compared with other IUD as well as MLCu250 (3,6,9]. The National Research Institute of Fertility Control (NRIFC) decided to evaluate MLCu375 for efficacy, acceptability and reasons for termination.

This paper is based on a presentation given at the Seventh International Meeting of the Society for the Advancement of Contraception, which was held in Singapore on 4–11 November, 1990.
Materials and methods

The MLCu375 is an IUD with 375 mm$^2$ of copper on its stem and a wire diameter of 0.4 mm. It has soft, flexible, horse-shoe-shaped plastic arms with blunt spurs on their lateral surface giving it a continuous fundus-seeking property. Because the soft arms do not stretch the uterine cavity, the device is expected to cause fewer expulsions.

The study was conducted during the period January 1986 to January 1989 in Karachi. Some 363 insertions of MLCu375 were performed and observed over a period of 18 months. The subjects were drawn from three family planning clinics situated in different parts of the city, catering for a low socioeconomic group of women.

Women deciding to use an IUD were asked to choose between Lippes Loop, Cu-T200 and MLCu375, after being informed about the merits of each device. Lippes Loop and Cu-T200 have been in use for many years and women are familiar with these; MLCu375 was new to them.

Subjects were included in the study only if they were healthy married women aged 18–40 years with at least one live birth, and if they did not fulfil the exclusion criteria of suspected pregnancy, malignancy of genital tract, malformation or distortion of uterus or cervix, undiagnosed vaginal bleeding, history of ectopic pregnancy, current or past pelvic infection and known allergy to copper. Women were also screened for abnormal pap smears at admission.

All 363 subjects were interviewed and clinically examined according to a predesigned protocol at admission and on follow-up visits scheduled at 1, 3, 6, 12 and 18 months. The screening medical and pelvic examinations were carried out by a physician while the IUD insertions and removals were performed by a trained paramedic (lady health visitor) following the standard technique. The medical officer's help was sought only when difficulty or complication occurred. No devices were inserted in the six weeks after termination of a pregnancy; all insertions were performed during the first five days of menstruation.

A pelvic examination was also performed at each follow-up visit to check for the presence of the IUD as well as for pregnancy. If suspected pregnancy was confirmed by a urinary pregnancy test, the IUD was removed immediately. Complaints were noted only when the subjects reported voluntarily, without prompting. Cervical pap smears were repeated on the 12-month visit. Women were also instructed to feel the IUD thread after every menstruation and immediately to report to the clinic if they could not feel the thread.

Women not returning for their scheduled follow-up appointment were reminded through home visits. Defaulters were released from study. Those who could not be contacted by any means were declared lost to follow-up.

Finally, the data were analyzed according to the life-table method of Tietze and Lewit.