Long-term evaluation of the clinical performance of the TCu200B and the TCu380A in Campinas, Brazil

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Abstract

The clinical performance of the TCu200B and TCu380A was evaluated by life table analysis in a cohort of women who wore an IUD from July 1979 to July 1982. This paper presents the results up to five years of use. No significant differences in age and parity were found between the users in the two groups. Overall performance was very good with both models. The cumulative continuation rate was 83.6, 60.9 and 46.1 at one, three and five years with the TCu200 and 84.0, 64.7 and 49.3 with the TCu380A in the same periods. Differences between both IUDs were not significant. The pregnancy rate was lower with the TCu380A and reached statistical significance from the fourth year on.

The authors conclude that both IUDs presented very good performance, the TCu380A being more effective, the only significant difference observed.

Introduction

Since the first modern publications reporting successful use [1,2], intrauterine devices (IUDs) have had a prominent place among the methods used for fertility regulation. After initial enthusiasm over the IUD and the development of a large number of models, the popularity of this method suffered a very serious setback when its use was associated with severe pelvic inflammatory disease and death of some users. Though it was shown that the more severe cases and stronger association were with only one model, the Dalkon Shield [3,4], and epidemiologic studies demonstrated no increased risk for monogamous women [5,6], the recovery of IUD prevalence has been slower than the excellent performance of the newest devices would lead one to expect.

The new generation of medicated IUDs allows the use of a smaller matrix,
improving tolerance, though effectiveness of the earlier copper-releasing IUD was no better than that of the Lippes Loop [7-9].

The second generation of copper IUDs has a larger surface area of copper, located both on the horizontal and vertical arms of the T. The most advanced model of this second generation, TCu380A, has shown higher contraceptive effectiveness than other inert or copper IUDs in comparative prospective studies [10-12]. Most of the trials have been limited to one or two years of follow-up. This is mainly because of difficulties in maintaining acceptable follow-up in longer observations. This paper describes a comparative evaluation of the clinical performance of two copper IUD models, the TCu200B and TCu380A, during five years of use.

Materials and methods

This is a retrospective study analyzing the clinical performance of all copper IUD insertions performed at the Family Planning Clinic of the Department of Obstetrics and Gynecology at the University of Campinas, from July 1979 through to June 1982. During that period, the TCu200B was inserted in 1708 women and the TCu380A in 288. The type of IUD inserted was defined only by its availability.

All subjects had at least one child, and were at risk of becoming pregnant. They had no past history of pelvic inflammatory disease or ectopic pregnancy. They also were required to be willing to return regularly for follow-up.

All the IUDs were inserted during the first five days of a menstrual period by trained nurses or physicians, including residents in training at the clinic. Follow-up visits were scheduled one, six and 12 months after insertion during the first year, and every 12 months thereafter for both groups.

The clinical performance was evaluated by life table analysis according to Tietze and Lewitt [13]. Significance between rates was tested by the method of chi square for life table [14]. The cut-off date for analysis was May 31, 1988.

Results

The distribution of subjects by age and parity is shown in Tables 1 and 2. There were no significant differences between users of the two models. A significantly larger portion of TCu380A acceptors had used the pill, while ‘other methods’ had been used by a significantly larger portion of TCu200B acceptors (Table 3).

The cumulative gross termination rates by reasons and the continuation rates in users of both IUDs are shown in Table 4.

The cumulative pregnancy rate was lower in users of TCu380A from the first to the fifth year, but differences reached statistical significance only in the last two years of observation.

The continuation rate was slightly but not significantly higher in users of TCu380A. Expulsion, bleeding and pain, infection, other medical and personal reasons did not show significant differences.