A decade of experience with TCu200

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Abstract

This paper summarizes ten years of experience with 2766 interval insertions of the TCu200 device. One hundred and twenty months of use were completed by 572 patients and the cumulative woman-months of use were 159,664. For evaluating the overall performance, gross cumulative and yearly specific life-table termination and continuation rates were calculated as suggested by Tietze [2]. The cumulative pertinent rates at the end of the ten-year follow-up period were as follows: pregnancy 10.2; expulsion 6.3; bleeding/pain 32.3; and removal for other medical reasons 19.4. The gross annual rates for the same conditions at the end of the first year of use were: 1.8, 2.4, 4.2, and 2.0, while in the tenth year they were: 0.6, 0.1, 4.4, and 2.8, respectively. The continuation rate was 89.1 at the end of the 12th month and 33.2 at the end of the 10th year. Based on this evaluation, the TCu200 IUD has a good overall performance and a longer lifespan than was previously expected.

Introduction

The TCu200 was the first medicated IUD tested for contraceptive use [1]. The suggested period of use for the copper devices is usually 3–5 years. However, recommendations for removal solely due to the time indication have been revised for a number of devices as clinical experience has accumulated showing that the protective effect of IUDs continues long after the period of use recommended by the manufacturers. At the Family Planning Center (FPC), Department of Obstetrics and Gynecology, University of Debrecen (UD), Hungary, TCu200 was introduced in the 1970s and, as the majority of the women were satisfied with the IUD, the device was not removed routinely after 3–5 years. The oldest TCu200 has been in use since then. This work summarizes a decade of experience with the device.
Materials and methods

Between 7 March 1977 and 30 January 1986, 2766 TCu200 IUDs were inserted in patients attending the FPC, UD. In an open prospective post-marketing study, these routinely inserted devices were evaluated.

Candidates were parous women requesting contraception and having no contraindications regardless of previous IUD use. The mean age was 29.3 years and mean parity was 1.8. The numbers of induced and spontaneous abortions were 0.9 and 0.3, respectively.

The insertion was carried out during the interval period. Neither immediate postabortal nor postpartal insertions were included in this study. Follow-up visits were scheduled for 1, 6 and 12 months after insertion and annually thereafter. Unscheduled check-ups were performed if problems arose.

For comparing the different follow-up periods (ordinal years), life-table (LT) rates were calculated as suggested by Tietze and Lewit [2]. This paper uses the gross rates. Because the annual rates are more conclusive in evaluating long-term IUD use [3], not only cumulative but also yearly specific LT rates were calculated on PC using a computer program created on the basis of Tietze’s description [2]. Statistically significant differences were set at \( p \leq 0.05 \).

Results

All 2766 cases were eligible for LT analysis. At the end of the first year, the number of cumulative woman-months of use (CWMU) was 29,296 and the number of women at risk was 2239. The number of those at risk at the end of the 10th year of follow-up was 572, and the total CWMU was 159,664 (Table 1). The corresponding figures for each year, along with the cumulative continuation and termination rates, are summarized in Table 1. The numbers of terminations by duration of use are given in Table 2. Based on these figures, cumulative (Table 3) and annual specific (Table 4) rates were calculated.

As planned pregnancy and other removals for personal reasons are usually not relevant for the type of device, only the so-called pertinent terminations (pregnancy, expulsion, removal for bleeding and/or pain, and for other medical reasons) are detailed here. Tables 3 and 4, however, show the corresponding figures.

It was found that pregnancy resulted in a total of 176 terminations, with a cumulative termination rate of 10.2 at the end of the tenth year (Table 3). The highest specific rate, 2.4, was recorded in the second year of use (Table 4). From the sixth year, the rates are below 1%. Of the 176 terminations due to pregnancy, 17 were ectopic, which is about 10% of all pregnancies. As Table 5 shows, after the second year of use the risk of unwanted pregnancy is significantly less if the rates of the earlier years are compared with those of the later years. No further statistical differences were found between the annual periods after the sixth year.

A total of 116 terminations were due to expulsion of the IUD. The cumulative termination rate at the end of the observation period was 6.3 (Table 3). The first year of use showed the highest risk for this type of termination (Table 4). The differences