ELSEVIER

Contraception 72 (2005) 342–345

Contraception

Original research article

Five years' experience with a small intracervical/intrauterine levonorgestrel-releasing device

Päivi Pakarinen[a,b,*], Tapani Luukkainen[b]

[a]Department of Obstetrics and Gynecology, Helsinki University Central Hospital, 00029 HUS Helsinki, Finland
[b]Steroid Research Laboratory, Institute of Biomedicine, University of Helsinki, 00029 HUS Helsinki, Finland

Received 23 February 2005; revised 25 April 2005; accepted 9 May 2005

Abstract

Objective: A randomized study was performed to compare the efficacy, safety and acceptability of a new model of an intracervical/intrauterine contraceptive device (ICD) releasing 20 μg of levonorgestrel (LNG) per day.
Methods: The LNG-ICD was inserted in Group I into the cervical canal and in Group II into the uterine cavity. Group I included 151 women (age, 18–43 years) whereas Group II included 147 (age, 19–43 years). The number of nulliparous women was 145.
Results: The 5-year results are presented here. The results showed a total continuation rate of 50%; the continuation rate in the cervical group and that in the uterine group were 53.6% and 46.3%, respectively — the difference being statistically insignificant ($p=.3593$). The main reason for termination was a wish for pregnancy, which is explained by the relatively young age and degree of nulliparity of the study population. During the first year, two pregnancies occurred in both groups. Two of these were ectopic, one in each group. The other two occurred after unnoticed expulsions. Thereafter, no pregnancies occurred. The cumulative gross rate for pregnancy was 1.3 and the Pearl index at 5 years was 0.425. The total expulsion rate was relatively high (11.1%). Expulsions occurring during the first few months of the first year were related to insertion. Removals because of bleeding and because of amenorrhea were low, the combined gross rate being 5.7 and the Pearl rate 1.8 at 5 years. Also, the gross rate of infection was low (0.7). The continuation was high in spite of a high rate of removals for planning pregnancy (15.4).
Conclusions: The method is safe and effective. There were only minor differences between the groups. There were no perforations and the incidence of infection was low. The device can also be used by young nulliparous women.

Keywords: Levonorgestrel-releasing intrauterine device; Intracervical device; Contraception

1. Introduction

A levonorgestrel-releasing intracervical contraceptive device (LNG-ICD) was designed so as to be easy to insert and to reduce the incidence of removals because of problems of bleeding and amenorrhea. A second frame modification, in a trial reported by Ratsula [1] with 198 users, was associated with no removals during the first 2 years due to amenorrhea.

The health benefits of the LNG-releasing intrauterine system (IUS), including a reduction in the duration of bleeding and a significant increase in serum ferritin concentration, have also been observed during use of the ICD. The increase in hemoglobin concentration, however, was insignificant because values were already at non-anemic levels before insertion of the ICD [1].

A comparative study [2] revealed that the ICD is likely to be acceptable and could have a unique contraceptive role. However, in spite of these positive observations, the results also included disappointments. First, the high rate of expulsions, many of them unnoticed, resulted in accidental pregnancies. Second, the removal rate because of bleeding problems was not improved in comparison with earlier models [3].

In the present study, two approaches were taken. The side arms of the device were strengthened and the small device was inserted into either the cervical canal or the uterine cavity. Results after the first year have been

* Corresponding author. Department of Obstetrics and Gynecology, Helsinki University Central Hospital, PO Box 140, 00029 HUS Helsinki, Finland. Tel.: +358 50 4271 531.
E-mail address: paivi.pakarinen@hus.fi (P. Pakarinen).

0010-7824/$ – see front matter © 2005 Elsevier Inc. All rights reserved.
doi:10.1016/j.contraception.2005.05.013

reported earlier [4]. The LNG concentrations in plasma were in the range of those associated with use of the LNG-IUS. Estradiol concentrations were not suppressed and serum progesterone concentrations were indicative of ovulation.

The contraceptive efficacy of this device is not based on ovulation suppression and the device is as effective in the cervical canal as it is in the uterine cavity. Initial results suggested that the frame of the device was not the reason for expulsions. Hence, follow-up was continued for another 4 years. The results at 5 years and annual accumulation of events are reported here.

2. Methods

The characteristics of the women selected by means of randomization into those who underwent intracervical insertion of the device and those who underwent intrauterine insertion in this study performed in two clinics in Helsinki have been reported earlier [4]. Women were assigned to the cervical or the fundal insertion group using a random-number table with group allocation predetermined and placed in consecutively numbered, opaque and sealed envelopes. As the women entered the study, they received a randomized envelope that was opened just before the LNG-ICD was inserted. The study was carried out according to the ethical principles set forth in the Helsinki Declaration and was approved by the ethical committees of the clinics. Age, weight, height, parity and number of abortions were comparable in the two groups. The degree of nulliparity was 48% in the women participating in the present study.

Ultrasonography was used for measurement of endometrial thickness before insertion, three times during the first year after insertion and thereafter at every visit. There was a planned visit once a year and the possibility of an extra visit if necessary. The measurements did not show any significant difference in endometrial thickness in the two groups at examinations carried out at 3, 6 and 12 months after insertion [5]. In some cases, the devices did not remain in the fundal part of the uterine cavity but migrated to a lower position; in addition, many devices placed in the cervical canal migrated to the uterine cavity. Hence, the two groups of women are labeled intracervical (Group I) and intrauterine (Group II) according to the sonographically determined location of the devices.

2.1. Statistical analyses

Differences in gross rates between the two groups (intracervical/intrauterine) were studied by survival analysis produced by the Kaplan–Meier method. Cox's proportional hazards models with hazard ratios and 95% confidence intervals were used to analyze the prognostic factors of expulsions. Computations were done using the SAS System for Windows (release 8.2/2001) [6].

3. Results

3.1. Pregnancies

There were four pregnancies during the early months of use. Two of these were tubal pregnancies, verified by histological examination. Two other early pregnancies were after unnoticed expulsions. The effectiveness of these small devices after the first few months of use was excellent. During the following period of observation, there was no single pregnancy, with nearly 950 women-years of exposure. Table 1 gives the number of events in the two groups at 1, 3 and 5 years according to the different reasons for discontinuation.

3.2. Expulsions

Expulsions were largely related to the immediate post-insertion period and mostly to one of the two clinics involved. The insertion technique differed from that in earlier studies [1]. In Group I, the device was pushed within the insertion tube, horizontal arms bending outside along the insertion tube, to the uterine cavity. The tube was removed and the device was gently pulled by its strings to the cervical canal such that the horizontal arms were resting in the inner mouth of the uterus. In Group II, the device was pushed identically within the tube up to the fundal part of the uterine cavity; the device was released rotating the tube and the tube was removed and the device was left in the fundal part of the uterine cavity. This was not always successful because often the device was still in the tube when it was withdrawn. In these cases, the tube was pushed in again and the device was released by means of repeated rotations. The plunger was eliminated to reduce the cost of the method.

3.3. Bleeding problems

Because amenorrhea was the reason for removal in only two women during 5 years of use, bleeding problems and

Table 1
Accumulation of events at 1, 3 and 5 years

Event	Year 1		Year 3		Year 5	
	Group I	Group II	Group I	Group II	Group I	Group II
Pregnancy	2	2	2	2	2	2
Ectopic	1	1	1	1	1	1
Intrauterine	1	1	1	1	1	1
Expulsions	17	10	19	12	19	14
Removals	8	10	38	47	49	63
Pain	2	0	6	4	6	5
Bleeding	1	3	5	7	10	7
Infection	0	1	0	1	0	2
Hormonal	2	1	5	7	7	8
Planning pregnancy	3	3	18	19	21	25
Other personal	0	0	1	5	1	9
Other reason	0	2	3	4	4	7
Any termination	27	22	59	61	70	79