Partial and complete expulsion of the Multiload 375 IUD and the levonorgestrel-releasing IUD after correct insertion

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OBJECTIVE: The contraceptive efficacy of intrauterine devices (IUD) is thought to relate to the position of the IUD in the uterine cavity. Several trials examined the number of copper IUD expulsions, but none evaluated the partial and complete expulsion rate of the levonorgestrel-releasing device (LNG-IUD). STUDY DESIGN: This retrospective cohort study compares the dislocation rate of the Multiload 375 IUD (ML 375) and the LNG-IUD in 214 women (107 subjects with each IUD). Transvaginal ultrasound was used to monitor the IUD position immediately after insertion, after 6 weeks, and later on at intervals of 6 months. The observation period included 3631 cycles. RESULTS: We detected a significantly lower number of dislocations in LNG-IUD users. Previous expulsion was associated with a significantly higher risk for a re-expulsion in both IUD groups. Hypermenorrhea was not associated with an increased dislocation rate in LNG-IUD users. CONCLUSION: Expulsions are less likely to occur with the LNG-IUD, which might contribute to its contraceptive efficacy.
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the levonorgestrel-releasing IUD after correct insertion

Gabriele S. Merki-Feld*, Danielle Schwarz, B. Imthurn, P.J. Keller

Clinic of Endocrinology, Department of Gynecology and Obstetrics, University Hospital, Frauenklinikstr. 10, CH-8091 Zurich, Switzerland

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Results: We detected a significantly lower number of dislocations in LNG-IUD users. Previous expulsion was associated with a significantly higher risk for a re-expulsion in both IUD groups. Hypermenorrhea was not associated with an increased dislocation rate in LNG-IUD users.

Conclusion: Expulsions are less likely to occur with the LNG-IUD, which might contribute to its contraceptive efficacy.

1. Introduction

Third generation copper intrauterine devices (IUDs) and the levonorgestrel-releasing device (LNG-IUD) are very safe contraceptive methods with a low failure rate [1]. The prevalence of IUD use differs greatly between regions and countries. In European countries the prevalence is higher (3–20%) in comparison to North America, where the prevalence is less than 1% [2]. One of the reasons for the low rate of IUD insertions is the concern that IUD users are at higher risk of pelvic inflammatory disease (PID). Exclusion of nulliparous women and women with multiple sexual partners from this contraceptive method contributes to the current low rate of genital infections in IUD users. Many women in their 30s and 40s have risk factors or contraindications for the use of combined hormonal pills. For this age group the IUD is an important contraceptive choice. A special advantage of the LNG-IUD is the positive effect on menorrhagia and hypermenorrhrea, both common menstrual problems in perimenopause. The risk of pregnancies in IUD users can be increased by incorrect insertions and partial or complete expulsions. Several studies show that the rate of complete expulsions varies from 2 to 8 per 100 women in the first year after insertion [3–5]. Partial expulsions may cause symptoms including menorrhagia or pain. Because of symptoms partial expulsions can be diagnosed in some women. However, asymptomatic IUD displacements are only detected, if regular sonographic controls of the IUD position are performed. Previous expulsion of an IUD, young age, hypermenorrhrea, nulliparity and uterus sounding ≥9.0 cm are associated with a higher rate of IUD dislocations [2,6,7]. Most downward migrations of IUD are thought to occur within 6 weeks after insertion [8]. In 1997 a new type of IUD the levonorgestrel-releasing device was introduced in Switzerland. The clinical observation of a very low dislocation rate in users of this IUD was the reason for us to perform a study to evaluate the dislocation rate of LNG-IUD in comparison with the third generation copper IUD Multiload 375 (ML 375). In contrast to previous studies...
reporting the rate of complete expulsions [1,9], our aim was to evaluate the rate of partial and complete expulsions, because both can cause unplanned pregnancies. That is why only women with documented ultrasound assessment of the IUD position were included.

2. Materials and methods

In the Family Planning Center of the University Hospital of Zürich (Switzerland), we inserted about 140 IUDs annually from 1997 to 2002. Using transvaginal ultrasound, we monitored the position of each intrauterine device immediately after insertion. Based on our guidelines, the IUD users have regular follow-up visits 6 weeks after insertion and later on 6 monthly. Every IUD insertion is documented with the name of the patient, the date of insertion and the type of IUD in a special list.

The data for this retrospective cohort study were compiled from patients attending our University Hospital Family Planning Center from January 1997 to March 2002. From the chronological list of IUD insertions, we identified all women with an LNG-IUD \((n = 118)\) and in each of these cases the chronologic next woman with a ML 375 IUD. All ML 375 IUDs had the regular size. Only those IUD users with a record of sonographic correct IUD location after insertion comprised the study group. Altogether 107 women with insertion of an LNG-IUD were in compliance with the inclusion criteria. Their data were compared to those of 107 ML 375 users. Both types of IUDs are effective for 5 years. The devices were inserted during days 1–5 of the menstrual cycle by experienced family planning doctors. Before insertion, the length of the uterus from endometrium to the external cervix was determined using a uterine sound. Women whose uterus sounded \(\geq 9.0\) cm were not included.

Gynecological examinations including Pap smear and chlamydia screening were performed before every IUD insertion. Evidence of PID, partial expulsion, planned pregnancies and adverse health effects were reasons for removal of the IUD prior to the end of 5 years. The observation period ranged from 6 weeks after insertion to 60 months.

Age, parity, hysterometry and previous IUD dislocations, as possible factors influencing the expulsion rate in both groups, were documented for all women. Hypermenorrhoea and dysmenorrhoea were frequent indications for the insertion of an LNG-IUD in the present study and are contraindications for the insertion of a copper-device. Therefore, it was investigated for the LNG-IUD exclusively, whether these two bleeding patterns may influence the rate of dislocations.

A 6.5 MHz multifrequency vaginal probe (GE-LOGIQ 200) was used for the transvaginal ultrasound. The distance between the top of the vertical arm of the IUD and the junction between the endometrium and the uterine cavity (IUD-ED) was measured in the mid-longitudinal plane (Fig. 1). Because the maximum IUD-ED to ensure adequate contraception is still under debate and we wanted to avoid unnecessary removals, we defined a partial expulsion as an IUD-ED of more than 10 mm [3,10]. This is in contrast to some authors, who define an IUD-ED above 3 or 7 mm as partial expulsion [11,12]. Women with partial expulsions were recommended to removal of the IUD and excluded from further follow-up for the present study.

2.1. Statistical analysis

The analyses were performed by using the Statview 4.01 data analyses software (Abacus Concepts, Berkeley, CA, USA). Student’s \(t\)-test (continuous data), \(\chi^2\) association test and the Fisher’s exact test (categorical data) were used to compare groups. The level of significance was set at a \(p\)-value \(\leq 0.05\).

3. Results

The data of 107 ML 375 users and 107 LNG-IUD users were eligible for this retrospective analysis. Altogether the evaluation comprised 1882 cycles with the Multiload IUD and 1749 cycles with the LNG-IUD. The two groups were comparable with regard to age, parity and months of follow-up (Table 1). More women with an LNG-IUD had a history
of a previous IUD dislocation. This difference was not statistically significant (Table 1). Eleven women did not return to the clinic for follow-up visits after the insertion. Therefore, the sonographic control of the IUD position 6 weeks after insertion included 100 LNG users and 103 ML 375 users. At this time, 4% of the LNG-IUD and 11% of the ML 375 IUD were diagnosed as partially or completely expelled ($p = 0.06$), according to the measurement of the IUD-ED (Table 2). Prior to the sonographic control after 6 months, five women wished removal of the device because of menorrhagia or pain (ML 375, $n = 2$; LNG-IUD, $n = 3$). Another six women in the LNG group (versus 10 women with the ML 375) were lost to follow-up after 6 weeks. In addition, the participants with dislocation after 6 weeks ($n = 15$) were excluded from further follow-up. Therefore, data for control visits 6 months after insertion were available for 80 ML 375 users and 87 LNG-IUD users (78% of the participants).

Over the entire study period from insertion to a maximum of 60 months, significantly more incorrect positions were observed in the ML 375 group (Table 2). One third of all dislocations (33%) were seen at 6 weeks after the insertion and 80% occurred during the first year. Table 3 demonstrates the influence of age, parity, hysterometry and history of expulsion on the rate of IUD dislocations. All analyses are performed for the whole study collective and separately for the two IUD types. In the group with the LNG-IUD we documented history of menstrual disorders, like dysmenorrhea and hypermenorrhea. Both symptoms were contraindications for the insertion of a copper-device and consequently reported only in the history of women with insertion of a LNG-IUD. Hypermenorrhea was reported in the history of 41 LNG-IUD users. Investigating the dislocation rate in the subgroup with hypermenorrhea, we did not find a difference compared to LNG-IUD users without baseline problems.

### Table 1

Characteristics of participants by device

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Multiload 375</th>
<th>Levonorgestrel-releasing IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>32.1 (6.8)</td>
<td>33.8 (7.1)</td>
</tr>
<tr>
<td>Parity</td>
<td>2.1 (1.0)</td>
<td>1.9 (0.9)</td>
</tr>
<tr>
<td>Uterine sounding (cm)</td>
<td>8.1 (0.6)</td>
<td>8.2 (0.7)</td>
</tr>
<tr>
<td>History of expulsion</td>
<td>14</td>
<td>22</td>
</tr>
<tr>
<td>Number of cycles</td>
<td>1882</td>
<td>1749</td>
</tr>
</tbody>
</table>

Data are given as mean (S.D.) or absolute numbers. No event rates significantly different between devices.

### Table 2

Position of two devices in the uterine cavity 6 weeks after insertion and at the end of the observation period

<table>
<thead>
<tr>
<th>Observation period</th>
<th>Multiload 375</th>
<th>Levonorgestrel-releasing IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correct</td>
<td>Dislocation</td>
</tr>
<tr>
<td>Six weeks</td>
<td>92</td>
<td>11</td>
</tr>
<tr>
<td>Insertion to a maximum of 60 months</td>
<td>63</td>
<td>28</td>
</tr>
<tr>
<td>Number of cycles</td>
<td>1882</td>
<td>1749</td>
</tr>
</tbody>
</table>

Values are given as absolute numbers. *$p \leq 0.06$ $\chi^2$-test; **$p \leq 0.05$ $\chi^2$-test.

### Table 3

Influence of age, parity, hysterometry length and earlier IUD dislocations on the rate of IUD dislocations

<table>
<thead>
<tr>
<th>IUD position</th>
<th>Age (years)</th>
<th>Parity (number)</th>
<th>Hysterometry (cm)</th>
<th>History of dislocations$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correct</td>
<td>Incorrect</td>
<td>Correct</td>
<td>Incorrect</td>
</tr>
<tr>
<td>LNG-IUD</td>
<td>33.7 (7.1)</td>
<td>34.2 (7.0)</td>
<td>1.8 (0.9)</td>
<td>2.4 a (0.6)</td>
</tr>
<tr>
<td>Multiload 375</td>
<td>32.7 (6.6)</td>
<td>30.0 (7.1)</td>
<td>2.0 (1.1)</td>
<td>2.3 (0.8)</td>
</tr>
<tr>
<td>All IUD</td>
<td>33.2 (6.9)</td>
<td>31.6 (7.3)</td>
<td>1.9 (1.0)</td>
<td>2.3 b (0.7)</td>
</tr>
</tbody>
</table>

Data are given as mean (S.D.) Unpaired $t$-test correct position vs. dislocation: (a) $p \leq 0.03$, (b) $p \leq 0.02$, (c) $p \leq 0.005$. Unpaired $t$-test hysterometry Multiload 375 vs. LNG-IUD: (d) $p \leq 0.004$. Fisher’s exact test correct position vs. dislocation: (e) $p \leq 0.004$.

$^a$ Number of women.
observation period in the LNG-IUD group (18% versus 29%, \( p \leq 0.05 \)). Instead of the CuT 380Ag, we used the ML 375 IUD in the present study. This should not have a major influence on our results, since the cumulative expulsion rate over 3 years is not different for both IUD types and has been reported to be 7–10% [17]. There are two other explanations for the different results. First, in our study, the number of dislocations is higher for both IUD types, because using transvaginal ultrasound, we did not only identify complete expulsions, but although partial expulsions [15,17,18]. This assumption is supported by the results of Petta et al. [3], who performed a sonographic follow-up of 235 women with a CuT 380Ag for 12 months. Within 1 year after insertion, the high rate of 15% of the IUDs were diagnosed to have moved downwards. This rate is somewhat lower compared to our 1 year data and distinctly higher than in studies without ultrasonographic monitoring of the IUD position. Second, difficult insertions were noted more frequently for the LNG-IUD in the study of Sivin et al. [15]. Because it was not evaluated whether those IUDs were in the correct position, we hold the view that at least some of the expulsions have been due to insertion failures. In our trial, women with documented failed insertions were excluded and all insertions were performed by experienced family planning doctors. Different study designs and the method of follow-up to determine the IUD position may explain the different results.

Transvaginal sonographic follow-up at 6 monthly intervals allowed us to determine the period with the highest risk for expulsion. For both IUD types more than 50% of the dislocations occurred within 6 months after insertion. Only 20% of all expulsions occurred more than 1 year after insertion. This observation is in accordance with previous trials evaluating the expulsion rate of copper-devices [15,17]. Predictors of copper-IUD expulsions are young age, excessive length of the endometrial cavity, re-insertion after expulsion, nulliparity and heavy menstrual flow [2,13,19,20]. There is little evidence concerning risk factors for the expulsion of the LNG-IUD. Diaz et al. [20] found an increased risk for dislocations in parous adolescents. The expulsion rate for the LNG-IUD has been reported to be slightly increased in women younger than 25 years [15]. Age did not have an influence on the dislocation rate in our study, probably because we usually do not insert IUDs in adolescents in our clinic and the youngest participant in our study was 23 years old at enrolment. Higher parity was associated with significantly more IUD dislocations in our study. This trend was more pronounced in LNG-IUD users. Nulliparity, but not higher parity, has been reported to be a risk factor for IUD expulsions by other authors [20]. It is reasonable to hypothesize that higher parity is often associated with higher uterine sounding depth and a larger uterine cavity. This assumption is supported by the observation that in the present study not only parity, but also uterine sounding depth was significantly higher in women with incorrect position of the LNG-IUD. The finding that the uterine sounding depth of LNG-IUD users with dislocation was significantly higher (0.6 cm) than that of ML 375 users supports the view, that the LNG-IUD may be less sensitive for a movement downwards, even in women with a larger uterine cavity.

Seventeen percent of our participants reported a previous IUD dislocation in their history. About 40% of these women experienced a partial or complete re-expulsion, which is similar to the 41% re-expulsion for the copper T 200B IUD reported by Bahamondes et al. [5]. This is the first study demonstrating that previous expulsion has to be considered a risk factor for re-expulsion in LNG-IUD users, too. Family planning doctors should consider this when scheduling follow-up visits for these women.

This study was not designed to detect the cause for the different expulsion rates of the two IUD types. However, it is known that the IUD frame produces foreign body reactions and contractions of the uterus. Furthermore, progesterone suppresses myometrial contractions [21]. In this trial we used two t-shaped devices, one releasing copper and one releasing levonorgestrel. Because the frames of the two devices are very similar, we hypothesize that the addition of the progestagen in the LNG-IUD diminishes the amount of myometrial contractions after insertion resulting in a lower number of downward migrations.

Using vaginal sonographic monitoring, we demonstrated a significantly lower rate of partial or complete expulsions in LNG-IUD users compared with ML 375 users. Considering that the LNG group included more women with risk factors for partial expulsion like previous dislocation and hypermenorrhea, we conclude that, after insertion, the expulsion rate of the LNG-IUD is lower than that for the ML 375 IUD.

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References