Five-year follow-up of two types of contraceptive device fitted during elective cesarean delivery

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ABSTRACT

Objective: To present follow-up data for patients fitted with a copper intrauterine contraceptive device (IUCD) or the levonorgestrel intrauterine system (IUS) during cesarean delivery. Methods: Between March 2006 and December 2011, a prospective study was undertaken of women who were scheduled to have a repeat cesarean for a singleton pregnancy and had chosen to undergo intraoperative fitting of an IUCD or the IUS. Participants were followed-up for up to 5 years using transvaginal ultrasonography, clinical evaluation, and a questionnaire. Results: Among 143 participants, 63 requested the IUCD and 80 the IUS. Misalignment was more common at 6 weeks with the IUS (37 [46.3%] patients) than with the IUCD (22 [34.5%]; P = 0.06). Spontaneous expulsion occurred in the IUCD group only (4 [6.3%] patients). No pregnancies were reported in the IUS group, whereas 4 (6.3%) women with the IUCD became pregnant. Conclusion: Although misalignment of an IUCD or the IUS is fairly common after intraoperative insertion, the contraceptive performance and menstrual pattern are not affected. Therefore, there is no need to remove or replace a misaligned IUCD or IUS.

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1. Introduction

Office insertion of intrauterine contraceptive devices (IUCDs), whether copper or hormonal, in women who have had repeat cesarean deliveries tends to be difficult and painful [1]. Such problems might be attributable to the high prevalence of uterine malposition and cervical tightness, particularly if insertion is tried early in the puerperal period. Additional difficulties are encountered in women with obesity, a high cervix, lactational amenorrhea, or a low pain threshold. These difficulties might cause a delay in contraceptive use and subsequently unplanned pregnancies and termination attempts. Additionally, compliance with delayed insertion is poor because women are unlikely to return for device insertion if it is not planned soon after delivery [2].

Intraoperative fitting of an IUCD after delivery of the placenta during elective cesarean delivery has been used for three decades as an alternative to office fitting [3]. Since 2005, intraoperative postplacental fitting has been reported for the levonorgestrel intrauterine system (IUS) [4]. Intraoperative fitting of contraceptive devices circumvents most of the difficulties associated with office insertion, including difficulty with or failure of insertion, pain, vaso-vagal attack, myometrial penetration, perforation, and ascending infection. Additionally, insertion of an IUS during cesarean delivery does not cause any additional adverse effects and does not impair breastfeeding or the growth and development of infants who are breastfed [5–7].

Sonography (vaginal and abdominal) has been used for more than four decades to monitor the placement of an IUCD [8,9]. After introduction of the IUS into clinical practice, sonography has been used in a similar fashion for placement, endometrial effects, blood flow, and effects on various pathologies [10–12]. Furthermore, ultrasonography has been used to guide the postplacental placement of an IUS [13].

Previously, a case series was published comparing patients with the IUCD and those with the IUS, both of which were fitted during elective cesarean delivery [7]. The aim of the present report is to present the long-term follow-up results for these patients. These data might help to offer women more effective and informative counseling about this contraceptive approach.

2. Materials and methods

Between March 10, 2006, and December 31, 2011, a prospective study was undertaken at Shatby Maternity University Hospital, Alexandria, Egypt. Eligible women scheduled to have an elective repeat cesarean delivery who had chosen to undergo intraoperative fitting of a copper IUCD or an IUS after counseling were included. Women with multiple pregnancies, an abnormally situated placenta, an abnormal uterine cavity, labor pain or rupture of membranes before cesarean delivery, or contraindications to IUCDs were excluded. Institutional review board approval and informed consent were obtained.

Counseling about postpartum contraception started during pregnancy and allocation was according to patient choice. The IUCD (Nova-T; Bayer Oy, Turku, Finland) or the IUS (Mirena; Bayer Oy, Turku, Finland) was fitted during cesarean delivery by placing it in the uterine fundus after removal of the placenta. The length of the thread was adjusted to the level of the incision so that the thread did not become trapped in sutures.

After the insertion, participants were followed-up for 5 years, unless removal was requested or expulsion occurred earlier. Participants were interviewed on a weekly basis for 6 weeks, then every month...
until the end of the first year, and thereafter every 3 months. During every visit, their weight was checked, transvaginal sonography was performed, and the participants completed a brief questionnaire.

Transvaginal sonography was performed by three professional sonographers. A sagittal view of the uterus was obtained. The IUCD was considered to be centrally placed if seen as a straight line in the sagittal view. The IUS was considered to be centrally placed if seen as two bright spots, one in the fundus and the other at the internal os. The position was confirmed by rotating the vaginal probe 90 degrees to obtain a transverse view.

The questionnaire included a menstrual diary and asked about adverse effects and satisfaction with the device. Satisfaction was addressed using several questions—e.g. “What is the main drawback of your method?”; “Is this method better than your previously used method (if any was used)?”; “Would you recommend this method to relatives and friends?” User satisfaction was calculated as a score based on the responses to the questions, with a higher score indicating greater satisfaction.

Statistical analysis was performed using SPSS version 14.0 (SPSS Inc, Chicago, IL, USA). The t test was used for comparisons between continuous variables and the χ2 was used for comparisons between qualitative variables. P < 0.05 was considered statistically significant.

3. Results

The study included 143 women: 63 had an IUCD fitted during cesarean delivery and 80 the IUS (Fig. 1). Women requesting the IUS were significantly older than were those opting for an IUCD (P = 0.03), but no other significant differences were noted (Table 1).

The positions of the devices varied considerably in both groups during the first few weeks after delivery. In 93 (65.0%) women, the device appeared to be floating in fluid and echogenic material probably representing clotted blood and degenerating decidua that had collected inside the uterine cavity. By week 6, the position was central for more women with an IUCD than with an IUS, although the difference was not significant (Table 2). Abnormal positions included devices seen transverse in the fundus, oblique in the cavity, and sometimes with the T-shaped configuration inverted upside down. By the end of first year, spontaneous correction of device alignment had occurred in only eight women in the IUCD group, who also resumed regular menstrual periods.

Heavy or normal periods were the predominant menstrual patterns in the IUCD group irrespective of the device position, where as amenorrhea and extreme oligomenorrhea/hypomenorrhea were the predominant patterns in the IUS group irrespective of the device position (data not shown).

Over 5 years of follow-up, no spontaneous expulsion occurred with the IUS, compared with four expulsions in the IUCD group (Table 2), which all occurred within the first 2 years. Four pregnancies occurred in the IUCD group; three were intrauterine pregnancies and one was an ectopic pregnancy. One of the intrauterine pregnancies occurred with a perfectly aligned IUCD, whereas the other two occurred with misplaced IUCDs. Two pregnancies ended in a spontaneous abortion in the first trimester and one continued to term. No pregnancies were reported in the IUS group.

The patient satisfaction scores were significantly higher in the IUS group than in the IUCD group (data not shown). By the end of the 5-year follow-up period, five women had requested removal of the IUCD (Table 2); three because of menorrhagia and two because of a desire to become pregnant. In the IUS group, three women requested device removal; two because of alleged adverse effects, and one because of a desire for conception. All women in the IUCD group had a successful office removal, whereas two women in the IUS group required anesthesia after failed office removal because of a tightly closed cervix with amenorrhea and nonvisible threads.

**Table 1** Obstetric and demographic characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>IUCD (n = 63)a</th>
<th>IUS (n = 80)b</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>32.3 ± 4.7</td>
<td>37.5 ± 3.3</td>
<td>0.01</td>
</tr>
<tr>
<td>Body mass index b</td>
<td>30.6 ± 2.3</td>
<td>31.4 ± 4.2</td>
<td>0.08</td>
</tr>
<tr>
<td>Parity</td>
<td>2.9 ± 1.2</td>
<td>3.6 ± 0.8</td>
<td>0.3</td>
</tr>
<tr>
<td>Previous cesarean deliveries</td>
<td>2.4 ± 0.9</td>
<td>3.1 ± 0.6</td>
<td>0.2</td>
</tr>
<tr>
<td>Initial weight, kg</td>
<td>72.4 ± 5.4</td>
<td>75.5 ± 2.2</td>
<td>0.1</td>
</tr>
<tr>
<td>Final weight, kg</td>
<td>70.8 ± 6.2</td>
<td>76.4 ± 3.4</td>
<td>0.07</td>
</tr>
<tr>
<td>Weight change, kg</td>
<td>3.7 ± 3.3</td>
<td>2.9 ± 3.1</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Abbreviations: IUCD, copper intrauterine contraceptive device; IUS, levonorgestrel intrauterine system.

**Table 2** Sonographic and clinical follow-up data.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>IUCD (n = 63)a</th>
<th>IUS (n = 80)b</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position at 6 wk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centrally placed</td>
<td>41 (65.1)</td>
<td>42 (53.8)</td>
<td>0.07</td>
</tr>
<tr>
<td>Misaligned</td>
<td>22 (34.9)</td>
<td>37 (46.3)</td>
<td>0.06</td>
</tr>
<tr>
<td>Contraceptive failure</td>
<td>4 (6.3)</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Spontaneous expulsion</td>
<td>4 (6.3)</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Requested removal</td>
<td>5 (7.9)</td>
<td>3 (3.8)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations: IUCD, copper intrauterine contraceptive device; IUS, levonorgestrel intrauterine system; NA, not applicable.

a Values are given as mean ± SD.

b Calculated as weight in kilograms divided by the square of height in meters.
4. Discussion

The present study has four main findings. First, after placement during cesarean delivery, both the IUCD and the IUS can appear abnormally placed on the uterine wall by transvaginal ultrasonography. Second, abnormal placement of the IUS did not affect its contraceptive performance or menstrual pattern, the predominant patterns being amenorrhea or extreme hypomenorrhea. Third, malposition of the IUCD was corrected spontaneously in some women, who also experienced resumption of menstruation. Fourth, IUCD malposition was not associated with changes in the menstrual pattern. The correlation between IUCD malposition and contraceptive failure is still unclear in view of the small number of pregnancies.

Early during the puerperium, the sonographic appearance of the contraceptive devices fitted during elective cesarean delivery varied widely. In a substantial number of women, the device appeared to be floating in fluid and debris collected inside the uterine cavity. After 6 weeks, the device was centrally placed in almost two-thirds of the women with an IUCD, compared with slightly more than half of the women in the IUS group.

In the present study, the IUCD was more likely to “self-correct” its position than was the IUS. This finding has also been reported after office application [14,15]. It is possible that the myometrial peristaltic activity associated with normal menstrual periods helps an IUCD to gradually assume the correct alignment within the cavity. Four pregnancies (both intrauterine and ectopic) occurred in the IUCD group, but the small number of pregnant women did not allow statistical correlation with the IUCD position. A previous study [16] found a correlation between the position of the IUCD within the uterine cavity and its contraceptive efficacy, indicating that pregnancies are more likely to occur with misplaced devices. With the IUS, however, because of its hormonal—rather than mechanical—mechanism of action, misplacement did not affect the efficacy. This finding is in agreement with the literature [17].

Spontaneous expulsion is one of the problems that interfere with the contraceptive effectiveness of IUCDs. Expulsions can occur because of improper placement from the start or because of a heavy period with gushes of blood dilating the cervix. With an IUS, the menstrual flow is typically decreased; therefore, IUS expulsion after correct placement—whether intraoperative or in the office—is unlikely. In the current study, no expulsions occurred in the IUS group, whereas the expulsion rate was 6% in the IUCD group. This finding was in agreement with the literature [18].

An important concern of women using hormonal contraception in general is the possibility of weight gain. Evidence about weight gain with oral or parenteral progestin-only contraception is conflicting. However, the limited data generally show a stable body weight with the IUS, but the menstrual flow is typically decreased; therefore, IUS expulsion after correct placement—whether intraoperative or in the office—is unlikely. In the current study, no expulsions occurred in the IUS group, whereas the expulsion rate was 6% in the IUCD group. This finding was in agreement with the literature [18].

User satisfaction with contraception is very important to ensure contraceptive continuation. In the present study, satisfaction was higher among women with the IUS than among those with the IUCD. Device removal on request was easier with the IUCD because of the regular periods and the patulous cervix. Even when the threads were not initially seen, the copper wire around the device could easily be caught with an endometriological biopsy suction curette and the IUCD could be pulled out. By contrast, an IUS fitted during cesarean delivery with no visible threads can be difficult to remove in an office procedure. Such difficulty was encountered in two of three women who requested removal of the IUS.

The data obtained in this large series with a long follow-up should be used for more informative and effective counseling of women considering the contraceptive options investigated. The important message of the present study is that an abnormal sonographic appearance of a contraceptive device fitted during elective cesarean delivery should not be a cause for concern. This message should reach practitioners to avoid the unnecessary removal of devices, particularly the IUS but also the IUCD, because this represents a loss of resources, which is of particular concern in low-income countries.

The present study has limitations, including the fact that selection of the device was based on patient choice without randomization, which might have affected user satisfaction. Moreover, the age in these groups differed, sonographic placement was evaluated using two-dimensional rather than three-dimensional ultrasonography (with greater interobserver variations), and the questionnaire on user satisfaction with the device was over simplified and not validated. These limitations should be addressed in future trials in this area.

In conclusion, the position of an IUCD or IUS can be atypical after correct placement—whether intraoperative or in the office—is unlikely. In the current study, no expulsions occurred in the IUS group, whereas the expulsion rate was 6% in the IUCD group. This finding was in agreement with the literature [18].