Intrauterine contraception: incidence and factors associated with uterine perforation—a population-based study

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STUDY QUESTION: What are the incidence and factors associated with uterine perforation by modern copper intrauterine device (Cu-IUD) and the levonorgestrel-releasing intrauterine system (LNG-IUS)?

SUMMARY ANSWER: Perforation incidence was similar to that reported in prior studies and did not vary between Cu-IUD and LNG-IUS groups. Lactation, amenorrhoea and a post-partum period of <6 months were common.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS: The study supports findings in prior studies. The incidence rate was low and factors associated with uterine perforation were similar to those in earlier reports.

DESIGN AND DATA COLLECTION METHOD: This retrospective population-based registry study included 68 patients surgically treated for uterine perforation by an intrauterine device (IUD)/intrauterine system (IUS) at clinics in the Helsinki and Uusimaa hospital district.

PARTICIPANTS AND SETTING: Records of 108 patients with probable uterine perforation by an IUD/IUS were analysed, leaving 68 patients treated for uterine perforation.

RECRUITMENT/SAMPLING STRATEGY: Patients with diagnostic and surgical treatment codes indicating uterine perforation by an IUD/IUS between 1996 and 2009 were retrospectively selected from the Finnish National Hospital Register.

DATA ANALYSIS METHOD: Patients with Cu-IUDs (n = 17) and the LNG-IUS (n = 51) were analysed as one group and also compared using Mann–Whitney and chi-square tests. IUD/IUS sales numbers were used to calculate incidences.

MAIN FINDINGS: The overall incidence of perforation was 0.4/1000 sold devices, varying annually from 0 to 1.2/1000. The proportion of both sold and perforating LNG-IUSs increased during the study period, but perforation incidence was not affected. Demographic characteristics in the Cu-IUD and LNG-IUS groups were similar. More than half of the devices (55%) were inserted at <6 months post-partum. Breastfeeding at the time of insertion was common, comprising 32% of all patients. Moreover, of the breastfeeding women, 90% had delivered within 6 month prior to insertion.

IMPLICATIONS: The population-based study setting represents a good overview of patients experiencing uterine perforation with an IUD/IUS. As previously reported, the post-partum period, lactation and amenorrhoea may increase the risk of perforation.

BIAS, LIMITATIONS AND GENERALIZABILITY: As the study setting revealed only symptomatic patients or those attending regular follow-up, the true incidence might be somewhat higher. As there is no specific diagnostic code for uterine perforation or treatment, it is unlikely that all cases of uterine perforation can be identified in a retrospective study.

STUDY FUNDING/POTENTIAL COMPETING INTERESTS: Helsinki University Central Hospital research funds are acknowledged.

Key words: IUD / IUS / perforation / incidence / contraception

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Introduction

Uterine perforation is an uncommon but feared complication of intrauterine contraception. Most previous studies on uterine perforation have concerned the use of copper intrauterine devices (Cu-IUDs). However, the levonorgestrel-releasing intrauterine system (LNG-IUS) is increasingly popular in many countries. Previously reported perforation rates with Cu-IUDs vary from 0 to 2.2/1000 insertions (Andersson et al., 1998; Caliskan et al., 2003; Harrison-Woolrych et al., 2003). In a clinical study in which a Cu-IUD and the LNG-IUS were compared, recorded perforation rates were 0/1000 follow-up years with the Cu-IUD and 1/1000 follow-up years with the LNG-IUS (Sivin and Stern, 1994). The few published studies on uterine perforation in connection with the LNG-IUS include one retrospective case study showing an incidence of 2.6/1000 insertions, based on intrauterine device (IUD) sales and perforations reported by gynaecologists, and one summary of reports from the New Zealand Intensive Medicines Monitoring Programme, monitoring adverse drug events, showing an incidence of 0.9/1000 insertions based on the results of a 3-year survey (Zouh et al., 2003; van Haudenhoven et al., 2006). In addition, the large ongoing international prospective EURAS-IUD study (European Active Surveillance Study for Intrauterine Devices) revealed perforation rates of 0.68/1000 insertions for the LNG-IUS and 0.41/1000 insertions for Cu-IUDs at 1 year of follow-up (Heinemann et al., 2011).

Most perforations are thought to occur at insertion either via the uterine sound or the inserter and thus the IUD/intrauterine system (IUS) is inserted directly into the abdominal cavity or passes there through an istrogenic opening in the uterine wall (Zakin et al., 1981a,b; Heartwell and Schlesselman, 1983; Andersson et al., 1998). Many patients are asymptomatic and perforation may be discovered at routine follow-up or in connection with an unintended pregnancy. Possible symptoms of perforation include abnormal bleeding patterns and abdominal pain. When the IUD threads are not visible during a check-up, perforation cannot be excluded. In most cases, the device can be found in the uterus (Marchi et al., 2012). As IUDs can be seen in vaginal ultrasonography, this is often enough to locate the device, but alternatively X-rays, computed tomography or magnetic resonance imaging can be used in locating missing devices (Boortz et al., 2012). The threads might have been cut too short, turned upwards or the device might have turned in utero, drawing the threads out of place. If the patient is pregnant, growth of the uterus retracts the threads. If the IUD/IUS cannot be found in utero, perforation must always be considered, although expulsion is more common (Millen et al., 1978; Zakin et al., 1981a,b; Sivin and Stern, 1994; van Grootheest et al., 2011).

Proposed risk factors of uterine perforation include the immediate post-partum period and breastfeeding, regardless of the timing of insertion (Heartwell and Schlesselman, 1983; Andersson et al., 1998; Caliskan et al., 2003; van Haudenhoven et al., 2006). Both Andersson and van Haudenhoven have discussed the role of uterine involution and increased uterine contractility as potential contributing factors to IUD perforation occurring in the post-partum period (Andersson et al., 1998; van Haudenhoven et al., 2006). Thus, the World Health Organisation (2009) recommends intrauterine contraception to be started after 4 weeks post-partum. Other potential risk factors include extremes of uterine posture, inexperience of the inserter and an inadequate insertion technique (Zakin et al., 1981a,b; Caliskan et al., 2003; Zouh et al. 2003; Harrison-Woolrych et al., 2003). Increasing parity has been reported both to increase as well as reduce the risk (Heartwell and Schlesselman, 1983; Caliskan et al., 2003).

IUDs have traditionally been a popular form of contraception in Finland, at present accounting for 18% of all contraceptive methods used and being second after oral contraceptives (Taloustutkimus, 2009). In addition, the LNG-IUS is increasingly used for treating bleeding disorders and as part of hormone therapy for climacteric symptoms (Andersson et al., 1992, Gemzell-Danielsson et al., 2011). The purpose of the present retrospective population-based study was to assess the incidence and factors associated with uterine perforation with current types of IUDs in the area of the hospital district of Helsinki and Uusimaa, which includes ~1.5 million inhabitants, 29% of the Finnish population (December 2011).

Materials and methods

Before initiation of the study, the Ethics Committees of the Hospital of Helsinki and Uusimaa as well as the hospital district of Helsinki and Uusimaa gave positive statements regarding the project. The Ministry of Social Affairs and Health and the National Institute for Health and Welfare gave permission to use the register and medical record data in the research.

The present data were taken from the National Care Register for Finnish Health Institutions, later called the Hospital Register. The register contains ICD-10 (International Classification of Diseases, 2010) and operation codes on all patients treated at Finnish hospitals. As there is no specific ICD-10 code for IUD/IUS perforation, subjects with potential uterine perforation were identified from the Hospital Register by using the operation codes of the Nordic Medico-Statistical Committee (NOMESCO) Classification of Surgical Procedures, available since 1997, for removal of an intra-abdominal or intrauterine foreign object (JAL10-11, JAL-20-22) combined with the ICD-10 codes implementing gynaecological procedures relating to IUD/IUS complications (T83.3, T19.3), insertion and follow-up (Z30). As ICD-10 was introduced in Finland in 1996, subjects treated from 1 January 1996 through 31 December 2009 were included in the present analysis. Patient selection is shown in Fig. 1. Combining these diagnostic and operation codes resulted in the identification of 3909 patients. By excluding codes unrelated to possible perforation and male patients, 370 patients with probable surgically treated uterine perforation were found nationwide. Records of 108 patients treated at the clinics of the hospital district of Helsinki and Uusimaa were examined by J.K., resulting in identification of 78 patients with surgically treated uterine perforations and 30 patients treated for other IUD/IUS-related reasons. Of the patients with perforation, 10 were excluded as the device had been inserted prior to the beginning of the study period, leaving 68 patients included in the study. The distribution of the type of surgically removed devices is shown in Fig. 2.

The number of IUDs/IUSs sold by a major pharmaceutical company (Bayer AG, Berlin, Germany) during the corresponding time period was used to represent the number of Cu-IUDs (NovaT®) and LNG-IUSs (Mirena®) inserted during the study period. These two devices account for more than 90% of nationally sold devices during the study period. The number of devices sold in the area of Helsinki and Uusimaa accounts for ~29% of nationally sold devices. Precise sales numbers for the Helsinki and Uusimaa area are known for the LNG-IUS starting from 1997 and for the Cu-IUD starting from 2004. Numbers prior to this are estimated to be...
status only. The incidence of surgically treated IUD/IUS perforation was calculated by comparing the above-mentioned sales figures with the number of surgically treated patients. Subjects were analysed both as one group and as separate groups by type of device, LNG-IUS versus Cu-IUD, using Mann–Whitney and chi-square tests as appropriate. Statistical significance was set at $P \leq 0.05$.

**Results**

**Demographics**

Patient demographics grouped by the type of device are shown in Table I. The groups did not differ statistically as regards age, BMI, parity, type of delivery, number of miscarriages, terminations of pregnancy or history of pelvic surgery. More women in the Cu-IUD group had a history of prior curettage, whereas multiple procedures were more common in the LNG-IUS group ($P = 0.05$).

**Incidence**

We found an overall incidence of uterine perforation of 0.4/1000 sold devices (both Cu-IUDs and the LNG-IUS) between 1996 and 2009. More perforations occurred in connection with the LNG-IUS during the latter half of the period (2003–2009), yet the incidence did not change significantly (Fig. 2). This is explained by increased LNG-IUS sales. Table II shows annual as well as overall incidences of uterine perforation in connection with both types of IUD.

**Characteristics of women undergoing surgical treatment for IUD/IUS perforation**

**Post-partum period and breastfeeding**

At insertion, 45 patients (66%) had given birth during the preceding 12 months (Fig. 3). There were 15 patients (22%) had had the device inserted 3 months post-partum and 38 (55%) at 6 months post-partum. One-third of the women (23) had not delivered within the year preceding insertion.

Among those with known lactation status, breastfeeding at the time of insertion was significantly more common in the Cu-IUD group (53% versus 25%, $P = 0.05$). Most breastfeeding women ($n = 19$, 90%) had given birth during the last 6 months ($P < 0.001$) and 17 of them were amenorrhoeic ($P < 0.001$).

**Insertion-related data**

The devices were inserted at different types of health-care units: 17 (25%) at primary health-care clinics, 14 (21%) at family planning clinics, 15 (22%) by private obstetricians/gynaecologists and 7 (10%) at hospitals. For 15 (22%) of insertions, no information was available. General practitioners inserted 27 (40%) and gynaecologists 22 (29%), but for 21 (31%), no information was available.

Pain at insertion was reported by 32 women (47%), whereas no pain or minimal pain was reported by 9 (13%). However, five (7%) of the patients had had the device inserted under general anaesthesia because of previous problems at insertion or following curettage or hysteroscopy. These five women had not delivered within the previous year. For 22 women (32%), no information on pain was available. The percentage of painful insertions was $\approx 70%$ in connection with both types of device. Breastfeeding women had reported more pain at insertion when compared with women not breastfeeding (75%...
versus 64%, \( P = 0.009 \). The clinically assessed uterine posture (anteversion or retroversion) at the time of detection of perforation was not related to reported pain at insertion (\( P = 0.32 \)). Of the patients, 36 (53%) had an anteverted uterus, 11 (17%) had a retroverted uterus and for 5 (7%) the physicians had varying opinions. Information was lacking on 16 patients (23%). Only 11 (16%) of patient records contained a comment on extensive flexion: 5 anteverted, 5 retroverted and in 1 case the assessment varied.

The median time from insertion to diagnosis was 5 months (0 days–69 months), and the median time from diagnosis to surgical treatment was 21 days (0 days–16 months).

Discussion

We found that women experiencing IUD/IUS perforation represent typical users of intrauterine contraception: women in their early 30's with a history of vaginal delivery. The incidence of perforation was 0.4/1000 sold devices in connection with both Cu-IUDs and the LNG-IUS. Annual variations regarding both types of device were similar, 0–1.2/1000 with Cu-IUDs and 0–0.9 with the LNG-IUS. Similar or somewhat higher perforation rates have been reported in prior studies. The incidence of Cu-IUD perforation in prospective as

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**Table I** Demographics of patients with surgically removed perforated IUD/IUS.

<table>
<thead>
<tr>
<th></th>
<th>LNG-IUS, ( n = 51 )</th>
<th>Cu-IUD, ( n = 17 ) *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td>33 (20–54)</td>
<td>32 (24–47)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>23.2 (17.9–39.6)</td>
<td>22.8 (19.7–36.5)</td>
</tr>
<tr>
<td>Data not available</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Parous</td>
<td>50 (98%)</td>
<td>17 (100%)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>2 (0–6)</td>
<td>2 (1–6)</td>
</tr>
<tr>
<td><strong>History of vaginal delivery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>44 (88%)</td>
<td>14 (82%)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>2 (1–6)</td>
<td>2 (1–6)</td>
</tr>
<tr>
<td>No</td>
<td>6 (12%)</td>
<td>3 (18%)</td>
</tr>
<tr>
<td><strong>History of Caesarean section</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13 (25%)</td>
<td>4 (24%)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>1 (1–3)</td>
<td>0 (1–3)</td>
</tr>
<tr>
<td>No</td>
<td>38 (75%)</td>
<td>13 (76%)</td>
</tr>
<tr>
<td><strong>History of miscarriage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12 (24%)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>1.5 (1–3)</td>
<td>1 (1–2)</td>
</tr>
<tr>
<td>No</td>
<td>39 (76%)</td>
<td>11 (65%)</td>
</tr>
<tr>
<td><strong>History of termination of pregnancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11 (22%)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>1 (1–2)</td>
<td>1 (1–2)</td>
</tr>
<tr>
<td>No</td>
<td>40 (78%)</td>
<td>11 (65%)</td>
</tr>
<tr>
<td><strong>Previous IUD use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (20%)</td>
<td>3 (18%)</td>
</tr>
<tr>
<td>No</td>
<td>10 (20%)</td>
<td>4 (24%)</td>
</tr>
<tr>
<td>Data not available</td>
<td>31</td>
<td>10</td>
</tr>
<tr>
<td><strong>History of pelvic surgery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26 (51%)</td>
<td>12 (71%)</td>
</tr>
<tr>
<td>No</td>
<td>25 (49%)</td>
<td>5 (29%)</td>
</tr>
<tr>
<td>Endometriosis (laparoscopy)</td>
<td>3 (6%)</td>
<td>0</td>
</tr>
<tr>
<td>Salpingectomy (ectopic pregnancy)</td>
<td>0</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Curettage</td>
<td>12 (24%)</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>&gt;1 procedure</td>
<td>5/12 (42%)</td>
<td>2/8 (25%)</td>
</tr>
<tr>
<td>LEEP treatment</td>
<td>5 (10%)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal surgery</td>
<td>1 (2%)</td>
<td>2 (12%)</td>
</tr>
<tr>
<td><strong>Breastfeeding at the time of insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13 (25%)</td>
<td>9 (53%)</td>
</tr>
<tr>
<td>No</td>
<td>18 (35%)</td>
<td>3 (18%)</td>
</tr>
<tr>
<td>Data not available</td>
<td>20 (40%)</td>
<td>5 (28%)</td>
</tr>
<tr>
<td><strong>Amenorrhea at the time of insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9 (18%)</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>No</td>
<td>11 (22%)</td>
<td>3 (18%)</td>
</tr>
<tr>
<td>Data not available</td>
<td>31 (60%)</td>
<td>6 (35%)</td>
</tr>
</tbody>
</table>

The data are presented as \( n \) (%) unless stated otherwise.

*Fincond 1, FlexiT 1, NovaT380Ag 10, unspecified type of Cu-IUD 5.

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**Table II** Incidence of uterine perforation, \( n/1000 \) sold IUDs/IUSs.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG-IUS annual variation</td>
<td>0.4–0.9</td>
<td>0.5</td>
<td>0.37</td>
</tr>
<tr>
<td>Cu-IUD annual variation</td>
<td>0–1.2</td>
<td>0–0.9</td>
<td>0.36</td>
</tr>
<tr>
<td>Combined annual variation</td>
<td>0.4</td>
<td>0.5</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Figure 3 Time between delivery and IUD/IUS insertion (months).
well as in retrospective studies has been reported to vary from 0.4 to 2.2/1000 insertions. The perforation incidence as regards the LNG-IUS has, however, been somewhat higher in retrospective studies, 0.9–2.6/1000 insertions, in comparison with 0.68/1000 insertions reported in the first large prospective study, the EURAS-IUD study (Heinemann et al., 2011).

To our knowledge, no prior population-based studies have been reported concerning the incidence of uterine perforation. The present work is also one of the largest studies in which factors associated with uterine perforation have been assessed. Previously published studies on Cu-IUD-associated perforation are case reviews and case series derived from single clinics as well as prospective multicentre studies (Zakin et al., 1981a, b; Heartwell and Schlesselman, 1983; Svin and Anderson, 1994; Andersson et al., 1998; Caliskan et al., 2003; Harrison-Woolrych et al., 2003), whereas studies on the LNG-IUS are case reports and reports on adverse drug events (Zou et al., 2003; van Haudenhoven et al., 2006; van Grootheest et al., 2011). The final results from the prospective EURAS-IUD study are still to come (Heinemann and Assmann, 2012).

As there is no specific diagnostic code for uterine perforation or treatment, it is unlikely that all cases of uterine perforation can be identified in a retrospective study. In the present study, we identified only cases treated by surgical means (laparoscopy/laparotomy or hysteroscopy). Thus, possible IUS/IUD perforations occurring at the time of insertion and treated immediately by removal of the device were missed by the present research strategy. In addition, many patients are asymptomatic as regards the perforation (van Grootheest et al., 2011). This study is likely to include only symptomatic patients and those attending regular follow-up visits. Furthermore, we were only able to identify subjects treated between 1996 and 2009, as a different coding system was used prior to this. The true incidence of all IUD-related perforations is likely to be somewhat higher than the present figures suggest.

Another shortcoming of the study is the lack of controls. As the devices were inserted in multiple health-care settings, identifying appropriate controls would have been very cumbersome. In addition, IUD/IUS sales figures were used as a surrogate marker of insertions. Even though this is prone to several uncertainties, it is assumed that the overall number of IUD/IUS sold over the period of 15 years is a reasonable proxy of all insertions occurring in the hospital district over the study period. However, prospective and systematic data collection remains the only truly reliable way of assessing the rates and risk factors of uterine perforation.

More than half of all the patients had given birth within the previous six months and at least one-third of them were breastfeeding and amenorrhoaic at the time of insertion. A combination of these factors was common, which coincides with findings in previous studies (Andersson et al., 1998). Only one of the breastfeeding women had delivered by Caesarean section (3 months prior to insertion), which suggests that a uterine scar is not a major risk factor. Breastfeeding women reported more pain at insertion than other patients with uterine perforations. This finding contradicts a previous hypothesis suggesting more easily occurring silent perforations (Chi et al. 1989; Andersson et al., 1998). There were more lactating women in the Cu-IUD group, but as this is a retrospective non-randomized study, it is impossible to draw conclusions from this. Although both devices are equally recommended post-partum and for lactating women, various health-care policies and the women’s preferences may have influenced the choice of device.

The clinical settings where insertion took place and the specialties of the inserting physicians differed markedly. This reflects the health-care system in Finland. Also, it is not the specialty of the inserting physician, but training and continuing insertion experience (National Institute for Health and Clinical Excellence, 2005) and following instructions (Harrison-Woolrych et al., 2003) that are essential for successful IUD/IUS insertions. Many general practitioners and doctors at family planning clinics insert IUDs/IUSs as often as, or even more frequently than, gynaecologists at private practices or hospitals. In this study, physicians working in the public sector inserted a large proportion of the devices, reflecting the fact that the majority of family planning services are provided by the public sector in Finland. A large number of insertions resulting in perforation were carried out by obstetrician gynaecologists. It may be speculated that women with a prior difficult insertion might have sought specialist services directly. This is highlighted by the fact that 10% of the perforating devices were inserted at hospitals, the majority of these procedures occurring under general anaesthesia.

Only a few uteri were assessed as having a steep flexion angle. The distribution of uterine posture was similar to that which is considered normal, and pain at insertion was not correlated with posture. Severe pain at insertion might indicate a complication, but as the majority of women experience some pain at insertion, this factor cannot be used as a way to separate successful insertions from complicated ones (Suonen et al., 2004; Heikinheimo et al., 2010). Difficulties in inserting the uterine sound or the inserter and pain continuing after insertion might be better indicators of complications.

In conclusion, as reported in prior studies with different settings, the incidence of uterine perforation was low, 0.4/1000 sold devices. No clinically significant differences in incidence or patient characteristics between the Cu-IUD and the LNG-IUS groups were found. More than half of all perforating devices were inserted within 6 months of delivery and many patients were lactating and amenorrhoaic at the time of insertion. Finally, as intrauterine contraception is one of the most widely used contraceptive methods worldwide, we propose that a specific code for uterine perforation associated with an IUD/IUS be added in future editions of globally used diagnostic classifications.

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Authors’ roles

All authors have equally participated in the study design, analysis of the data, manuscript drafting and critical discussion.

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Conflict of interest

O.H. has lectured and designed educational events with Bayer Ag and MSD, and serves occasionally on scientific advisory boards for these companies. The other authors have no conflicts of interest to declare.

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