The value of transvaginal ultrasound to monitor the position of an intrauterine device after insertion. A technology assessment study

C.D.de Kroon, J.C.van Houwelingen, J.B.Trimbos and F.W.Jansen

Departments of Gynaecology and Medical Statistics, Leiden University Medical Center, P.O.Box 9600, 2300 RC Leiden, The Netherlands

To whom correspondence should be addressed. E-mail: f.w.jansen@lumc.nl

BACKGROUND: The intrauterine device (IUD) is an effective contraceptive method. The contraceptive power as well as the side-effects of IUD are thought to relate to the position of the IUD in the uterine cavity. We assessed the accuracy of clinical evaluation of IUD position. METHODS: A prospective comparative study was performed. The clinical evaluation was compared with the TVU measurement of IUD position both immediately after insertion and 6 weeks after insertion. The primary outcome measures were the positive and negative predictive values (PPV and NPV) of the clinical evaluation of IUD position. RESULTS: 195 women were included consecutively, 181 women (92.8%) were available for follow-up. The PPV and NPV of clinical evaluation of IUD position immediately after insertion were respectively 0.60 (95% CI: 0.39–0.81) and 0.98 (95% CI: 0.96–1.0). The prevalence of an abnormally positioned IUD was 7.7% (95% CI: 3.9–11.4). The PPV and NPV of the clinical evaluation at follow-up were respectively 0.54 (95% CI: 0.26–0.81) and 1.0 (95% CI: 0.98–1.0). The prevalence of abnormal position was 4.0% (95% CI: 1.7–7.1). CONCLUSION: Clinical evaluation is an excellent test for the evaluation of the position of an IUD and routine TVU is not indicated for this purpose.

Key words: contraception/follow-up/gynaecological examination/intrauterine device/transvaginal ultrasound

Introduction

The intrauterine position of an intrauterine contraceptive device (IUD) is thought to be closely related to its contraceptive power (Bernaschek et al., 1981; Tadesse et al., 1985; Anteby et al., 1993). IUD located more cervically may prevent conception to a lesser degree compared to adequately localized IUD (Anteby et al., 1993). Therefore proper insertion of an IUD is of utmost importance. Moreover, follow-up after the first menses is recommended since the first month is suggested to be the period with the highest risk of downwards migration and spontaneous expulsion (Anteby et al., 1993). The gynaecological interview and pelvic examination, in combination with self-examination, can be used to ensure adequate localization of the IUD (American College of Obstetricians and Gynecologists, 1992). For the above reasons, insertion and follow-up of IUD has been routine in general practice (Harrison-Woolrych et al., 2002).

Currently, transvaginal ultrasound (TVU) is used increasingly to complete the gynaecological examination in hospital settings (Valentin, 1999). The routine use of TVU to monitor the position of the IUD after insertion has been advocated (Bonilla-Musoles et al., 1996). There is much evidence that shows TVU to be highly accurate in monitoring the location of any type of IUD (Petta et al., 1996; Faúndes et al., 1997, 2000; Palo, 1997; Aleem et al., 1992). The IUD–endometrium distance (IUD–ED) seems to be the most relevant measurement, especially for copper IUD (Petta et al., 1996; Faúndes et al., 1997, 2000). However, the maximum IUD–ED to ensure adequate contraception is under debate (Petta et al., 1996; Faúndes et al., 1997), especially since T-shaped IUD tend to accommodate in their position during the first 3 months after insertion (Faúndes et al., 2000). Therefore removal of all ‘abnormally located’ IUD at TVU may result in a high number of unnecessary removals (Petta et al., 1996; Faúndes et al., 2000).

The silent incorporation of routine TVU in gynaecology and especially in IUD follow-up needs urgent evaluation (Valentin, 1999; Rivera and Best, 2002). Before adopting the routine use of TVU for this purpose, and consequently transfer the insertion of IUD from general practice to the gynaecological outpatient department, the clinical value of this phenomenon should be evaluated and guidelines adjusted accordingly. The aim of this prospective study was to evaluate the clinical relevance of the routine use of TVU immediately after and 6 weeks after the insertion of an IUD.
Materials and methods
All women who attended the outpatient Department of Gynaecology of the Leiden University Medical Center for the insertion of an IUD between July 1, 2001 and January 1, 2003 were eligible for this study, regardless of type of IUD. After informed consent, women were included and the IUD inserted according to our protocol. Pain medication was not prescribed routinely while insertion was preferably performed during or just after menses.

The clinician who inserted the IUD had to fill out a standardized form with questions about the procedure: (i) whether the IUD was thought to be located properly (adequate position) or erroneously (inadequate position) inside the uterine cavity; and (ii) whether the procedure was with or without complications and/or difficulties. Clinicians were divided into groups according to their experience (respectively <25, 25–75 and >75 inserted IUD).

Immediately after the insertion of an IUD, an independent sonographer who was unaware of the clinician’s answers to the above-mentioned questions performed TVU. A 5–7.5 MHz multi-frequency vaginal probe and a Power Vision 6000 ultrasound machine (Toshiba Medical Systems, The Netherlands) were used. With TVU, 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 (Figure 1). Whenever this junction could not be identified clearly, the IUD–ED was calculated by subtracting half of the double endometrial thickness from the distance between the IUD and the endo-myometrial junction (Figure 2) (Petta et al., 1996; Faündes et al., 1997; 2000). The mean IUD–ED was calculated from three independent measurements. In 20 non-selected consecutive women, a reliability analysis was performed by means of calculation of the intra-class correlation of two independent IUD–ED measurements (Khan and Chien, 2001; Sackett and Haynes, 2002).

According to our protocol, all women had a follow-up visit 6 weeks after insertion. At this visit, a standardized interview was taken concerning complaints of the IUD with emphasis on abdominal pain and cramping, bleeding disorders and complaints possibly due to the threads of the IUD. A gynaecological examination was performed to monitor the position of the IUD by estimating the length of the threads. By this means, the position of the IUD was evaluated clinically. Thereafter TVU was performed and the IUD–ED measured as described above. The sonographer again was unaware of the results of the interview and the gynaecological examination. Whenever the IUD–ED was $>$5.0 mm, removal of the IUD was advised. All further follow-up was independent of participation in the trial.

The predictive values and likelihood ratios with 95% confidence intervals (95% CI) of the clinical evaluation of IUD localization were calculated using the IUD–ED as the gold standard. A multiregression analysis was used to calculate the multivariate odds ratios (OR with 95% CI) of risk factors for inadequate insertion and inadequate IUD position at follow-up. Multivariate OR (with 95% CI) were also calculated for risk factors for improper clinical evaluation of the position of the IUD both immediately after insertion and at follow-up.
Student’s t-test (continuous data), χ²-test and Fisher’s exact test (categorical data) were used to compare groups; the level of significance was set at $P < 0.05$.

**Results**

A total of 195 consecutive women were eligible and included in the study. The mean age was 33.2 years (SD 7.3; range 17–49 years). Seventy-nine women were nulliparous (40.5%) while the others had delivered at least once. Most women (73.8%) had never had an IUD before. The levonorgestrel-releasing intrauterine system (Mirena®) was inserted 114 times (58.5%), all other women had a copper IUD inserted: Multiload® 63 (32.3%) and Nova-T® and 18 (9.2%) times. Women who had a Nova-T® were significantly younger (28.2 versus 33.8 years, $P < 0.01$) and more often nulliparous (89 versus 30%, $P < 0.01$) compared with the other women.

**Validity analysis**

After insertion, the clinician was certain about adequate position of the IUD in 175 cases (90%). According to the IUD–ED measurements, 172 of these IUD were positioned adequately [negative predictive value (NPV) of clinical evaluation: 0.98; 95% CI: 0.96–1.00]. According to the clinician, the IUD was positioned inadequately in 20 cases (10%), in 12 of these the IUD–ED was indeed $> 5.0$ mm [positive predictive value (PPV) of clinical evaluation: 0.6; 95% CI: 0.39–0.81]. The 2×2 table and likelihood ratios (with 95% CI) are shown in Table I. In a total of 15 women, the IUD–ED was $> 5.0$ mm. In eight of these women, the IUD was removed because of this erroneous location.

The data from 181 women (92.8%) were available for follow-up 6 weeks after insertion. Fourteen women were lost to follow-up: in seven cases (3.6%) the sonographer was not available at the scheduled follow-up and seven women (3.6%) did not attend at their scheduled follow-up appointment. In all 14 women who were lost to follow-up, the adequacy of the position of the IUD had been ascertained by TVU immediately after insertion. The characteristics (age, parity and type of IUD) of these women did not differ significantly from the rest of the women. The IUD had been removed immediately after insertion in eight women (4.1%), who were excluded from further analysis.

Of the remaining 173 women, the clinician was certain about the adequate position of the IUD in 160 (91.9%) women. In all these women, the IUD–ED was $\leq 5.0$ mm (NPV of the clinical evaluation at follow-up: 1.0). In 13 women (8.1%) the clinician concluded, according to the results of the gynaecological interview and pelvic examination, that the IUD was located inadequately. In six of these, the IUD–ED was indeed located $> 5.0$ mm (PPV of the clinical evaluation at follow-up: 0.54; 95% CI: 0.26–0.81). In seven women, the IUD had been inserted inadequately; in two of these women, the IUD was still located inadequately at follow-up. In the remaining five women, the IUD had migrated upwards to an adequate intrauterine position. The 2×2 tables and likelihood ratios of the clinical evaluation of IUD position are shown in Table II.

**Multiregression analysis: prediction of IUD position**

The two significant variables for the prediction of inadequate position of the IUD immediately after insertion ($n = 15$) were the type of IUD (Nova-T versus other types respectively: 5/18 versus 10/177; OR: 5.93; 95% CI: 1.89–18.6; $P < 0.01$) and complicated insertion (complicated versus uncomplicated respectively: 6/12 versus 13/171; OR: 5.47; 95% CI: 1.99–14.9; $P < 0.01$). Experience of the inserting clinician did not significantly influence adequacy of insertion (threshold $< 25$ and $< 75$ inserted IUD respectively; OR: 1.67; 95% CI: 0.31–9.2, $P = 0.56$; and OR: 2.27; 95% CI: 0.61–12.6, $P = 0.19$). In contrast to women with an adequately positioned IUD, all women with an inadequately positioned IUD had complaints at follow-up (8.4 versus 100%, OR: 11.9, 95% CI: 7.2–19.6). ‘Complaints at follow-up’ was the only significant variable for inadequate position at follow-up (OR: 96.61; 95% CI: 6.34–1471, $P < 0.01$). Due to the low prevalence of complaints at follow-up, it was not possible to differentiate which of the complaints was the single most significant predictor of inadequate position of the IUD.

**Multiregression analysis: correctness of clinical evaluation**

Immediately after insertion, the clinician evaluated the position of the IUD to be incorrect in 11 cases (5.6%; eight false

<table>
<thead>
<tr>
<th>Table I. The results of the clinical evaluation of the position of the intrauterine device (IUD) immediately after insertion compared with transvaginal ultrasound (TVU) measurement of the IUD-endometrial distance ($&gt; 5.0$ mm = inadequate position)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate position of IUD according to TVU</td>
</tr>
<tr>
<td>Prevalence of inadequate position</td>
</tr>
<tr>
<td>PPV of the clinical evaluation</td>
</tr>
<tr>
<td>NPV of the clinical evaluation</td>
</tr>
<tr>
<td>LR +ve test</td>
</tr>
<tr>
<td>LR –ve test</td>
</tr>
</tbody>
</table>

PPV = positive predictive value; NPV = negative value; LR = likelihood ratio.
negative evaluations and three false positive evaluations). Complicated insertion was the only significant predictor of incorrect clinical evaluation (OR: 2.89; 95% CI: 1.25–6.67, \( P = 0.01 \)). Inexperience (<25 inserted IUD) was not of significant influence in the incorrect clinical evaluation immediately after insertion (OR: 1.81; 95% CI: 0.36–9.2; \( P = 0.47 \)). At follow-up, the clinical evaluation was incorrect in six cases (3.5%; all false negative evaluations). ‘Complaints at follow-up’ was the only significant predictive variable (OR: 11.09; 95% CI: 1.51–81.39; \( P = 0.02 \)). Again, inexperience was not a significant variable for improper clinical evaluation (OR: 0.71; 95% CI: 0.11–4.7; \( P = 0.71 \)). At follow-up, highly experienced clinicians did not significantly more often evaluate the position of the IUD incorrectly (OR: 1.39; 95% CI: 0.22–8.91, \( P = 0.69 \)).

Reliability analysis

The intra-class correlation (alpha) for repeatability was 0.99 (95% CI: 0.98–0.99). Table III shows the reliability analysis of the IUD–ED measurement stratified for type of IUD.

Discussion

The routine use of transvaginal ultrasound to monitor the position of the IUD is not indicated since our results show that without clinical suspicion of an erroneous position, the chances of an inadequately positioned IUD are negligible (NPV immediately after insertion and at follow-up respectively: 0.98 and 1.00). In other words, clinical evaluation is a good test for evaluating the position of the IUD, especially at follow-up. Only in the case of clinical suspicion of inadequate positioning may additional TVU be helpful, since 60% of these IUD are still positioned adequately in the uterine cavity after all (PPV: 0.6 and 0.54 respectively). Therefore the use of TVU may prevent the unnecessary removal of adequately located IUD in women with complaints.

In our opinion, the development of evidence-based guidelines for the insertion of an IUD and follow-up of IUD users is mandatory (Rivera and Best, 2002). Although the IUD is used infrequently, despite its reliability and cost-effectiveness (Mishell, 1998), its use may increase because of three reasons. First, nulliparity is no longer a contraindication (Hubacher et al., 2001). Second, the levonorgestrel-releasing intrauterine system has been shown to be highly effective for the treatment of menorrhagia and dysfunctional uterine bleeding (Crosignani et al., 1997; Monteiro et al., 2002). Third, due to recent attention to the increased risk of venous thrombosis as a result of the use of oral contraceptives, especially third generation combined oral contraceptives, some women may switch from hormonal to non-hormonal contraceptive methods (Vandenbroucke et al., 2001).

As suggested for proper diagnostic research (Sackett and Haynes, 2002), we minimized the bias of the sonographer since he was unaware of both the opinion of the clinician about the position of the IUD and of the difficulties at insertion; the sonographer was also unaware of the conclusion of the clinical evaluation at follow-up. However, for ethical reasons it was not possible to withhold the results of the TVU immediately after insertion to the clinicians and the patients. This may have biased both the sonographer and the clinician in their evaluation at follow-up, especially in the seven women with inadequate position of the IUD after insertion.

Our results indicate that clinicians with relatively little experience in inserting and monitoring IUD, like most general practitioners, are still capable of doing so. The number of incorrect clinical evaluations of IUD position did not differ significantly between inexperienced (<25 IUD inserted) and experienced (>25 IUD inserted) clinicians, either immediately after insertion or at follow-up (OR respectively: 1.81; 95% CI: 0.39–9.2; and 0.71; 95% CI: 0.11–4.7). Inexperienced and experienced clinicians were equally accurate in inserting IUD (OR: 1.67; 95% CI: 0.31–9.2).

Table II. The results of the clinical evaluation of the position of the intrauterine device (IUD) 6 weeks after insertion compared with transvaginal ultrasound (TVU) measurement of the IUD–endometrium distance (>5.0 mm = inadequate position)

<table>
<thead>
<tr>
<th></th>
<th>Inadequate position of IUD according to TVU</th>
<th>Adequate position of IUD according to TVU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate position of IUD according to clinical evaluation</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Adequate position of IUD according to clinical evaluation</td>
<td>0</td>
</tr>
<tr>
<td>Prevalence of inadequate position</td>
<td>4.0%</td>
<td></td>
</tr>
<tr>
<td>PPV of the clinical evaluation</td>
<td>0.54 (0.26–0.81)</td>
<td></td>
</tr>
<tr>
<td>NPV of the clinical evaluation</td>
<td>(0.98–1.0)</td>
<td></td>
</tr>
<tr>
<td>LR +ve test clinical evaluation</td>
<td>27.7 (12.6–60.7)</td>
<td></td>
</tr>
<tr>
<td>LR –ve test clinical evaluation</td>
<td>0 (–)</td>
<td></td>
</tr>
</tbody>
</table>

PPV = positive predictive value; NPV = negative value; LR = likelihood ratio.
TVU has been shown to be able to monitor the position of all different types of IUD (Bonilla-Musoles et al., 1996; Petta et al., 1996; Faúndes et al., 1997, 2000; Palo 1997); however, this is the first report on the excellent reliability of the IUD–ED measurement by TVU (intra-class coefficient 0.99). We choose 5.0 mm as threshold for abnormal IUD position as consensus between earlier reports. First Faúndes showed that in 90% of women without complaints of their copper IUD, the IUD–ED was <7.0 mm (Faúndes et al., 1997). Petta showed that if IUD were removed whenever the IUD–ED was >3.0 mm, this resulted in a significant reduction in spontaneous expulsion (Petta et al., 1996). Since there is no evidence concerning the optimal IUD–ED for levonorgestrel-releasing intrauterine systems, we also decided to use 5.0 mm, although there are reasons to believe that this particular IUD might be as effective, both in the prevention of pregnancy as well as for the treatment of menorrhagia, if it is located more cervically (Andersson and Rybo, 1990; Andersson et al., 1994). Whether 5.0 mm is the most effective IUD–ED to ensure adequate contraception remains to be elucidated. However, investigation of the most effective IUD–ED is difficult because of the large number of women needed.

In conclusion, the results of our prospective study show that TVU is not necessary on a routine basis to monitor the position of the IUD, neither immediately after insertion nor at the recommended follow-up after 6 weeks. Clinicians with little experience are equally capable of inserting and monitoring IUD when compared with more experienced clinicians. Therefore there is no need to refer women from primary to secondary care for insertion of an IUD. This is, especially from the cost-effectiveness point of view, highly favourable. Only in the case of clinical suspicion of inadequate location of the IUD, as a result of the gynaecological interview and examination, may the use of TVU be beneficial and cost-effective since this decreases the number of unnecessarily removed IUD.

References


Submitted on May 6, 2003; accepted on July 9, 2003.

No need for TVU to monitor IUD position after insertion.