Is 2-dimensional transvaginal ultrasonography necessary 6 weeks after insertion of the levonorgestrel 52-mg intrauterine device?

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BACKGROUND: In Dutch practice, gynecologists are used to assessing the position of the LNG-IUD by performing a two-dimensional transvaginal ultrasonography (TVUS) directly after insertion and do not routinely invite patients for another consultation 4-12 weeks after insertion. There is no consensus whether a TVUS six weeks after insertion is routinely needed.

OBJECTIVE: This study aimed to assess the incidence of malposition using 2-dimensional transvaginal ultrasonography during routine investigation 6 weeks after insertion. In addition, we investigated the relationship between malposition of the levonorgestrel 52-mg intrauterine device and unfavorable bleeding patterns and pelvic pain.

STUDY DESIGN: We performed a large prospective cohort study. Patients seeking a levonorgestrel 52-mg intrauterine device were eligible for inclusion. Transvaginal ultrasonography was performed to check position of the levonorgestrel 52-mg intrauterine device immediately after insertion and 6 weeks later. Patients filled in questionnaires about bleeding pattern and pelvic pain 6 weeks after insertion.

RESULTS: From March 2015 to December 2016, we enrolled 500 patients. Data from the transvaginal ultrasonography assessment 6 weeks after insertion were available for 448 patients, and complete data (transvaginal ultrasonography and questionnaire data) were available for 363 patients (72.6%). Malposition rate was 6.3% (28/448 patients). Malposition was seen in 15 of 198 patients (7.6%) with unfavorable bleeding and/or pelvic pain and in 3 of 165 patients (1.8%) with favorable bleeding patterns and no pelvic pain (P=.03). Malposition was seen in 14 of 186 patients (7.5%) with an unfavorable bleeding pattern and in 4 of 177 patients (2.3%) with favorable bleeding patterns (P=.008). Malposition was seen in 5 of 50 patients (10%) with pelvic pain and in 13 of 313 patients (4.2%) without pelvic pain (P=.08).

CONCLUSION: The malposition rate of the levonorgestrel 52-mg intrauterine device observed using transvaginal ultrasonography 6 weeks after insertion was 6.3%. If patients have no complaints of unfavorable bleeding and/or pelvic pain, the risk for malposition is low (1.8%) and a routine transvaginal ultrasonography is not necessary. However, if patients experience unfavorable bleeding, a transvaginal ultrasonography should be considered to exclude malposition, because the effect of malposition on contraceptive effectiveness is unsure. Future research should focus on cost-benefit analysis.

Key words: 2-dimensional vaginal ultrasonography, bleeding, LNG-intrauterine device, malposition, pain

Introduction

The levonorgestrel intrauterine system, referred to as the levonorgestrel 52-mg intrauterine device (LNG-IUD), is a T-shaped contraceptive device. Levonorgestrel induces cervical mucosal thickening, suppresses endometrium growth, and, in some women, inhibits ovulation.1 These mechanisms are responsible for the contraceptive effect and reduction of menstrual blood loss.

Levonorgestrel induces cervical mucosal thickening, suppresses endometrium growth, and, in some women, inhibits ovulation.1 These mechanisms are responsible for the contraceptive effect and reduction of menstrual blood loss. To confirm intrauterine position of the LNG-IUD, clinical examination by speculum to evaluate the length of the threads 6 weeks after insertion seems to...
**Why was this study conducted?**

Correct position of the levonorgestrel 52-mg intrauterine device can be confirmed by 2-dimensional transvaginal ultrasonography (TVUS). However, the meaning and timing of routine TVUS to confirm the correct position is a subject of discussion. Given the low occurrence of malposition in asymptomatic patients, routine TVUS after insertion is not necessary. However, if patients experience either unfavorable bleeding or pelvic pain, TVUS should be considered to exclude malposition, because the effect of malposition on contraceptive effectiveness is unsure.

**Key findings**

If patients experience unfavorable bleeding, a TVUS should be considered to exclude malposition.

**What does this add to what is known?**

Future research should focus on cost-benefit analysis for standard TVUS to check for malposition of LNG-IUD.

be a suitable test for evaluation because complete expulsion or perforation can be ruled out by checking for the presence of the threads. However, other kinds of malposition, like embedding of the stem in the myometrium, could be missed because this position does not affect the length of the threads that protrude from the ostium. This kind of malposition can be diagnosed by transvaginal ultrasonography.

Beside a complete expulsion and perforation, the clinical impact of these malpositions is a subject of debate. Consequently, we wonder if it is necessary to routinely check for these kinds of malposition.

The Dutch guideline “Contraception” for general practitioners advises gynecologic examination 6 weeks after insertion by speculum to rule out a cervi- gynecologic examination 6 weeks after insertion if insertion took place outside lower uterine segment or cervix), TVUS should be considered to exclude malposition, because the effect of malposition on contraceptive effectiveness is unsure.

The correct position of the levonorgestrel 52-mg IUD, as defined in the user’s guide, was described to be malpositioned. Malposition was classified as displacement (rotation or inferior positioning in the lower uterine segment or cervix), embedment (penetration of the LNG-IUD into the myometrium without written information about this study. Additional information was provided during the consultation with the gynecologist, resident, or physician assistant who was authorized to insert IUDs. Before insertion, medical history was taken (eg, previous gynecologic surgery), patient characteristics were collected (age, body mass index (BMI), parity, reason for insertion, number of consecutive LNG-IUD, previous form of contraception used, cycle day during insertion, position of uterus, endometrial thickness), and results of TVUS performed before insertion were recorded. After signing informed consent, the IUD was inserted. Patients were included between March 2015 and December 2016. Immediately after insertion of the LNG-IUD, the resident, gynecologist, or physician assistant who performed the insertion performed TVUS to check the LNG-IUD for correct position. If the LNG-IUD was incorrectly positioned, they were still excluded from the study. All residents, gynecologists, and the physician assistant were well trained and performed TVUS on a daily basis. Local protocol to assess the position of the LNG-IUD consisted of describing the location of the stem of the LNG-IUD. After 6 weeks, the patients were invited for a second visit, and TVUS was performed by an experienced sonographer (E.M. or A.v.H. acknowledged below) on a Philips iU22 with transducer C5-1. Patients were asked to complete questionnaires 6 weeks after insertion. Questionnaires were sent by email or (if requested) by post 6 weeks after insertion. If questionnaires were not returned by post or email, we tried to contact the patients telephonically and performed telephonic interviews.

The LNG-IUD was marked as correctly positioned if the device was located in the cavity of the uterus. The vertical stem should extend straight down in the uterine cavity on sagittal plane. If localization deviated from this description, it was described to be malpositioned. Malposition was classified as displacement (rotation or inferior positioning in the lower uterine segment or cervix), embedment (penetration of the LNG-IUD into the myometrium without...
extension through the serosa), expulsion (passage either partially or completely through the external cervical ostium), or perforation (penetration through both the myometrium and the serosa, partially or completely). These definitions were used to describe IUD position directly after insertion, and also 6 weeks thereafter. In the questionnaires, patients were asked about their bleeding pattern (presence of bleeding or spotting with the following options: no bleeding, regular menstruation, sometimes a day of spotting [maximum of once a week], HMB, several bleeding days a week, several spotting days a week, continuously spotting, completely irregular cycle). Patients were asked to rate pelvic pain on a 5-point Likert scale. They were also asked to score bleeding and pain for the period of 4 to 6 weeks before the ultrasound (6 weeks after insertion).

For data analysis, patients were divided into the following 2 groups based on the results of TVUS 6 weeks after insertion: a group with the LNG-IUD in correct position and a group with a malpositioned LNG-IUD. Symptoms of bleeding and pelvic pain were compared between groups. Variables were computed into different dichotomous variables. Menstruation patterns classified as no bleeding, regular menstruation, or sometimes a day of spotting (maximum of once a week) were grouped into the category of favorable bleeding pattern. Menstrual patterns classified as HMB, several days a week bleeding days, several spotting days a week, continuously spotting, or completely irregular cycle were grouped into the category of unfavorable bleeding pattern. Pelvic pain was computed as a dichotomous variable; the options always pain and often pain were grouped together in the category of pelvic pain. Patients were excluded from the analyses if no ultrasound was performed 6 weeks after insertion. The sonographers were blinded to the results of the questionnaires. The investigators who entered the data of the questionnaires into SPSS (IBM Corp., Armonk, NY) were blinded to the results of the ultrasound.

Data analysis was performed using SPSS. Significance was set at $P = .05$. Categorical variables were expressed in counts and percentages. If data were continuous and normally distributed, the mean and standard deviation were used to express data. In cases with non-normally distributed data, the median and interquartile range (IQR) were used. Fisher exact tests and chi-square tests were used to analyze categorical data. The Mann-Whitney U test was used for analyzing continuous variables. Patients with missing ultrasonography data were excluded from the study. Data missing from the questionnaires were registered as missing data, and these data were not imputed.

### Results

In total, 500 patients agreed to participate in our study from March 2015 to December 2016. Fourteen patients were excluded; 1 was a duplicate, 8 patients were younger than 18 years, 3 patients had myomas, and 2 refused to participate. For 448 patients, TVUS was performed 6 weeks after insertion. The number of completed questionnaires 6 weeks after insertion was 374 (83.5%). Of these patients, 363 patients underwent TVUS to check for malposition.

The incidence of malposition 6 weeks after insertion was observed in 28 of 448 patients (6.3%); of those, the LNG-IUD was expelled (positioned in the cervix) in 19 of 28 (67.9%), it was displaced in the lower uterine segment in 6

### Table 1

**Patient Characteristics (n = 448)**

| Variables                        | Normal position (n = 420) | Malposition at six weeks (n = 28) | P-value |
|----------------------------------|--------------------------|----------------------------------|---------|
| Age, years; median (IQR)         | 36 (16)                  | 36.5 (18)                        | 0.89*   |
| BMI, kg/m²; median (IQR)         | 24 (6)                   | 24 (7)                           | 0.19*   |
| Day in menstrual cycle during insertion; median (IQR) | 5 (8) | 6 (6) | 0.60* |
| Reason for LNG-IUS use; (%)      |                          |                                  | 0.75#   |
| Contraception                    | 314 (74.8)               | 20 (71.4)                        |         |
| Heavy menstrual bleeding         | 56 (13.3)                | 6 (21.4)                         |         |
| Both                             | 33 (7.9)                 | 2 (7.1)                          |         |
| Endometriosis and/or dysmenorrhea| 10 (2.4)                 | 0                                |         |
| Frequent urinary tract infections| 1 (0.2)                  | 0                                |         |
| Missing                          | 5 (1.2)                  | 0                                |         |
| Parity                           |                          |                                  | 0.88*   |
| Nulliparity                      | 151 (36.0)               | 9 (32.1)                         |         |
| Multiparity                      | 261 (62.1)               | 19 (67.9)                        |         |
| Missing                          | 8 (1.9)                  | 0                                |         |
| Number of LNG-IUS                |                          |                                  | 0.611#  |
| 1                                | 206 (49.0)               | 17 (60.7)                        |         |
| 2                                | 143 (34.0)               | 4 (14.3)                         |         |
| 3 or more                        | 65 (15.5)                | 7 (25.0)                         |         |
| Missing                          | 6 (1.4)                  | 0                                |         |

* using the Mann-Whitney U test; # using the Pearson’s chi-squared test

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of 28 (21.4%), it was in transverse position (displacement) in 2 of 28 (7.1%), and the IUD in 1 patient was embedded with the shaft in the myometrium. A total of 7 of the 28 patients chose to insert a new LNG-IUD. For those patients, we have no further data. Table 1 shows the baseline patient characteristics per group, namely patients with the LNG-IUD in the correct position and patients with the LNG-IUD in malposition. The 2 groups were similar with regards to parity, age, reasons for insertion, and BMI. In the malposition group, 22 of 28 (78.6%) patients used the LNG-IUD for contraceptive reasons and the others had it inserted for HMB. Of the 19 patients with expulsion, 6 patients (31.6%) used the LNG-IUD for HMB and 13 patients (68.4%) used it for contraception. Patient baseline characteristics were similar among patients who completed the questionnaires and those who were lost to follow-up. In the malposition group, questionnaires were completed by 18 of 28 patients (64.3%) compared with 345 of 420 patients (82.1%) in the correct position group.

In total, 363 patients who underwent TVUS to check for malposition returned the questionnaires after 6 weeks. In 11 of 18 patients with a malpositioned LNG-IUD, the LNG-IUD was expelled (9 of these patients used the LNG-IUD for contraception); in 2 of 18, it was in transverse position; in 1 of 18, it was embedded with the shaft in the myometrium; and 4 were displaced in the lower uterine segment.

Six weeks after insertion, 186 of 363 patients (51%) had unfavorable bleeding patterns, and 177 of 363 patients (49%) reported favorable bleeding patterns. Table 2 shows a significantly higher proportion of patients with unfavorable bleeding in the malposition group than in the correct position group (77.8% vs 49.9%; P=.008). In the group with unfavorable bleeding with the LNG-IUD in malposition, 8 patients described continuously spotting, 2 patients described HMB, 2 patients described bleeding for several days a week, and 2 patients described a completely irregular cycle. The remaining 4 patients had favorable bleeding.

Six weeks after insertion, 50 of 363 patients (13.8%) reported pelvic pain and 313 of 363 patients (86.2%) reported no pelvic pain. There was no significant difference in pelvic pain between the correct position group and the malposition group (P=.08).

Malposition was seen in 15 of 198 patients (7.6%) with unfavorable bleeding and/or pelvic pain and in 3 of 165 patients (1.8%) without symptoms (P=.03). In Table 3, the relation between the symptoms and position of the LNG-IUD is shown. The most common malposition was LNG-IUD located in the cervix. In this group, 9 of 19 (47.7%) patients experienced unfavorable bleeding.

### TABLE 2

|                  | Malposition | Normal position | Total 363 | p-value |
|------------------|-------------|-----------------|-----------|---------|
| Unfavorable bleeding | 14/18 (77.8%) | 172/345 (49.9%) | 186 | 0.008 |
| Favorable bleeding  | 4/18 (22.2%)  | 173/345 (50.1%) | 177 |       |
| Pelvic pain          | 5/18 (27.7%)  | 45/50 (13.0%)   | 50  | 0.08  |
| No pelvic pain      | 13/313 (4.2%) | 300 (95.5%)     | 313 |       |
| Favorable bleeding without pelvic pain | 3 (16.7%) | 162 (47.0%) | 165 | 0.03 |
| Unfavorable bleeding OR pain | 11 (61.1%) | 149 (43.2%) | 160 |       |
| Unfavorable bleeding AND pain | 4 (22.2%) | 34 (9.9%) | 38  |       |

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different definitions are used to describe malposition. This makes it difficult to compare rates described among the studies performed.

We did not collect data on the results of pelvic examination 6 weeks after insertion of the IUD. Therefore, we cannot compare the results of pelvic examinations with those of ultrasound findings.

**Interpretation**

Our malposition rate might be higher than what is reported in the literature, because we classified several different positions (ie, expulsion, transverse, and displacement) as malposition. In the literature, malposition rates range from 5.6% to 10%. One of the reasons that we might have a higher rate than some of these studies is that we included displacement in the lower uterine segment as malposition as well. We included both patients using the LNG-IUD for contraception and those who used it for HMB. Expulsion rates were not higher when patients used the LNG-IUD for HMB. This observation is in line with the study of Furlani et al. In addition, 1.8% of malpositions were asymptomatic. These malpositions might be missed in studies in which only patients with complaints were checked for malposition. In our study, most IUDs were inserted by well-trained doctors and physician assistants. However, as supported by the study of de Kroon et al, the experience of the inserting clinician did not influence adequacy of insertion.

In the study by de Kroon et al., they evaluated the malposition rate and relationship between complaints and malposition in 195 patients with an LNG-IUD (114) and a copper IUD (81). The incidence of malposition was 4%. De Kroon et al calculated that the odds ratio of complaints being a predictor of malposition was 11.09 (95% confidence interval, 1.51–81.39). However, they did not define the term complaints. They concluded that TVUS may be helpful in case of clinical suspicion (the clinician who inserted the IUD filled in a form about whether the IUD was thought to be positioned properly or improperly), because 60% of IUDs were positioned properly as seen using TVUS, although the clinician suspected malposition after insertion. Moreover, van Schoubroeck et al described a relationship between malposition and unfavorable bleeding. At 4 to 6 weeks, 43% to 50% of patients with a malpositioned LNG-IUD reported moderate or heavy bleeding compared with 29% to 30% of patients with an LNG-IUD in the correct position. However, this was not statistically significant (P=.21). These numbers are lower than in this study in which almost 78% of patients with malposition reported unfavorable bleeding compared with almost 50% of patients with the LNG-IUD in correct position (P=.008).

Because evidence is scarce, the reliability of the contraceptive effect of a malpositioned LNG-IUD remains uncertain.

**Future research**

Future research should focus on the clinical relevance of a malpositioned LNG-IUD. In case of bleeding and/or pain, the risk for malposition increases to 7.6%. A main issue is that there is no evidence available on the extent to which IUD malposition affects the reliability of contraception. This information is needed to perform a proper cost-effectiveness analysis.

For copper IUDs, 1 study (with 32 patients) showed that 70% of copper IUDs change from malposition directly after insertion to correct position within 3 months. Similar evidence for the LNG-IUD is lacking. Future studies should focus on the changes in position of the LNG-IUD. This might prevent unnecessary removals.

**Conclusion**

Our results show a significant risk (6.3%) for malposition of the LNG-IUD, as seen with TVUS, 6 weeks after insertion. If patients have no complaints of unfavorable bleeding and/or pelvic pain, the risk for malposition is low (1.8%), and routine TVUS after 6 weeks is not necessary. However, if patients experience unfavorable bleeding, the position of the LNG-IUD should be evaluated to exclude malposition, because the effect of malposition on contraceptive effectiveness is unsure. Future research should focus on cost-benefit analysis in symptomatic patients.

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