Predicting Painful or Difficult Intrauterine Device Insertion in Nulligravid Women

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OBJECTIVE: To assess the relationship of preinsertion vaginal ultrasound assessment and menstrual and gynecologic history as predictors of difficult or painful intrauterine device insertion in nulligravid women.

METHODS: Nulligravid women seeking contraception were invited to participate in this nonrandomized study and given the choice between the levonorgestrel-releasing intrauterine system or a copper-releasing intrauterine device. All 165 enrolled women were interviewed and a pelvic examination, including vaginal ultrasonography, was performed before insertion. Insertion difficulties and pain intensity were recorded and assessed against uterine measurements and background characteristics.

RESULTS: Most insertions were assessed as easy (n=144 [89.4%]) and only two (1.2%) failed. Most women had uterine measurements smaller than the studied devices.

RESULTS:

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FINANCIAL DISCLOSURE

Dr. Suhonen has received lecture fees from Bayer and MSD Finland, and she is a member of the Advisory Board for Contraception MSD Finland. Dr. Heikinheimo serves occasionally on advisory boards for Bayer Healthcare, Gedeon Richter, and MSD/Merck and has designed educational events with these companies. The other authors did not report any potential conflicts of interest.

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LEVEL OF EVIDENCE: II

The safety and efficacy of long-acting reversible contraception (LARC) on reducing unintended pregnancy is widely recognized and both contraceptive implants and intrauterine devices (IUDs) are recommended as first-line contraception for nulliparous and adolescent women. Several studies have shown both groups of women to be satisfied IUD users. However, fear of a painful or difficult insertion may discourage these women from choosing an IUD and also prevent physicians from recommending the devices to them.

Recent studies indicate that uterine size might be an important factor affecting successful IUD use. A review found that device size and shape affected the rate of expulsions and problems with pain or
An ultrasonography study revealed a significant difference in uterine fundal width between nulliparous and parous women. Therefore, the size of the uterus in relation to the size of the IUD used may play a role in the successful use of intrauterine contraception. Nevertheless, the potential effects of uterine size and uterine flexion angle on IUD insertion and user satisfaction have not been studied prospectively.

Our primary aim was to examine the value of preinsertion vaginal ultrasonography in evaluating the size of the uterine cavity as well as the flexion angle of the uterus in predicting difficult, unsuccessful, or painful IUD insertion in nulligravid women because this group of IUD users is increasing. However, because insertion is also likely to be affected by factors other than anatomical ones, the effects of various background characteristics and menstrual history were also assessed.

MATERIAL AND METHODS
This clinical study on 161 nulligravid women was conducted at the Centralized Family Planning Clinic of the City of Helsinki. The women were recruited between January 1, 2011, and July 31, 2012. Approvals for the study were granted by the Ethics Committees of the City of Helsinki Health Center and the Hospital District of Helsinki and Uusimaa. The study was registered at www.clinicaltrials.gov (NCT01685164).

Women seeking contraception and contacting the clinic were initially interviewed by a nurse and counseled concerning contraceptive alternatives. Nulligravid women requesting their first IUD were invited to participate in the study. All participants signed a written consent document. The women were given a choice between the levonorgestrel-releasing intrauterine system and a copper-releasing IUD according to their own preferences and medical recommendations. Both devices are T-shaped and measure 32×32 mm. The insertion tubes, however, differ in diameter. The traditional levonorgestrel-releasing intrauterine system insertion tube has an outer diameter of 4.75 mm, whereas the newer Evoinserter has a diameter of 4.40 mm. The outer diameter of the copper-releasing IUD insertion tube is 3.65 mm. Women with a structural uterine abnormality, submucous uterine fibroid, endometrial polyp, current gynecologic infection, or suspicion of malignancy were excluded. Additional exclusion criteria in the copper-releasing IUD group were anemia, bleeding disorder, Wilson’s disease, and allergy to copper or nickel. For women with a history of heavy menstrual bleeding, the levonorgestrel-releasing intrauterine system was primarily recommended.

Demographic characteristics as well as menstrual bleeding and pain-related details were recorded before insertion. The women reported their level of menstrual pain as none/minimal, disturbing, or severe. When analyzing the results, disturbing and severe menstrual pain were combined as dysmenorrhea. In addition, the effect of severe menstrual pain was analyzed separately as severe dysmenorrhea. Besides menstrual data, abdominal pain, dyschezia, and dyspareunia in relation to the menstrual cycle as well as a history of prior abdominal or gynecologic surgery, vaginal or cervical procedures, and possible gynecologic or other medical conditions were also recorded.

Altogether, 165 women were recruited. A majority chose the levonorgestrel-releasing intrauterine system (113 women [68.5%]) while 52 women (31.5%) chose the copper-releasing IUD. One woman was excluded from the study because of a bicornuate uterus. Three women underwent IUD insertion but were excluded from further analysis as a result of poor quality of the ultrasonographic pictures, preventing measurement analysis. The women were routinely asked to take pain medication (800 mg ibuprofen or 1,000 mg paracetamol) 1 hour before insertion, as is the standard at the clinic, and to empty their bladder immediately before examination. All IUDs were inserted by one experienced physician (S.S.). Insertion was performed primarily postmenstrually, except in cases of amenorrhea related to the contraceptive method used before IUD insertion.

Before insertion, the inserting physician evaluated uterine position by palpation and carried out a vaginal two-dimensional ultrasonography to measure the uterus. The lengths of the uterine cervix and cavity were measured separately in a sagittal plane and the total uterine length was calculated by summing these measurements. The width of the uterine cavity was measured at the widest possible point at the fundal level (cornu to cornu) in a transverse plane. Uterine cavity area was calculated from cavity length and fundal width. The flexion angle was determined from ultrasonographic pictures by measuring the angle between the cavity and the cervical length measurements (Fig. 1).
Because uterine position (anteversion compared with retroversion) proved insignificant in the initial analysis regarding insertion difficulties and pain, flexion angles between 0° and 180° were used in further analyses. Thus, a straight (unflexed) uterus had a flexion angle approaching 180°. The more flexed (anteverted or retroverted) the uterus, the smaller the angular degree. The length of the uterus from the fundal endometrial surface to the external cervical os measured by a metallic uterine sound was also recorded.

Insertion pain was evaluated immediately after insertion by both the woman and the physician using a five-step Likert-like scale (none, mild, moderate, severe, and intolerable).

Insertions were classified as easy, difficult, or failed. The ease compared with difficulty of the insertion was evaluated by the physician performing the insertions. The possible need of cervical dilatation with a metallic Hegar dilator was recorded as was the use of a silicone uterine sound if used to explore the cervical canal before insertion. Paracervical blockade using lidocaine (10 mg/mL) or sublingual administration of misoprostol (0.4 mg) were used only in cases where insertion pain or cervical stenosis initially prevented insertion. Because the new smaller levonorgestrel-releasing intrauterine system inserter was introduced during the study period, both this and the prior inserter were used according to availability. After insertion, all women were followed for 1 year at the clinic. The follow-up data will be analyzed and reported separately.

Data analysis was performed using SPSS Statistics 21.0. Fisher’s and χ² tests were used to analyze categorical variables and the Mann–Whitney U test was used for continuous variables. Binomial logistic regression was used when analyzing uterine size measurements and flexion angle in relation to the insertion process as well as when analyzing the effects of menstrual pain and the amount of bleeding. For finding measurements predicting a difficult or painful insertion, uterine size measurements and flexion angles were grouped by 50th percentiles, quartiles as well as by quintiles. The receiver operating characteristics curve was used to search for threshold measurements for insertion difficulties and painful insertions by classifying insertion as easy compared with not easy (including difficult and failed insertions) and none-to-moderate pain compared with severe-to-intolerable pain. The best point estimate for sensitivity and specificity for each variable was then read and different points suggested on the curve also tested to determine a possible threshold measurement. Analyses were initially carried out separately according to the type of IUD and type of levonorgestrel-releasing intrauterine system inserting tube used, but when no significance was detected, further analyses were carried out on the group as a whole and type of IUD was used as a confounding variable in multivariate regression analysis. Statistical significance was set at a level of less than 0.05.

RESULTS

The characteristics of the women as well as their self-reported menstrual history are shown in Table 1. The women who chose the levonorgestrel-releasing intrauterine system were slightly younger, reported more bleeding and menstrual pain, and experienced menstrual pain for 1 day longer than those who chose the

![Fig. 1. A. An anteroposterior view of a uterus depicting measurements taken by ultrasonography. A, Uterine cavity length; B, cervical length; A and B, total uterine length; C, fundal width. B. The uterine flexion was calculated as the angle between A and B measured in the sagittal plane. Examples of three differently angled uteri: D₁, 25th percentile flexion angle (89˚); D₂, mean flexion angle (120˚); D₃, 75th percentile flexion angle (146˚) in the case of a retroverted uterus. Kaislasuo. IUD Insertion in Nulligravid Women. Obstet Gynecol 2014.](image)
The pain also more frequently started before bleeding. A majority of women choosing the levonorgestrel-releasing intrauterine system reported the need of pain medication during menstruation as opposed to the copper-releasing IUD users. Most women with a history of dysmenorrhea (n = 78/161 [48.4%]) chose the levonorgestrel-releasing intrauterine system (n = 63/78 [80.7%], odds ratio [OR] 3.21, 95% confidence interval [CI] 1.58–6.55, \( P = .001 \)). Particularly severe dysmenorrhea (n = 30 [18.6%]) affected selection toward the levonorgestrel-releasing intrauterine system (OR 14.00, 95% CI 2.37–82.72, \( P = .004 \)); 28 out of 30 of these women (93.3%) chose the levonorgestrel-releasing intrauterine system. Self-reported heavy menstrual bleeding also affected choice toward the levonorgestrel-releasing intrauterine system (n = 44, 27.3%, OR 7.02, 95% CI 2.32–21.18, \( P = .001 \)).

The majority of women reported using some form of contraception before the IUD. Combined oral contraceptive pills and the condom were most popular, representing 31% each. Eighteen percent had used progestin-only pills, 7% the contraceptive vaginal ring, 3% progestin implants, and one woman (0.5%) the depot medroxyprogesterone acetate injection.

Uterine size measurements and flexion angles are shown in Figure 2. The uterine sound measurement was 75.0 ± 7.6 mm (mean ± standard deviation) and the total uterine length as measured by ultrasonography was 64.1 ± 8.4 mm. The difference between the sound and the ultrasound measurements was 11.7 ± 7.9 mm independent of uterine size. As measured by ultrasonography, the cavity length was 35.1 ± 6.2 mm, the cervical length 29.0 ± 4.5 mm, and the fundal width 23.1 ± 3.9 mm. Flexion angles ranged from 61° to 173°, the mean being 119.6° degrees (Fig. 1 [C2] and Fig. 2C). Uterine measurements were smaller than the studied devices in the majority of women. Cavity length was shorter than 32 mm in 53 women (32.9%) and fundal width smaller than 32 mm in 158 women (98.1%).

Most insertions (n = 144 [89.4%]) were classified as easy. The proportion was somewhat larger in the copper-releasing IUD group, 94.2% (49/52) compared with 86.7% (98/113) in the levonorgestrel-releasing intrauterine system group (\( P = .30 \)). In 15 women (9.3%), insertion was classified as difficult.
13 (11.7%) in the levonorgestrel-releasing intrauterine system group and two (3.9%) in the copper-releasing IUD group. Five difficult insertions required no additional cervical procedures, whereas metallic Hegar dilators were used in 10 cases (6.2%) combined with paracervical blockade in six cases (3.7%) where pain would have prevented insertion otherwise. Misoprostol was used in three cases (1.9%) with cervical

Fig. 2. A. Uterine measurements (mm) by ultrasonography and sound measurement (mean±standard deviation and minimum/maximum). B. Cumulative percentages of uterine measurements (mm). C. Distribution of flexion angles.

stenosis combined with Hegar dilators and in one case also with paracervical blockade. In addition, in 11 cases (6.8%) classified as easy, a silicone sound in addition to the standard metallic sound was needed before insertion to explore the cervical canal. Only two insertions failed, one because of pain (copper-releasing IUD) and one insertion (levonorgestrel-releasing intrauterine system) was cancelled because of small uterine measurements (total uterine length by ultrasonography 42 mm and sound measurement 45 mm).

All women reported pain at insertion. The distribution of pain intensity at insertion grouped by type of device is shown in Figure 3. Pain was commonly assessed one step milder by the physician than the woman \(P<.001\). Eighteen women (11.2%) reported mild pain, 49 women moderate pain (30.4%), 91 women (56.5%) severe insertion pain, and three women (1.9%) intolerable pain. There was no difference in pain perception between the two levonorgestrel-releasing intrauterine system insertion tubes, but women who had the copper-releasing IUD inserted experienced less severe and none intolerable pain \(n=23\) [45.1%] compared with \(n=71\) [64.5%], OR 0.45, 95% CI 0.23–0.89, \(P=.02\); Fig. 3). However, this difference became insignificant when adjusted for level of self-reported menstrual pain \(OR 0.6, 95% CI 0.29–1.22, P=.16\).

No correlation between prior cervical procedures (loop electrosurgical excision procedure or laser conization, \(n=6\) [2.5%]) and a difficult insertion was found. No significant differences in the success or ease of insertion regarding the two levonorgestrel-releasing intrauterine system insertion tubes and the copper-releasing IUD inserter were found. Although only 98 women (60.9%) were menstruating at the time of insertion, the absence of bleeding during insertion did not correlate with ease of insertion or pain experience. No association between uterine position or participant-reported abdominal pain, dyschezia or dyspareunia, and insertion difficulty or pain was found.

Uterine size measurements and flexion angles were analyzed with logistic regression. Univariate analysis suggested a correlation between a difficult insertion and small uterine length measurements and flexion angle (Table 2). Other factors tested, but remaining insignificant, were type of IUD, bleeding at insertion, uterine position, age, and body mass index (BMI, calculated as weight (kg)/[height (m)]²). Multivariate analysis was carried out for uterine measurements and it revealed a significant correlation between insertion difficulties and smaller total uterine length, smaller cervical length, and flexion angle (Table 2). For the purpose of defining measurements associated with difficulties, these were grouped by median, quartiles, and quintiles. A total uterine length smaller than the median (64.4 mm) was associated with difficult insertion \(OR 3.63, 95% CI 1.13–11.67, P=.03\) and this persisted when adjusted by type of IUD, age, BMI greater than 30, uterine position, bleeding status at insertion, and other uterine measurements \(OR 5.59, 95% CI 1.01–28.89, P=.04\). Similarly, flexion angle smaller than the median \(122°\) was associated with difficulties in both univariate \(OR 5.36, 95% CI 1.48–19.47, P=.01\) and multivariate analysis \(OR 5.82, 95% CI 1.54–21.98, P=.009\). Quartile and quintile analysis revealed no significant associations. For the purpose of finding threshold measurements

![Fig. 3. Distribution of insertion pain as assessed by the participant and the physician.](image-url)
predicting difficulties, the uterine measurements then were depicted on the receiver operating characteristic curve. True-positives varied from 0.60 to 0.88 but increasing true-positives, the false-positives were high with values ranging from 0.20 to 0.74. The best prediction was for total uterine length (true-positive 0.65, false-positive 0.24, threshold 61.9 mm) and flexion angle (true-positive 0.60, false-positive 0.18, threshold 117.5°), but for all uterine measurements, the proportion of difficult insertions in women with measurements smaller than the best threshold was only 19–23%. Thus, no absolute threshold measurements predicting difficult insertion could be found.

Similarly, as for predicting insertion difficulties, uterine measurements were analyzed as continuous variables by logistic regression and then grouped by median, quartiles, and quintiles as well as depicted on receiver operating characteristic curves to find measurements predicting severe or intolerable pain. In univariate analysis, the odds for severe or intolerable pain decreased with increasing fundal width and cavity area, but significance was lost in multivariate measurement analysis (Table 3). When grouping by size, smaller median total uterine length and cavity area were associated with more pain in univariate analysis, but in multivariate analysis, the significance was lost (data not shown). Quartile and quintile analyses showed no significance and receiver operating characteristic curves revealed no predictive threshold measurements (data not shown).

Severe dysmenorrhea was the only predictor of severe or intolerable insertion pain and the odds ratio increased in multivariate analysis (Table 3). Other factors tested include type of IUD, bleeding at insertion, uterine position, age, BMI, smoking, dyschezia, dyspareunia, other abdominal pain, and cervical procedures, all insignificant.

DISCUSSION

Nine of 10 insertions in nulligravid women were assessed as easy. Smaller uterine length measurements and a steeper flexion angle predicted difficulties, but no absolute measurements predicting a difficult insertion could be determined. Severe dysmenorrhea was the only predictor of severe or intolerable insertion pain.

Uterine measurements were small compared with the size of the most commonly used T-shaped IUDs (32×32 mm). One third had a cavity length smaller and nearly all women a fundal width narrower than 32 mm. Although uterine measurements in this study are somewhat smaller than in earlier studies, the findings are similar to those published earlier.\textsuperscript{10,11} Recently, a smaller levonorgestrel-releasing intrauterine system (LNG-IUS12) has been introduced.\textsuperscript{13} When comparing uterine measurements against its measurements (28×30 mm), one fifth had a cavity measurement shorter and still 9 of 10 a narrower fundal width. In a study comparing LNG-IUS12 and the traditional levonorgestrel-releasing intrauterine system, approximately 5.0% compared with 6.7% experienced severe insertion pain and 22.2% compared with 35.4% moderate pain, respectively. The difference of 4 mm in the horizontal arm width and 2 mm in length gave surprisingly little effect on the insertion pain. However, the proportion of easy insertions was higher with the smaller LNG-IUS12, 94.6% compared with 86.2%.\textsuperscript{14} Numbers are similar to those observed in this study where easy copper-releasing IUD insertions were somewhat more common, 94.2% compared with

\begin{table}[h]
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\caption{Odds of a Difficult (n=15 [9.2%]) or Failed (n=2 [1.2%]) Insertion as Compared With Easy Insertion (n=144 [88.4%]) Among All 161 Studied Women With Every Increasing mm/cm² in Size or Increasing Degree of Flexion Angle}
\begin{tabular}{llllll}
\hline
Parameter & Range & \multicolumn{2}{c}{Univariate Analysis} & \multicolumn{2}{c}{Multivariate Analysis} \\
& & OR (95\% CI) & \(P\) & OR (95\% CI) & \(P\) \\
\hline
Total uterine length (mm) & 42.3–88.0 & 0.91 (0.85–0.97) & .003 & 0.86 (0.78–0.96) & .006 \\
Cavity length (mm) & 21.4–50.9 & 0.90 (0.82–0.98) & .02 & — & — \\
Cervical length (mm) & 13.7–48.5 & 0.86 (0.76–0.97) & .01 & — & — \\
Fundal width (mm) & 13.8–35.0 & 0.98 (0.86–1.12) & .77 & 1.02 (0.80–1.31) & .85 \\
Uterine cavity area (cm²) & 16.37–72.36 & 0.96 (0.92–1.01) & .12 & 1.02 (0.91–1.14) & .71 \\
Flexion angle (degrees) & 61–173 & 0.97 (0.94–0.99) & .01 & 0.96 (0.93–0.99) & .004 \\
\hline
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OR, odds ratio; CI, confidence interval.
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\textsuperscript{*} [(cavity length×fundal width)/2]/104 model 1 represents multivariate analysis with total uterine length, fundal width, cavity area, and flexion angle. In model 2, total uterine length was replaced by cavity and cervical length for analysis. Background characteristics and menstrual data were left out as they were insignificant in univariate analyses.
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\end{table}
86.7%. Because the outer diameter of the copper-releasing IUD inserter (3.65 mm) and the LNG-IUS12 inserter (3.8 mm) is smaller than that of the traditional levonorgestrel-releasing intrauterine system (4.75 and 4.4 mm) and because the majority of our difficult insertions required cervical dilatation, the difficulties are likely to be largely accounted for by a tight cervix and not by uterine size. However, the effect of a steep flexion angle is not to be forgotten and gentle straightening of the uterus with a tenaculum should also be emphasized, as also recommended in practical guidelines.

All women reported pain at insertion and pain was more intense than that assessed by the physician, a finding also earlier described. The proportion of women reporting severe insertion pain was larger in this study than in prior studies. This may be affected by the timing of pain assessment. In previous studies, the pain assessed immediately after insertion has been shown to be significantly greater than that assessed at 3 minutes after insertion. Moreover, the significance of patient anticipation and fear before insertion is increasingly emphasized along with the importance of patient counseling and an appropriate clinical setting. Nonetheless, most women would undergo a repeat insertion, regardless of level of pain.

This was a nonrandomized study. However, it concerns a large group of prospectively studied nulligravid women. Strengths also include clinical evaluation and insertion by a single experienced physician, eliminating the effects of physician inexperience and interindividual variation as factors affecting preinsertion evaluation and insertion. This is supported by the low rate of difficult insertions as compared with rates twice as high with physicians inexperienced in the procedure. In studies in which a difficult insertion was clearly defined, the definition has been the same as that in our study and rates of use of Hegar dilators, paracervical blockade, and misoprostol have been similar to ours. Ultrasound evaluation and insertion by a single physician might inversely be considered a limitation, although insertion was done irrespective of ultrasound findings. Measurements were taken but used only for analysis of clinical outcome, not for the decision of insertion. Timing of pain assessment only immediately after insertion is a limitation because this eliminates the possibility to adjust for expected pain and anticipation. Two equally sized IUD groups could also have strengthened analysis, but because the majority of Finnish women opt for a levonorgestrel-releasing intrauterine system, we were not able to collect more copper-releasing IUD users without prolonging our study markedly.

Dysmenorrhea, the only predictor of insertion pain in our study, is associated with uterine hypercontractility and changes in uterine blood flow. Reversing the vasoconstriction caused by prostaglandins in women with dysmenorrhea decreases menstrual pain. In addition, women with dysmenorrhea have an altered

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis + Model 1</th>
<th>Multivariate Analysis + Model 2</th>
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<tbody>
<tr>
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<td>OR (95% CI)</td>
<td>P</td>
<td>OR (95% CI)</td>
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<tr>
<td>Total uterine length (mm)</td>
<td>42.3–88.0</td>
<td>0.96 (0.93–1.00)</td>
<td>.05</td>
<td>0.98 (0.92–1.05)</td>
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<td>Cavity length (mm)</td>
<td>21.4–50.9</td>
<td>0.95 (0.90–1.00)</td>
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<td>0.97 (0.90–1.04)</td>
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<tr>
<td>Cervical length (mm)</td>
<td>13.7–48.5</td>
<td>0.97 (0.90–1.04)</td>
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<tr>
<td>Fundal width (mm)</td>
<td>13.8–35.0</td>
<td>0.90 (0.82–0.97)</td>
<td>.01</td>
<td>0.90 (0.76–1.07)</td>
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<tr>
<td>Uterine cavity area (cm^2)*</td>
<td>16.37–72.36</td>
<td>0.96 (0.93–0.99)</td>
<td>.005</td>
<td>0.98 (0.91–1.05)</td>
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<tr>
<td>Flexion angle (degrees)</td>
<td>61–173</td>
<td>0.99 (0.98–1.01)</td>
<td>.43</td>
<td>0.99 (0.97–1.01)</td>
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<tr>
<td>Self-reported level of menstrual pain, n (%)</td>
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<td>0.009</td>
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<td>0.002</td>
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OR, odds ratio; CI, confidence interval.

*The correlation between insertion pain and menstrual pain is also shown.

Univariate Analysis

Table 3. Odds of Severe (n=91 [56.5%]) or Intolerable (n=3 [1.9%]) Insertion Pain as Compared With Mild-to-Moderate Pain (n=67 [41.6%]) Among All 161 Studied Women With Every Increasing mm/cm² in Size or Increasing Degree of Flexion Angle

Univariate Analysis

Multivariate Analysis + Model 1

Multivariate Analysis + Model 2
central nervous system response to pain as well as immunologic factors and steroid hormone levels differing from those without dysmenorrhea. These physiologic factors support our findings on insertion pain related to dysmenorrhea, because insertion irritates the uterus, thus causing a physiologic response. Consequently, identifying means of sufficient analgesia for these women is important. Equally important is counseling women coming to IUD insertion and proper insertion technique, including clinical evaluation by palpation and sound measure. However, ultrasound evaluation before insertion does not give additional information and must not limit access to IUD use.

REFERENCES


