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Levonorgestrel Intrauterine Device Use for Medical Indications in Nulliparous Adolescents and Young Adults

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ABSTRACT

Purpose: Intrauterine devices (IUDs) are highly effective at preventing pregnancy. Levonorgestrel (LNG) IUDs also have beneficial effects on menstrual bleeding and abdominal and pelvic pain. Although there are increasing data on use of IUDs for contraception in adolescents and for medical indications in adults, there are extremely limited data on LNG IUD use for medical indications in adolescents. Our objective is to describe the characteristics and experiences of LNG IUD use in nulliparous adolescents and young women using IUDs for medical indications.

Methods: We conducted a retrospective chart review of all nulliparous patients ages 22 and younger who underwent LNG IUD insertion at a tertiary care children's hospital between July 1, 2004 and June 30, 2014 primarily for non-contraceptive indications. Descriptive statistical analysis was performed.

Results: We identified 231 LNG IUDs placed in 219 nulliparous women for medical indications during this time period. Mean patient age was 16.8 years (±2.2). Only 41% reported ever being sexually active. IUD continuation rate at 1 year was 86%. The amenorrhea rate at 1 year was 51%. Approximately 80% of women reported improvements in menstrual bleeding and abdominal and pelvic pain. Side effects and complications were low.

Conclusions: This study provides evidence that LNG IUDs are effective, well-tolerated, and safe menstrual management options in young nulliparous women, including younger adolescents and those who have never been sexually active. This method is an excellent first-line therapy option for adolescents and young women for both contraceptive and non-contraceptive indications, regardless of age, parity, or sexual activity.

Key Words: adolescent, nulliparous, never sexually active, intrauterine device, heavy menstrual bleeding, abnormal uterine bleeding, dysmenorrhea, endometriosis

IMPLICATIONS AND CONTRIBUTIONS: Levonorgestrel intrauterine devices reduce unintended pregnancies and improve menstrual bleeding, abdominal and pelvic pain, and quality of life for adult women with menstrual problems. This study shows that they are also effective, well-tolerated, and safe menstrual management options for adolescents.

Adolescents increasingly use intrauterine devices (IUDs) for contraception,[1, 2] especially since both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics now recommend long-acting reversible contraception, including implants and IUDs, as first-line contraceptive options for all adolescents.[3-5] However, IUD use in adolescents and nulliparous women remains low.[6, 7]

The levonorgestrel (LNG) IUD also has beneficial effects on menstrual bleeding. There is evidence that the 5-year 52mg LNG IUD improves bleeding in women with heavy menstrual bleeding, and it is FDA approved for this indication in adults.[8-10] Adolescents commonly

experience abnormal uterine bleeding and menstrual pain, with a dysmenorrhea prevalence as high as 93%. These complaints are the most common reasons adolescents seek gynecologic care and frequently impact school attendance and activity participation.[11] A small study on LNG IUD use in 13 adolescents with bleeding disorders showed significant improvement in subjective and objective measures of menstrual bleeding.[12] Adults have also successfully used IUDs off-label for dysmenorrhea, chronic pelvic pain, and endometriosis.[13, 14] There is also increasing concern for endometrial hyperplasia and malignancy as obesity rates rise in adolescents, as unopposed estrogen due to obesity and anovulation are known risk factors for these conditions.[15, 16] Although endometrial hyperplasia and cancer are far more prevalent in older women, these complications can occur in adolescents and women under 25.[17] While the mainstay of treatment is combined estrogen-progestin hormonal methods, including combined oral contraceptive pills, patches, and vaginal rings, some patients have contraindications to estrogen use, including hypertension, migraines with aura, and history of thrombotic events.[15, 18]

Although there are increasing data on LNG IUDs for contraception in adolescents and medical indications in adults, there are extremely limited data on LNG IUD use for medical indications in adolescents.[19] The objective of this study is to describe the characteristics, outcomes, and complications of levonorgestrel IUD use in nulliparous adolescents and young women for medical, non-contraceptive indications.

METHODS

We performed a retrospective chart review of females with successful LNG IUD placements at Cincinnati Children's Hospital Medical Center between July 1, 2004 and June 30, 2014. We

queried hospital electronic medical records coding and billing databases to identify all IUD insertions during this time period. We then reviewed the medical records of all identified patients to determine whether they met inclusion criteria. Inclusion criteria were nulliparity, age 22 or younger, and non-contraceptive primary indication for IUD use. These medical indications included, but were not limited to, heavy menstrual bleeding, abnormal uterine bleeding, dysmenorrhea, and chronic pelvic pain. We defined nulliparity as lack of prior pregnancies beyond 20 weeks gestation. As there is no consistent age for the definition of adolescents in the literature, we chose a maximum age of 22, as that is our institution's maximum patient age in the absence of complex medical conditions or congenital anomalies. In our institution, minors have the right to confidential reproductive care and can consent to contraception and contraceptive procedures without their parent or guardian's knowledge and consent, regardless of the indication for use. An exception to minors' right to consent for IUD insertion is that hospital protocol requires parent or guardian consent for procedures performed under anesthesia.

If there were multiple indications for IUD use, we identified the main reason for IUD insertion. For example, if a patient presented for heavy menstrual bleeding and was sexually active, the primary indication was medical and she met inclusion criteria for this study. If a patient presented for contraception and also reported heavy menstrual periods, the primary indication for IUD use was considered contraceptive and she was excluded. For patients with multiple IUD insertions during this time period, we included each insertion separately. We were unable to include unsuccessful IUD insertions given the reliance on coding and billing databases for subject identification. We also excluded patients if their primary use of the IUD was contraceptive or for menstrual management in those with physical, intellectual, or developmental disabilities, as this is a unique patient group that might not be comparable to the general

population. All IUD insertions were performed by pediatric and adolescent gynecology physicians, including trainees, and a single adolescent medicine physician.

We conducted a chart review for all identified patients. All information was obtained via the chart review and not from diagnosis or billing codes. A single reviewer performed all data abstraction to ensure consistency, with regular oversight by the primary investigator. Data collected included demographics (age, race, body mass index [BMI], insurance, parity); indications for IUD use; location of placement (office, operating room [OR]); past or current sexual activity; medical comorbidities; and prior hormonal contraceptive or menstrual management methods.

We also abstracted baseline menstrual bleeding and associated abdominal and pelvic pain; continuation rates at each year; and amenorrhea, menstrual bleeding information, and abdominal and pelvic pain and complaints at each year. We defined amenorrhea as the complete absence of menstrual bleeding for three months, as defined by the World Health Organization and used in most contraception trials.[20] We abstracted information on change in menstrual bleeding from the chart by comparison of reported bleeding frequency, duration, and flow at each year to that described prior to insertion. We determined bleeding to be increased if explicitly documented in the chart or if flow was heavier or there were more frequent or prolonged bleeding episodes. We defined bleeding as decreased if explicitly documented or if bleeding was less frequent, of shorter duration, or lighter in flow. We concluded that bleeding was unchanged if explicitly documented or the described bleeding was similar to prior to IUD insertion. We similarly determined change in reported abdominal or pelvic pain and cramping, whether associated with bleeding or not, from documentation compared to prior reports.

We also recorded all reported side effects beyond the six-week initial follow-up appointment, given the known initial adjustment period, as well as any complications, including pregnancy, pelvic inflammatory disease (PID), device expulsion, malposition, or uterine perforation. PID was a clinical definition and was considered a complication of IUD use only within 20 days of insertion due to the known associated risk of infection during that time period.[21] We defined expulsion as partial extrusion of the device through the cervix or complete expulsion from the uterus, malposition as a device within the uterus but with concern for extension into the myometrium or position in the lower uterine segment on imaging, and perforation as an IUD in the abdominal or pelvic cavity outside the uterus.

We performed descriptive statistical analysis with χ^2 tests on abstracted data using SAS, version 9.3 (SAS Institute, Cary, NC). This study was approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board.

RESULTS

A total of 874 LNG IUDs were placed in adolescents and young women (ages 9-33) at our institution during this time period. Of these, 231 met inclusion criteria for the study (Figure 1). All IUDs were 5-year 52mg LNG IUDs. Ten patients received two IUDs during the study period: four reached the full duration of IUD use and had removal and replacement, one underwent simultaneous removal and replacement due to new onset of breakthrough bleeding, one had removal due to persistent breakthrough bleeding and pelvic pain that worsened after IUD removal and thus desired replacement, and four had expulsions and desired replacement. A single patient had three IUDs, as her first two were expelled. There was an increasing number of IUDs placed each year of the study period (Figure 2).

Table 1 shows patient demographics and baseline characteristics. The mean patient age at IUD insertion was 16.8 years (range 12-22). Only 41% of patients reported ever being sexually active. Almost one-quarter had contraindications to estrogen use, including hypertension, migraines with aura, and personal history of a thrombotic event. Most patients had tried at least one prior menstrual management method, but 15% chose an IUD as their first method. Primary indications for use were heavy menstrual bleeding (n=100), abnormal uterine bleeding (n=42), dysmenorrhea (n=32), and endometriosis (n=38).

Sixty-two percent of patients underwent IUD placement under anesthesia in the Operating Room. Of these, 108 (76%) occurred at the time of other procedures, most commonly bariatric surgery (n=48, 44%) or a diagnostic laparoscopy for pelvic pain (n=35, 32%). Gynecology is part of the pre-operative evaluation for all menarchal women who undergo bariatric surgery in our institution due to the high prevalence of menstrual irregularities in this population,[15] as well as the recommendation to avoid pregnancy for 12-24 months after surgery. This is especially important in adolescents, as pregnancy rates after bariatric surgery are double that of the general adolescent population.[22] In addition, many women with severe obesity have contraindications to estrogen use, there are thrombotic risks of estrogen-containing medications in the perioperative period, and there is decreased absorption and efficacy of oral hormonal medications after bariatric surgery due to malabsorption. We discuss all menstrual management and contraceptive options and offer intra-operative IUD insertion. In the subgroup of 48 women having bariatric surgery, the primary indication for IUD use in all patients was heavy menstrual bleeding, abnormal uterine bleeding, or menstrual bleeding abnormalities due to polycystic ovarian syndrome (PCOS). Ten (21%) patients reported being sexually active, and an additional 22 (46%) reported that they planned to become sexually active in the near future. It was

significantly more likely for IUDs used for heavy menstrual bleeding to be placed in the office ($p<0.001$), while the OR was the preferred placement location for indications of abnormal uterine bleeding and need for endometrial protection related to PCOS ($p=.003$). This was likely due to the high incidence of anovulatory bleeding and PCOS syndrome in the bariatric surgery population.

There was no standardized approach to pre-medication, which was at the discretion of the individual provider. Of the 89 patients with office IUD insertions, 66% (n=59) received pre-procedure non-steroidal anti-inflammatory medication and/or off-label use of oral misoprostol. Dilation of the cervix with an os finder or Pratt dilators was performed only for cervical stenosis that limited completion of the procedure. This occurred for only 16 (7%) of all insertions, 12 of which were in the OR. The mean uterine length as measured by uterine sound was 7.5cm (range 6-10cm). There was only one patient who had an unsuccessful office IUD insertion and subsequently underwent a successful insertion in the OR at the time of another procedure. Thirty-one patients had a pre-placement ultrasound for various reasons. Of these, only 18 (58%) of the uterine length measurements were within 1cm of the uterine sound length. There was at least a 2cm discrepancy for five (16%) patients.

For the 171 patients who had follow-up data at one year, the one-year IUD continuation rate was 86% (Table 2). Continuation rates decreased each subsequent year, with 35% of those with full follow-up data (n=46) using their IUD for the full 5-year duration of use. Thirty-three patients had known IUDs removals prior to the full duration of IUD use.

Half of patients reported amenorrhea at one year. This rate remained steady over the course of IUD use, except for a 13% reported amenorrhea rate at two years. Given this unusual finding, we explored data related to amenorrhea in more detail. Of the 76 patients who reported menstrual

bleeding at two years, 36 (47%) had been amenorrheic at one year. Forty-eight percent of the patients with menstrual bleeding at two years and for whom there was follow-up data were amenorrheic at three years. Patients who reported menstrual bleeding at two years were less likely to be seen for problem visits related to their IUDs than those who were amenorrheic at that time (25 vs. 82%, $p<0.001$). Comparison of menstrual bleeding and continuation data showed that 57 of the 76 (75%) patients with reported bleeding at two years still had their IUDs in place at the end of the study period.

Analysis of overall menstrual bleeding profiles revealed that 81% of patients reported less bleeding one year after IUD placement. Only 3% endorsed increased bleeding. Among women with dysmenorrhea or pelvic pain prior to IUD insertion, 79% reported improvement at one year; 7% noted worsened pain. Forty-six patients had medical management of breakthrough bleeding or abdominal or pelvic pain beyond the initial 6-week follow up visit. There was no standardized protocol to define which patients required intervention and with which treatment options. The patient and clinician used a shared decision-making approach to determine management. The primary intervention was norethindrone acetate (n=37, 80%), but a few patients underwent treatment with estrogen therapy or combined oral contraceptive pills (n=2, 4%), tranexamic acid (n=2, 4%), or empiric antibiotics for suspected endometritis (n=5, 11%), although they all had negative testing for sexually transmitted infections.

Abdominal and pelvic pain and cramping were the most common reported side effects of IUD use, affecting 18% of patients at one year, with decreasing incidence over time (Table 3). Other side effects, including acne, mood changes, and weight gain, were uncommon. Complications were rare; the most common was device expulsion (5%). There were five partial and six complete expulsions. Pelvic inflammatory disease occurred in three patients (1%). There were

eight other cases of PID diagnosed more than 20 days after IUD insertion and were thus not considered complications of IUD use. All cases of PID except one occurred in patients who were sexually active. There were no uterine perforations or pregnancies in the cohort.

DISCUSSION

We found that the one-year continuation and amenorrhea rates for levonorgestrel IUD use in our cohort of nulliparous adolescents and young adults using IUDs for non-contraceptive indications were equal to or greater than those reported for contracepting adolescents and adults.[23-27] The continuation rate at one year is higher than that reported in the largest systematic review of IUD continuation in adolescents.[28] That study differed from ours significantly in that it included contracepting, mainly parous patients and excluded special populations, such as those with chronic disease. Our study included many patients with chronic medical conditions who may particularly benefit from this menstrual management, as their medical conditions and other medications may be contraindications to other methods.[18] In addition, our continuation rate is much higher than for other contraceptive methods, which range from 40-49% at one year.[29]

IUD use steadily increased at our institution over the study period. This likely reflects a combination of factors. First, there is increasing awareness and use of IUDs in the United States as a whole.[2] In addition, both gynecologic and pediatric societies changed their positions and official statements on the appropriateness of IUD use in nulliparous women, and especially adolescents, during this time period.[3-5] The passage and implementation of the Patient Protection and Affordable Care Act and its contraception coverage provision in March 2010 reduced the cost barrier for contraception. This may have contributed to increased IUD use, including for non-contraceptive indications. Lastly, there was likely increased anecdotal

information on the safety and efficacy of IUD use for non-contraceptive indications within our own institution that led to increased use and referrals from other providers for IUD provision.

This is the first formal description and analysis of IUD use at our institution. In addition to continuation rates, we also characterized changes in menstrual bleeding profiles and gynecologic pain due to IUD use. The amenorrhea rates at years one and three through five were approximately 50%. However, this rate was low at year two, which is an unusual finding. We explored our data with no clear explanation for this finding, which is a limitation of a retrospective chart review. As 20 patients reported amenorrhea at both one and three years but not at two years, a small amount of self-limited menstrual bleeding may have caused the low rate at two years. Reassuringly, patients who were not amenorrheic at two years were actually less likely to present for a problem visit than those who were amenorrheic. In addition, 75% of the patients with breakthrough bleeding at two years maintained their IUDs in place throughout the entire study period, indicating that the experienced bleeding was not enough to drive IUD removal. More significantly, approximately 80% of patients reported overall improvement in both menstrual bleeding and dysmenorrhea or pelvic pain one year after IUD insertion. Providers can use this information to counsel patients about expected changes and reassure them that the common initial irregular bleeding and cramping improves over time and may be self-limited, although more data are needed to further elucidate the time course of menstrual bleeding pattern changes.

We reported on IUD use in previously undescribed populations, with successful placement in patients as young as 12. In addition, 59% of our patients had never been sexually active. Misconceptions among adolescents[30-32] and providers[33-35] remain the biggest barriers to IUD use in adolescents and may be even more significant for those who would benefit from

menstrual management but do not require contraception, especially younger women and those who have never been sexually active. A review article on the use of levonorgestrel IUDs for medical indications in adolescents notes that LNG IUDs have been shown to be effective alternatives to combined oral contraceptives and depot medroxyprogesterone acetate, although these methods are much more commonly used. [19] A randomized study of oral contraceptives versus LNG IUDs in nulliparous women ages 18-25 who desired contraception showed greater subjective improvements in bleeding (49.3% vs. 22%, p=0.001) and pain (p=0.021) in the IUD group.[36] There are minimal data on changes in menstrual bleeding patterns and associated abdominal and pelvic pain in adolescents using progestin-only pills, hormonal injections, or hormonal implants, with no comparative studies among these methods.

Concerns about IUD use in adolescents include increased risk of PID and device expulsion.[29, 37] Our study showed that complications were rare, with a 1% risk of PID, <1% rate of malposition, and 5% risk of expulsion. Contrary to concerns of increased complications in adolescents and nulliparous women, with reported expulsion rates as high as 22%, complications in our study were similar to or lower than those reported in adults.[27, 38, 39]

The major limitation of this study is its retrospective nature, which involved missing data and reliance on adequate documentation. One reviewer abstracted all the data for consistency, which may result in ascertainment bias, although there were regular meetings with the study team to try to prevent this. There were no standardized scales for measures such as bleeding and pain, with reliance on subjective patient report and provider documentation. There was also loss to follow up of some patients, either overall or at different time points through the study period. While some patients may have presented to outside providers or hospitals for care or complications, this is unlikely as our institution is the only pediatric hospital in the area. Lastly, many patients who

had their IUDs placed in the later years of the study period had not yet reached the full duration of IUD use and were thus excluded from some longer-term analyses. Although the sample size was fairly large, it was too small to allow for robust multivariate analysis.

Our population is also somewhat unique. Our setting in a large, urban tertiary care center with complex patients and specialized providers may have introduced selection bias, although our practice also provides routine gynecologic care for children, adolescents, and young women. In addition, more than half of our IUD placements occurred in the Operating Room. In all but one case, this was not as a result of unsuccessful office placement. Some OR insertions were due to patient unwillingness or inability to tolerate office pelvic exams. The majority occurred at the time of another surgery, either for convenience or as routine practice in the case of bariatric surgery. Providers should consider the OR setting for patients who would benefit from IUDs but cannot tolerate office placement. However, this substantially increases the cost of IUD insertion. Although we had no issues with insurance coverage, cost analysis studies are needed for this subgroup. There are now two slightly smaller IUDs on the market that might increase successful office insertion, although their lower hormonal content may decrease their efficacy for medical indications and they also still require office pelvic exams.

In conclusion, this is the largest study of LNG IUD use for medical indications in nulliparous adolescents, many of whom are younger than typically reported in the literature and have never been sexually active.[19, 40, 41] Our data did not substantiate any the concerns usually cited as reasons to avoid use in adolescents, including increased risk of infection and expulsion. Further research is needed to prospectively assess outcomes, complications, and satisfaction in this population, but these data are very promising and show that the LNG IUD is a viable option for this population. This information can be used to increase patient and provider knowledge and

comfort with this highly effective, safe menstrual management method in nulliparous adolescents and young adults.

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Figure Title

Figure 1. Flow chart of study subjects

Figure 2. Trend in IUD insertions by year