

Original Research Article

Observational study of feasibility and acceptability of the levonorgestrel-releasing intrauterine device as a long-acting reversible contraceptive in a primary care setting in India

Sharad Iyengar^{a,*}, Kirti Iyengar^b, Ankit Anand^c, Virendra Suhalka^a, Manju Jain^a

^a Action Research and Training for Health Society, Udaipur, Rajasthan, India

^b Sexual & Reproductive Health Specialist, Udaipur, Rajasthan, India

^c Population Research Centre, Institute for Social and Economic Change, Bengaluru, India

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ABSTRACT

Objectives: The levonorgestrel-releasing intrauterine device (LNG-IUD) is a well-accepted contraceptive across developed countries, yet there is limited experience in use and acceptance amongst women living in low-resource, developing country settings. We studied the feasibility of providing the LNG-IUD through a primary care service, and its acceptability amongst women living in a low-income, rural-tribal community in India.

Study design: We conducted an observational study of feasibility and acceptability at four health facilities (three rural, and one urban) in Rajasthan, India. Women seeking contraception were offered the LNG-IUD in addition to existing contraceptive methods. We followed all those who adopted LNG-IUD from August 2015 to September 2019 ($n = 1266$) till discontinuation or 12 months, whichever was earlier. The primary outcome was continuation rate and acceptability, and the secondary outcome was change in hemoglobin levels, which we measured before insertion and at 12-month follow-up, using Sahli's method.

Results: Most users lived in villages, were illiterate, belonged to marginalized groups, had 2 or more children, and wished to limit births when they adopted the method. The 12-month continuation rate was 87.6%. Amongst all users, 7.4% of women sought removal for side effects and 2% for change in reproductive intention, while another 2% reported spontaneous expulsion. Most continuing users reported hypomenorrhea (54%) or amenorrhea (42%) by 12 months of use. User satisfaction was high at 91.6%, with 92% of women rating their experience as equaling or exceeding expectations. Moderate and severe anemia reduced, and mean hemoglobin levels increased by 0.7 g/dL ($p < 0.01$).

Conclusion: Primary care clinics can feasibly deliver LNG-IUD, with high acceptability amongst women living in low resource settings. Given the paucity of long-acting reversible contraceptive options and high prevalence of anemia among women in India and similar countries, the method should be piloted through the public health system.

Implications: Long duration of contraceptive action, ability to reduce menstrual bleeding and reduce anemia, reversibility, and easy removal, combine to make LNG-IUD acceptable to women, especially in regions with high prevalence of anemia. This study demonstrates the feasibility and acceptability of introducing LNG-IUD in a low resource, primary care setting.

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1. Introduction

Having launched a national program for family planning in 1952, India was slow to expand contraceptive choice by introducing newer methods, especially for younger couples. Till 2016, re-

versible contraceptive methods available in the public health system included condoms, combined oral pills, emergency contraceptive pills, and the Copper IUD. In 2016, depot medroxyprogesterone acetate (DMPA) injections and Ormeloxifene (a nonsteroidal, non-hormonal oral contraceptive) were introduced into the program.

Over several decades, India's method mix has been heavily skewed towards female sterilization, which contributed 83% to modern contraceptive use in 1998–1999, declining to 67% in

* Corresponding author.

E-mail address: chiefexecutive@arth.in (S. Iyengar).

2019–2021 [1] – a change that was more marked amongst higher income groups, possibly because of better access to reversible options. The public health system emphasizes providing permanent methods to couples that have “completed their families” and do not wish to have more children. However, a large proportion of women that wish to limit births might not prefer sterilization for a variety of reasons, including apprehensions about undergoing surgery, enforced postsurgical rest from household duties, and in case they wish to bear a child again. Meanwhile, the Copper IUD remains unpopular – apprehensions about abdominal pain, increased menstrual bleeding, and discharge appear to dissuade potential users. [2,3].

The levonorgestrel-releasing intrauterine device (LNG-IUD), a safe and effective long-acting reversible contraceptive, has additional noncontraceptive benefits including reduction of menstrual bleeding and anemia [4–7]. The LNG-IUD has gained popularity in high-income countries and in Africa, yet large-scale use and public sector availability in other developing countries has been modest [8,9]. Although licensed in India in 2000, its use as a contraceptive has been limited by high cost and nonavailability in the public health system. In the initial years, the device retailed at almost \$200, this was reduced to about \$52 by 2021 after the government introduced national price control [10].

With a view to providing women with a reliable, long-term, reversible contraceptive option that could also help alleviate anemia, we introduced LNG-IUD in a low-resource setting in India. We designed an observational study to test the feasibility and acceptability of LNG-IUD as a long-acting reversible contraceptive when delivered through a primary care service.

2. Methods

2.1. Study area

Rajasthan (population 81 million, 2021 estimates) is a northern Indian state with educational and health indicators that lag the national average. The total fertility rate is 2.0 and the prevalence of modern contraception is 62.1% of which 68.8% is attributable to sterilization and 2.3% to the Copper-IUD [1]. Action Research & Training for Health (ARTH) is a nonprofit organization that contributes to improving the health status of underprivileged communities in India. ARTH provides subsidized reproductive health services, including reversible contraceptives (combined oral pills, condoms, DMPA injections, emergency pills, and Copper IUDs), first-trimester abortion, delivery, and newborn care, and treatment of common conditions through one urban and three rural health facilities, and a network of 607 community health entrepreneurs, all women, that together serve a population of 550,000 in southern Rajasthan. A gynecologist visits each facility once or twice a week, while locally resident, trained nurse-midwives are available round the clock.

2.2. Introduction of LNG-IUD

ARTH adapted standard WHO resource materials on LNG-IUD to train its providers (doctors, nurse-midwives, and counselors) on counseling, screening, insertion, follow-up, and management of side effects. Doctors and nurse-midwives already experienced in Copper-T insertion were trained to assess eligibility, insert the device and follow up. Four health facilities started offering Levonorgestrel 52 mg intrauterine device (Pregna) as a contraceptive option [11], in addition to existing contraceptives. A gynecologist and later nurse-midwives under medical supervision inserted the device. The cadre of women community health entrepreneurs living in 439 villages and urban wards promoted the

service. These entrepreneurs had been trained to provide reproductive health information and commodities including pregnancy test kits, contraceptives, sanitary pads, and menstrual cups at nominal cost to the community. We additionally offered women a local-language, toll-free telephone helpline, and used printed materials, videos, wall hoardings, and a village communication campaign for promotion.

We branded this hormonal IUD service as *Mukti* (Hindi for “freedom”) and positioned it as an option for either spacing or limiting the next birth. *Mukti* was offered as an effective, non-surgical, long-term, hormonal contraceptive that reduced excess menstrual bleeding and protected women from anemia, at an affordable cost of Rs. 499 (\$6.8), with those belonging to the marginalized tribal community having to pay only Rs. 299 (\$4). This charge covered consultation, screening, insertion, and cost of a device, it was subsidized by a project grant and subsidized device cost from the manufacturer. Providers counseled women seeking contraception about all available options including referral for permanent contraception. Pregnant women seeking antenatal care and those seeking abortion received information on this as well as on other methods. If and when they opted for LNG-IUD, written informed consent was taken for participation in the observational study before insertion of the device. Privacy and confidentiality were maintained during counseling, insertion, and follow-up, as is the norm at the facilities.

2.3. Study instruments and follow-up measures

We recorded information on sociodemographic profile, prior and current use of contraception, prior abortion, and phase of insertion; and measured hemoglobin using Sahli’s method. After insertion, we advised women to follow up at 6 and 12 months and made discreet telephonic reminders 1–2 weeks before scheduled dates.

A follow-up questionnaire recorded continuation of use and menstrual patterns. Acceptability was measured (in terms of satisfaction, experience compared to expectations, recommendations to a friend or sister, and husband’s perceptions) after 12 months amongst those who continued and at the point of removal or reported expulsion, for the rest. For those who followed up at the clinic, a nurse-midwife conducted per speculum examination to check device status and tested for hemoglobin at 12 months. Those who did not follow up for a month after the 12-month due date received a discreet telephone call or home visit by a social scientist. For maintaining confidentiality during phone calls, the research staff first inquired from women whether they were able to talk in private. If this was not possible, they deferred the interview. While making home visits, interviewers did not share the real purpose of the visit with family or neighbors – they spoke to women only if privacy could be ensured, and otherwise engaged in light conversation about children’s and women’s general health.

For women who we followed up through phone calls or at home, the questionnaire was the same, but speculum examination and hemoglobin testing could not be provided. Women who did not come to the clinic and could not be contacted despite three attempted telephone calls and a home visit were considered lost to follow-up. The primary outcome was continuation rate and acceptability, and the secondary outcome was a change in hemoglobin levels.

2.4. Analysis

We tabulated user profile, removal rate, user satisfaction, etc. using count and percentages and calculated mean and confidence intervals for hemoglobin levels measured at baseline and after 12 months. We used multivariate logistic regression analysis by age,

residence, caste, education, children, phase of insertion, reproductive intention, and side effects, to assess removal and satisfaction rates. ARTH's Institutional Ethics Committee reviewed and approved the observational study.

3. Results

During August 2015–September 2019, 1266 women adopted LNG-IUD as a contraceptive at ARTH health facilities, consented to participate in the study, and were followed up.

3.1. Follow-up status

We were able to follow up 1240 (97.9%) out of 1266 eligible women, including 818 (66.0%) at the clinic, 237 (19.1%) over telephone, and 185 (14.9%) by home visit. The remaining 26 were not followed up because addresses were untraceable (12), women had migrated or resided outside our coverage area (nine), or refused to follow-up (three). Two women died four and 12 months after insertion from unrelated causes, as ascertained by verbal autopsy. Regression analysis of factors influencing clinic follow-up revealed that urban women (OR 1.81, 95% CI 1.18 – 2.78) and those with prior contraceptive experience (OR 1.53, 95% CI 1.16 – 2.03) were more likely to have followed up at the clinic as compared to rural women and those with no prior contraceptive experience. Follow-up at 6 months was for providing clinical care—813 (64.6%) women followed up at clinics at or shortly after six months. All results presented in this paper are based on a 12-month follow-up.

3.2. Sociodemographic characteristics

Eighty-five percent of users lived in rural areas, nearly two-thirds belonged to socioeconomically underprivileged “scheduled” (as listed in a schedule of the Constitution of India) caste or tribal groups and 57% were illiterate. All were currently married, and 87% had 2 or more living children. An overwhelming majority (82%) did not want more children, yet for most (58.8%) women, this was the first contraceptive experience (Table 1). Although women adopted the LNG-IUD as a contraceptive, nearly 10% reported having heavy menstrual bleeding prior to insertion, while 19% reported pain during menses.

3.3. Continuation rates

Of those followed up at 12 months, 1086 (87.6%) women were continuing with the method, 129 (10.4%) had opted for removal and 25 (2%) reported spontaneous expulsion. Of those who sought removal, 31 (2.5%) had a change in reproductive intention following change in personal or family circumstances, while 92 (7.4%) had experienced side effects, the commonest being spotting, heavy menstrual bleeding, and abdominal pain (Table 2). Removals were higher amongst younger women, those who had side effects, and those who had used the method for spacing or had adopted it during the postabortion phase. However, regression analysis revealed that only 2 variables correlated with removal – women reporting side effects (OR = 15.33, 95% CI 10.06–23.38) and women aged 18–24 years (OR= 2.76, 95% CI 1.06–7.19) (Table 3).

3.4. Menstrual patterns and acceptability

Amongst women continuing with the method at 12 months, 54% reported hypomenorrhea, 42% reported amenorrhea, and 1% reported heavy bleeding. Amongst all users, 91.6% women were satisfied with the method, 92.0% said their experience equaled or exceeded expectations, and a similar proportion said they would

Table 1

Characteristics of women who adopted the LNG-IUD in Rajasthan, India, August 2015 to September 2019 ($n = 1266$)

Category	Indicator	Number (%)
Residence	Rural	1083 (85.5%)
	Urban	183 (14.5%)
Education	Illiterate	721 (57.0%)
	Primary school (educated for 1–5 y)	261 (20.6%)
	Middle school (educated for 6 or more y)	284 (22.4%)
Age (years)	15 – 19	4 (0.3%)
	20 – 24	236 (18.6%)
	25 – 29	502 (39.7%)
	30 – 39	503 (39.7%)
	40 – 49	21 (1.7%)
Age (years)	Mean (SD)	28.2 (4.3) y
Caste group	Scheduled tribes	703 (55.5%)
	Scheduled castes	114 (9.1%)
	Other	449 (35.4%)
Living children	0	5 (0.4%)
	1	154 (12.2%)
	2	482 (38.1%)
	3 and above	625 (49.4%)
Reproductive Intention	Wishes to space	204 (16.1%)
	Wishes to limit	1040 (82.1%)
	Uncertain	22 (1.7%)
Ever use of contraception	Yes	523 (41.2%)
	No	743 (58.8%)
Current contraceptive use	Yes	259 (20.5%)
	No	987 (78.5%)
Phase of insertion	Interval	889 (70.2%)
	Immediate postpartum (within 48 h of delivery)	108 (8.5%)
	Late postpartum (between 6 wk and 6 mo after delivery)	46 (3.6%)
	Postabortion	223 (17.6%)

Table 2

Continuation status and reasons for removal amongst women who adopted LNG IUD in Rajasthan, India from August 2015 to September 2019 ($n = 1240$ users who were followed up at 12 months)

Continuation status	Number (percentage)
Status at 12 mo	
Continuing	1086 (87.6%)
Got device removed within 12 mo	129 (10.4%)
Reported spontaneous expulsion within 12 mo	25 (2.0%)
Reasons for removal within 12 mo ($n = 129$)	
Change in reproductive intention (wanted another child, remarriage, husband died, family resistance)	31 (2.5%)
Side effects	92 (7.4%)
Heavy or continuous bleeding/ spotting	40 (3.2%)
Amenorrhea	3 (0.2%)
Abdominal pain	39 (3.1%)
Other	10 (0.8%)
Wanted to switch to another method	6 (0.5%)

recommend LNG-IUD to their friend or sister if they needed a contraceptive. As reported by users, most husbands who became aware that their wife was using the device, had a positive or neutral attitude towards it (Table 4). Removal rates were not higher amongst women having amenorrhea or scanty periods but were higher amongst those with heavy menstrual bleeding (OR 5.48, 95% CI 2.02–14.88), pain during periods (OR 17.8, 95% CI 2.07–153.11) and those with spotting between periods (OR 6.63, 95% CI 3.06–14.34). Further, women without side effects were more likely to be satisfied (OR= 62.0, 95% CI 31.1–125.1).

Table 3
Removal of LNG-IUD within 12-months by selected characteristics, from August 2015 to September 2019 in Rajasthan, India (*n* = 129 women)

Indicator	Value	Odds ratio for removal of LNG IUD (95% CI) ^a
Age (years)	>=35	
	18 – 24	2.76 (1.06 – 7.19)
	25 – 29	1.82 (0.81 – 4.07)
	30 – 34	1.29 (0.58 – 2.84)
Place of residence	Rural	
	Urban	0.85 (0.47 – 1.55)
Reproductive Intention	Wants to limit	
	Wants to space/uncertain	1.48 (0.82 – 2.66)
Phase of insertion	Interval	
	Early postpartum	0.75 (0.33 – 1.69)
	Late postpartum	0.45 (0.12 – 1.69)
	Postabortion	1.54 (0.92 – 2.57)
Side effects	No	
	Yes	15.33 (10.06 – 23.38)
Caste group	SC	
	ST	1.24 (0.59 – 2.62)
	Others	1.40 (0.64 – 3.04)
Education	Illiterate	
	Up to primary school	0.84 (0.48 – 1.46)
	Middle school and above	0.62 (0.34 – 1.15)
Number of children (continuous variable)		0.97 (0.77 – 1.22)

^a Multivariate logistic regression analysis, adjusted for all variables in the table (age, place of residence, reproductive intention, phase of insertion, side effects, caste group, education and number of children).

Table 4
Acceptability of LNG-IUD amongst women who adopted the device from August 2015 to September 2019 in Rajasthan, India (*n* = 1240 users who followed up)

Indicator	Users
User satisfaction	
Satisfied with method	1136 (91.6%)
Not satisfied	104 (8.4%)
Experience compared to expectations	
Better	409 (33.0%)
Equaled expectations	731 (59.0%)
Worse than expected	77 (6.2%)
Data not available	23 (1.9%)
Husband's perception towards the method	
Positive	928 (74.8%)
Neutral	212 (17.1%)
Negative	40 (3.2%)
Husband not aware	37 (3.0%)
Data not available	23 (1.9%)
Which contraceptive method would she advise a friend or sister in a similar situation?	
LNG-IUD	1141 (92.0%)
Other contraceptive or none	99 (8.0%)

3.5. Hemoglobin levels

Of 818 women who followed up at the clinic, 780 (95.4%) had hemoglobin tested. Hemoglobin could not be tested for 460 women receiving home or telephonic follow up, and in a minority of those who followed up at the clinic. There was no significant difference in the baseline hemoglobin (g/dL) values of those who followed up at clinics (mean 9.59, SD 1.03) as compared to those who did not follow up at clinics (mean 9.68, SD 1.15). Women whose hemoglobin was tested at 12 months were significantly more likely to be urban residents or to have had prior contraceptive experience. There were no other differences between those tested and those not tested. Comparison of hemoglobin levels at baseline and after 12 months (Table 5, Fig. 1) shows that the proportions of women with moderate and severe anemia (with hemoglobin levels below 9 g/dL) were lower at 12 months, and mean hemoglobin levels were higher by 0.7 g/dL ($p < 0.01$). The overall proportion of women with anemia was 89.6% at baseline and 68.9% at 12 months follow-up.

Table 5
Hemoglobin values at baseline and 12 months after insertion amongst women who adopted LNG-IUD from August 2015 to September 2019 in Rajasthan, India (*n* = 780 women who underwent both hemoglobin assessments)

Hemoglobin level (g/dL)	Baseline (%)	at 12 mo follow-up (%)	Paired <i>t</i> test value: 0.000
< 7	3 (0.4%)	0 (0.0%)	
7 – 8.9	156 (20.0%)	52 (6.7%)	
9 – 10.9	541 (69.3%)	485 (62.2%)	
11 and above	80 (10.3%)	243 (31.2%)	
Mean	9.5 (SD: 1.03)	10.2 (SD: 1.18)	

4. Discussion

Our study suggests that it is feasible to deliver the levonorgestrel-releasing intrauterine device as a long-acting reversible contraceptive option in a primary care setting and that women accept it well— over 90% were satisfied with the method and felt that their experience equaled or exceeded expectations. Acceptability of LNG-IUD has been studied in middle and high-income countries and amongst educated women in Europe [12,13], the United States [14], Brazil [15], and China [16]. These studies have reported satisfaction rates of 77% to 90%, with scanty menses or amenorrhea being reasonably well tolerated by most women. An international survey of 18 countries in Europe and the near east reported that 95% of users were satisfied [17]. Experience in Kenya also has shown that 87% of users were satisfied [18]. A study from Nigeria found that common reasons for women choosing the LNG-IUD included reduced menstrual bleeding (61%) and long duration of action (52%) [19]. Studies in Kenya, Zambia, and China also show that the desire for fewer side effects and reduced menstrual bleeding were important reasons for women to adopt the device [16,20]. Our study is the first on the acceptability of LNG-IUD in a low-resource, predominantly rural setting in Asia.

The large majority (87%) of women who adopted LNG-IUD, already had 2 or more children, and 82% expressed their intention to limit childbearing. During preinsertion consultation, women had been counseled about all options including free tubectomy and vasectomy services, which were available at government health facilities in the area. They however opted to pay a nominal amount

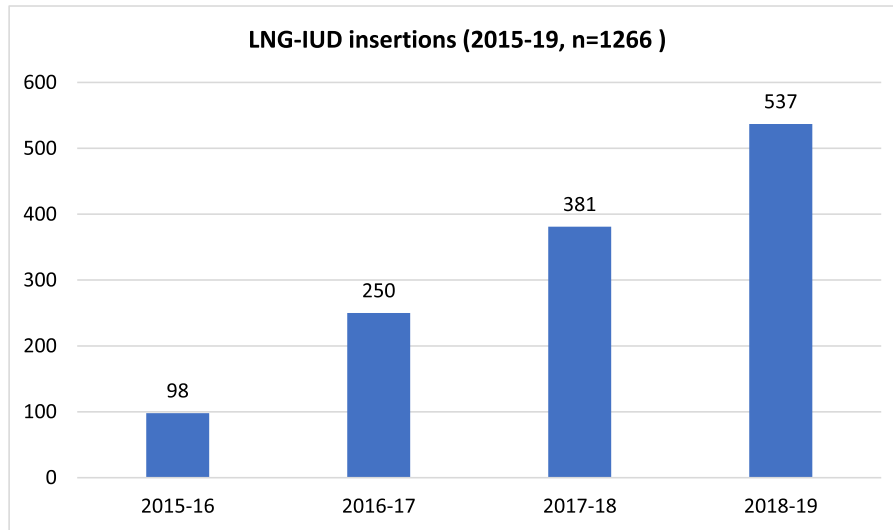


Fig. 1. Number of LNG-IUD insertions over the years (2015–2019, n = 1266). LNG-IUD = levonorgestrel-releasing intrauterine device.

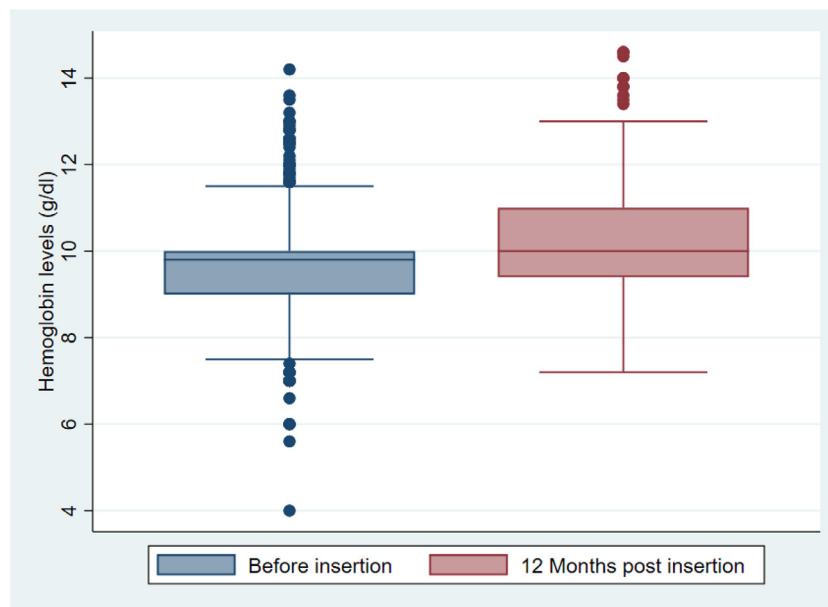


Fig. 2. Box plot showing distribution of hemoglobin levels amongst women (n = 780) at baseline and at 12 months after insertion of LNG-IUD. LNG-IUD = levonorgestrel-releasing intrauterine device.

to access a long-acting reversible method. This suggests that for significant numbers of women living in low resource settings, attributes like reversibility and reduction in bleeding remain a priority, even for the purpose of limiting childbirth. Recent analysis from 2018 has shown that 6.9% of women had sterilization regret in India [21], hence the decision to adopt permanent contraception must be a complex one for most individuals. Meanwhile, if women with two or more children are not offered any reversible alternative, they run the risk of unwanted pregnancy. Developing countries such as Thailand, Bhutan, and Vietnam, have achieved high coverage of modern contraception largely from the use of reversible contraceptive methods. The addition of a reliable long-acting reversible contraceptive option like the hormonal IUD might therefore contribute to reducing India's skewed method mix, by encouraging greater contraceptive adoption by younger women and by those who seek a long-term, but not a permanent method.

The 12-month continuation rate in our series was 87.6%, comparable to that from studies in the US (87%–88%) [22,23], and lower than that from a prospective survey in China (93%) [16]. Apart from 2% women reporting spontaneous expulsion, the commonest reason for removal included side effects, especially spotting, heavy menstrual bleeding or abdominal pain. Probably because of social and religious restrictions related to menstruation, several women found spotting unacceptable, even if total blood loss was reduced. A trial that compared LNG-IUD and TCu380A over seven years reported higher rates of discontinuation due to amenorrhea from Chinese sites and due to excessive bleeding from non-Chinese sites, signaling cultural differences in the response to bleeding changes [24]. A global scoping review too has highlighted substantial variability in women's responses to contraceptive-induced menstrual bleeding changes [25]. A study of LNG-IUD users in Finland revealed that premature removal was triggered by excessive bleeding, spotting, infection, or pain [26]. A majority of women viewed

amenorrhea and infrequent periods more positively than heavy menstrual bleeding or spotting. Our results are similar – they show higher continuation and satisfaction rates amongst those with scanty or no periods as compared to those who experienced heavy bleeding or spotting. They nevertheless underscore the importance of counseling and continuing support to women adopting the hormonal IUD. The second major reason for early removal in our series was a change in women's personal circumstances or reproductive intention – this is integral to the reversible nature of the contraceptive option, and is the reason why women in the first place choose a reversible method.

The LNG-IUD offers distinct noncontraceptive benefits, the most important being reduction of menstrual bleeding and improvement in iron deficiency anemia [27,28]. A systematic review has shown a significant decrease in hemoglobin and ferritin levels amongst Copper IUD users, especially if they were borderline anemic, but an increase in the same amongst LNG-IUD users, 12 months after insertion [4]. Our study corroborates this finding. Improvement in hemoglobin levels from the use of LNG-IUD is especially relevant in the Indian context where over half of all women in the reproductive age group are anemic [1], and anemia contributes significantly to morbidity and indirect maternal deaths [29,30].

We advised women to return to the clinic for follow-up and offered reimbursement of travel costs. Urban women with better access to transport, and those with prior contraceptive experience were more likely to return to the clinic for follow-up, hence our findings on change in hemoglobin status could be biased in favor of these categories.

Several circumstances favor the addition of the LNG-IUD to the basket of methods offered by India's public health system. There is adequate indigenous manufacturing capacity that can meet domestic needs. Skills required for inserting or removing an LNG-IUD are comparable to those required for the Copper – T, hence available provider skills could with minimal additional training, be used for LNG-IUD services. More importantly, the method could help to reduce unmet need for spacing as well as limiting, while protecting the large majority of users from anemia. Cost considerations could act as a barrier to large-scale introduction, yet costs are expected to drop as procurement crosses 100,000 devices and could reach \$8–\$10 per unit if volumes reach 1–2 million annually (M. Taparia, Pregna International, personal communication, October 5, 2021). The cost of the LNG-IUD may be compared to that of the subdermal implant, with which it shares some attributes. Implants currently cost donors \$8–\$9 per unit [31], when procured at volumes of more than 8 million. Hence at the volumes required for introduction in the public health system of a large country like India, the price is likely to drop substantially. The hormonal IUD is often compared to the Copper IUD, which costs governments and donors significantly less. However, important differences between women's experiences with these methods should be considered, as also the value addition from the alleviation of anemia, menorrhagia, and dysmenorrhea. When women were given choice of contraceptive methods without cost in the US, four times more women opted for the hormonal IUD than the Copper IUD [14].

Being the most widely used intrauterine device in developed countries, the LNG-IUD is associated with high satisfaction rates and is on WHO essential drug list. A 27-year review of DHS data from 11 countries has shown that each additional contraceptive method increases modern contraceptive use by four to eight percentage points [32]. We recommend that pilot interventions be undertaken with a view to introducing the LNG-IUD as a primary care service within the family planning programs of low and middle-income countries. Further, we recommend cost-effectiveness studies comparing LNG-IUD to other contraceptive methods, in terms of the dual effect on long-term contraception and reduction of anemia.

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Declaration of Competing Interest

Conflict of interest: We declare no competing interests.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.conx.2022.100079](https://doi.org/10.1016/j.conx.2022.100079).

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