Open Journal of Obstetrics and Gynecology, 2014, 4, 190-196
Published Online March 2014 in SciRes. http://www.scirp.org/journal/ojog
http://dx.doi.org/10.4236/ojog.2014.44032

Levonorgestrel Intrauterine System (LNG IUS) in Menorrahgia: A Follow-Up Study

Gupta Taru, Gupta Nupur, Gupta Sangeeta*, Bhatia Pushpa, Jain Jyoti, Kumar Sushma

ESI PGIMSR, Basaidarapur, New Delhi, India
Email: *tarugupta1971@yahoo.com

Received 11 November 2013; revised 10 December 2013; accepted 18 December 2013

Abstract

Objective: To study the acceptability, efficacy, adverse effect and user satisfaction of Levonorgestrel intrauterine system (LNG IUS) for treatment of menorrahgia. Method: This was an observational descriptive study conducted in ESI PGIMSR over a period from Jan 2008-June 2011. 70 women presented in O.P.D with heavy menstrual bleeding having no contraindication for device, consenting for LNG IUS underwent its insertion. Menstrual pattern, pictorial blood loss assessment chart score, adverse effects, and rate of acceptability and satisfaction were recorded at 3, 6 and 12 months after procedure. Results: The mean age of the sample was 39.92 yrs ± 3.27. Indication for device insertion was DUB in 81.42% (57), fibroid 8.57% (6), adenomyosis in 10% (7). The expulsion rate was 4.2% (3), removal rate was 7.14% (5) and continuation rate is 88.57% (62). 2.28% (3) patients underwent hysterectomy because of continuous bleeding even after 3 - 4 months of insertion. On follow-up at one year out of 62 patients, 33.87% (21) were amenorrhic and 51.61% (32) have regular period, while 3.07% (2) patients had irregular period. Conclusion: LNG IUS is a less invasive, effective treatment modality for menorrahgia with reasonable efficacy.

Keywords

Levonorgestrel Intrauterine System; Menorrhagia; Pictorial Blood Loss Assessment Chart; Fibroid Uterus

1. Introduction

Menorrahgia constitutes a considerable problem for many female, causing discomfort, anxiety and decreased quality of life. Menorrahgia is experienced by up to 30% of women in their child bearing age and accounts for 60%

*Corresponding author.

How to cite this paper: Taru, G., Nupur, G., Sangeeta, G., Pushpa, B., Jyoti, J. and Sushma, K. (2014) Levonorgestrel Intrauterine System (LNG IUS) in Menorrahgia: A Follow-Up Study. *Open Journal of Obstetrics and Gynecology*, **4**, 190-196.
http://dx.doi.org/10.4236/ojog.2014.44032

of general population. It is a common cause of iron deficiency anaemia in healthy fertile female [1] [2]. By definition, menorrahgia denotes regularly timed episodes of bleeding that are excessive in amount (>80 ml and/ duration of flow > 5 days) [3]-[5].

The prevalence of menorrhagia typically ranges from 9% to 14% in studies that assessed menstrual blood loss objectively with acid haematin or from 20% to 52% in studies based on subjective assessment with pictorial blood loss assessment chart (PBAC) [6].

Until recently, conservative medical treatment has been disappointing, and surgical alternatives like endometrial ablation and endometrial resection have been developed. The role of these surgical alternatives in the treatment of menorrahgia is not currently clear.

One minimally invasive procedure for control of menorrahgia is levonorgestrel intrauterine device. It consists of a 32 mm T shaped polyethylene frame with a reservoir containing 52 mg of LNG covered by a silicon membrane [7]. LNG is released from this IUS at a rate of 20 microgram/24 hrs and a stable plasma concentration of 150 - 200 pg/ml is achieved after the first few weeks of insertion. The plasma concentration of LNG in patients using LNG IUS is less than 25% of that seen with 150 microgram of oral LNG [7].

By slowly releasing the progestin LNG in to uterine cavity, LNG IUS suppresses endometrial growth causing atrophy of endometrial glands, decidualisation of stroma, thickening of cervical mucosa and desensitisation of the endometrium to oestrogen, which all lead to excellent control on menorrahgia, providing in parelled a highly satisfactory contraceptive action [7].

In present study, the efficacy of LNG IUS in case of menorrahgia was evaluated.

2. Method

Between Jan 2008-June 2011, 70 women who had menorrahgia were recruited for the study. The study was observational descriptive study conducted in the Department of Obstetrics and Gynaecology, ESIPGIMSR, New Delhi. Women were allocated to LNG IUS insertion, after detailed counselling. Informed consent was obtained for each woman prior to procedure. Data were collected prospectively and analysed.

Criteria for exclusion were patient with active genital tract infection, severe anemia (<7 gm%), pregnancy, abnormal cervical cytology, premalignant and malignant endometrial histology, previous endometrial resection and ablation, history of thromboembolism, liver disease, fibroid (larger than 2.5 cm, >3 in number or submucosal), adnexal tumour or cyst and thyroid disorder.

A detailed history of demographic profile, obstetric history, any medical and surgical illness and detailed menstrual history regarding amount and duration of bleeding was taken. Subjective assessment of menstrual blood loss was done with pictorial blood loss assessment chart (PBAC). A score was calculated by multiplying number of pads used with duration of flow with degree of staining 1, 5, 20 for slightly, moderately and heavily soiled pad respectively.

PABC score > or = 100 was considered as menstrual blood loss >/= 80 ml, was considered as diagnostic of menorrhagia.

Routine investigation included hemogram, liver function test, kidney function test, coagulation profile and thyroid function test and gynaecological examination including cervical smear and endometrial sampling were done to rule out cervical or endometrial neoplasia. A transvaginal ultrasonography was used to evaluate possible cause of menorrahgia including fibroid, endometrial polyp and adnexal pathology.

All women had negative urine pregnancy test prior to LNG IUS insertion. LNG IUS was inserted within 7 days of the start of menstruation under i.v sedation. Any complication such as uterine perforation, haemorrhage, and abdominal cramps were recorded and they were observed for one hour after insertion. Accurate LNG IUS position was documented with transvaginal USG. At the time of discharge, patient was prescribed antibiotics and painkiller.

After the procedure, all patients were advised to keep a menstrual record including length of menstrual cycles, days of bleeding, and number of stained pads in one day, amount of staining and note any adverse effects namely spotting, abdominal cramps and pains, breast tenderness, headache, acne, mood changes and weight gain. Patients were assessed by using pictorial method after 3, 6 and 12 months of use.

The primary outcome included the menstrual pattern namely amenorrhea and reduction in bleeding score. The secondary outcome was the rate of patient satisfaction. Amenorrhea was defined as absence of bleeding for atleast 3 months, “non response” as continuous menorrahgia, “regular cycle” when bleeding occurred in an inter-

val between 25 - 32 days and length of bleeding was not more than 5 days. Patient satisfaction was recorded on a scale of 0 - 5 with 0 being "least satisfied" and 5 being "most satisfied".

5 parameters *i.e*. general well being, mental health, effect on menstrual blood loss, adverse effects and overall acceptability were assessed and score of 0 or 1 given for problem or no problem respectively.

3. Results

In our study, 70 women underwent LNG IUS insertion over 3.5 years for heavy menstrual bleeding. The mean age of patients was 39.92 ± 3.27 years. Majority of patients were above 35 yrs (55). 51.42% (36) in the study group were Para 3 or more with mean parity of 2.84. 73% patients belonged to lower socioeconomic strata and were less educated up to class 12th. In our institute, patients are insured beneficiaries and LNG IUS was provided free of cost to them. Indication for insertion was dysfunctional uterine bleeding (DUB) in 81.42% (57), fibroid in 8.57% (6), and rest 10% (7) had adenomyosis. On histological examination of endometrium, 60% (42) patients had proliferative endometrium, 18.57% (13) with secretory endometrium, simple hyperplasia without atypia in 21.4% (15).

The women in whom LNG IUS inserted are followed up at 3, 6 and 12 months (**Table 1**). At 3 months, 46.15% (n = 30) had irregular periods which reduced to 3.07% (n = 2) at 1year of use. At 12 months follow-up, 33.87% (n = 21) become amenorrhic and 51.61% (n = 32) presented with regular cycle. During first 3 months of use, 4.28% (n = 3) had spontaneous expulsion of device whereas 2 patients *i.e*. 2.28% requested for removal because of severe pain abdomen. During 4 - 5 months of insertion, 3 more patients asked for removal in view of irregular menstrual bleeding. Out of 5 patients who had removal, 3 (4.28%) underwent hysterectomy.

1) Outcome in DUB

Out of 57 DUB patients, 1 had spontaneous expulsion of device during her first menstrual bleeding and 2 got it removed for severe pain within 2 months of insertion. One patient got it removed in 4th month of insertion due to irregular excessive bleeding. **Table 2** depicts the effects of LNG IUS on menstrual blood flow in patients with DUB.

2) Outcome in fibroid

Out of 6 patients with fibroid, 1 had spontaneous expulsion of the device during her first menstrual bleeding. 1 got it removed for irregular bleeding at 4th month of insertion. **Table 3** shows the effect of LNG IUS on menstrual blood flow in patients with fibroid uterus.

3) Outcome of adenomyosis

Out of 7 patients with adenomyosis, 1 had spontaneous expulsion of device during her first menstrual bleeding. 1 got it removed for irregular bleeding at 4th month of use. **Table 4** depicts the effects of LNG IUS on menstrual blood flow in patients with adenomyosis.

Table 1. Effect on menstrual flow.

Duration	3 months (n = 65)	6 months (n = 62)	12 months (n = 62)
Irregular period	30 (46.15%)	9 (14.51%)	2 (3.07%)
Regular period	33 (50.07%)	38 (61.29%)	32 (51.61%)
Amenorrhoea	2 (3.07%)	11 (17.74%)	21 (33.87%)
Lost to follow-up	0	4 (6.45%)	7 (11.29%)

Table 2. Effect on menstrual flow in patients with DUB.

Menstrual pattern	3 months (n = 54)	6 months (n = 53)	12 months (n = 53)
Menorrhagia	22 (40.74%)	8 (15.09%)	1 (1.88%)
Normal period	30 (55.55%)	32 (60.37%)	26 (49.05%)
Amenorrhoea	2 (3.70%)	9 (16.98%)	19 (35.84%)
Lost to follow-up	0	4 (7.54%)	7 (13.20%)

Table 3. Effect on menstrual flow in patients with fibroid.

Menstrual pattern	3 months (n = 5)	6 months (n = 4)	12 months (n = 4)
Menorrhagia	4 (80%)	0	0
Normal period	1 (20%)	3 (75%)	3 (75%)
Amenorrhoea	0	1 (25%)	1 (25%)
Lost to follow-up	0	0	0

Table 4. Effect on menstrual flow in patients with adenomyosis.

Menstrual pattern	3 months (n = 6)	6 months (n = 5)	12 months (n = 5)
Menorrhagia	4 (66.67%)	1 (20%)	1 (20%)
Normal Period	2 (33.33%)	3 (60%)	3 (60%)
Amenorrhoea	0	1 (20%)	1 (20%)
Lost to follow-up	0	0	0

Our study had statistically significant improvement in haemoglobin (Hb) levels. The mean pre insertion Hb level was 8.16 gm%, at 3 months 9.41 ± 0.8, at 6 months 9.35 ± 0.7 and at 12 months 11.03 ± 0.93.

At 3 months of use, 70% (49) had satisfaction score of >4 which gradually improve with continuation of use to 94.5% (52) at 12 months. **Table 5** shows the satisfaction score among the users against time.

In our study, no major adverse effect was observed. At 3 months follow-up 30% of patients had intermenstrual spotting. **Table 6** list the adverse effects observed with the use of LNG IUS.

Although 73% patients were less educated, it was the effect of counselling and its reinforcement at subsequent visit which had led to the continuation of use of this device.

4. Discussion

This is an observational descriptive study which provides further evidence of effectiveness of LNG IUS in patient having menorrahgia. It provides a non surgical alternative, which is reversible and spare fertility [8]. Continuation rate of 88.57% after one year shows high patient acceptance.

In idiopathic menorrahgia, the use of LNG IUS is associated with a significant reduction in the number of days of bleeding and menstrual blood loss [9]. This effect is based on the marked local action of intrauterine release of LNG on the endometrium.

Comparative trial from various studies suggests the use of LNG IUS can be therapeutic alternative to endometrial ablation or hysterectomy in woman with menorrahgia [10] [11].

REDUCTION IN MENSTRUAL BLOOD LOSS (MBL) (%)

The **Table 7** shows comparative reduction in MBL with continuation of use of device in our study with those of others [12]-[16]. Sample size of our study was comparable with that of Kaunitz *et al.* [13] and the reduction in MBL with the use of LNG IUS was also comparable. Endrikat *et al.* [14] and Xaio *et al.* [16] though had a smaller sample size, had 94% and 84% reduction in MBL respectively at 1 year of use.

The LNG IUS may be reasonable treatment for selected women with fibroid associated menorrahgia. In women with fibroids, uterine size not larger than 12 weeks & with a regular uterine cavity, LNG IUS substantially reduces menstrual bleeding [17]. **Table 8** shows reduction in MBL in patients with fibroid in our study with those of others.

LNG IUS AND FIBROID UTERUS

According to a prospective study conducted in Mumbai(2003-2004) by Sushil *et al.*, at 12 months out of 20 women in 19 IUD remain in situ (95%); of whom 15(78%) reported amenorrhea and 4 (22%) with intermenstrual bleeding [18]. In our study, at 12 months, 33.87% attained amenorrhea, 51.61% with regular bleeding and rest 3.07% showed irregular period.

Another descriptive study conducted in 60 patients in Peshawar from June 2004-June 2007 by Utman *et al.*,

Table 5. Satisfaction score.

Satisfaction score	3 months (n = 70)	6 months (n = 58)	12 months (n = 55)
0-1	13 (18.57%)	6 (10.34%)	0
2-3	8 (11.42%)	2 (3.44%)	3 (5.45%)
4-5	49 (70%)	49 (84.48%)	52 (94.5%)

Table 6. Adverse effects of LNG IUS.

Complications	At 3 months	At 6 months	At 12 months
Expulsion	3 (4.2%)	-	-
Perforation	-	-	-
Intermenstrual spotting	21 (30%)	8 (12.90%)	2 (3.22%)
Abdominal cramps	14 (20%)	-	-
Weight gain	2 (3%)	2 (3.22%)	2 (3.22%)
Vaginitis	4 (6.1%)	1 (1.61%)	-
Headache	5 (7.69%)	-	-
Breast tenderness	-	-	-
Ovarian cyst	-	-	-

Table 7. Comparison of reduction in MBL.

	Sample	At 3 months	At 6 months	At 12 months
Our Study 2011	n = 70	53.84%	79%	85.48%
Chattopdhyay *et al*., 2011	n = 42	54%	91.54%	92.25%
Kaunitz *et al*., 2010	n = 82	62%	71%	87%
Endrikal *et al*., 2009	n = 20	78%	94%	94%
Utman *et al*., 2011	n = 60	-	67%	85%
Xiao *et al*., 2003	n = 34	-	79%	84%

Table 8. Comparison of reduction in MBL in patients with Fibroid.

Study	Sample size	Duration months	Reduction in MBL at 12 months	Expulsion
Our study 2011	6	12	83.3%	1 (18%)
Sayed *et al*., 2010	29	12	91%	3 (10%)
Murat *et al*., 2010	40	6	85%	-
Shawki *et al*., 2009	67	12	88%	-
Soysal *et al*., 2005	32	12	90%	10 (31%)
Grigoreva *et al*., 2003	69	12	84%	4 (5.79%)
Mercorio *et al*., 2003	32	12	69%	4 (12.5%)

Table 9. Comparison of adverse effects.

Study/Sample size	Our study 2011 (70)	Utman *et al*., 2011 (60)	Sushil *et al*., 2005 (40)	Kriplani *et al*., 2007 (63)	Kaunitz *et al*., 2010 (82)	Chattopdhya *et al*., 2011 (42)	Reid *et al*., 2005 (25)
Irregular bleeding	30%	13%	22%	71%	-	28.5%	44%
Perforation	-	-	-	-	-	-	-
Expulsion	4.2%	10%	-	-	5%	2.38%	16%
Pain	20%	-	-	38%	-	4.76%	32%
Weight gain	3%	-	5%	30.5%	-	-	
Headache	7.69%	-	-	13.3%	10%	-	40%
Vaginitis	6.1%	3.33%	-	33.3%	11%	-	
Ovarian cyst	-	-	-	-	13%	-	24%
Breast tenderness	-	-	-	-	-	-	24%

Table 10. Continuation rate and satisfaction rate.

	Our study 2011	Utman *et al*., 2011	Sushil *et al*., 2005	Chattopdhya *et al*., 2011	Endrikat *et al*., 2009	Kaunitz *et al*., 2010	Reid *et al*., 2005
Continuation rate	88.58%	80%	95%	88.1%	95%	95%	84%
Satisfaction rate	94.54%	80%		96.3%	85%	85%	82%

showed acceptance rate of 80% (48) and discontinuation rate 20% (12) [15]. Whereas in our study acceptance rate was 88.57% (n = 62), discontinuation rate 7.14% (5) and spontaneous expulsion in 4.28% (3).

Table 9 depicts the various adverse effects observed in different studies [12] [13] [15] [18]-[20].

Table 10 shows the continuation rate & satisfaction rate a 1 year of use in our study & those of others [12]-[15] [18] [19].

The efficacy of LNG IUS in the management of DUB is similar to endometrial resection and it can be used as 1st or 2nd line option for medical management of DUB and due to its added contraceptive effects, it may become 1st line treatment for younger patients.

5. Conclusion

LNG IUS can be a good alternative to the medical and surgical treatment for menorrahgia in benign condition with high acceptability rate and good efficacy. It dramatically reduces the amount of bleeding in a few months. Due to its reversibility and contraceptive action it may be the first line of treatment in younger women who desire contraception as well. LNG IUS had minimal side effect leading to good continuation rate.

References

[1] Shaw, R.W. (1994) Assessment of Medical Treatment for Menorrhagia. *British Journal of Obstetrics and Gynaecology*, **101**, 8-15.

[2] Liu, Z., Doan, Q.V., Blumenthal, P. and Dubois, R.W. (2007) A Systematic Review Evaluating Health-Related Quality of Life, Work Impairment, and Health Care Costs and Utilization in Abnormal Uterine Bleeding. *Value Health*, **10**, 183-194. http://dx.doi.org/10.1111/j.1524-4733.2007.00168.x

[3] Stewart, A., Cummins, C., Gold, L., Jordan, R. and Phillips, W. (2001) The Effectiveness of the Levonorgestrel-Releasing Intrauterine System in Menorrhagia: A Systematic Review. *British Journal of Obstetrics and Gynaecology*, **108**, 74-86. http://dx.doi.org/10.1016/S0306-5456(00)00020-6

[4] Chimbira, T.H., Anderson, A.B. and Turnbull, A.C. (1980) Relation between Measured Menstrual Blood Loss and Patient's Subjective Measurement of Loss, Duration of Bleeding, Number of Sanitary Towels Used, Uterine Weight and Endometrial Surface Area. *British Journal of Obstetrics and Gynaecology*, **87**, 603-609. http://dx.doi.org/10.1111/j.1471-0528.1980.tb05013.x

[5] Monteiro, I., Bahamondes, L., Diaz, J., Perrotti, M. and Petta, C. (2002) Therapeutic Use of Levonorgestrel-Releasing Intrauterine System in Women with Menorrhagia: A Pilot Study. *Contraception*, **65**, 325-328. http://dx.doi.org/10.1016/S0010-7824(02)00283-4

[6] National Collaborating Centre for Women's and Children's Health (2007) Heavy Menstrual Bleeding. Clinical Guideline January. Commissioned by the National Institute for Health and Clinical Excellence.

[7] Nagrani, R., Bowen-Simpkins, P. and Barrington, J.W. (2002) Can the Levonorgestrel System Replace Surgical Treatment for the Management of Menorrhagia? *BJOG*, **109**, 345-347. http://dx.doi.org/10.1111/j.1471-0528.2002.01274.x

[8] Latheenmakhi, P., Haukkamaa, M. and Paullaka, J. (1998) Open Randomized Study of LNG Intrauterine System as Alternative to Hysterectomy. *BMJ*, **316**, 122-125.

[9] Luukkainen, T. (2000) The Levonorgestrel Intrauterine System: Therapeutic Aspects. *Steroids*, **65**, 699-702. http://dx.doi.org/10.1016/S0039-128X(00)00177-X

[10] Hurskainen, R., Teperi, J., Rissanen, P., *et al*. (2004) Clinical Outcomes and the Costs with the Levonorgestrel Releasing Interuterine System or Hysterectomy for Treatment of Menorrhagia. *JAMA*, **291**, 1456-1463. http://dx.doi.org/10.1001/jama.291.12.1456

[11] World Health Organization (2008) Medical Eligibility Criteria for Contraceptive Use. WHO, Geneva.

[12] Chattopdhyay (2011) Clinical Outcome of Levonorgestrel Intrauterine System in Idiopathic Menorrhagia. *European Journal*, **15**, 764-768.

[13] Kaunitz, A.M., Bissonnette, F. and Monteiro, I. (2010) Levonorgestrel Releasing Intrauterine System or Medroxy Progestrone for Heavy Menstrual Bleeding: A Randomized Controlled Trial. *Obstetrics & Gynecology*, **116**, 625-632.

[14] Endrikat, J., Shapirott and Lukkari-lax, E. (2009) A Canadian Multicentre Study Comparing the Efficacy of a Levonorgestrel Releasing Intrauterine System to an Oral Contraceptive in Women with Idiopathic Menorrhagia. *Journal of Obstetrics and Gynaecology Canada*, **31**, 340-347.

[15] Utman, *et al.* (2012) Levonorgestrol IUS in Menorrhagia. A Three Years Follow Up Study. *JPMI*, **96**, 79-83.

[16] Xiao, B., Wu, S.C. and Chang, J. (2003) Therapeutic Effects of the Levonorgestrel Releasing Intrauterine System in the Treatment of Idiopathic Menorrhagia. *Fertility and Sterility*, **79**, 963-969.

[17] Grigorieva, V., Chen-Mok, M., Tarasova, M., *et al*. (2003) Use of Levonorgestrel Releasing Intrauterine System to Treat Bleeding Related to Uterine Leiomyomas. *Fertility and Sterility*, **79**, 1194-1198. http://dx.doi.org/10.1016/S0015-0282(03)00175-4

[18] Sushil, *et al.* (2005) Therapeutic Use of LNG Intrauterine System for Menorrhagia Due to Benign Lesion—An Alternative to Hysterectomy? *The Journal of Obstetrics and Gynecology of India*, **55**, 541-543.

[19] Reid, P.C. and Virtanen-Kari, S. (2005) Randomised Comparative Trial of the Levonorgestrel Intrauterine System and Mefenamic Acid for the Treatment of Idiopathic Menorrhagia; A Multiple Analysis Using Total Menstrual Blood Loss and Pictorial Blood Assessment Charts. *British Journal of Obstetrics and Gynaecology*, **112**, 112-115.

[20] Kriplani, A., Singh, B.M. and Lal, S. (2007) Efficacy, Acceptability and Side Effects of LNG IUS for Menorrhagia. *International Journal of Gynecology & Obstetrics*, **97**, 190-194.