iatrogenic causes categorized as non-structural conditions. In a substantial proportion of women, the HMB cause remains unknown and is referred to as functional or idiopathic menorrhagia[2].

Medical therapy including oral contraceptive pill, progestagens as well as non hormonal therapy with tranexamic acid or non-steroidal anti-inflammatory drugs (NSAID) are advised as first line treatment where no definitive organic causes identified. However most women aren't wiling to continue there treatment and usually elect to other treatment even surgical [3,4].

Hysterectomy has tradionally, been regarded as the definitive surgical treatment for HMB and recently hysterectomy was reported to be the cost effective therapy for HMB[5,6]. However hysterectomy is major surgical procedure with significant physical, emotional sequelae as well as social and economic burdens (5,6). So many women asked for less invasive treatment modality even after they are counceled regarding that treatment success, is not always assured[7].

Levonorgestrel intrauterine system (LNG-IUS) and endometrial ablation (EA) are two frequently less invasive treatment for HMB choiced by women[6,7].

The effectiveness of ING-IUS on HMB was reported to reduce menstrual blood loss by 79 - 90%[8,9,10,11]. The RCOG guideline recommend LNG-IUS after failed medical treatment despite unproven cost-effectiveness [12]. Substantial proportion (up to 60%) of women discontinue to use LNG-IUS within 5 years due to unscheduled bleeding, pain and/or systemic progestrogenic side effects[12].

Endometrial ablation (EA) is effective minimally invasive surgical procedure that has become a well established alternative to medical treatment or hysterectomy to manage menorrhagia in selected cases[6]. However EA is under utilized as most of non-resectoscopic endometrial ablation are not available in developing countries and its disposable is so costly. Moreover due to high risks associated with monopolar resectoscopic endometrial resection and its outcomes, which is operator dependent, Rollerball ablation (RBA) is choiced in this study as its results is less operator dependent[1,4,5,27]. Several trials compared LNG-IUS with transcervical endometrial resection (TCER) or balloon thermal ablation (BTA). However the trials are small, with short period of follow up and contain a lot of noncompliance, this makes interpretation of outcome difficult [10,14,15,16,17,18,19].

This trial was conducted to compare LNG-IUS with RBA regards efficacy, safety and satisfaction due to lack of adequate research covering this area.

Patients and Methods

This prospective trial was an open label, randomized controlled trial, conducted at Department of obstetrics and gynecology, Benha University Hospital, Benha Egypt, between October 2014 and March 2017. Patients enrolled in this study consecutively and were eligible to be included if they were older than 35 years and less than 45 years, had no desire for future fertility, complaining of HMB with pictorial bleeding assessment chart (PBAC) score > 100 with failed medical treatment[20]. Exclusion criteria were sonographic abnormality as submucosual leiomyoma, intramural fibroid more than 3 cm in diameter, large subserosal leiomyoma or endometrial polyp, if transvaginal ultrasound (TVS) was not confirmatory, a saline sonohysterography was performed, acute pelvic inflammatory disease, gynecologic precancerous lesions as cervical intraepithelial neoplasia, atypical endometrial hyperplasia, gynecological cancer, adenomyosis, severe dysmenorrhea, severe premenstrual pain, chronic pelvic pain, medical contraindication to LNG-IUS and RBA, previous transcervical endometrial resection (TCER), uninvestigated postcoital bleeding and untreated abnormal cervical cytology. All women whom participated in this trial provided written informed consent. Also, Ethical approval for the trial were obtained from Banha Faculty of Medicine ethical committee.

All participants were subjected to a detailed clinical history, as completed physical examination including PBAC scoring[20]. All preoperative investigation were undertaken including CBC, cervical smear, transvaginal ultrasonography, saline sonohystrography and endometrial sampling.

The short form - 36 (SF-36) is a questionnaire instrument was used to assess the patient quality of life before and after the procedures. The SF- 36 is consisting of 36 questions grouped into eight health - related aspects of the patient's quality of life. The SF-36 assesses a full range of health states and includes multi-item scales, evaluating each

health concepts including: physical functioning (PF), role limitations due to physical health (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE) and mental health (MH). From question under each of the eight groups considered, item scores are coded, summed and transformed to a scale ranging from 0 (worst health status) to 100 (best health status). It has been used in various settings with different population groups and with both medical and psychiatric conditions. Researches have shown that, the SF-36 is a valid and reliable measuring tool for assessing differences between groups defined by age, sex, socioeconomic status and clinical condition[21 & 22].

Both RBA procedures and LNG-IUS (Mirena®, Schering Co., Turku, Finland) insertions were done by the author, the RBA procedures were done under spinal anesthesia with sedation after 4 - 6 weeks of oral cidolut nor 5mg every 6 hour (cide - Egypt) to induce endometrial thining, while the LNG – IUS insertions were inserted without anesthesia after assessing uterine cavity length with sound as per manufacturers instructions, with aids of TVS.

RBA was performed by 26F rigid resectoscope of KARL STORZ (Tuttingen - Germany) equipped with a Hopkins 30° optic. Glycine 1.5% were used with hysteromat of KARl STORZ to distend the uterine cavity. The fluid deficit were considered to be, the difference between used bottles and the collected in suction container with that suspected to be lost. A deficit up to 1000 ml Glycine was considered the limit after which the procedure was stopped. The rollebar was used to coagulate the whole uterine cavity and rollerball to coagulate the fundus and the uterine cornea with 80 w coagulation current.

Follow up was under taken at 3, 12, 24 months after RBA procedures and ING-IUS insertions to assess the menstrual blood loss by PBAC score(20) (standardized sanitary products were arranged to be used during fulfillment of PBAC score in order to allow for comparisons of the PBAC score to be made), quality of life by SF-36 questionnaire(21,22) and patient's satification by 5 point likert's scale of very satisfied (5 points), satisfied (4 points), border line (3 points), unsatisfied (2 points), very unsatisfied (1 point). Failure of treatment was considered if a major change in treatment was occurred. In RBA arm, is initiation of medication or another alternative therapy or hysterectomy while in LNG-IVS arm, is loop spontaneous expulsion or elective removal or initiation of alternative treatment modality. If women didn't complete PBAC score, SF-36 questionnaire to the end of the study, the patient's last measured response was applied to the subsequent scheduled observations for which data were not available[24].

Participants were randomly allocated into two groups (LNG-INS and RBA) in a 1 : 1 ratio using closed enveloped method. Women, data collectors were not blind to group assignment after randomization, as it was not possible.

A minimum sample of 35 women were required for each treatment arm (LNG-IUS or RBA), at study power of 80% (type 2 or beta error of 0.2) and 5% significance level (type I or Alpha error of 0.05) to detect difference of 30 point in PBAC score[20], assuming that PBAC score after RBA was be 40.2 ± 45[13] and as Herman et al. concluded from previous studies that up to 50 point difference in PBBAC score in women with HMB between treatment modalities was considered clinically significant[23]. To compensate for up to 20% dropout, 84 women were needed for this study.

The primary outcome measures of this study was evaluation the efficacy of RBA and LNG - IUS in reduction of HMB as measured with PBAC score and increase of hemoglobin values. Secondary outcome measures were the evaluation of the safety and satisfaction of RBA and LNG-IUS with SF-36 and 5 points satisfaction scale as well as procedures related complications treatment failures and need for hysterectomy over 2 year follow up period.

Statistical analysis were by intention to treat and were performed by statistical calculator and free trial of MedCalc easy - to - use statistical software for windows desktop (www.wedcolc.org) 2017 (MedCalc, software, bvba). Continuous variables were presented in terms of means, stander deviations and ranges while categorical variable are presented in terms of frequencies and percents. Student's t test for paired sample and independent samples were used to compare continuous variables as baseline demographic, clinical criteria, changes in PBAC score, changes in hemoglobin values and changes in SF-36 score. Fisher's exact test was used to compare categorical variables as amenorrhea rate and satisfaction rate. P values as well as mean difference with 95% confidence intervals (CIs) were used to determine

significance, $P < 0.05$ was considered statistically significant.

Results

In this trial, 110 women were assessed in gynecology outpatient clinic, twenty women (18.1% of women assessed) were excluded from this study while 6 (5.4%) women declined to participate. These 20 women were excluded as they had TVS abnormalities (9 women had submucous leiomyoma, 4 women had endometrial polyp, 3 has adenxal Mass and 4 women had atypical endometrial hyperplesia. Eighty - Four women were eligiable and were randomized into RBA group (42 women) and LNG - IUS (42 women). A study flow chart is shown in figure (1).

Table (1) presents the baseline demographic and clinical criteria of women included in trial of RBA versus LNG-IUS for treatment of HMB and shows no significant differences between both groups.

Objectively assessed menstrual blood loss measured by PBAC score was significantly decreased in both trial arms compared with the pre-intervention scores ($P < 0.0001$). At 3,6 months PBAC scores were significantly lower in RBA than LNG-IUS group but there were no significant difference between the two groups as regards PBAC scores at 12, 24 months as well as the means difference between pretreatment scores and 24 months scores. A similar trend was also noticed as regards the amenorrhea rates, as at 3 months the rate of amenorrhea was significantly higher in RBA group than LNG-IUS group while after that the rate of amenorrhea increase in ING-IUS group despite that it doesn't reach significant level (Table 2). Following RBA and ING-IUS, statistically significant increase in hemoglobin were noted during study period, in RBA group preoperative mean hemoglobin was 9.4 ± 1.4 g/dl raised to 12.9 ± 0.6 g/dl, at 24 months ($P < 0.0001$). While in ING - IUS group it was raised from 8.9 ± 1.3 g/dl to 12.7 ± 0.3 g/dl at the same study period ($P < 0.0001$). While there was no significant difference between both groups regards the mean rise in hemoglobin ($P = 0.34$), (Table 2).

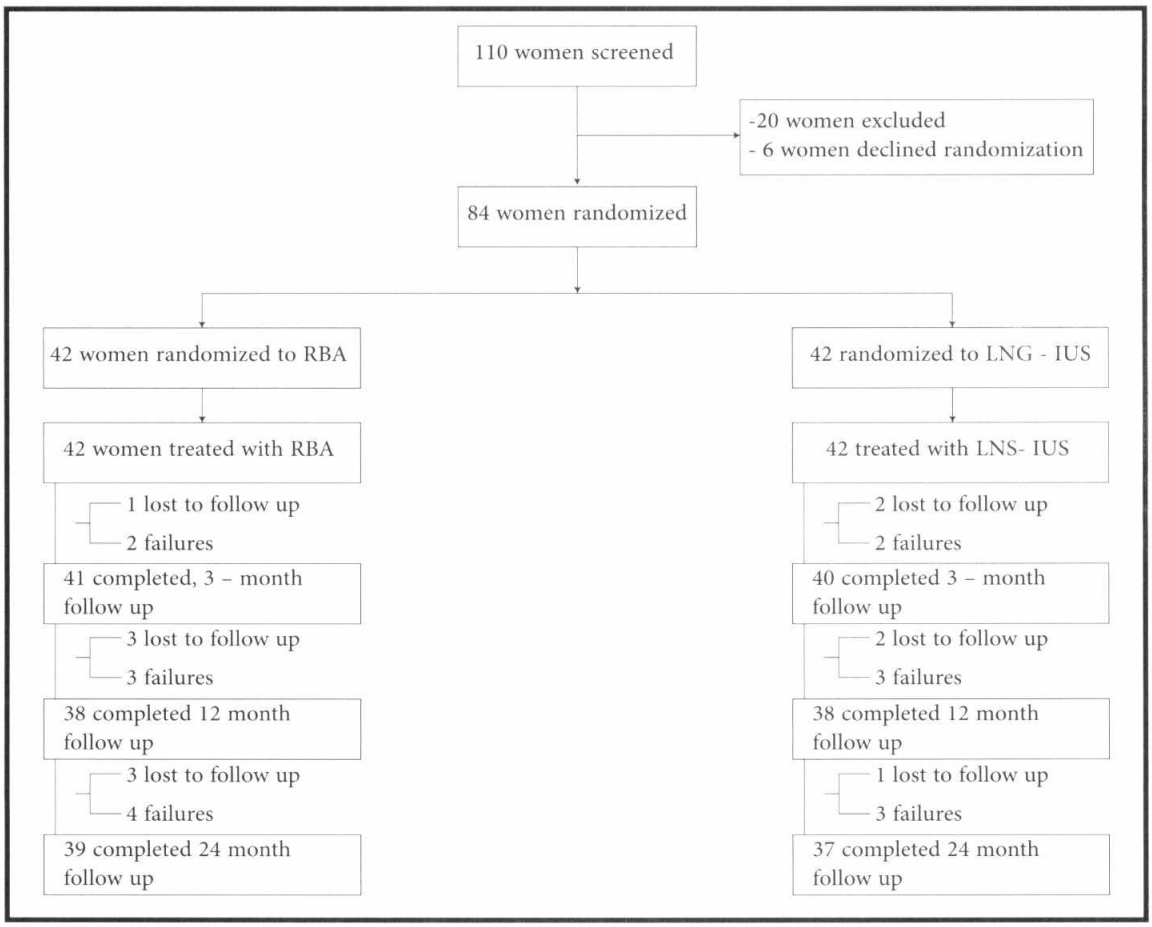
Table (3) presents testing of treatment arms regards their ability to maintain their efficacy in control HMB over time - frame of the trial. The results of repeated measures ANOVA with Tukey as a post test for each arm indicate that in both arms, when base line PBAC scores or hemoglobin values were compared to the following values, the variations among column medians during follow up are significantly larger than expected by chance ($P < 0.001$). Variations among column medians in LNG - IUS arm regards PBAC at 3 months versus 6 months ($P < 0.001$), 3 months versus 12 months ($P < 0.001$), 3 month versus 24 months ($P < 0.001$) indicating a slower stepwise efficacy in controlling HMB. Moreover, variations among column median as regards hemoglobin values at 3 months versus 6 months ($P < 0.001$), 3 months versus 12 months ($P < 0.001$) and 3 months versus 24 months ($P < 0.001$) indicating a slower stepwise increase in hemoglobin values in LNG-IUS arm.

Quality of life was evaluated with SF-36 questionnaire at enrollment, 3, 6, 12, 24 months. For women who failed the treatment and those whom lost to follow, the SF-36 at time of last evaluation was utilized in subsequent evaluation as a proxy for their quality of life had they continued with treatment. Table (4) presents mean SF-36 for overall and for each treatment arm and shows that both treatments improve quality of life starting from 3 months after treatment and maintained through the time frame of the study ($P < 0.0001$), however there were no significant differences between treatment at any evaluation point.

Participants evaluation regards satisfaction and recommendation of their treatment to her friend was presented in table (5) and shows that there were no statistically significant differences between the two treatment arms.

Treatments failures were evaluated at 3, 6, 12, 24 months as shown in figure (1). In RBA arm, nine (21.4%) treatment failures, two at 3 months, three at 12 months and four at 24 months, 8 (19%) of them with HMB and one with severe dysmenorrhea. In LNG-IUS there were 8 (19%) treatment failures two at 3 months due to ING-IUS expulsion while three (7.1%) at 12 months with election to remove the LNG-IUS due to unscheduled bleeding and 3 at 24 month due to HMB. Among, the eight treatment failures with ING-IUS arm, 3 (7.1%) opt to do EA with TCER during study period and five (11.9) choiced hysterectomy while in nine treatment failures with RBA, 6 (14.2%) underwent hysterectomy and three (7.1%) choiced to repeat EA with TCER during the study period. No complication from RBA procedures or LNG-IUS insertions were reported during study period.

Figure (1): RBA and LNG – IUS trial flow chart



Abbreviation: RBA: Rollerball ablation, **LNG-IUS**: levonorgestrel intrauterine system, **HMB** : Heavy menstrual bleeding.

Table (1): Baseline demographic and clinical criteria of women underwent RBA and LNG - IUS for treatment of HMB.

Variable	RBA (No = 42)	LNG-IUS (No = 42)	P value[a]
Age	41.23 ± 8.51 (35 - 45)	42.85 ± 6.32(36-44)	0.32
Parity	3.91 ± 1.82 (2 - 6)	3.45 ± 1.30 (2-7)	0.18
Body mass index (Kg/m2)	28.35 ± 4.61(23.30 - 35.50)	28.5±3.85(21.33 - 36.50)	0.87
Duration of menstrual flow (day)	8.6 ± 4.1 (5 – 17)	9.6 ± 4.6 (5 - 18)	0.29
PBAC score	534.3 ± 250.2 (210 - 850)	542.2 ± 215.2(260 - 830)	0.87
Duration of HMB (year)	1.85 ± 1.51 (0.35 - 5.2)	1.86 ± 1.35(0.6 - 4.6)	0.97
Hemoglobin gm/dl	9.4 ± 1.4 (8.2 - 10.16)	8.9 ± 1.3 (8.1 - 10.2)	0.09
Uterocervical length (cm)	8.60 ± 1.2 (8 - 10)	8.70 ± 1.2 (8 - 10)	0.09
Endometrial thickness at time of treatment (mm)	4.1 ± 3.3 (3 - 6)	7.8 ± 2.8 (6 - 10)	<0.0001*
SF – 36 score	56.8 ± 18.6 (40 - 70)	55.7 ± 16.8 (41- 72)	0.77

Abbreviations: **PBAC**: pictorial bleeding loss assessment chart, **RBA** : Rollorball ablation, **LNG-IUS** : levonorgestrel intrauterine system, **HMB**: heavy menstrual bleeding, SF-36: Short form – 36 questionnaire.

- Values: were given as mean ± standard deviation (range).
- P < 0.05 : statistically significant.

Table (2): Comparison of primary outcome (PBAC and hemoglobin changes) between RBA and LNG-IUS groups for treatment of HMB.

Variable	RBA (No = 42)	LNG-IUS (No = 42)	P value[a]
(1) PBAC - 3 months	36.6 ± 19.6	-62.7 ± 18.5	<0.0001, (95% CI: -34.3 to 17.82)
- 6 months	38.7 ± 18.4	-48.7 ± 13.5	0.005 (95% C.I: -17.0 to -2.99)
- 12 months	40.2 ± 16.5	- 44.2 ± 14.5	0.24
- 24 months	41.6 ± 14.6	- 41.3 ± 15.6	0.92
- Δ mean decrease in PBAC score	497.7 ± 180.8	479.5 ± 175.6	
Pvalue[b] comparing pretreatment with at 24 months	< 0.0001 (95% CI : -566.8 to-434.3)	< 0.0001 (95% CI:-569.9 to -416.03)	
(2) Hemoglobin g/dl - 3 months	11.8 ± 0.6	10.6 ± 0.9	<0.0001 (95% CI: -1.53 to - 0.86)
- 6 months	12.1 ± 0.7	11.8 ± 0.6	0.03 (95% CI: 0.58 to - 0.01)
- 12 months	12.6 ± 0.4	12.4 ± 0.4	0.02 (95% CI: -0.37 to -0.02)
- 24 months	12.9 ± 0.6	12.7 ± 0.3	0.05
- Δ mean increase in HB g/dl	3.5 ± 0.8	3.8 ± 1.9	0.34
Pvalue[b] comparing pretreatment with at 24 months	< 0.0001 (95% CI : 3.03 to 3.90)	< 0.0001 (95% CI: 3.39 to 4.20)	
(3) No(%) of women with amenorrhea - 3 months	9 (21.4%)	1 (2.3%)	0.0071 (95% CI : 4 - 34)
- 6 months	6 (14.2%)	4 (9.5%)	0.50
- 12 months	5 (11.9%)	7 (16.6%)	0.54
- 24 months	3 (7.1%)	9 (21.4%)	0.06

Abbreviations: **PBAC**: pictorial bleeding loss assessment chart, **RBA** : Rollorball ablation, **LNG-IUS**: levonorgestrel intrauterine system, **HMB**: heavy menstrual bleeding, SF-36: short form – 36 questionnaire, CI: Confidence interval, **Δ**: mean difference, **HB**: Hemoglobin.
- values were given as mean ± standard deviation or number (percents). as appropriate. .
- P < 0.05 : statistically significant.
(a) : t test of independent sample.
(b) : t test of paired sample.

Table (3): Comparison of RBA and LNG – IUS as regards PBAC scores and hemoglobin (g/dl) values within the time frame of the study (repeated – measures ANOVA).

	RBA (n = 42)				LNG-IUS (n = 42)			
	Δ↓ PBAC score	Pvalue	Δ ↑ HB.g/dl	P value	Δ↓ PBACscores	Pvalue	Δ↑ HB.g/dl	P value
Comparison of: -Baseline vs. 3months	497.7	<0.001	2.4	<0.001	479.5	<0.001	1.7	<0.001
-Baseline vs. 6months	495.6	<0.001	2.7	<0.001	493.5	<0.001	2.9	<0.001
-Baseline vs. 12months	494.1	<0.001	3.2	<0.001	498	<0.001	3.5	<0.001
-Baseline vs. 12months	492.7	<0.001	3.5	<0.001	500.9	<0.001	3.8	<0.001
-3 Month vs. 6months	-2.3	>0.05	0.3	>0.05	14	<0.05	1.2	<0.05
-3 Month vs. 12months	-3.6	>0.05	0.8	>0.05	18.5	<0.05	1.8	<0.05
-3 Month vs. 24months	-5	>0.05	1.1	>0.05	21.4	<0.05	2.1	<0.05
-12 Month vs. 24months	-1.4	>0.05	0.3	>0.05	2.9	>0.05	0.3	>0.05

Abbreviations: **PBAC**: pictorial bleeding loss assessment chart, **RBA** : Rollorball ablation, **LNG-IUS**: levonorgestrel intrauterine system, **Δ** : mean difference, ↑: increase, ↓: decrease, **AVOVA**: Analysis of variance, **HMB**: heavy menstrual bleeding, SF-36: short form – 36 questionnaire, **CI**: Confidence interval.
- values were given as mean ± standard deviation.
- **P < 0.05** : statistically significant.

Table (4): Quality of life comparison between RBA and LNG – IUS groups at randomization, 3, 6, 12, 24 months including treatment failures for treatment of HMB.

SF-36 scores	Overall (no = 84)	RBA (no = 42)	LNG – IUS (no = 42)	P value[a]
- Randomization	56.4±17.2(40 -72)	56.8 ±18.6(40-70)	55.7 ±16.8(41-72)	0.77
- 3 months	76.8±12.8(60-90)	75.9 ±13.8(61-89)	76.8 ±13.6(62-92)	0.76
- 6 Months	78.1±13.4(62-91)	77.6 ±14.6(61-89)	78.2 ±13.6(62-92)	0.85
- 12 months	75.8±14.2(62-86)	78.3 ±13.8(61-86)	74.3 ±14.6(63-93)	0.20
- 24 months	76.3±18.4(63-93)	74.2 ±18.6(64-94)	77.8 ±20.1(63-89)	0.39
- Δ mean increase in SF-36 scores	19.9 ± 4.2 (95% CI:14.4 - 25.3)	17.4 ±3.9 (95% CI:9.3-25.4)	22.1 ±5.6 (95% CI:14.0 -30.1)	
- at randomization vs 24 months (p value)[b]	< 0.0001	< 0.0001	< 0.0001	

Abbreviations: **RBA**: Rollorball ablation, **LNG-IUS**: levonorgestrel intrauterine system, **HMB:** heavy menstrual bleeding, SF-36: short form – 36 questionnaire, **CI**: Confidence interval.
- values were given as mean ± standard deviation (range).
- $P < 0.05$: statistically significant.
(a) : t test of independent sample.
(b) : t test of paired sample.

Table (5): Comparison the degree of patients satisfaction between RBA and LNG-IUS in treatment of HMB.

Variable	RBA (No = 42)	LNG-IUS (No = 42)	P value[a]
- Highly satisfied	11(26.1%)	7 (16.6)	0.29
- Satisfied	18 (42.8%)	21 (50%)	0.51
- Borderline	4 (9.5%)	3 (7.1%)	0.09
- Unsatisfied	4 (9.5%)	5 (11.9%)	0.72
- Highly unsatisfied	5 (11.9%)	6 (14.2%)	0.75

Abbreviations: **PBAC**: pictorial bleeding loss assessment chart, **RBA**: Rollorball ablation, **LNG-IUS**: levonorgestrel intrauterine system, **HMB**: heavy menstrual bleeding, SF-36: short form – 36 questionnaire.
- a values: were given as number (percents).
- $P < 0.05$: statistically significant.

Discussion

In this current prospective study two well known treatment modalities for HMB were compared directly to each other as after careful reviewing of literatures, direct comparison between hysteroscopic RBA and LNG-IUS couldn't be found. However there are numerous studies comparing LNG-IUS with hysteroscopic TCER[10, 16, 25, 26] as well as comparing LNG-IUS with 2nd generation EA procedures as thermal ballow ablation[15,17,18,19] and a current on going trial comparing LNG-IUS with Novasure EA[23].

The LNG - IUS is a T shaped polyethylene frame (32 mm x 32mm). Its vertical stem contain a 1:1 mixture of 52 mg of levonorgestrel (LNG) and polydimethsiloxane. Over 5 year, LNG – IUS delivers 20 mg LNG into uterine cavity, hence reach systemic circulation with steady serum level of 150 - 200 pg/ml, hence its systemic progestogenic side effects. The LNG - IUS induced endometrial atrophy resulting in controlling HMB beside its contraceptive effect as well as it major advantage over the EA procedures which is the reversibility[1,3,5,8,9,12].

Rollarball ablation is hysteroscopic EA procedure when compared to TCER it is less operator dependent as well as it is easier and with fewer associated sequels[1,4,5,27].

Assessment of RBA versus LNG-IUS through literatures could be made indirectly. Soysal et al.[13] as well as Loffer[28] comparing RBA versus TBA with thermochoice, the first in setting with myoma induced HMB while the second in setting of functional HMB. Both trials reporting that similar successful results obtained with both EA procedures at short term[13] as well as long term following[28].

Indirectly, the results of this trial are in agreement with that of Soysal et al.[19] where they compared LNG-IUS versus TBA on 72 women and they found that on 12 months post treatment the reduction of PBAC scores was significantly geater in TBA ($\Delta\downarrow$ PBAC 388.2 ± 21 versus 343 ± 27, $P < 0.001$). However no significant difference were reported as regards mean changes in hemoglobin values as well as regards health related quality of life as assessed by SF-36. However, Borrington et al.[17]

compared LNG-IUS versus TBA on 50 women and reported similar effectives of both procedures despite no significance difference regards PBAC score at 6 months post treatment. In this study hysterectomy rate after both procedures were equal 3/25 in LNG-IUS arm versus 5/25 in TBA arm. Busfield et al. randomized 83 women into LNG-IUS (42) and TBA (41) and reported results on 79 women as 3 were excluded. They found that both procedures were effective in control of HMB but the long term results in control of PBAC scores were significant with LNG-IUS when compared TBA (mean PBAC at 24 months 20 ± 28.8 versus 75 ± 91 with P = 0.002). However similar results with no significance difference were reported on quality of life assessed with SF-36 questionnaire.

Also, Soysal and Soysal[29] compared 32 insertions of LNS-IUS with 32 historical control of TBA in selected case of myoma-related HMB and they reported that slower step wise reduction in PBAC scores as well as a slower stepwise increase in hemoglobin values in LNG-IUD arm but they reported earlier significant difference in reduction of PBAc scores and increase in hemoglobin values at 3 months post treatment evaluation despite no significant difference as regards this items in repeated follow up at 6 and 12 months. The earlier results in favor of RBA in this study could be explained by pretreatment induction of Endometrial thinking in RBA arm while the slower stepwise effect in LNG-IUS arm may be related to the additive temporal effects of sustained release of LNG on the endometrium as the local antiproliferative effect of LNG increases over time results in bleeding decreases over time.

Hysterectomy is gold stander in achieving 100% cessation of HMB when compared to Medical or conservative procedures, However randomized studies on quality of life reported higher improvement in LNG-IUS arm inspite of continuing bleeding[29]. Trials comparing LNG-IUS with hysterectomy[30, 31], found despite that 50 (42%) of 119 women randomized to LNG-IUS eventually underwent hysterectomy the satisfaction rates were similar in both groups. In this trials the rates of hysterectomy were similar between both groups and the overall rates of hysterectomy 11/82 (13%) is less than this reported in trials of hysterectomy versus LNC-IUS as women in the study comparing hysterectomy with LNG- IUS were willing to consider hysterectomy at trial entery and so they were a different population from those entering a trial evaluating conservative ablation therapy, namely RBA with LNG-IUS. A systematic review of five randomized controlled trials comparing TCER with hysterectomy[6] found that both procedures are effective and satisfaction rates are high in both, despite that hysterectomy is with high complications, sequales and costs[6]. Several trials compared second generation EA with TCEA and RBA[13,28, 32, 33, 34, 35, 36] and not shown any significant difference in term of efficacy.

This trial was randomized prospective controlled study covering the direct comparison between RBA and LNG - IUS and extend to 24 months follow when compared to Most randomized and observational studies which were relatively small and with relatively shorter duration of follow up which usually 12 months. However, this trials may be under powered to detect other items may be important to be evaluated regard LNG-IUS as expulsion rates and hysterectomy rates differences between EA procedures and LNG – IUS insertions for treatment of HMB.

Conclusion

This study has shown the LNG – IUS insertion results in comparable stepwise decrease in mean PBAC scores as well as increase in hemoglobin values when compared to RBA. Also both treatment modalities are associated with similar high level of patient satisfaction and quality of life. Furthermore, up to 13% of women treated with this modalities for HMB underwent hysterectomy. Neither treatment of them is superior to other in term of efficacy, safety and satisfaction, and treatment choice should be tailored base on surgeon skill, as well as the individual women preference.

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