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(5).

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 chosen 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 sonohysterography 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\textsuperscript{(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 hystromat of KARI 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 LNG-IUS insertions to assess the menstrual blood loss by PBAC score\textsuperscript{(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\textsuperscript{(21, 22)} and patient’s satisfaction 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-IUS 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\textsuperscript{(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 1 or Alpha error of 0.05) to detect difference of 30 point in PBAC score\textsuperscript{(20)} assuming that PBAC score after RBA was be 40.2 ± 45\textsuperscript{(13)} and as Herman et al. concluded from previous studies that up to 50 point difference in PBAC score in women with HMB between treatment modalities was considered clinically significant\textsuperscript{(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 adnexal Mass and 4 women had atypical endometrial hyperplasia). Eighty - Four women were eligible 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 $9.4 \pm 1.4 \text{ g/dl}$ raised to $12.9 \pm 0.6 \text{ g/dl}$, at 24 months ($P < 0.0001$). While in ING-IUS group it was raised from $8.9 \pm 1.3 \text{ g/dl}$ to $12.7 \pm 0.3 \text{ g/dl}$ 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 efficiecy 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 LNG-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) chose hysterectomy while in nine treatment failures with RBA, 6 (14.2%) underwent hysterectomy and three (7.1%) chosen to repeat EA with TCER during the study period. No complication from RBA procedures or LNG-IUS insertions were reported during study period.
110 women screened
-20 women excluded
-6 women declined randomization
84 women randomized

42 women randomized to RBA
-1 lost to follow up
-2 failures
41 completed, 3-month follow up
-3 lost to follow up
-3 failures
38 completed 12 month follow up
-3 lost to follow up
-4 failures
39 completed 24 month follow up

42 randomized to LNG - IUS
-2 lost to follow up
-2 failures
40 completed 3-month follow up
-2 lost to follow up
-3 failures
38 completed 12 month follow up
-1 lost to follow up
-3 failures
37 completed 24 month follow up

**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.

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

**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.

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

**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).

<table>
<thead>
<tr>
<th></th>
<th>RBA (n = 42)</th>
<th>LNG-IUS (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Δ↑ PBAC score</td>
<td>P value</td>
</tr>
<tr>
<td>Comparison of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Baseline vs. 3months</td>
<td>497.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Baseline vs. 6months</td>
<td>495.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Baseline vs. 12months</td>
<td>494.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Baseline vs. 12months</td>
<td>492.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- 3 Month vs. 6months</td>
<td>-2.3</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>- 3 Month vs. 12months</td>
<td>-3.6</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>- 3 Month vs. 24months</td>
<td>-5</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>- 12 Month vs. 24months</td>
<td>-1.4</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

- 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.

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>RBA (No = 42)</th>
<th>LNG-IUS (No = 42)</th>
<th>P value(^{(a)})</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Highly satisfied</td>
<td>11 (26.1%)</td>
<td>7 (16.6%)</td>
<td>0.29</td>
</tr>
<tr>
<td>- Satisfied</td>
<td>18 (42.8%)</td>
<td>21 (50%)</td>
<td>0.51</td>
</tr>
<tr>
<td>- Borderline</td>
<td>4 (9.5%)</td>
<td>3 (7.1%)</td>
<td>0.09</td>
</tr>
<tr>
<td>- Unsatisfied</td>
<td>4 (9.5%)</td>
<td>5 (11.9%)</td>
<td>0.72</td>
</tr>
<tr>
<td>- Highly unsatisfied</td>
<td>5 (11.9%)</td>
<td>6 (14.2%)</td>
<td>0.75</td>
</tr>
</tbody>
</table>

**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 progestostogenic 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\(^{(1, 3, 5, 8, 9, 12)}\).

Rollorball ablation is hysteroscopic EA procedure when compared to TCER it is less operator dependent as well as it is easier and with fewer associated sequel\(^{(1, 4, 5, 27)}\).

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 thermochoic, 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 (\(\Delta\) 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.\(^{(17)}\)
Mohamed Farag El Sherbeny
compared LNG-IUS versus TBA on 50 women
and reported similar effective 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
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
to 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 in spite of
continuing bleeding(20). Trials comparing LNG-
IUS with hysterectomy(20, 31), found despiate 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 entry
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(13,26, 32, 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.

Acknowledgement : The author want to thank
his colleges, fellows, patients and data collectors
whom helping him in completing this study.

References
1. Middleton LJ, Champaneria R, Daniels JP,
Bhattacharya S, Cooper KG, Hilkin NH, et
al. Hysterectomy, endometrial destruction,
levonorgestrel releasing intrauterine system
(Mirena) for heavy menstrual bleeding : systematic
review and meta - analysis of data from individual
2. Munro MG, Critchley HO, Broder MS, et al.
FIGO classification system (PALM - COEIN) for
causes of abnormal uterine bleeding in nongravid
women of reproductive age. Int J Gynaecol Obstet
2011; 113 : 3 - 13.


25. Bongers MY, Mol BW: Thermal balloon ablation versus endometrial resection for treatment of...


