Author Year	Study design	Population	Results	Strengths	Weaknesses	Quality
Tasci, 2008 *New evidence*	Prospective observational study Location: Turkey Age range: 32-53 Follow-up time: 12 months	46 women with menorrhagia who had completed their families and had no contraindications to using the IUD	<u>Hemoglobin:</u> At 12 months mean hemoglobin level increased 2.09±1.97 g/dL (p=0.000) Baseline hb: 11.13±1.61 12 months: 13.22±1.50 Mean increase in hematocrit 3.98±5.6 <u>Amenorrhea:</u> 67.4% (n=31) developed amenorrhea or hypomenhorrhea at 1 year <u>Fibroids:</u> In 25 fibroid cases (54%) 20 women saw a decrease in myoma volume (p=0.04, negative difference: n=20)	Adequate follow-up time Measurement of hormones Prospective No loss to follow-up	Small sample size No comparison group Doesn't define menorrhagia Did not report side effects	II-3, poor
Chattopdhyay, 2011 *New evidence*	Prospective observational study Location: India Age range: 35-55 Follow-up time: 36 months	42 women age 35-55 with menorrhagia and without organic pelvic pathology	<u>PBAC:</u> Significant reduction in PBAC after 3 months (p<0.001) and continued reductions through 36 months <u>Dysmenorrhea:</u> 85% of patients were relieved of dysmenorrhea by month 3 and the rest at 6 months <u>Amenorrhea:</u> 40.74% of patients had amenorrhea by 1 year, however 2.63% had heavy bleeding at the end of 6 months <u>Hb levels:</u> Significant improvement (p<0.001), maximum improvement seen at 12 months from mean 9.8 to 12.13	Prospective Detailed inclusion/exclusion criteria Objective measurement of menorrhagia Adequate follow-up time	Large loss to follow-up No side effects reported Small sample size Little information on drop outs No comparison group	II-3, poor
Desai, 2012 *New*	Prospective observational study	40 women age 41-50 with menorrhagia due to benign causes	<u>Menstrual pattern:</u> At 3 months: 7.5% (n=3) had regular cycles 60% (n=24) had spotting	Prospective Detailed description of	Small sample size No comparison	II-3, poor

evidence	Location: India Age range: 41-50 Follow-up time: 12 months		12.5% (n=5) had infrequent cycles with scanty menstruation 20% (n=8) had HMB At 6 months 32.5% (n=13) had spotting 27.5% (n=11) had infrequent cycles with scanty menses 22.5% (n=9) had amenorrhea 7.5% (n=3) had HMB At 12 months 32.5% (n=13) were spotting 27.5% (n=11) had infrequent cycles with scanty menses 22.5% (n=9) had amenorrhea <u>Expulsions and removals:</u> 4 IUDs (10%) were expelled with clots within 6 months	continuations Detailed inclusion/exclusion criteria	group No side effects reported Data relies on self-report Older age range	
Endrikat, 2009 *New evidence*	Randomized control trial LNG-IUS: 20 women—only reporting this arm Oral contraceptive: 19 women Location: Canada Age range: over 30 Follow-up time: 12 months	39 healthy women with menorrhagia.	<u>PBAC:</u> MBL w/IUS declined significantly from baseline to 12 months ($p<0.001$). LNG-IUS median score decreased from 228 to 13 (mean change 83%) <u>Hemoglobin:</u> Significant increase ($p<0.001$). LNG-IUS mean increase from 126 to 134 g/L at 12 months. <u>Menorrhagia severity:</u> Decreased severity in every group At 6 months LNG-IUS significantly lower ($p=0.045$) <u>Adverse effects:</u> 1 person in LNG-IUS had an inguinal hernia that was considered non-treatment related.	Defines menorrhagia Detailed inclusion/exclusion criteria Prospective Randomized Side effects and adverse effects reported Adequate follow-up time	Small sample size	II-3, good Only grading on LNG-IUS arm

Goni, 2009 *New evidence*	Prospective observational study Location: Spain Age range: mean 44.3 Follow-up time: 12 months	82 women with idiopathic menorrhagia that were indicated to have a hysterectomy but inserted an LNG-IUS instead	<u>Duration of cycle:</u> Increased from 26.9 to 52.6 days by 12 months ($p<0.0001$) <u>Number of days of bleeding per cycle:</u> Decreased from 8.9 to 5.0 days by 12 months ($p<0.0001$) <u>Number of sanitary measures:</u> Decreased from 29.3 to 8.1 by 12 months ($p<0.0001$) <u>Intensity of bleeding:</u> 98.8% reported intense bleeding at baseline to 6.4% by 12 months. 81.0% reported no or scarce bleeding by 12 months and 86.9% reported no limitations in daily activities. After 1 year 15.9% of women developed amenorrhea <u>Hemoglobin:</u> Increased from 11.0 to 13.0 g/dl at 1 year ($p<0.0001$) <u>Ferritin:</u> Increased from 17.4 to 43.6 ng/ml at 1 year ($p<0.0001$) Expulsion (n=3)	Prospective Defines menorrhagia Detailed inclusion/exclusion criteria Large sample size Adequate follow-up time Adverse effects and side effects reported Detailed description of women who discontinued the LNG-IUS	Bleeding measured by self-report No comparison group	II-3, good
Gorgen, 2008 *New evidence*	Prospective observational study Location: Turkey Age range: 26-55 Follow up-time: 6 months	66 premenopausal women who had sought care in the previous year for menorrhagia	<u>PBAC:</u> Significantly decreased ($p<0.001$) from mean 150.88 to 38.95 by 6 months, a 74% decrease <u>Adverse effects:</u> 46.6% reported no adverse effects. 16.7% had spotting and 13.3% had pelvic pain <u>VAS scores:</u> -Pelvic pain: decreased from 4.32 to 3.55	Detailed inclusion/exclusion criteria Adverse effects reported Prospective	No definition of menorrhagia Short follow-up time No confirmation of medical records No comparison	II-3, very poor

			(p=0.024)		group	
Gupta, 2006 *New evidence*	Prospective cohort study Groups: LNG-IUS: 25 women—only reporting on this arm TCRE: 25 women Location: India Age Range: mean 39.24 Follow-up time: 12 months	50 healthy women with a PBAC score of 100 or greater who had been unresponsive to oral or injectable hormonal and nonhormonal treatment for at least 1 year	<u>PBAC:</u> Reduction at 12 months, 98.6% for LNG-IUS From 463.86 in LNG-IUS to 14.53 <u>Hemoglobin levels:</u> Significant increase in levels at 6 and 12 months (p=0.024), At 12 months concentrations increased by 5.5% in LNG-IUS group (from 11.60 to 12.24 g/dL in LNG-IUS) <u>Expulsions:</u> 2 expulsions	Comparative study—1st to compare LNG-IUS with TCRE in developing country Detailed inclusion/exclusion criteria Confirmation of menorrhagia (PBAC score > 100) among participants prior to entry into study Detailed drop-out information	Small sample size No discussion of confounding Homogenous population	II-3, fair Only grading on LNG-IUS arm
Gupta, 2013 *New evidence*	Randomized control trial Groups: LNG-IUS: 285 women Other medical treatments: 286 women Location: United Kingdom Age Range: 25-50 Follow-up time:	571 women with menorrhagia reported in at least 3 consecutive menstrual cycles	<u>MMAS:</u> Improved significantly by 13.4 points over 2 years Benefit of LNG-IUS greater in women with BMI>25 (p<0.001)	Large sample size Long follow-up time Detailed inclusion/exclusion criteria	MMAS data from self-report Treatments could be switched if patient desired, and a large number of women did switch Number of adverse events reported but no description	II-3, very poor Only grading on LNG-IUS arm

	24 months				No definition of serious adverse events	
Koh, 2006 *New evidence*	Prospective observational study Location: Singapore Age range: 30-49 Follow-up time: 6 months	41 healthy, parous women with menorrhagia (PBAC > 100) for at least 2 consecutive cycles before the study	<u>MBL:</u> Menorrhagia reduced 61% (26/41) by 1st month, 88% (35/41) at 3 months and 100% (41/41) after 6 months. At 6 months 39% (16/41) women became amenorrhoeic <u>Hb and hematocrit:</u> Increase in Hb from 117 g/L at baseline to 136. (p=0.01)Hematocrit increased from 0.37 to 0.40 at 6 months (p=0.05)	Detailed inclusion/exclusion criteria Confirmation of menorrhagia (PBAC score> 100) among participants prior to study entry Detailed outcome measurements	Sparse data on characteristics of populations, aside from outcome measurements Small sample size Short follow-up time	II-3, fair
Lee, 2013 *New evidence*	Prospective cohort study Groups: LNG-IUS: 483 women Conventional Medical Therapies: 164 women Location: Various clinics in China, Taiwan, Hong Kong, Indonesia, Malaysia, Pakistan, Korea, and Thailand Age range: 18-45	647 healthy women age 18-45 diagnosed with HMB	<u>Bleeding pattern:</u> LNG-IUS by 12 months: -Number of bleeding days reduced by mean 4.0 days -Number of spotting days reduced by mean 0.3 days -Dysmenorrhea remission in 76.1% of women (n=363) -PMS resolved in 77.6% of women (n=337) -HMB persisted in 2.1% of women (n=10) <u>Adverse effects:</u> 4.6% device related complications (17 expulsions, 2 dislocations, and 1 breakage)	Detailed inclusion/exclusion criteria Comparison group Large sample size Adverse events reported	Imbalanced populations in groups No definition of menorrhagia Outcomes based on “validated” patient questionnaire—no explanation of what this means Widespread population, no knowledge of how clinics diagnose menorrhagia	II-3, poor Only grading on LNG-IUS arm

	Follow-up time: 12 months					
Lete, 2008 *New evidence*	Prospective observational study Location: Spain Age range: mean 43.13 Follow-up time: 12 months	225 women with idiopathic menorrhagia	<u>Bleeding:</u> -Cycle length: increased from 26.16 days at baseline to 29.17 days at 1 year (p=0.0077) -Number of sanitary products: decreased from 30.34 to 8.97 at 1 year (p<0.0001) -Number of bleeding days: decreased from 7.60 to 4.69 at 1 year (p<0.0001) <u>Hb and S-Fe:</u> Increase in hb from 11.72 to 13.33 g/dL and increase in ferritin from 16.73 to 42.70 ng/mL at 1 year	Large sample size Adequate follow-up time Prospective Adverse events reported	No definition of menorrhagia Data based on self-report No comparison group No inclusion/exclusion criteria reported	II-3, poor
Malgalhaes, 2007 *New evidence*	Prospective cohort Groups: LNG-IUS for women with idiopathic menorrhagia (n=32) LNG-IUS for women with menorrhagia due to uterine leiomyomas (n=27) LNG-IUS for women desiring contraception (n=28) Location: Brazil Age range: 21-51	87 women with menorrhagia Conducted in private gynecological clinic Excluded women with history of PID in preceding 2 years and those at risk or with previous history of STIs	<u>Menstrual bleeding patterns:</u> After 36 months amenorrhea and oligomenorrhea were most frequent patterns, occurring in 45-57% and 33-39% of users in 3 groups, respectively; amenorrhea was higher in contraception group (57.1%) and in women with idiopathic menorrhagia (53.4%) than women in group with menorrhagia due to leiomyomas (44.5%) (p=0.27) Prevalence of spotting approx. 3 times higher (11%) in women with menorrhagia caused by leiomyomas and nearly double (7.7%) in women with idiopathic menorrhagia compared with control group (4%) p=0.24	Detailed inclusion/exclusion criteria; detailed measurement assessments of criteria Comparative study with control group Detailed follow-up	Lack of measurement of menorrhagia Homogenous population No discussion of confounding	II-3, fair Only grading on idiopathic menorrhagia arm

	Follow-up time: 36 months					
Sesti, 2012 *New evidence*	Randomized control trial Groups: LNG-IUS: 36 women LSH: 36 women LSH: Laparoscopic supracervical hysterectomy Location: Italy Age range: 35-50 Follow-up time: 24 months	72 healthy premenopausal women with menorrhagia that was unresponsive to other medical treatment and had no desire for more children	<u>PBAC:</u> Significantly reduced <u>Bleeding patterns:</u> -Spotting: At 24 months 5 women in LNG-IUS group (13.9%) reported spotting -Amenorrhea: At 24 months 1 (2.8%) LNG-IUS woman was amenorrhoeic. -LNG-IUS group had significant improvement in bleeding frequency and length (p=0.000) at 3 and 6 months. At 12 months 10 women (27.8%) reported an even more reduced bleeding frequency and length. At 24 months patients reported an increased bleeding frequency and length from 3 months. (p=0.000) <u>Hb:</u> Both groups were significantly improved. At 3, 6, 12, and 24 months LSH group had more significant improvement	Detailed inclusion/exclusion criteria Detailed operation procedure Adequate follow-up time Defines menorrhagia	Some data from self-report	II-3, good Only grading on LNG-IUS arm
Silva-Filho, 2012 *New evidence*	Prospective randomized control trial Groups: LNG-IUS. 30 women TBA: 28 women TBS: thermal balloon ablation Location: Brazil Age range: Over	58 healthy women with menorrhagia that has been unresponsive to other treatment Five year follow-up of treatment	<u>Hb:</u> LNG-IUS hb increased from 12.5±0.3 to 14.41±0.3 g/dL (p=0.0056) <u>Bleeding pattern:</u> -LNG-IUS associated with less MBL after 5 years (p=0.001) -LNG-IUS: No patients had increased MBL and 35.3% had amenorrhea	Detailed inclusion/exclusion criteria Detailed treatment methods Accounts for development of menopause	No adverse effects reported Data relies on patient self-report	II-3, fair Only grading on LNG-IUS arm

	35 Follow-up time: 5 years (follow-up of previous study)					
Shabaan, 2011 *New evidence*	Prospective randomized control trial Groups: LNG-IUS : 56 women—only reporting on this arm COC: 56 women Location: Egypt Age range: 20-50 Follow-up time: 12 months	112 women complaining of excessive menstruation	<u>Expulsions:</u> 1 expulsion <u>Menstrual blood loss:</u> Reduction significantly higher at 12 months in LNG-IUS group (p=0.013) with alkaline hematin method MBL reduced from 300 mL at baseline to 44.4 mL at 12 months for LNG-IUS group PBAC reductions significantly higher in LNG-IUS group at 12 months (p<0.001)	Detailed exclusion criteria Small loss to follow-up Objective measurement of blood loss	Menorrhagia not confirmed by a physician and not defined Measured hemoglobin and serum ferritin but did not report on them No report on adverse effects	II-3, poor Only grading on LNG-IUS arm
Kaunitz, 2010 and Kaunitz, 2012 (follow-up to 2010 study) *New evidence*	Randomized control trial Groups: LNG-IUS: 82 women—only following this arm Oral medroxyprogesterone acetate: 83 women Location: USA Age range: over	165 women with idiopathic heavy menstrual bleeding, 80 mL blood loss or more per cycle	<u>MBL:</u> Significantly greater reductions in LNG-IUS group. 80% of women experience a 70% decrease by 6 months Average decrease 128.8 mL <u>Adverse effects:</u> No deaths or serious adverse effects 2 partial expulsions 2 full expulsions <u>Hemoglobin levels:</u> Increased from 12.4 g/dL to 13.4 <u>Serum ferritin:</u> Increased from 19.0 mcg/L to 34.0	Defines menorrhagia Detailed exclusion criteria Reported adverse effects	Short follow-up time	II-3, good

	18 Follow-up time: 6 months					
Palmara, 2013 *New evidence*	Prospective observational study Location: Italy Age range: 29-44 (premenopausal) Follow-up time: 12 months	40 women, 24 premenopausal and 16 postmenopausal. The 24 women had idiopathic AUB or endometrial hyperplasia Only reporting on premenopausal women	<u>Efficacy:</u> For fertile women, at 6 months 72.7% (n=16) reported a regular menstrual cycle and 13.6% (n=3) reported intermenstrual spotting. 13.6% (n=3) of women reported amenorrhea At 12 months 68.2% (n=15) reported regular menstrual cycle and 0 women reported intermenstrual spotting. 31.8% (n=7) reported amenorrhea.	Adequate follow-up time	Small sample size No comparison group Menorrhagia not defined Side effects not reported Includes postmenopausal women	II-3, very poor
Kriplani, 2007 *New evidence*	Prospective observational study Location: India Age range: 29-52 Follow-up time: 36 months	63 Indian women age 29-52 with idiopathic menorrhagia or menorrhagia due to uterine fibroids	<u>Expulsion:</u> Expelled in 6 patients (9.5%), twice in 2 patients <u>Menstrual blood loss:</u> 3 months: menorrhagia cured in 35 patients (77.7%) 36 months: cured in all patients By 1 month: Significant decrease in mean number of bleeding days (p=0.01) and mean PBAC score (p=0.00) and further reductions as time went on 18 patients developed amenorrhea (28.6%) <u>Dysmenorrhea:</u> Completely relieved in 31 of 40 patients (77.5%) at 3 months At 24 months no dysmenorrhea in any patient	Detailed exclusion criteria Objective measurement of blood loss	Very little description of patients' symptoms before intervention No definition of menorrhagia	II-3, good

			Hemoglobin levels: Significant mean increase (1.06±1.7 gm/dL, p=0.000) by 12 months Outcome in patients with fibroids: 25 patients had fibroids. 3 (12%) developed menorrhagia, 10 (40%) had intermenstrual spotting that stopped between 3 and 6 months 3 expulsions (12%)			
Shaw, 2007 *New evidence*	Randomized control trial 33 women randomized to TBA 33 women randomized to LNG-IUS—only recording LNG-IUS arm Location: United Kingdom Age range: 25-49 Follow-up time: 12 months	66 women with idiopathic menorrhagia for whom oral medication had failed	PBAC: Significant decrease in median scores during 12 months of follow up (p<0.001) At 9 and 12 months no patient had a PBAC score greater than 120 Hb and serum ferritin: Hb levels rose by 6 months from 12.1±1.7 g/dL to 12.8±.6 Serum ferritin levels rose by 6 months from 18.4±10.1 mg/L to 19.8±9.7 Bleeding patterns: 6 of 23 patients had amenorrhea at 12 months (26%) At 3 and 6 months median number of days of bleeding was 14.6 At 9 and 12 months median number of days of bleeding was 4.2	Defines menorrhagia Detailed inclusion and exclusion criteria	Hb and serum ferritin not reported at 12 months	I, fair
De Souza, 2010 *New evidence*	Randomized control trial LNG-IUS: 30 women—only reporting on this arm TBA: 28 women	58 women with idiopathic menorrhagia	Hb levels: Significant increase by 12 months (p<0.001) Menstrual blood loss: Significant reduction in blood loss by 12 months (p<0.001)	Menorrhagia confirmed by objective testing	Very little data provided Baseline characteristics reported poorly	II-3, very poor Only grading on LNG-IUS arm

	Location: Brazil Age range: mean 41.9 Follow-up time: 12 months					
Ghazizadeh, 2011 *New evidence*	Randomized control trial LNG-IUS: 52 women—only reporting on LNG-IUS group TCRE: 52 women Location: Iran Age range: 35-45 Follow-up time: 12 months	104 women age 35-45 with menorrhagia	PBAC: Significantly decreased at 6 and 12 months ($p<0.0001$) Score at 6 months was 60.38±110.65 Amenorrhea: 11.1% Spotting: 6 patients (12.7) reported spotting Expulsions: 9 patients	Detailed inclusion and exclusion criteria	Mixed population of women suffering from menorrhagia caused by different medical conditions	II-3, fair Only grading on LNG-IUS arm
Theodoridis, 2009 *New evidence*	Non-randomized control trial LNG-IUS: 42 women—only reporting on this arm Endometrial thermal rollerball ablation: 37 women Location: Greece Age range: mean	79 Greek women with idiopathic menorrhagia	Duration of uterine bleeding: Baseline: 6.8 days 6 months: 2.7 days 12 months: 2.2 days		Very little data	II-3, very poor

	37.3 Follow-up time: 12 months					
Yazbeck, 2006 *New evidence*	Prospective observational study 1999 – 2000 10 centers in France Age range: mean 43 ± 5.3 years Follow-up time: 36 months	52 women presenting with menorrhagia resistant to treatment without contraindications for LNG-IUD use	Data available: 42 at 6 months; 40 at 12 months; 20 at 24 months & 14 women at 3 years Four patients discontinued LNG-IUS and had surgery during 1st year. <u>PBAC Score</u> Score declined from 254.0 to 23.5 from baseline to 6 months. 36 (86.7%) women experienced at least ≥ 60% decline in PBAC score in first 6 months. Score stabilized between 6-12 months. <u>Hemoglobin (g/dl)</u> Baseline mean: 12.9±1.3 12 months: 14.0±1.1, p<0.001 <u>Ferritin (ng/ml)</u> Baseline mean: 27.4±25.5 12 months: 45.4±27.3, p<0.01 <u>Dysmenorrhea</u> Baseline: n=25/44 (56.8%) 6 months: n=5/40 (12.5%) 12 months: n=5/32 (15.6%), p<0.001	Clear inclusion and exclusion criteria Prospective evaluation Provided power calculation	Loss to follow up during all periods Needed 52 women to demonstrate benefit of avoiding surgery, but only 42 women with data at 12 months	II-3, fair
Tam, 2006 *New evidence*	Randomized control trial LNG-IUS: 22 women—only following this arm Thermal balloon endometrial	44 women with menorrhagia that failed to respond to conventional medical therapy	<u>Bleeding pattern:</u> 5 women (33.3%) remained menorrhagic 0 women had amenorrhea 2 women had spotting (13.3%) 4 women had hypomenorrhea (26.7%) 4 women had normal bleeding (26.7%) <u>Expulsions:</u> 2 expulsions (11%)	Adequate follow-up time	No confirmed diagnosis of menorrhagia Small sample size No definition of menorrhagia	II-3, very poor

	ablation: 22 women Location: Hong Kong Age range: Over 40 Follow-up time: 12 months		<u>Hemoglobin levels:</u> Significant improvement at 12 months From 9.3 g/dL to 10.3		No objective measurement of bleeding No description of how bleeding was measured No follow-up appointments before 1 year	
Busfield 2006	<u>Design</u> Randomized comparative trial <u>2 Groups:</u> LNG IUS: 42 women Thermal Balloon Ablation (TBA): 41 women <u>Location</u> New Zealand <u>Follow-up</u> 24 months	<u>Characteristics</u> 42 women in the LNG-IUS group with the age distributions: 16.7% less than 40 years, 50.0% between 40 and 44 years, and 33.3% between 45 and 49 years, with self-described heavy menstrual bleeding, and did not have any ultrasound, laboratory or hysteroscopic abonormalities.	<u>Menstrual Status Trends</u> <u>(Baseline n=42, Follow-up n=40, excluding treatment failures)</u> 1 Serious complication: actinomycoses <u>Total PBAC Score:</u> Significant decrease from baseline to follow-up: Mean, (SD) Baseline: 490 (419) 3 months: 125.0 (198.5) 6 months: 72.1 (118.6) 12 months: 41.1 (86.5) 24 months: 20.6 (28.8) <u>Amenorrhea:</u> Increase from baseline to follow-up: (n, %) 3 months: 2 (5.6) 6 months: 3 (9.4) 12 months: 6 (20) 24 months: 9 (35) <u>Menstrual Symptoms Trends</u> <u>(Baseline n=42, Follow-up n=40, excluding treatment failures)</u> <u>Number Days of Heavy Bleeding: Mean (SD),</u> *=significant change Decrease from baseline to follow-up (which plateau)		54.8% of participants had undergone sterilization or vasectomy, thus a large percentage of the study population did not use this method for contraceptive purposes Did not account for possible onset of menopause during trial No objective measure of 'heavy bleeding' provided	II-3, fair

			Baseline: 3.8 (2.0) 3 months*: .4 (1.0) 12 months: .5 (1.3) 24 months: .3 (.8)			
Reid 2005	Design Randomized comparative trial 2 Groups: LNG IUS Mefenamic acid Location United Kingdom Follow-up 6 cycles Dates May 1996- December 1998	Characteristics 51 women with a mean age of 39.4±4.4 years in the LNG IUS group and 38.5±4.2 years in the mefenamic acid group with objectively proven idiopathic uterine bleeding (menstrual blood loss of ≥ 80 mL) Initial Distribution LNG IUS: 25 Mefenamic acid: 26	0 Lost to follow-up Discontinuations (n=4) Partial expulsions: 2 Complete expulsion: 2 Median Menstrual Blood Loss (significant difference between each time period p<.005) Baseline: 122 (81-375) Cycle 3: 12 (0-240) Cycle 6: 5 (0-45) Total Menstrual Fluid Loss (significant difference between each time period p<.005) Baseline: 183 (103-527) Cycle 3: 53 (0-459) Cycle 6: 27 (0-156) PBAC Score (significant difference between each time period p<.005) Baseline: 240 (91-545) Cycle 3: 49 (0-286) Cycle 6: 25 (0-402) 2 serious adverse events: 1) Hypertension (strong family history) 2) Chlamydial Endometritis	Objective confirmation of menorrhagia among participants prior to entrance in to study	Sparse baseline characteristics of participants provided	II-3, fair
Hurskainen 2004 Hurskainen 2001	Design RCT: LNG-IUS v hysterectomy Follow-up 6 months	Characteristics: 236 women ages 35-49 Complaints of menorrhagia, completed desired family size	LNG-IUS Group Bleeding Patterns 43 (75%) amenorrhea or oligomenorrhea 11 (19%) irregular bleeding 3 (6%) scanty bleeding Mean MBL	Detailed methodology provided (scales used, recruitment, etc) Detailed drop-	Only 58% of study participants had objective menorrhagia according to study criteria	II-3, fair

	12 months 5 years Location Finland Dates 10/1/94-10/6/2002	Distribution 119 LNG-IUS 117 Hysterectomy	only 4 had enough bleeding pattern to submit samples at 5 years baseline: 130mL ± 116 follow-up: 17mL ± 11.3 Range: 8-32mL Hemoglobin & Serum Ferritin Levels Significant increase in blood hemoglobin & serum ferritin concentrations	out information	(MBL≥80mL)	
Radesic 2004	Design Descriptive study Location New Zealand Dates June 1998- June 2002	Characteristics: 78 women (ages unknown) who had an LNG-IUS inserted at Palmerston North Hospital for the treatment of Dysfunctional Uterine Bleeding (99% for regular or irregular heavy periods)	1 expulsion (but subsequent reinsertion) Overall improvement: 78% 61 reported lighter or no periods 23 minimal spotting 21 amenorrhoeic 8 heavy/irregular bleeding 2 heavier Dysmenorrhea: 3 increased 9 unchanged menstrual pain 57 subjectively significant improvement	Standardized measurements	Non-standardized insertion 65% response rate	II-3, good
Rauramo 2004 Istre 2001	Design Open RCT: LNG-IUS v endometrial resection Follow-up 6 weeks; 6, 12, and 36 months Location Norway Enrollment Dates 3/24/93-10/12/95	Characteristics: 59 women Ages 30-49 years (mean: 41.4 ± 3.8 years) With idiopathic menorrhagia, a regular uterine cavity ≤ 10 cm long, who are pre-menopausal and no wish for further pregnancy Distribution: 30 L-IUD 29 transcervical	**At 36-month follow-up:** MBL PBAC results: showed significant decrease (p=.001) Baseline: 261.5 (60-1503) Follow-up: 7.0 (0-101) MBL < 60mL not achieved in 3 women Blood Hemoglobin & Serum Ferritin Significant increase in concentration (p=.001) Bleeding Days Significant decrease p<.001 Baseline: 25 Follow-up: 0 Significant decrease in median # days	Standardized measures & methodology Appropriate follow-up time Detailed information for both 12-month and 36-month follow-ups	Low follow-up rate (63.3%) No power information provided No information on drop-outs provided after 12 months	II-3, good

		endometrial resection (TCRE)	spotting; p<.001 Baseline: 22 days Follow-up: 1 day Amenorrhea Baseline: 0 women Follow-up: 6 women Menstrual Pain Significant decrease in # days with mild pain from baseline to 36 months (p=.001) Significant decrease in # days with moderate/severe pain from baseline to 36 months (p=.001) Adverse Effects 1 case of edema 3 endometriosis 2 PID 1 partial expulsion 1 partial expulsion			
Barrington 2003	Design RCT: LNG-IUS v Endometrial Thermal Ablation (ETA) Follow-up 6 months Location England	Characteristics: 50 women (ages not given) with menorrhagia refractory to medical therapy Distribution: 25 LNG-IUS 25 ETA	LNG-IUS Group Amenorrhoeic: 3 PBAC: 16 improved 2 unchanged (pre mean =107, pre median= 75, post mean =31, post median= 19)		Baseline characteristics of population not provided Small sample size p-values within groups not provided	II-3, fair
Xiao 2003	Design Prospective study Follow-up every 3 months for 36 months Location China	Characteristics: 34 parous women 27-34 years of age (mean: 35 ± 4.4 years) who experienced regular or heavy menstrual bleeding with a normal sized or slightly	Lost to follow-up: 2 Expulsions: 4 2 complete 2 partial Length of spotting Range: 30 to 90 days, Median: 42 days Hb Concentrations g/L	Good length of Follow-up time Standardized methods of measuring	Recruitment information missing	II-3, good

	Dates Initiated: 1996	enlarged uterus with an average menstrual blood loss (MBL) over 80ml and failure in previous treatments with hormones or traditional medicine	significant increase from baseline to each follow-up (3, 6, 12, 24 and 36 months): p<.0001 mean range: 121.5 to 138.7 Serum Ferritin significant increase from baseline to each follow-up (3, 6, 12, 24 and 36 months): p<.0001 mean range: 21.9 to 92.8 Bleeding Trends: Alternating between amenorrhea and spotting Increasing time correlated with increasing amenorrhea rates MBL Average Reduction: 86.3% Baseline: 124.2mL, 6 to 36 months ranged from 26.4 to 2.7 mL. (78.7% to 97.7% reduction range) Change in MBL: Over 1/3 amenorrhoeic ¼ scanty spotting			
Henshaw 2002	Design Retrospective cohort study 2 groups: LNG-IUD and Microwave endometrial ablation (MEA) Location Australia Follow-up	LNG-IUD Characteristics: 55 women (aged 36.8 ± 9.8 years in LNG-IUD group and 41.3 ± 7.7 years in MEA group) with either hospital records or treating specialists' medical records indicating treatment for heavy menstrual loss using either LNG-IUD or	Mean Bleeding Score: Significant change (p<.0001) pre-treatment: 30.7 post-treatment: 8.2 Mean Dysmenorrhea Score: Significant change (p<.0025) pre-treatment: 13.2 post-treatment: 6.2		Study design Non-standardized measures Necessary sample size not mentioned	II-3, fair

	for LNG-IUD group: 20.9 ± 12.6 months Dates 1998-2001	MEA between 1998 and 2001 Initial Distribution: LNG-IUD: 23 MEA: 39				
Monteiro 2002	Design Descriptive prospective non-comparative study Follow-up 3, 6, 9 and 12 months Location Brazil Dates 3/99-12/03	Characteristics: 44 women ages 22 to 49 who were on waiting lists for hysterectomy or endometrial ablation for menorrhagia after unsuccessful medical treatment	At 12 Months: -6 expulsions Hb concentration (g/L): improved in all patients significant change from 102 ± 14 to 128 ± 19 (p<.01) Bleeding Patterns Trend: 3 months: over 60% spotting abnormal uterine bleeding not well controlled 2 complained of Menorrhagia 6-12 months: (at 12 months, 35 remaining women) amenorrhea most frequent Amenorrhea: 21 Oligomenorrhea: 8 Spotting: 4 Normal: 2	Frequent follow-ups standardized measures	limited population generalizability high expulsion rate	II-3, fair
Nagrani 2002 Barrington 1997	Design Prospective study Location South Wales Follow-up: 3 months, between 6 and 9 months, between 4 and 5 years	Characteristics: 50 women aged 28 to 53 years who failed to respond to a combination of antiprostaglandins and antifibrinolytics who were awaiting surgical treatment in form of endometrial ablation or hysterectomy	***3 months:42 women*** 6 spontaneous expulsions (4 re-insertions) Bleeding Patterns 5 sig. reduction in menstrual scores reduction in clots & flooding Dysmenorrhea 80% improvement Ferritin Level: no significant change (p=.1133; 95% CI:-	Considered uterine cavity length of participants	High loss to follow-up Non-standardized and non-participant friendly data measures regarding mean blood loss	II-3, poor

	(mean follow-up time: 54.2 months) Dates: 1995-1996		15.99 to -.01) ***4 to 5 years**: 23 women remaining, 23 dropouts* 5 spontaneous expulsions (2 re-insertions) Bleeding Patterns: Amenorrhea: 8 (34.78%) Occasional: 13 (56.52 %) Regular cyclical: 2 (8.69%)		Characteristics of those who declined to participate were not provided Older age range of participants (menopausal possibility)	
Soysal 2002	Design Open, parallel group RCT: LNG-IUD v Thermal Balloon Ablation (TBA) Location Turkey Follow-up 3, 6 and 12 months Dates 10/99 – 11/01	LNG-IUD Group Characteristics: 36 women aged 43.8 ± 2.7 years with no further desire for childbearing, complaining of dysfunctional menorrhagia who refused or not responded to medical treatment Distribution: 36 LNG-IUD 36 TBA	Mean PBAC scores Significantly lower at 12 months (408 ± 101 to 55.0 ± 11, p-value: <.0001) -77% successful cases (as defined by PBAC score of ≤ 75) Hemoglobin value Significant increase (9.1 ± 1.5, to 12.6 ± 0.6 (gl/dl), p-value <.0001)	Standardized insertion technique	Small sample size	II-3, fair
Romer 2000	Design Non-randomized study 2 Groups: LIUD Roller-Ball endometrial ablation Location Germany	L-IUD Characteristics: 15 patients aged 36±6 years recommended for endometrial ablation Initial Distribution: LNG-IUD: 15 Roller-Ball endometrial ablation: 15	Menstrual Pattern, # of women Amenorrhea: 6 Hypomenorrhea: 5 Hypermenorrhea: 4 Eumenorrhea: 0		Measurement techniques not provided (how did they determine amenorrhea, etc?) Selection criteria not elaborated upon No consistent	II-3, fair

	Follow-up 12 to 24 months Dates n/a				follow-up times No Insertion consistency	

Table Key

Hb	Hemoglobin
HMB	Heavy Menstrual Bleeding
IUD	Intrauterine Device
L-IUD	Levonorgestrel Intrauterine Device
LNG-IUD	Levonorgestrel Intrauterine Device
LNG-IUS	Levonorgestrel Intrauterine System
MBL	Menstrual Blood Loss
MMAS	Menorrhagia Multi-Attribute Score
n/a	not available
PBAC	Pictorial Blood Assessment Chart
PID	Pelvic Inflammatory Disease
RCT	Randomized Control Trial
VAS	Visual Analogue Score