

El Marsafawi A, El Agawany A.

Abstract

Mirena is a recent long acting reversible contraceptive (LARC) which is producing 20 micrograms of levonorgestryl/day. It is indicated as a contraceptive and in management of different medical conditions. This study is designed to study the safety, effectiveness and tolerability of mirena as contraceptive. Also, study the effectiveness of merina in different other medical indications. The study was conducted on 490 cases who were followed for 5 years. The most common menstrual pattern in the 1st follow up visit was irregular spotting. After that in the next follow up visits, amenorrhea and hypomenorrhea were the commonest menstrual patterns in Mirena users in the different indications. The commonest cause of loop removal was heavy menstrual bleeding in non contraceptive group and desire for pregnancy in contraceptive group. There was no cases of uterine perforation and only one case of occurrence of pregnancy in the 4th year of IUDS use.

Introduction

Mirena is a T shaped polyethylene structure with the stem encased by a cylinder containing polydimethylsiloxane and levonorgestryl. The cylinder has permeable membrane that regulates continuous daily hormone release of twenty microgram/day. The Mirena is currently approved for 5 years following insertion. Levonorgetryl in Mirena acts peripherally on cervical mucus making it thick and impermeable to sperms. Also, it renders endometrium atrophic. (1)

Mirena is indicated as a highly effective contraceptive method and other non contraceptive indications as treatment of heavy menstrual bleeding, premenstrual tension syndrome and endometrial hyperplasia. (2)

Aim of the work

The aim of this study was to evaluate:

- I- The contraceptive effectiveness, acceptability, failure and side effects of Mirena.
- II- Use of Mirena in non contraceptive indications and its effectiveness in management of these indications.

Patients

The study was conducted on 490 females in the reproductive age. The indications of Mirena application were contraception "n: 351", abnormal uterine bleeding due to endometrial hyperplasia "n: 62", interstitial and subserous myomas "n: 37", submucous myomas type 2 "n:12", adenomyosis "n: 25" and idiopathic thrombocytopenic purpura "n: 3".

Exclusion criteria:

1. Nullipara
2. PID
3. STDs or history of STDs

Dr. Amani El Marsafawi.
E-mail: oashkar254@hotmail.com
Mobile number: 01113656665

4. Active cervicitis
5. Congenital uterine anomalies
6. Submucous myomas type O and 1
7. Desire of pregnancy within next two years

Method

All cases were subjected to:

- Full history taking focusing on menstrual, reproductive and medical history.
- General, abdominal and pelvic examination.
- Both abdominal and transvaginal ultrasonography "TVS".
- Insertion of Mirena IUDS.
- Post-insertion TVS.
- Recording of any complications during insertion as perforation, syncope and bleeding.
- Follow up visits were after 3 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years intervals or till IUDS removal for any reason.
- In every follow up visit, full history taking especially menstrual, symptomatology, general, abdominal and pelvic examination and TVS were done to every case.
- Acceptability, effectiveness, tolerability and non contraceptive benefits were recorded in every case.

Results

The study was carried on 490 mirena users throughout a 10 year period of time (from January 2007 till January 2017). Mirena users were classified into 6 groups according to indication of IUDS insertion. All users were followed for 5 years, duration of use of mirena. No perforation or bleeding were happened in all cases. Syncope has been happened in 6 cases out of 490 users with a percent 1.2%.

Table (1): Pattern of menstrual blood flow in all groups through follow up period.

All group (n=490)	
Follow up 3 months (n=490)	
- Normal flow	151 (30.8%)
- Irregular spotting	315 (64.3%)
- Amenorrhea	7 (1.4%)
- Excessive flow	16 (3.3%)
- Missed FU	1 (0.2%)
Follow up 6 months (n=489)	
- Normal flow	107 (21.9%)
- Irregular spotting	19 (3.9%)
- Amenorrhea	186 (38.0%)
- Hypomenorrhea	159 (32.5%)
- Excessive flow	8 (1.6%)
- Missed FU	2 (0.4%)
- Loop removal	8 (1.6%)
Follow up 1 year (n=479)	
- Normal flow	58 (12.1%)
- Amenorrhea	206 (43.0%)
- Hypomenorrhea	193 (40.3%)
- Excessive flow	6 (1.3%)
- Missed FU	8 (1.7%)
- Loop removal	8 (1.7%)
Follow up 2 years (n=463)	
- Normal flow	17 (3.7%)
- Amenorrhea	349 (75.4%)
- Hypomenorrhea	84 (18.1%)
- Missed FU	3 (0.6%)
- Loop removal	10 (2.2%)
Follow up 3 years (n=450)	
- Normal flow	58 (12.9%)
- Amenorrhea	228 (50.7%)
- Hypomenorrhea	155 (34.4%)
- Missed FU	5 (1.1%)
- Loop removal	4 (0.9%)
Follow up 4 years (n=441)	
- Normal flow	112 (25.4%)
- Amenorrhea	174 (39.5%)
- Hypomenorrhea	149 (33.8%)
- Loop removal	5 (1.1%)
- Pregnancy	1 (0.2%)
Follow up 5 years (n=435)	
- Normal flow	185 (42.5%)
- Amenorrhea	99 (22.8%)
- Hypomenorrhea	151 (34.8%)

This table represents the follow up of all mirena users all through the five years in different indications. In the first follow up visit (after 3 months), most of the users had irregular spotting (n: 315, 64.3%). Amenorrhea was the presentation of only 7 users (1.4%). Normal menstrual flow was the presentation of 151 users (30.8%). In the second follow up visit (after 6 months), the number of users complaining from irregular spotting was reduced to only 19 users (3.9%). Most of users were either presented by amenorrhea (n: 186= 38%) or hypomenorrhea (n: 159=32%). In this follow up visit we had 2 missed follow up visit and 8 IUDs removal because of heavy menstrual bleeding. Amenorrhea was the main presentation in the 3rd follow up visit (after 1 year), 4th follow up visit (2 years) 5th follow up visit (3 years) and 6th follow up visit(4 years). Those amenorrhic users were 206 (43%), 349 (75.4%), 228 (50.7%) and 174 (39.5%) in those follow up visits respectively. IUDS was removed in 8 users (1.7%) and there were 8 missed users in 3rd follow up visit. IUDS was removed in 10 users in the 4th follow up users while it was removed in only 4 users in the 5th follow up visit. In the 6th follow up visit, we had only 5 removals and 1 user got pregnant. In the last follow up visit (at the end of 5 years) all IUDSs were removed. Normal menstrual blood flow was the predominant and was found in 185 users (42.5%).

Table 2: percentage of normal and abnormal menstrual blood flow through the follow up period in all groups.

All group (n=490)	
Follow up 3 months (n=489)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	158 (32.3%)
- Any abnormality	331 (67.7%)
Follow up 6 months (n=487)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	452 (92.8%)
- Any abnormality	35 (7.2%)
Follow up 1 year (n=471)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	457 (97.0%)
- Any abnormality	14 (3.0%)
Follow up 2 years (n=460)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	450 (97.8%)
- Any abnormality	10 (2.2%)
Follow up 3 years (n=445)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	441 (99.1%)
- Any abnormality	4 (0.9%)

Follow up 4 years (n=441)	
• Normal flow OR Amenorrhea OR Hypomenorrhea	435 (98.6%)
• Any abnormality	6 (1.4%)
Follow up 5 years (n=435)	
• Normal flow OR Amenorrhea OR Hypomenorrhea	435 (100.0%)
• Any abnormality	0 (0.0%)
Test of significance	
• Cochran's Q test	1649.849
• p value	p=0.000

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

All times of follow up showed statistically significant difference in the good outcome when compared with first follow up at 3 months (using Dunn-Sidek method of pair-wise comparison)

Irregular spotting was the main presentation in the 1st follow up visit as we had 315 users complaining of it (64.3%), which was decreased to 19 users in the 2nd follow up visit (3.9%) and disappeared in the next follow up visits.

Fig.(1): percentage of normal and abnormal menstrual blood flow through the follow up period in all groups.

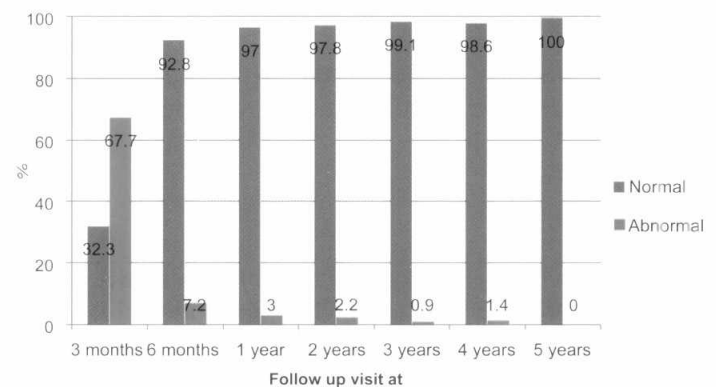


Table 3: Pattern of menstrual blood flow in submucous myoma group

LSM1&2 group (n=12)	
Follow up 3 months (n=12)	
- Normal flow	4 (33.3%)
- Irregular spotting	6 (50.0%)
- Amenorrhea	2 (16.7%)
Follow up 6 months (n=12)	
- Normal flow	5 (41.7%)
- Irregular spotting	2 (16.7%)
- hypomenorrhea	5 (41.7%)

Follow up 1 year (n=12)	
- Normal flow	3 (25.0%)
- Amenorrhea	6 (50.0%)
- hypomenorrhea	3 (25.0%)
Follow up 2 years (n=12)	
- Amenorrhea	10 (83.3%)
- hypomenorrhea	2 (16.7%)
Follow up 3 years (n=12)	
- Amenorrhea	9 (75.0%)
- hypomenorrhea	3 (25.0%)
Follow up 4 years (n=12)	
- Normal flow	2 (16.7%)
- Amenorrhea	6 (50.0%)
- hypomenorrhea	4 (33.3%)
Follow up 5 years (n=12)	
- Normal flow	5 (41.7%)
- Amenorrhea	2 (16.7%)
- hypomenorrhea	5 (41.7%)

All of the cases were having heavy menstrual bleeding. Mirena IUDs was inserted in 12 patients with submucous myoma in which less than 50% of the myoma was in the cavity (Lsm2) as a method of treatment of heavy menstrual bleeding and contraception at the same time. In the 1st follow up visit (3 months) there was 50% irregular spotting and 50% normal flow or amenorrhea with no single case of heavy bleeding. Irregular spotting was reduced to 16.7% in the 2nd follow up visit (6 months). The next follow up visits showed that all the patients had either normal menstrual blood flow, hypomenorrhea or amenorrhea which was considered as marked improvement of the condition.

Table 4: percentage of normal and abnormal menstrual blood flow through the follow up period in submucous myoma group.

LSM1&2 group (n=12)	
Follow up 3 months (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	6 (50.0%)
- Any abnormality	6 (50.0%)
Follow up 6 months (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	10 (83.3%)
- Any abnormality	2 (16.7%)
Follow up 1 year (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	12 (100.0%)
- Any abnormality	

Follow up 2 years (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	12 (100.0%)
- Any abnormality	
Follow up 3 years (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	12 (100.0%)
- Any abnormality	
Follow up 4 years (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	12 (100.0%)
- Any abnormality	
Follow up 5 years (n=12)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	12 (100.0%)
- Any abnormality	
Test of significance	
- Cochran's Q test	29.455
- p value	0.000*

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

There was marked improvement in the menstrual blood flow. There was significant difference between the 1st follow up visit and other follow up visits as regards the percentage of abnormal uterine bleeding. There was no significant difference between the other visits.

Fig.(2): percentage of normal and abnormal menstrual blood flow through the follow up period in submucous myoma group.

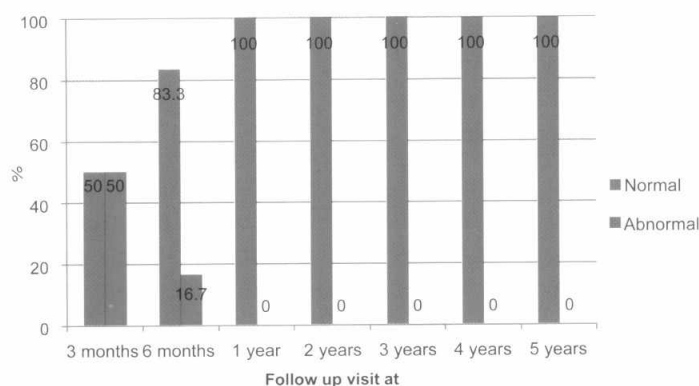


Table 5: Pattern of menstrual blood flow in other myoma group

Liomyoma (Other) group (n=37)	
Follow up 3 months (n=37)	
- Normal flow	20 (54.1%)
- Irregular spotting	12 (32.4%)
- Amenorrhea	5 (13.5%)
Follow up 6 months (n=37)	
- Irregular spotting	3 (8.1%)
- Amenorrhea	12 (32.4%)
- hypomenorrhea	22 (59.5%)
Follow up 1 year (n=37)	
- Normal flow	3 (8.1%)
- Amenorrhea	21 (56.8%)
- hypomenorrhea	13 (35.1%)
Follow up 2 years (n=37)	
- Normal flow	1 (2.7%)
- Amenorrhea	26 (70.3%)
- hypomenorrhea	8 (21.6%)
- Loop removal	2 (5.4%)
Follow up 3 years (n=35)	
- Normal flow	2 (5.4%)
- Amenorrhea	21 (56.8%)
- hypomenorrhea	12 (32.4%)
Follow up 4 years (n=35)	
- Normal flow	7 (18.9%)
- Amenorrhea	14 (37.8%)
- Hypomenorrhea	13 (35.1%)
- Loop removal	1 (2.7%)
Follow up 5 years (n=34)	
- Normal flow	8 (21.6%)
- Amenorrhea	9 (24.3%)
- hypomenorrhea	17 (45.9%)

All of the cases were having heavy menstrual bleeding. Mirena IUDS was inserted in 37 patients with interstitial and subserous myomas as a method of treatment of heavy menstrual bleeding and contraception at the same time. In the 1st follow up visit (3 months) there was marked improvement of the complaint. Irregular spotting as an abnormal presentation was found in 12 cases (32.4%) in the 1st follow up visit and in only 3 cases (8.1%) in the 2nd follow up visit which disappeared in the following visits. Merina IUDS was removed in 2 users in the 4th follow up visit (after 2 years) and only one user in the 6th follow up visit (4th year) because of heavy menstrual bleeding.

Table 6: percentage of normal and abnormal menstrual blood flow through the follow up period in other myoma group.

Liomyoma (Other) group (n=37)	
Follow up 3 months (n=37)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	25 (67.6%)
- Any abnormality	12 (32.40%)
Follow up 6 months (n=37)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	34 (91.9%)
- Any abnormality	3 (8.1%)
Follow up 1 year (n=37)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	37 (100.0%)
- Any abnormality	
Follow up 2 years (n=37)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	35 (94.6%)
- Any abnormality	2 (5.4%)
Follow up 3 years (n=35)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	35 (94.6%)
- Any abnormality	2 (5.4%)
Follow up 4 years (n=35)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	34 (91.9%)
- Any abnormality	1 (2.7%)
Follow up 5 years (n=34)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	34 (100.0%)
- Any abnormality	
Test of significance	
- Cochran's Q test	60.429
- p value	0.000*

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

There was marked improvement in the menstrual blood flow. There was significant difference between the 1st follow up visit and other follow up visits as regards the percentage of abnormal uterine bleeding. There was no significant difference between the other visits.

Fig.(3): percentage of normal and abnormal menstrual blood flow through the follow up period in other myoma group.

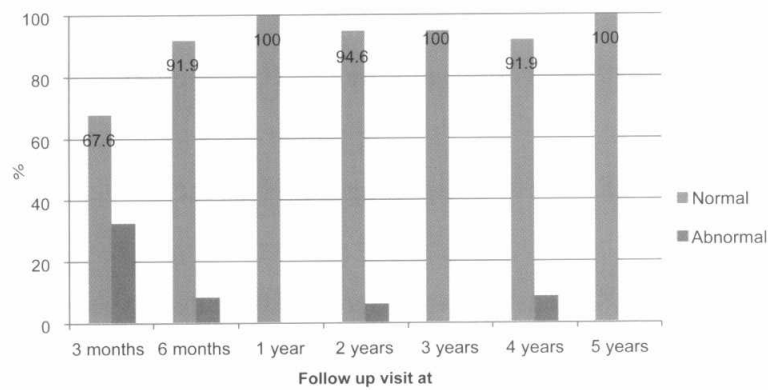


Table 7: Pattern of menstrual blood flow in adenomyosis group

Adenomyosis group (n=25)	
Follow up 3 months (n=25)	
- Normal flow	3 (12.0%)
- Irregular spotting	15 (60.0%)
- Excessive flow	6 (24.0%)
- Missed FU	1 (4.0%)
Follow up 6 months (n=24)	
- Normal flow	3 (12.5%)
- Irregular spotting	6 (25.0%)
- Hypomenorrhea	9 (37.5%)
- Excessive flow	3 (12.5%)
- Loop removal	3 (12.5%)
Follow up 1 year (n=21)	
- Amenorrhea	3 (14.3%)
- Hypomenorrhea	15 (71.4%)
- Loop removal	3 (14.3%)
Follow up 2 years (n=18)	
- Amenorrhea	12 (66.7%)
- Hypomenorrhea	6 (33.3%)
Follow up 3 years (n=18)	
- Amenorrhea	12 (66.7%)
- Hypomenorrhea	6 (33.3%)
Follow up 4 years (n=18)	
- Normal flow	6 (33.3%)
- Amenorrhea	9 (50.0%)
- Hypomenorrhea	3 (16.7%)
Follow up 5 years (n=18)	
- Normal flow	9 (50.0%)
- Amenorrhea	6 (33.3%)
- Hypomenorrhea	3 (16.7%)

Merina IUDS was inserted in 25 patients who had adenomyosis as a treatment of pain and heavy menstrual bleeding. Irregular spotting was seen in 15 users (60%) in the 1st follow up visit and in only 6 users (25%) in the 2nd follow up visit and disappeared in the next follow up visits. Heavy menstrual bleeding was the presentation in 6 patients in the 1st follow up visit. In the 2nd follow up visit 3 of them asked for IUDS removal because of bleeding while the other 3 patients asked for IUDS removal in the 3rd follow up visit for the same reason. Only one case was missed from the 1st follow up visit.

Table 8: percentage of normal and abnormal menstrual blood flow through the follow up period in adenomyosis group.

Adenomyosis group (n=25)	
Follow up 3 months (n=24)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	3 (12.0%)
- Any abnormality	21 (84.0%)
Follow up 6 months (n=24)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	12 (50.0%)
- Any abnormality	12 (50.0%)
Follow up 1 year (n=21)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	18 (85.7%)
- Any abnormality	3 (14.3%)
Follow up 2 years (n=18)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	18 (100.0%)
- Any abnormality	
Follow up 3 years (n=18)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	18 (100.0%)
- Any abnormality	
Follow up 4 years (n=18)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	18 (100.0%)
- Any abnormality	
Follow up 5 years (n=18)	
- Normal flow OR Amenorrhoea OR Menstrual spotting OR Hypomenorrhoea	18 (100.0%)
- Any abnormality	
Test of significance	
- Cochran's Q test	72.947
- p value	0.000*

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

Only 3 patients (12%) were improved and they had normal menstrual blood flow in the 1st follow up visit. The number of patients with improved menstrual pattern was increased to 12 patients (50%) in the 2nd follow up visit. Still, the number of patients with better menstrual pattern increased to 18 patients (85.7%) in the 3rd follow up visit. The IUDS was removed in 6 patients in the 2nd & 3rd follow up visits because of heavy menstrual bleeding. Merina IUDS was successful in management of adenomyosis in 18 patients out of 24 (75%).

Fig.(4): percentage of normal and abnormal menstrual blood flow through the follow up period in adenomyosis group.

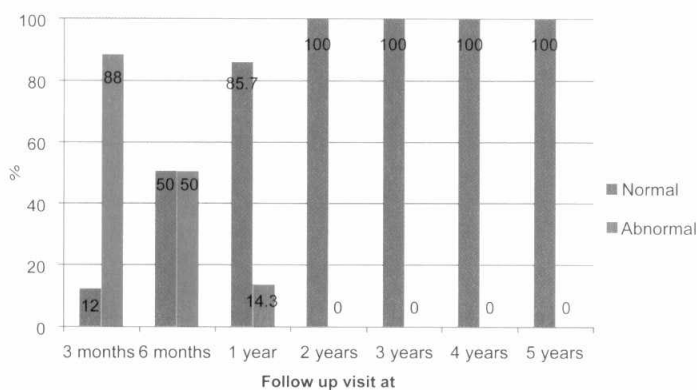


Table 9: Pattern of menstrual blood flow in abnormal uterine bleeding group.

Abnormal uterine bleeding group (n=62)	
Follow up 3 months (n=62)	
- Normal flow	18 (29.0%)
- Irregular spotting	34 (54.8%)
- Excessive flow	10 (16.1%)
Follow up 6 months (n=62)	
- Normal flow	27 (43.5%)
- Irregular spotting	7 (11.3%)
- Hypomenorrhoea	18 (29.0%)
- Excessive flow	5 (8.1%)
- Loop removal	5 (8.1%)

Follow up 1 year (n=57)	
- Normal flow	14 (24.6%)
- Amenorrhea	7 (12.3%)
- Hypomenorrhea	25 (43.9%)
- Excessive flow	6 (10.5%)
- Loop removal	5 (8.8%)
Follow up 2 years (n=52)	
- Normal flow	15 (28.8%)
- Amenorrhea	31 (59.6%)
- Loop removal	6 (11.5%)
Follow up 3 years (n=46)	
- Normal flow	20 (43.5%)
- Amenorrhea	19 (41.3%)
- Hypomenorrhea	7 (15.2%)
Follow up 4 years (n=46)	
- Normal flow	31 (67.4%)
- Amenorrhea	15 (32.6%)
Follow up 5 years (n=46)	
- Normal flow	31 (67.4%)
- Amenorrhea	15 (32.6%)

Merina IUDS was inserted in 62 patients complaining of abnormal uterine bleeding not due to organic causes. Irregular spotting was seen in 34 patients (54.8%) in the 1st follow up visit and decreased to only 7 patients (11.3%) in the 2nd follow up visit and was not seen after that. Heavy menstrual bleeding was the presentation in 10 patients (16.1%) in the 1st follow up visit. IUDS was removed from 5 users (8.1%) in 2nd follow up visit with persistence of heavy menstruation in the other 5 patients. Heavy menstruation was seen in 11 patients in the 3rd follow up visit, the IUDS was removed in 5 of them and the IUDS was removed in the 4th follow up visit from the other 6 patients. Forty six (74.2%) patients out of the 62 had improved menstrual pattern with merina loop.

Table 10: percentage of normal and abnormal menstrual blood flow through the follow up period in abnormal uterine bleeding group.

Abnormal uterine bleeding (n=62)	
Follow up 3 months (n=62)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	18 (29.0%)
- Any abnormality	44 (71.0%)
Follow up 6 months (n=62)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	45 (72.6%)
- Any abnormality	17 (27.4%)

Follow up 1 year (n=57)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	46 (80.7%)
- Any abnormality	11 (19.3%)
Follow up 2 years (n=52)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	46 (88.5%)
- Any abnormality	6 (11.5%)
Follow up 3 years (n=46)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	46 (100.0%)
- Any abnormality	
Follow up 4 years (n=46)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	46 (100.0%)
- Any abnormality	
Follow up 5 years (n=46)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	46 (100.0%)
- Any abnormality	
Test of significance	
- Cochran's Q test	174.672
- p value	0.000*

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

Merina IUDS was inserted in 62 patients with abnormal uterine bleeding not due to organic causes. Accepted menstrual patterns had been achieved in 46 patients (74.2%) within the 1st year of loop application. Mirena was removed in 16 patients in the 1st 2 years because of heavy bleeding.

Fig.(5): percentage of normal and abnormal menstrual blood flow through the follow up period in abnormal uterine bleeding group.

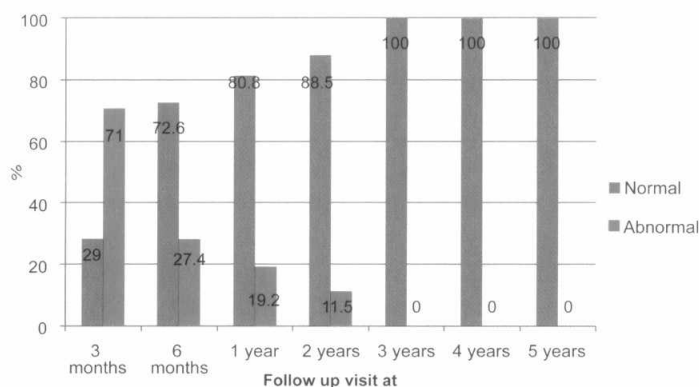


Table 11: Pattern of menstrual blood flow in contraception group.

Contraception group (n=351)	
Follow up 3 months (n=351)	
- Normal flow	105 (29.9%)
- Irregular spotting	246 (70.1%)
Follow up 6 months (n=351)	
- Normal flow	69 (19.7%)
- Irregular spotting	1 (0.3%)
- Amenorrhea	174 (49.6%)
- Hypomenorrhea	105 (29.9%)
- Missed FU	2 (0.6%)
Follow up 1 year (n=349)	
- Normal flow	35 (10.0%)
- Amenorrhea	169 (48.4%)
- Hypomenorrhea	137 (39.3%)
- Missed FU	8 (23.3%)
Follow up 2 years (n=341)	
- Amenorrhea	270 (79.2%)
- Hypomenorrhea	66 (19.4%)
- Missed FU	3 (0.9%)
- Loop removal	2 (0.6%)
Follow up 3 years (n=336)	
- Normal flow	35 (10.4%)
- Amenorrhea	167 (49.7%)
- Hypomenorrhea	125 (37.2%)
- Missed FU	5 (1.5%)
- Loop removal	4 (1.2%)
Follow up 4 years (n=327)	
- Normal flow	66 (20.2%)
- Amenorrhea	129 (39.4%)
- Hypomenorrhea	127 (38.8%)
- Loop removal	4 (1.2%)
- Pregnancy	1 (0.3%)
Follow up 5 years (n=322)	
- Normal flow	132 (41.0%)
- Amenorrhea	65 (20.2%)
- Hypomenorrhea	125 (38.8%)

Mirena IUDS was used for contraception in 351 clients who were having normal regular menstruation or lactating. Irregular spotting was the presentation of 246 clients (70.1%) in the 1st follow up visit. This number was reduced to only one client (0.3%) in the 2nd follow up visit and disappeared after that in the next follow up visits. We had missed cases in the 2nd follow up visit, 8 missed cases in the 3rd follow up visit, 3 missed cases in the 4th follow up visit and 5 missed cases in the 5th follow up visit with a total number of 18 missed follow up cases all through follow up period. The main presentations were either amenorrhea or hypomenorrhea through the follow up

period except the 1st visit. We had only one case of pregnancy at the end of the 4th year of use of mirena IUDS. Mirena IUDS was removed in 10 cases, 2 in the 4th follow up visit, 4 in the 5th follow up visit and 4 in the 6th follow up visit. IUDS was removed in those cases either due to client non satisfaction on the menstrual pattern or desire for pregnancy.

Table 12: percentage of normal and abnormal menstrual blood flow through the follow up period in contraception group.

Contraception (n=351)	
Follow up 3 months (n=351)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	105 (29.9%)
- Any abnormality	246 (70.1%)
Follow up 6 months (n=349)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	348 (99.7%)
- Any abnormality	1 (0.3%)
Follow up 1 year (n=341)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	341 (100.0%)
- Any abnormality	
Follow up 2 years (n=338)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	336 (99.4%)
- Any abnormality	2 (0.6%)
Follow up 3 years (n=331)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	327 (98.8%)
- Any abnormality	4 (1.2%)
Follow up 4 years (n=327)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	322 (98.5%)
- Any abnormality	5 (1.5%)
Follow up 5 years (n=322)	
- Normal flow OR Amenorrhea OR Hypomenorrhea	322 (100.0%)
- Any abnormality	
Test of significance	
- Cochran's Q test	1332.045
- p value	0.000*

Any abnormality include: irregular spotting OR excessive flow OR loop removal OR pregnancy

Irregular spotting was the main presentation in the 1st follow up visit while amenorrhea and hypomenorrhea were the main presentation in the next follow up visit.

Fig.(6): percentage of normal and abnormal menstrual blood flow through the follow up period in contraception group.

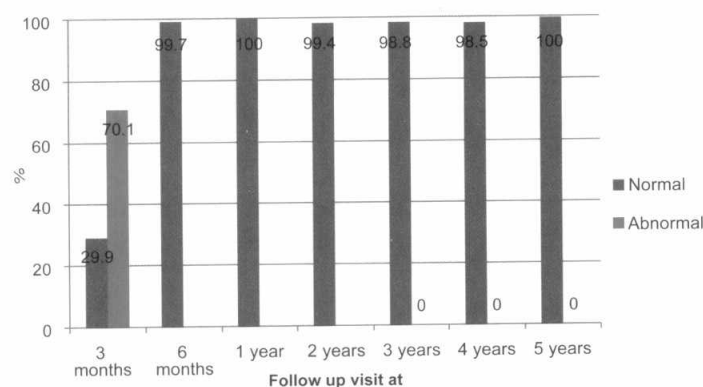


Table 13: Pattern of menstrual blood flow in ITP group.

ITP group (n=3)	
Follow up 3 months (n=3)	
- Normal flow	1 (33.3%)
- Irregular spotting	2 (66.7%)
Follow up 6 months (n=3)	
- Normal flow	3 (100.0%)
Follow up 1 year (n=3)	
- Normal flow	3 (100.0%)
Follow up 2 years (n=3)	
- Normal flow	1 (33.3%)
- hypomenorrhea	2 (66.7%)
Follow up 3 years (n=3)	
- Normal flow	1 (33.3%)
- hypomenorrhea	2 (66.7%)
Follow up 4 years (n=3)	
- Normal flow	1 (33.3%)
- hypomenorrhea	2 (66.7%)
Follow up 5 years (n=3)	
- Normal flow	1 (33.3%)
- hypomenorrhea	2 (66.7%)

Mirena IUDS was inserted in 3 patients who had idiopathic thrombocytopenic purpura (ITP). The condition of the 3 patients was improved all through the follow up period. The number of patients was so small that we could not do statistical analysis.

Discussion

The contraceptive profile of Mirena IUDS is well established, with efficacy similar to that achieved with sterilization and rapid return to fertility after discontinuation of use. The Mirena IUDS is typically associated with transient menstrual disturbance during the first few months of use, but this usually settles with continued use, with a concomitant decrease in menstrual blood loss.(3)

The aim of this study was to evaluate the contraceptive effectiveness, acceptability, failure and side effects of Mirena. Furthermore, evaluate the use of Mirena in non contraceptive indications and its effectiveness in management of these indications.

The study was conducted on 490 cases. Mirena was used for contraceptive indication in 351 clients, and was used in 139 patients for other medical indications. Medical indications included abnormal uterine bleeding (n:62), adenomyosis (n:25), subserous and interstitial myomas (n:37), submucous myoma type 2 (n:12) and idiopathic thrombocytopenic purpura (n:3). There were 19 cases of missing follow up visits with a follow up percent 96.13%. One of them was in the subserous myoma group and the other 18 were in the contraception group. The one in the subserous myoma group was missed from the 1st follow up visit. The other missing clients in contraception group were distributed as follows: 2 clients in the 2nd visit, 8 clients in the 3rd visit, 3 clients in the 4th visit and 5 clients in the 5th visit. There were 36 cases of loop removal with a percent of 7.35%. The loop was removed in 8 cases in the 2nd follow up visit because of heavy menstrual bleeding, 3 of them in the adenomyosis group and 5 in the abnormal uterine bleeding group. Another 8 IUDS were removed in the 3rd follow up visit. Three of them were in the adenomyosis group and 5 in abnormal uterine bleeding group. We had 10 cases of loop removal in the 4th follow up visit, 2 in the contraception group, 1 of them wanted to be pregnant and the other cause of removal was weight gain. Eight patients asked for removal of the loop because of heavy menstrual bleeding, 6 of them were in the abnormal uterine bleeding group and 2 in the subserous myoma group. Because of desire of pregnancy, 4 clients in the contraception group asked for removal of the IUDS in the 5th follow up visit. Six cases asked for IUDS removal in the 6th follow up visit, 1 of them was in the subserous myoma group due to heavy menstrual bleeding, and the other 5 cases were in the contraception group. The IUDS was removed in 1 of them because of occurrence of pregnancy, 2 of them did not accept amenorrhea any longer and the other 2 because of desire of pregnancy. Regarding the menstrual pattern, irregular spotting was prevalent in the 1st follow up visit (64.3%), decreased to 3.9% in the 2nd follow up visit and disappeared after that. Amenorrhea and hypomenorrhea were the dominant presentation after the 1st follow up visit up to the end of the follow up period. So, we can conclude that merina IUDS may cause irregular spotting in the early few months of insertion which disappear within 6 months after insertion. The main menstrual presentations were amenorrhea, hypomenorrhea and to a lesser extent, normal menstrual

blood flow. Excessive menstrual bleeding was seen in 24% of the adenomyosis group and 16.1% of the abnormal uterine group in the 1st follow up visit. The incidence of heavy menstrual bleeding decreased after that but with variable percentage. It was the cause of IUDS removal in 6 patients in the adenomyosis group and 16 patients in the abnormal uterine bleeding group throughout the follow up period. The use of mirena IUDS in cases of fibroid uterus (submucous, interstitial or subserous) in this study was very successful in control of heavy menstruation. We can conclude that mirena IUDS can be used in patients with fibroid uterus for both control of heavy bleeding and contraception. The use of mirena IUDS in patients with adenomyosis may lead to good results regarding bleeding and pain control. Only 6 patients asked for removal of the IUDS in this group because of failure in controlling bleeding. So, we can consider that use of mirena for treatment and as contraception in patients with adenomyosis is a fair method and can give good results. The same conclusion is applicable to the use of mirena IUDs in management of abnormal uterine bleeding as the use of mirena IUDS lead to good control of bleeding in a fair percentage of those patients. The use of mirena IUDS in patients with idiopathic thrombocytopenic purpura in this study gave excellent results but the number of patients were very small. We cannot recommend its use in management of this disease. The incidence of pregnancy in our study was 0.2% and it is the percentage in a study carried on by Trussell (4). We inserted Mirena in only one case during caesarean section, but it was expelled out after 10 days and it was not included in the study. We did not try it again. Puzey M. (5) inserted Mirena in 33 patients during caesarean section without expulsion, perforation or occurrence of pregnancy. There was no perforation in all our cases. This may be due to high proficiency of the health providers who inserted the IUDS and the use of ultrasound pre and post insertion. Heinemann K et al (6) had 1.4% incidence of uterine perforation in his extended study on 61,448 IUDS users. This difference may be due to a much higher number of users in his study.

Conclusion

1. Mirena IUDS is a very good contraceptive method with a failure rate 0.2%.
2. Mirena users may have irregular spotting in the first few months (maximum 6 months) which disappear after that.
3. The main menstrual pattern in mirena users are amenorrhea, hypomenorrhea followed by normal menstrual blood flow.
4. Mirena can be used for treatment of heavy menstrual bleeding in many conditions such as fibroid uterus, adenomyosis and abnormal uterine bleeding.
5. The use of mirena as a method of management of idiopathic thrombocytopenic purpura needs elaborate research with more cases.

References

1. Hoffman BL, Schorge JO, Bradshaw KD, Halvorson LM, Schaffer JI, Corton MM, Contraception and sterilization in: Williams Gynecology, 2016: 108-9
2. Jansen JT, Nelson AL, Costales AC, Subject and clinical experience with the levonorgestryl-releasing intrauterine system. *Contracept* 2008; 77(1):22-9
3. Mansour D, The benefits and risks of using a levonorgestryl releasing intrauterine system for contraception. *Contracep* 2012;85(3): 224-34
4. Trussell J, Contraceptive failure in the United States. *Contracep* 2011; 83(5): 397-404
5. Puzey M, Mirena at caesarean section. *Europ J contracep* 2005;10(3):164-7
6. Heinemann K et al, Risk of uterine perforation with LN-IUD and copper IUD in European active surveillance study on intrauterine devices. *Contracep* 2015; 91(4) : 274-9