

# The use of Mirena in the treatment of menorrhagia in Basra

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## ABSTRACT

**Objective :** To evaluate the efficacy and safety of mirena in the long term treatment of heavy menstrual blood loss in women with benign causes in Basra.

**Maternal and Methods :** A prospective observational study, non comparative study, conducted at Basra maternity and child hospital over a period of four years from 1<sup>st</sup> of Jan.2009 to the first of Jan. 2013. It consist of 112 women. All have heavy menstrual bleeding for benign causes having no contraindication for the device all women were followed up at 3 months, 6 months and 12 months.

**Result :** Majority of women had menstrual spotting after 3-6 months, followed by infrequent menstruation, scanty period or Amenorrhaea, (71.4%) continued to use mirena beyond 1 years. while the discontinuation rate was (29.6%). Haemoglobin and serum ferritin and PCV level increased over 12 months of use, It was found that the most common side effect were bleeding disturbance (16%) no pregnancies occur during the study period , so mirena is a safe and effective option for women with menorrhagia in perimenopausal period.

## Introduction:

Menorrhagia, defined as regular but heavy menstrual vaginal bleeding of more than 80ml from a secretory endometrium is a common disorder, the prevalence is between 9-28% of women aged between 16-45 years and increased with age<sup>(1)</sup>. The usual length of menstrual bleeding is four to six days, and the usual amount of blood loss is 10-35 ml<sup>(2)</sup>. When menstrual blood loss exceeds 80ml, the incidence of anaemia (haemoglobin less than 12 g/dL) is increased significantly. Anaemia is one of the most wide spread, and most neglected, nutritional deficiency disease in the world today<sup>(3)</sup>. In perimenopause, approximately 25% of women will have at least one episode of heavy flow, it usually occurs when cycles are regular and before the onset of skipped cycles. Perimenopause is a time of higher than normal oestrogen and lower progesterone level<sup>(4)</sup>. It was found that hysterectomy is carried out on 60% of women referred to secondary care with menorrhagia<sup>(5)</sup>. However it is associated with a high level of postoperative complication occasional mortality and is believed to increase the risk of developing other disease including urinary incontinence<sup>(5)</sup>. A LNG .IUS (mirena) was originally developed as a contraceptive and licensed in the U.K in 1995. Although only licensed for contraception at present. It may be used on anamed. Patient bases for the treatment of menorrhagia its use has eventually exceed 90%, it may offer an alternative to hysterectomy in women

considering surgery for menorrhagia. Mirena consists of a t-shaped polyethylene frame (t. body) with a steroid reservoir (hormone elastomer core) around the vertical stem. The reservoir containing a total of 52 µg levonorgestel. It is intended to provide an initial rate of 20µg of levonorgestral perday mirena has mainly progestogenic effects in the uterine cavity. Morphological changes of the endometrium are observed, including stromal pseudodecidualization, glandular atrophy, a leukocyte, infiltration and decrease in glandular and stromal mitoses<sup>(6)</sup>.

## Maternal and Methods:

A prospective observational study was conducted for the first time in Iraq to study the efficacy of LNG.IUS in the treatment of menorrhagia due to benign lesion of the uterus in perimenopausal women. One hundred twelve women who attend Basra Maternity and Child Hospital with history of heavy menstrual bleeding due to benign lesion and completed a one year follow up were included in the study from the period of the 1<sup>st</sup> of January 2009 to the 1<sup>st</sup> of January of 2013. All these women underwent a pap smear, a transvaginal sonography and an endometrial biopsy, women with fibroid larger than 5cm and malignancy were excluded. Also women with history of active liver disease, adnexial tumor or cyst, pelvic inflammatory disease were excluded.

All patients were counseled for the insertion of mirena and its complications, all were informed regarding the initial few months of bleeding and infrequent menstruation and finally amenorrhea. All women were asked to observe the blood loss subjectively before and after the mirena. All the patients were followed after 3,6,12 months. A full Gynaecological examination including

vaginal ultrasound were performed to locate the mirena. All women were tested at each visit and pre insertion for their haemoglobin level ferretin and haematocrit was observed mirena was inserted with 5-7 days of cycle. All were asked not to use other hormonal contraceptive methods or other drug treatment (e.g iron). All women were signed an informed consent. The statistical analysis was carried out by using t test and value of  $P < 0.05$  were considered significant.

### Results:

During this study 112 women had mirena for heavy menstrual blood loss over the study period. The mean age of

the study sample 44.5 years and were multipara and they were obese, anaemic with normal blood pressure as shown in table -1-.

**Table -1- Demographic characteristic n=112.**

Age (year)	44.5(31-50)
Parity	P6 (4-10)
Weight (kg)	73 (49-96)
Height (cm)	158 (149-172)
Blood pressure (mmHg)	
Systolic	120 (110-140)
Diastolic	85 (70-90)
HB%	8.2 (6.3-9.2)
Haematocrit	36.6 (27.9 -41.2)
S.Ferritin	49.9 ng /m/(36.7-90.3)
Endometrial thickness before insertion mms	11(mm) (6-16)
Length of uterine cavity in (wk)	10 (8-12)
Length of the cycle (days)	28 (21-35)
Duration of flow (days)	6 (4-10)

**Table -2- Etiology of menorrhagia .**

Cause of menorrhagia	No.	%
Ovulatory /endometrial dysfunction	56	50
Fibroid	16	14.2
Endometrial hyperplasia	22	19.6
A denomyosis	18	16.01
Total	112	100%

Table -2- Show that 50% of women with HMB has idiopathic cause they are ovulating but had endometrial dysfunction followed by 19.6 endometrial hyperplasia.

**Table -3- Bleeding pattern during follow up period.**

Bleeding patter	3 month		6 month		12 month	
Regular cycle	-	-	-	-	-	-
Spotting	56	50%	32	28.5%	10	8.9%
Infrequent cycle with scanty menses	36	32.1%	28	25%	22	19.6%
Amenorrhea	-	-	44	39.2%	76	67.8%
HMB	16	14.2%	4	3.2%	-	-
Expelled	4	3.4%	2	1.7%	2	1.7%
Removed	-	-	2	1.7%	2	1.7%
Total	112	100	112	100	112	100

Table -3- Shows that 67.8% after the insertion of mirena and after one year develops amenorrhea.

**Table -4- Haemoglobin, Ferritin and haematocrit before and after LNG. IUS insertion.**

	Pre insertion	3 month	6 month	12 month	p.value
HB%	8.2	9.1	10.2	11.2	0.0001
Serum ferritein	47.9	90.8	136.2	168.5	0.0001
Haematocrit	36.6	39.2	40.6	43.9	0.0001

Table -4- Shows that there is significant increase in the haemaglobin and serum ferritein and haematocrit after one year after LNG.IUS insertion.

**Table -5- Side effect**

Side effect	No.	%
Infrequent cycle	22	19.6
Amenorrhea	76	67.8
Spotting	10	8.9
Headache	4	3.2
Breast tenderness	10	8.9
Dizziness	2	1.7
Pelvic pain and discharge	6	5.3

The most common side effect were infrequent cycle and amenorrhea.

**Table -6- Acceptability**

Acceptability	No.	%
Acceptance of device	80	71.4
Discontinuation	4	3.2
Alternate to hysterectomy	16	14.2
Removal	4	3.2
Expelled	8	7.1
Total	112	100

Table -6- Shows that 71.4% they were satisfied about mirena while 14.2% were ended up on hysterectomy.

## Discussion:

Menorrhagia is a common symptom in perimenopausal women. Medical treatment for benign lesions causing menorrhagia include non hormonal and hormonal treatment for several months, many patients refuse to take these medication because of prolonged treatment and adverse effect<sup>(7,8,9)</sup>. While surgical treatment such as hysterectomy and endometrial ablation require hospitalization and anesthesia, the risk of surgical intervention, anesthetic complications and surgical site infection are considerable. Recently mirena was found to be an effective non surgical minimally invasive long term treatment for menorrhagia<sup>(10)</sup>. In this study Table (1) shows that most of our patients were perimenopause, multipara, obese with thickened endometrium normotensive, but they were anaemic and the main cause of menorrhagia was ovulatory endometrial dysfunction (50%) followed by endometrial hyperplasia (19.6%) as shown by Table (2). Table (3) shows that after 3 months after mirena around (50%) of studied group still have spotting which reduced to (28.5%) and (8.9%) after 6,12 months respectively. While (67.8%) after one year have a menorrhagia after mirena insertion and these findings was in agreement with other studies done by Milson et al<sup>(11,12)</sup>. Antifibrinolytic agent reduce the bleeding by 40-50% prostaglandin synthesise inhibitor reduce the bleeding by 20-25%, hormonal treatment reduce the bleeding by 40-50% and mirena reduce

the bleeding by 86-97%<sup>(13)</sup>, while our study mirena reduce the bleeding by 97.3%, so mirena shows the greatest reduction in menstrual blood loss and hence been proposed as an alternation to hysterectomy, and medical treatment. Around 10.3% who removes or expelled the mirena and this is attributed to amenorrhoea perse in middle age women lead to discontinuation of the method or due to anxiety and cultural non acceptance or lack of experience in inserting the device, and this was in agreement with a study done by Anderson et al<sup>(14)</sup>, and this can be reduced if proper training of service provides in the insertion technique. Table (4) shows after one year of mirena insertion the haemoglobin level increased to 11.2gm/dL and serum ferritin to 168.5 and haematocrit to 43.6% and the different was statistically significant, so mirena is a better option for women who were suffering from menorrhagia and anaemia. No major side effect was noticed after mirena insertion they were negligible when compared with the previous heavy bleeding. While the acceptance rate was (71.4%) and around 14.2% they choose hysterectomy because some women may not be willing to tolerate the irregular period that some times occur in the initial phase after mirena insertion hence counseling before insertion and reassurance may improve the acceptance patients and this is shown in table -6-. So treatment with mirena saved the cost, both

physically and financially of surgical intervention which had been the usual solution when medical treatment failed so mirena being very useful, effective, safe, an innovative, convenient non

surgical and reversible method for the treatment of menorrhagia and it represent a real advance in the treatment of menorrhagia in women do not want hysterectomy or long term medical treatment.

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### الخلاصة

دراسة تتابعيه لتقييم كفاءة وأمان اللولب العلاجي لحالات النزف الشديد لأسباب حميدة أجريت في مستشفى البصرة للنسائية والأطفال منذ الفترة الأول من كانون الثاني 2009 لغاية الأول من كانون الثاني 2013 وشملت 112 امرأة تعاني من نزف رحمي شديد لأسباب حميدة في الرحم ولا يوجد أي مانع من استخدام اللولب العلاجي وتمت متابعتهم بعد ثلاثة وستة واثنا عشر شهرا ووجد انه 71.4% من النساء تابعن العلاج باللولب وارتفعت نسبة الهيموغلوبين والفرتين خلال سنة من استخدام اللولب وكانت نسبة 16% لازلن يعانين من اضطراب الدورة بعد سنة من استخدام اللولب لذلك يعتبر اللولب العلاجي بديل جيد لعلاج النزف الرحمي من قلع الرحم أو الدواء الهرموني لفترة طويلة .