"THE LEVONORGESTREL INTRAUTERINE SYSTEM AS AN ALTERNATIVE TO HYSTERECTOMY FOR TREATMENT OF ABNORMAL UTERINE BLEEDING"

By

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Dissertation submitted to BLDE University, Vijayapur.

In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY

IN

OBSTETRICS AND GYNAECOLOGY

Under the guidance of

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Place: Vijayapur **Dr. PALLAVI HOSAMANI**

Date

ABSTRACT

OBJECTIVE:

To study the role of levonorgestrel intra uterine system as an alternative to hysterectomy for the treatment of abnormal uterine bleeding.

MATERIALS AND METHODS:

This was an prospective and observational study conducted in BLDE University's Shri B M Patil Medical College, Hospital and Research Centre over a period from November 2015 to August 2016 with one year follow up.40 women presented out patient and in patient with abnormal uterine bleeding having no contraindication for device, underwent LNG IUS insertion after the consent. Menstrual pattern, satisfaction and rate of acceptability recorded one year after insertion.

RESULTS:

After LNG-IUS insertion in DUB patients ,97.5% patients had significant decrease in blood loss and treatment failure rate 2.5%(1 out of 40 patients). 25 % of women had normal periods , 50% of women had oligomenorrhea and 7.1% complained of intermenstrual bleeding and 1 patient requested for hysterectomy out of 40 post LNG-IUS insertion after follow up of 1 year .1 women required removal of LNG-IUS as she was dissatified with LNG-IUS. Majority of the patients were satisfied with the treatment .No major side effect was noted.

CONCLUSION:

LNG-IUS is an excellent treatment modality for patients of DUB, with good patient satisfaction. It is highly effective in controlling blood loss, well tolerated and better alternative for hysterectomy in all age groups.

Keywords: LNG-IUS, Dysfunctional uterine bleeding, hysterectomy.

LIST OF ABBREVATIONS:

DUB	– Dysfunctional uterine bleeding.
AUB	– Abnormal uterine bleeding.
LNG-IUS	– Levonorgestrel intrauterine system.
PMDS	– Polydimethylsiloxane.
MBL	– Menstrual blood loss.
USG	– Ultrasonography.
No	– Number.
Hb	– Haemoglobin.
CBC	– Complete blood count.
B.P	– Blood pressure.
HMB	– Heavy menstrual bleeding.
IUD	– Intra uterine device.
D&C	– Dilatation and curettage.
LAVH	– Laproscopic assisted vaginal hysterectomy.
EM	– Endometrium.
NSAIDS	– Non steroidal anti inflammatory drugs.
PID	– Pelvic inflamatory drugs.
FSH	– Follicle stimulating hormone.
LH	– Leutinizing hormone.

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INTRODUCTION

About 80% of all hysterectomies are carried out for non oncological reasons and abnormal uterine bleeding is one of the most common indications for this surgical procedure in women of child bearing age[1]. AUB is defined as state of abnormal uterine bleeding without any clinical detectable organic, systemic, and iatrogenic cause (pelvic pathology, e.g. tumor, inflammation or pregnancy is excluded). The abnormal bleeding patterns can be annoying and adversely affect the woman's life since unpredictable or heavy bleeding can lead to psychological social, medical and sexual problems and thus necessitate appropriate and adequate treatment[3]. Of all the alternative treatments for abnormal uterine bleeding, levonorgesterol intra uterine system is one among them. The local administration of levonorgesterol shows a major effect on the endometrium, which becomes atrophic and inactive with few glands and scarce mitotic activity[1]. Efficacy in terms of menstrual bleeding reduction evaluated one year after the insertion of device has been reported in between 65% and 90% and adverse effects usually related to gestagens are less frequent and less severe.[1]

LNG-IUS is being shown to be cost effective than hysterectomy and other surgical techniques used in the management of menorrhagia[1]. This advantage is important in terms of health care expenditure as on increasing number of women with abnormal uterine bleeding seek for medical assistance leading to major cost implication[1].

Countries with widespread use of the LNG –IUS are witnessing a significant reduction in the rates of hysterectomy. Approved indications for the clinical use of LNG-IUS in more than 100 countries are for treatment of heavy menstrual bleeding,

contraception and endometrial protection during oestrogen replacement therapy, in recent studies it is well tolerated in the short and midterm treatment of fibroid related menstrual bleeding ,the symptomatic treatment of endometriosis and adenomyosis and in cases of endometrial hyperplasia.

This study aims to evaluate the hysterectomy cancellation rates after a year of treatment with the levonorgesterol intra uterine system[1].

AIMS AND OBJECTIVES

To study the role of levonorgestrel intra uterine system as an alternative to hysterectomy for the treatment of abnormal uterine bleeding.

REVIEW OF LITERATURE

In the late 19th century Intra Uterine Device called 'stem pessaries' were introduced which were made out of glass or metal and look like mushrooms.

By the 20th century the new and improved version of IUD made of silk worm guts made by a German doctor named Dr Richard Richter which was recorded in the medical journal in 1909[6].

In 1930, Dr Ernst Grafenberg & Dr Tenrei Ota wrapped the IUD in a silver wire so that it could be detected in X-rays.

In 1960 Johns Hopkins designed the Dalkon Shield IUD which was derived from the design of Incon Ring that resulted in high expulsion rates.

Dalkon Shield and its spikes dug into the walls of uterus, making it extremly difficult to remove when women wished, which lead to infection

The DalkonSheild made worry of IUD's for many many decades.

By the time of 90's much safer version of IUD's became available and popular in Europeand it was a simpler 'T' shaped and made with softer plastic.

Since 1998 worldwide several new IUD's were under the development

- Lippes-Loop
- Saf-t-coil
- Dana-Super
- Dana cuprum

- Copper-T
- Copper-7
- Multiload
- Progestron IUD

- IUD's were invented in 19th century but came to wide spread in the late 1950'swhen flexible plastic devices were invented by Jack Lippes& others.
- RitvaHuskainen,et al conducted a study in 2004,LNG –IUS Seemed to be an appropriate alternative to hysterectomy for all women who perceived their MBL heavy.
- Alvaro ZapicoGoni. et al in the study in 2009 interpreted that LNG-IUS meets the effectiveness and tolerability criteria for being considered as a first choice treatment option for women with idiopathic menorrhagia
- In 2013 ,Osamashawki, et al in the study , Concluded that for women in their reproductive years, the LNG-IUS has become one of the most acceptable medical treatments for menorrhagia, reducing referrals to specialists , and decreasing the resource operative treatment.

ABNORMAL UTERINE BLEEDING .

Is a symptom and not a disease

As abnormal uterine bleeding without any clinically detectable organic, systemic and iatrogenic cause.

It occurs in various forms. A rational approach and accurate diagnosis depends on recognizing following types

DEFINITIONS:

- Menorrhagia :

Is cyclical bleeding at normal intervals which is excessive in amount or duration.

- Polymenorrhea:

Is cyclical bleeding which is normal in amount but which occurs at too frequent intervals of less than 21 days.

- Polymenorrhagia:

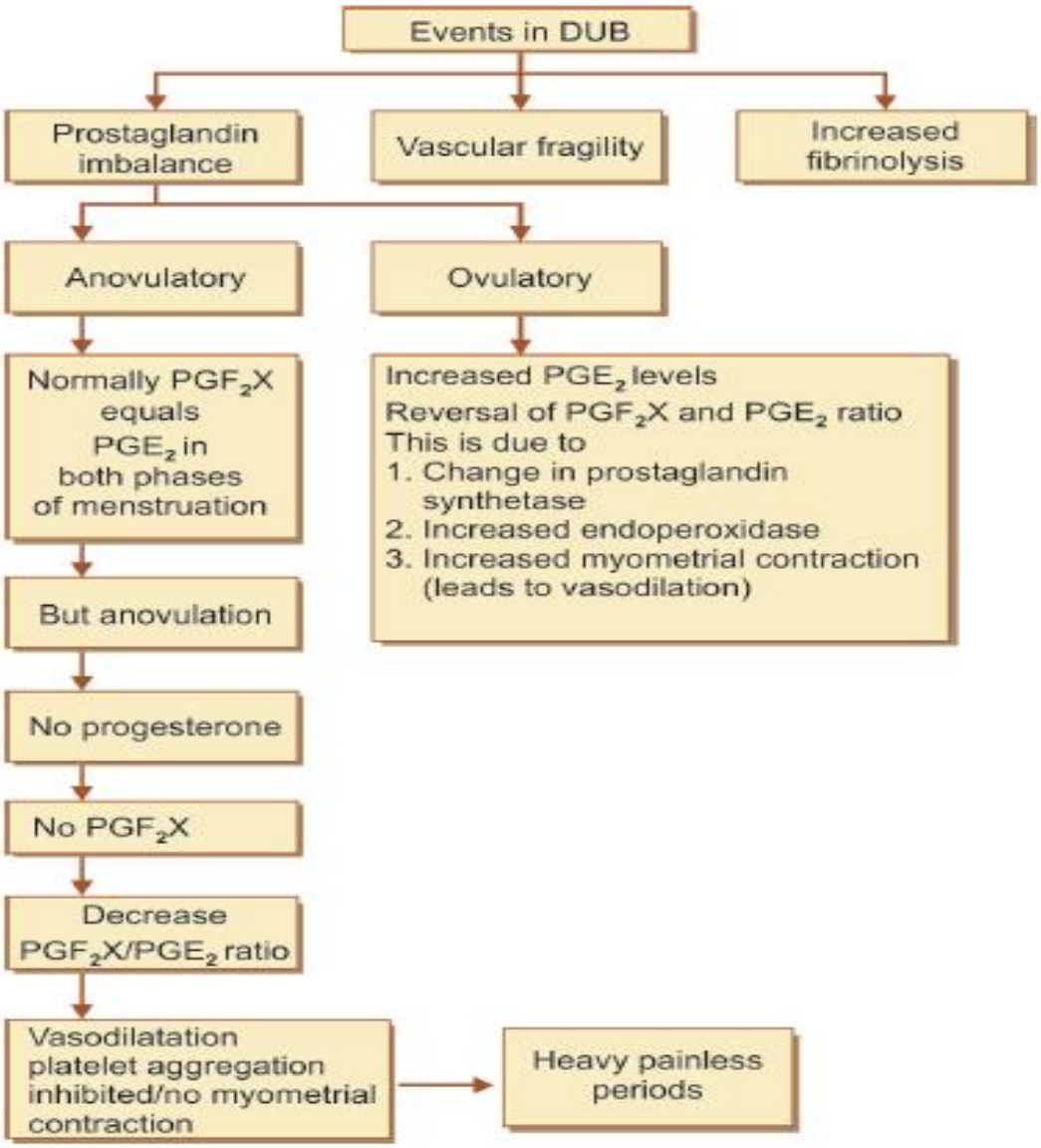
Is cyclical bleeding which is both excessive and too frequent.

- Metrorrhagia:

Is bleeding of any amount which is acyclical and which occurs irregularly or continuosly in between normal cycles.

DEFINITION	INTERVAL	FREQUENCY	AMOUNT	OTHERS
Polymenorrhea	Regular	Increase	Normal	<21 days
Menorrhagia	Regular	Normal	Excessive	>7days >80ml
Oligomenorrhea	Regular	Decrease	Normal	>35 days
Metrorrhagia	irregular	Normal	Normal	
Menometrorrhagia	irregular	Normal	Excessive	Combination metromeno+

PATHOPHYSIOLOGY:



Physiological mechanism of hemostasis in normal menstruation :

- Platelet adhesion formation.
- Formation of platelet plug with fibrin to seal the bleeding vessels.
- Localised vasoconstriction .
- Regeneration of endometrium.
- **Biochemical mechanism** involved are.

In increased endometrial ratio of PGF2 alpha /PGE2, PGF2alpha causes vasoconstriction and reduces bleeding.

In anovulatory DUB, there is decreased synthesis of PGF2alpha and the ratio of PGF2 alpha/PGE2 is low.

Anovulatory cycles are not associated with dysmenorrhea as level of PGF2 alpha is low.

Endometrial abnormalities may be primary or secondary to incordination in the hypothalamo-pituatary –ovarian axis.

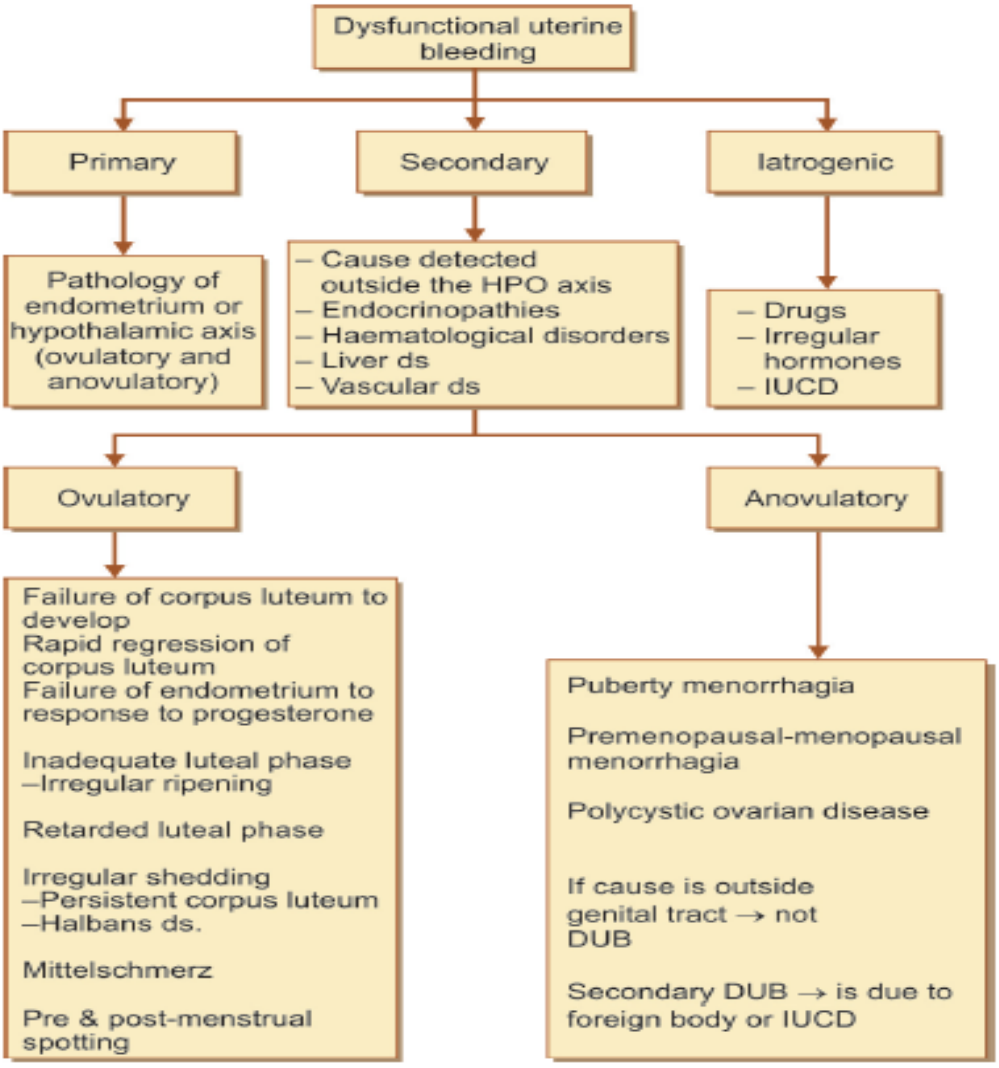
Thus more prevalent in extremes of reproductive period-adolescence and premenopauseor following childbirth and abortion.

Emotional influences, worries, anxieties or sexual problems sometimes are enough to disturb the normal hormonal imbalance.

Abnormal bleeding may be associated with or without ovulation.

1. Ovular bleeding.
2. Anovular bleeding.

Classification of AUB



- **Ovular bleeding**:

  - **Polymenorrhea or polymenorrhagia:**

    Usually occurs following childbirth and abortion, during adolescence and premenopausal period and in pelvic inflammatory disease.

  - **Oligomenorrhea:**

    Primary ovularooligomenorrhea is rare .It may be met in adolescence and preceding menopause. The disturbance may be due to ovarian unresponsiveness to FSH or secondary to pituitary dysfunction.

    There is undue prolongation of the proliferative phase with secretory phase.

    Endometrial study reveals secretory changes.

Functional menorrhagia:

Ovular menorrhagia is uncommon

Two varities are found.

- Irregular shedding of the endometrium.
- Irregular ripening of the endometrium.

Irregular shedding of the endometrium:

Abnormality usually met in extremes of reproductive period.

Normally, regeneration of the endometrium is completed by the end of third day of menstruation.

In irregular shedding, desquamation is continued for a variable period with simultaneous failure of regeneration of the endometrium.

Causes:

- Incomplete withdrawl of LH even on 26th day of cycle

  ⇩

  Incomplete atrophy of the corpus luteum

  ⇩

  Persistent secretion of progesterone.

- Persistent LH

  Inhibition of FSH

  Suppresses the ripening of the follicle in next cycle.

  Less estrogen-less regeneration.

Endometrial sampling after 5th or 6th day of onset of menstruation reveals a mixture of secretory and proliferative endometrium.

Irregular ripening of the endometrium:

Poor formation and inadequate function of the corpus luteum. Secretion of both estrogen and progesterone is inadequate to support the endometrial growth.

Endocrine profile in the luteal phase shows persistent low level of urinary pregnanediol and that of plasma progesterone.

Endometrial study prior to or soon after spotting reveals patchy areas of secretory changes amidst proliferative endometrium.

Anovular bleeding:

- Menorrhagia:

  Anovulatory bleeding is usually excessive .In the absence of growth limiting progesterone due to anovulation, the endometrial growth is under the influence of estrogen

- Cystic glandular hyperplasia:

  Mainly in Premenopausal women.

  It may be due to disturbance of rhythmic secretions of the gonadotrophins or problem with the ovaries. Slow increase in secretion of estrogen but no negative feedback inhibition of FSH. Gradual level rise in amenorrhoea for about 6-8weeks.After some period estrogen level falls resulting in endometrial shedding with heavy bleeding.

  Bleeding is prolonged until the endometrium and blood vessels regenerate to control it. Variable degree of myohyperplasia with symmetrical enlargement of uterus to a size of about 8-10 weeks due to simultaneous hypertrophy of muscles.

  Cystic changes are involved in one or both ovaries.

- **Investigations;**

  Before going for investigations, case should be evaluated for

  - Menstrual abnormality,
  - Systemic, iatrogenic or organic pelvic pathology.
  - Identify possible etiology of DUB.
  - History should be elicited.

- Bimanual examination including speculum examination should be done in all cases except in virgins, rectal examination done to exclude palpable pelvic pathology.
- Blood values:

  Hemoglobin estimation done.

  Platelet count

  Prothrombin time.

  Bleeding time.

  Partial thromboplastin time.

- Thyroid profile.
- Ultra sonography.

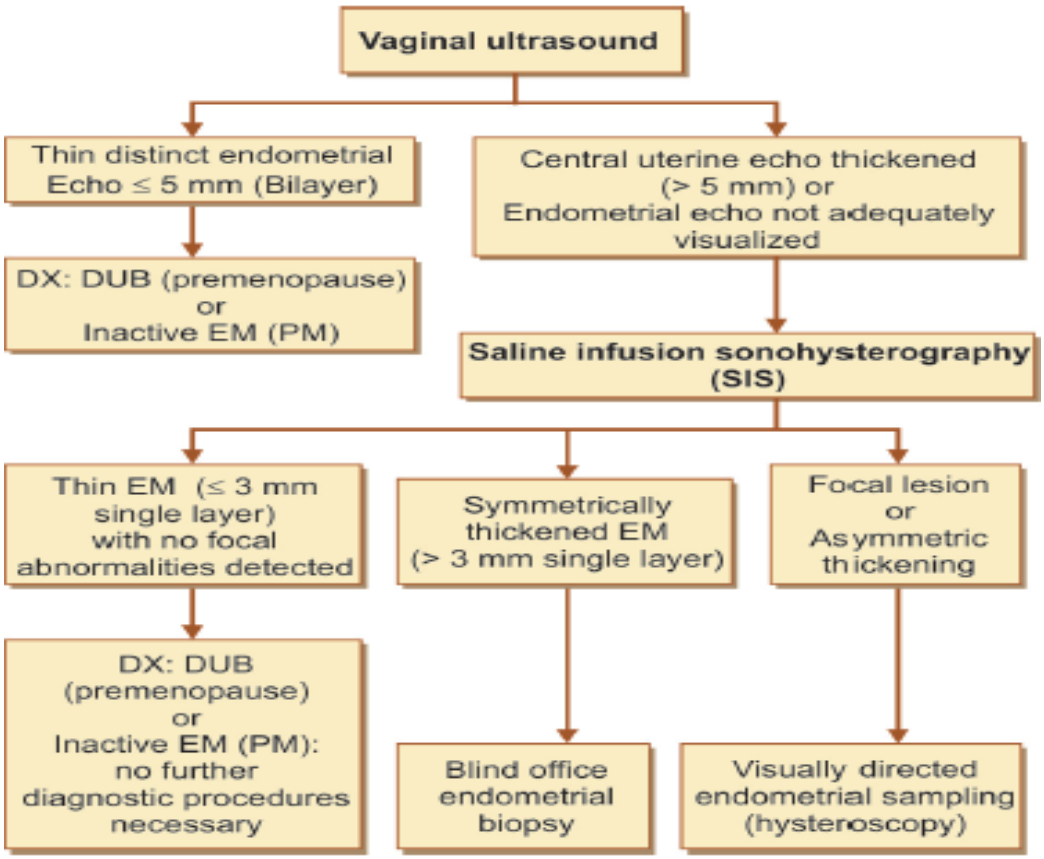
Is an adjunct if pelvic examination is unreliable mainly in obese women or retroverted uterus.

Vaginal transducer in excluding organic pelvic lesions.-enlarged uterus, leiomyomas,

Adenomyosis, complications of pregnancy, ovarian cyst, endometriosis.

Endometrial thickness can be measured by transvaginal scan.

Clinical algorithm for ultrasound based triage for any patient with AUB



- Hysteroscopy.

  Better evaluation of endometrial lesion and to take biopsy from the offending site under direct vision.

- Endometrial sampling:

  To exclude local intrauterine lesion such as uterine polyp, tubercularendometritis and carcinoma as a cause of bleeding. Done on outpatient basis, pipelle sampler is easy to use.

- Laproscopy: To exclude unsuspected pelvic pathology. Such as endometriosis, PID or ovarian tumour (granulose cell tumour)
- Endometrial biopsy: Diagnostic uterine curettage (D&C)

  To exclude organic lesions in the endometrium

  To determine the functional state of the endometrium.

Treatment:

General measures:

- Rest
- Sedatives if anxiety present
- Dietetic errors and any cause of emotional upset should be corrected.
- Anaemia should be corrected.

Medical management:

- **Non hormonal methods:**

Prostaglandin synthetaseinhibitiors:

- Prostaglandin E compounds are increased in menorrhagia.
- Mefenamic acid, 250-500mg thrice daily is effective in reducing menorrhagia.

Antifibrrinolytic agents:

Tranexemic acid 1gram, two to four times daily.

e-aminocaproic acid(EACA) 3g.four to six times daily.

Tranexemic acid acts by inhibiting the tissue plasminogen activator, a fibrinolysis enzyme which is raised in DUB

Hormones:

Oestrogens:

- If bleeding is heavy or is anovulatory and unresponsive to progestogens, parenteral conjugated equine oestrogens (CEE) can be given.
- Dose of 12.5 mg IV to stop bleeding and repeated after 12 hours if necessary.

Oestrogens and progestogens:

- Combined oral contraceptive can be used in ovulatory DUB.
- Sequential oestrogen and progestin can be used.
- Endometrium taken through its full cycle and should shed normally 2-20 days after course is completed.

PROGESTOGENS:

- Anovulatory type of dysfunctional uterine bleeding in girls and young women.
- Progesterone injection or orally.
- It converts the hyperplastic endometrium into a secretory phase and then precipitate normal shedding when treatment discontinued.
- Progestogens may be administered cyclically 3 months.
- Progesterone and IUCD have been used in anovulatory DUB.
- IUCDs have advantage of avoiding daily administration and systemic side effects.
- Blood loss decreased by 90%.

Emily (Levonorgestrel releasing intrauterine system.)

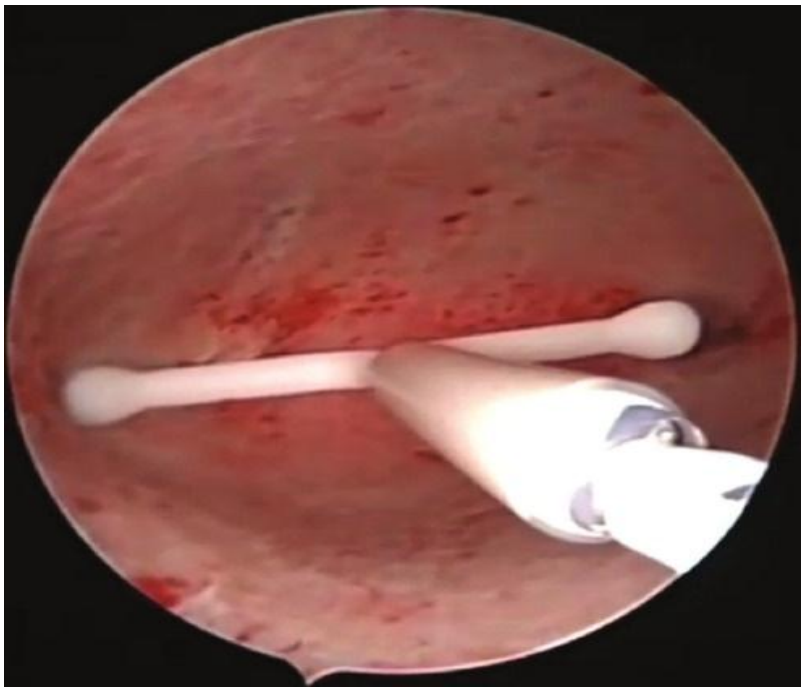


Figure 1: Hysteroscopic view of LNG IUS inside the uterine cavity

Design and composition of Emily:

- Hormone releasing system placed in the uterus to prevent pregnancy for upto 5 years.
- It also lessen menstrual blood loss in women who have heavy menstrual flow.
- Emily is M shaped.
- It is made of flexible plastic and contains a progestin hormone called levonorgestrel.
- Two threads are attached to Emily.

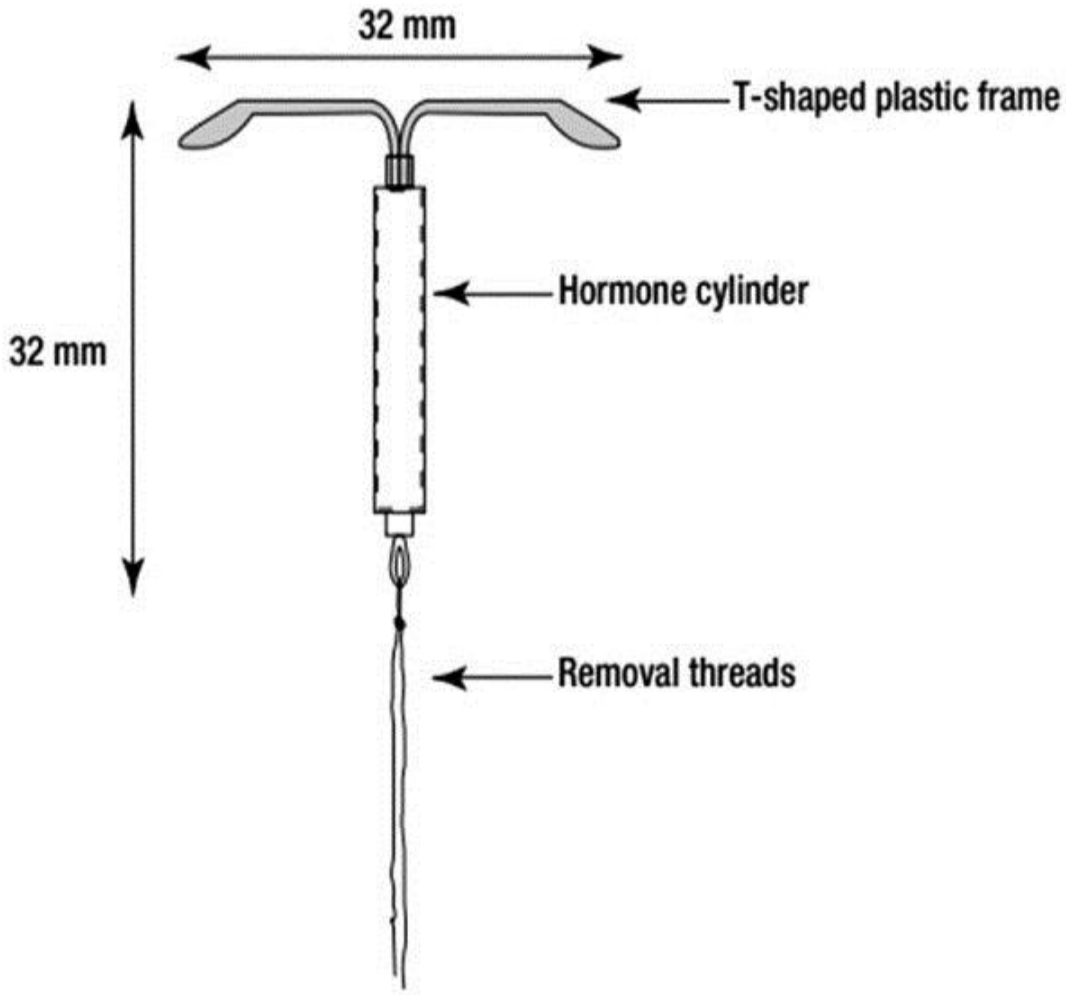


Figure 2 : Schematic illustration of levonorgestrel intrauterine system

Mode of action of Emily:

It works in several ways.

- It thickens cervical mucus, thin the lining of the uterus, inhibit sperm movement and reduce sperm survival.
- It reduces menstrual bleeding by thinning the lining of the uterus.

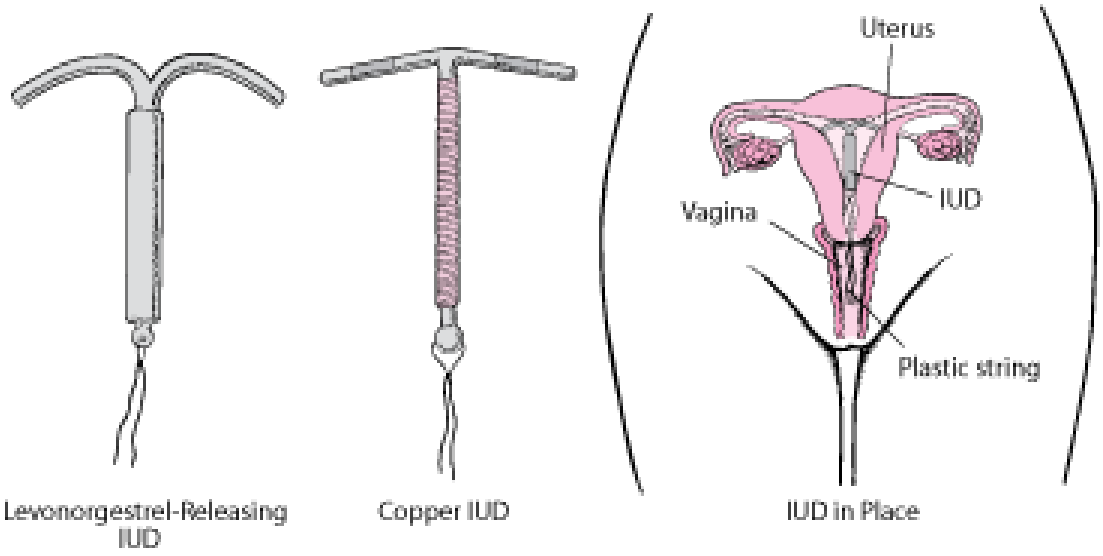


Figure 3: Showing different IUD's and showing IUD in place.

Indications;

- Needs treatment for menorrhagia.
- Reversible birth control method.

Contraindications for Emily:

- Might be pregnant.
- Pelvic inflammatory disease.
- Liver disease.
- Fibroid.
- Breast cancer suspected.

ANDROGENS:

- Androgens will control DUB of any type ,but are to be avoided because of virilising effects
- In women of more than 40 years, 5-10mg methyltestosterone daily can be given but not longer than 2 months.

Danozol:

- 200-400mg for 12 weeks reduces the blood loss by 50%.

GnRHanologues:

- Gonadotrophinanologues used mainly for bleeding associated with leiomyomas can be used in DUB as well.

SURGICAL MEASURES:

The place of surgery in the treatment of excessive bleeding without an organic basis.

Last resort in young girls but may be considered earlier in women over the age of 40 years.

Curettage:

Diagnostic and it appears to be curative.

Levonorgestrel intrauterine device

T shaped frame made by polydimethylsiloxane.

Contains 52mg LNG.

Releases 20microgram / 24hours of hormone. Effective for 5 years.

Mode of action:

Uniform suppression of endometrial proliferation.

Renders cervical mucus scarce and viscous.

Does not suppress ovulation but does not affect ovarian function.

Lowers progesterone during luteal phase

Efficacy:

Failure rate 0.5–1.1%

Pearl index 0.14.

Endometrial Effects:

- Levonorgestrel is 19-nortestosterone derivative interferes with proliferation-stimulating effects of oestrogen despite presence of N plasma estradiol levels.
- Down regulation of oestrogen receptors. Anti-mitotic effect on endometrium.

TRANSCERVICAL ENDOMETRIAL RESECTION

Criteria for Transcervical Endometrial Resection

- Abnormal or excessive menstrual bleeding
- No relief from medical therapy
- Benign endometrial histology and Pap Smear.
- Uterus size less than 10 weeks.
- Submucous fibroid less than 6 cm.
- Completed family.

Anaesthesia:

- Sedation/Local anaesthesia
- Spinal/Epidural anaesthesia

Advantages

- Safe and effective
- Rapid recovery
- Quicker

- Less costly
- Easier.
- Adequate tissue can be obtained for histopathology.

MICROWAVE ENDOMETRIAL ABLATION

- Introduced by Microsulis of UK in 1994.
- Fastest treatment within 3 minutes.
- Indicated in DUB with or without dysmenorrhoea who do not wish to have hysterectomy.

Treatment

- Transvaginal scan to assess uterus.
- Endometrial biopsy to rule out malignancy.

Analgesia

- Nonsteroidal anti-inflammatory drugs (NSAIDs).
- Local cervical block with 4-quadrant technique.

Safety:

- Low power and low energy
- No risk of earthing injury
- No risk of perforation
- No fluid overload
- No risk of haemorrhage

It is safe, effective, quick, easy and reusable.

Global Endometrial Ablation Techniques:

Several simpler procedures are being developed for the blind ablation of the endometrium.

Fluid-filled thermal balloons are placed in the uterus.

These use hot water or saline delivered by disposable balloon catheters under sophisticated computer control to regulate temperature.

Other techniques which have been tried include radio frequency thermal balloon, three-dimensionalbipolar ablation, microwave endometrial ablation, laser interstitialhyperthermyusing an Nd:YAGlaser, and cryoablation.

These methods are still under trial and long-term results are awaited.

Hysterectomy

When the patient is over 40 years of age, and when the haemorrhage fails to respond to simpler measures, hysterectomy is indicated.

It is the treatment of choice in all cases of persistent or recurrent postmenopausal bleeding for which there is no obvious cause.

Hysterectomy can usually be carried out easily by the vaginal route and this involves little risk.

In younger women, this is to be avoided whenever possible.

A detailed preoperative work-up including hysteroscopy is essential in all young women, to be sure that this operation is warranted.

The exact procedure depends on the patient and the surgeon—vaginal, abdominal or laparoscopy-assisted vaginal hysterectomy (LAVH) have all been used, but the last is not usually required unless there are adhesions or some other pelvic lesion.

MATERIALS AND METHODS

METHOD OF COLLECTION OF DATA:

SOURCE OF DATA:

This study will include out patient and in patient in BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre who will bediagnosed with abnormal uterine bleeding. The patients will be informed in all respects and informed consent will be obtained.

PERIOD OF STUDY: November 2015 to august 2016 with one year follow up.

SAMPLING:

According to the study [1] shows that efficacy of menstrual bleeding reduction in one year after the insertion of the device ,81% (average of 65% to 97%) considering 95% confidence level and at 15% allowable error, the calculated sample size is 40

Formula used to calculate the sample size is

$$N = \frac{Z\alpha^2 \times P \times (100-p)}{L}$$

zα – z value at α level 95%

P- efficacy of menstrual bleeding reduction

L-allowable error

n=1.96*1.96*81*19/

5912.222/146.6

40.05

Hence minimum 40 cases will be included in the study.

STATISTICAL ANALYSIS:

Following statistical tests will be used to compare the results:

i) Diagrammatic presentations.

ii) Mean ± SD

iii) Paired t test

ANOVA test if necessary

METHODOLOGY :

Information will be collected through pre tested and structured proforma for each patient. Qualified patient will be undergoing detailed history, clinical examination and routine investigation

PERIOD OF STUDY: November 2015 to august 2016 with one year follow up.

DETAILS OF THE STUDY:

INCLUSION CRITERIA:

All patients who are diagnosed as abnormal uterine bleeding will be explained about the procedure in their language and who agree to give consent will be included in the study.

EXCLUSION CRITERIA:

- Pelvic infections.
- Malignant and premalignant conditions.
- Cases with pregnancy complications.
- Acute liver disease or liver tumors.
- Hypersensitivity to levonorgesterol.
- Uterine fibroids.
- Thyroid complications.
- Post menopausal bleeding.
- Bleeding diathesis.

RESULTS AND OBSERVATION

Table 1 : Percent distribution of obstetric score with no of patients.

Obstetric History	No. of Patients	Percentage
Nulligravida	1	2.5
P1L1	1	2.5
P2L1D1	1	2.5
P2L2	9	22.5
P3L2D1	1	2.5
P3L3	21	52.5
P4L4	5	12.5
P5L5	1	2.5
Total	40	100.0

Patients with different obstetric history does not differ significantly, Comparatively multi gravida percentage is more than nulligravida. Here P3L3 with 52.5% and nulligravida with 2.5

Graph : 1 Obstetric History of Patients(%).

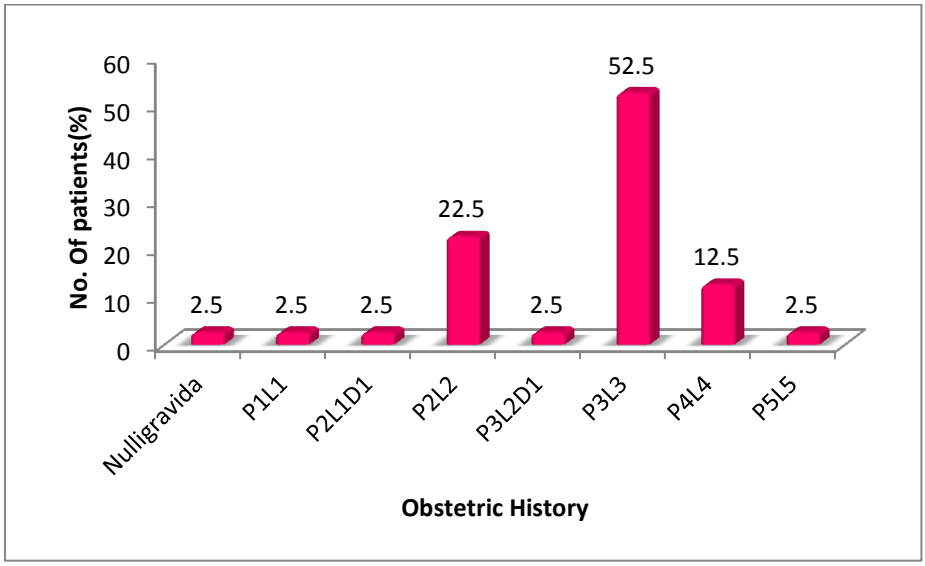


TABLE 2 : Menstrual patterns at baseline and at 1 year follow up

Menstrual history	No. of Patients	After follw up of 1 year
Normal period	0	25
Oligomenorrhea	0	50
Intermenstrual spotting	0	7.1
Amenorrhoea	0	22.5
Persistent menorrhagia	100	0
Dysmenorrhea	0	10.7
Polymenorrhea	0	0
Total	40	

10 patients out of 40 had normal periods, 20 patients had oligomemorrhea at 1 year follow up. None of the patients followed up till 1 year, had persistent menorrhagia or polymenorrhea.

Only one patient had persistent menorrhagia who underwent premature removal. The patient who had premature removal excluded from further follow up, after removal as they underwent hysterectomy.

Graph 2 : Percentage distribution of follow up of patients with abnormal uterine bleeding.

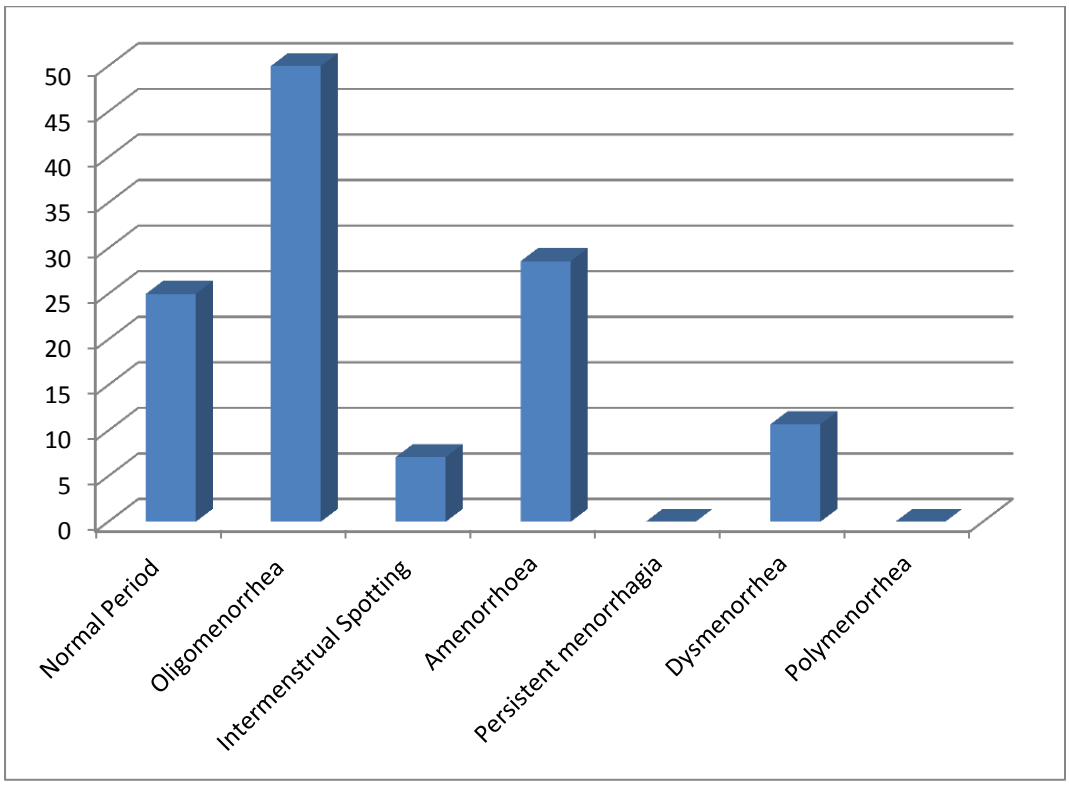


TABLE 3 : PERCENTAGE DISTRIBUTION OF OF PATIENTS IN TERMS OF PALLOR:

Pallor	No. of Patients	Percentage	After 1 year follow up
Absent	39	97.5	40
Present	1	2.5	0
Total	40	100.0	100

Out of 40 patients, 97% of people recruited in the study with normal haemoglobin levels, and rest 2.5% with normal haemobin level. At the end of one year significant increase in the haemoglobin is seen with overall improvement in the health of the patient with normal.

Graph 3 : Distribution of Patients according to Pallor

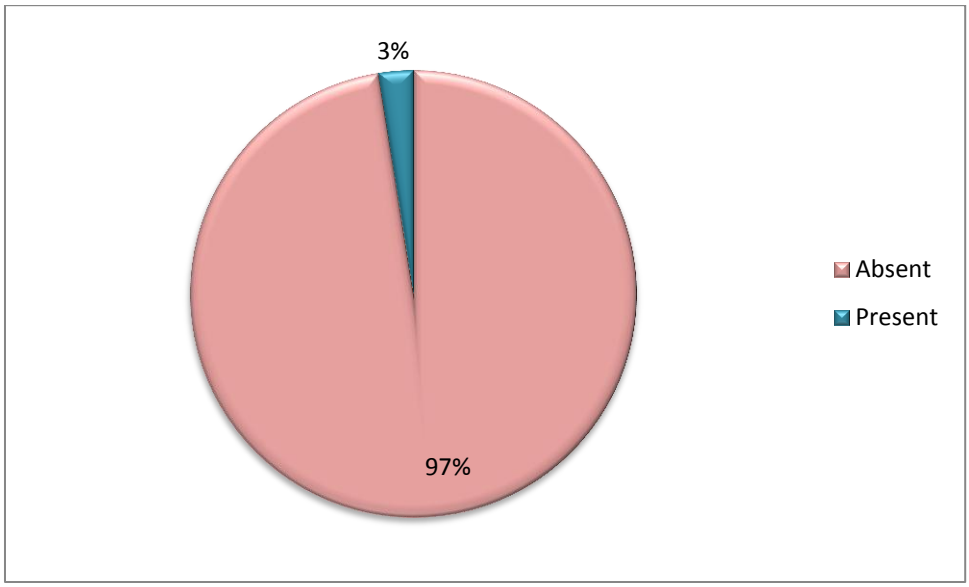


TABLE 4 : DISTRIBUTION OF PATIENTS IN TERMS OF USG.

USG	NO OF PATIENTS	PERCENTAGE
NORMAL	**40**	**100**

In present study, all 40 patients who were enrolled, were selected with normal endometrial thickness and no detected abnormality in the USG.

Hence 100% of patients with normal ultrasonography.

TABLE 5 : PERCENTAGE DISRIBUTION OF PATIENTS UNDERWENT HYSTERECTOMY

NO OF PATIENTS	HYSTERECTOMY	PERCENTAGE
39	NO	97.5
1	YES	2.5
40	TOTAL	100.0

In present study, out of 40 patients, one patient undergone hysterectomy.

It comes with success rate of 97.5%, after one year of follow up.

One patient with persistent menorrhagia, lead to premature removal and underwent hysterectomy.it comes with 2.5% of failure rate.

COMMENT: LNG-IUS has better results and significant reduction in bleeding over a period of one year

Graph 4 : Number of patients undergone Hysterectomy.

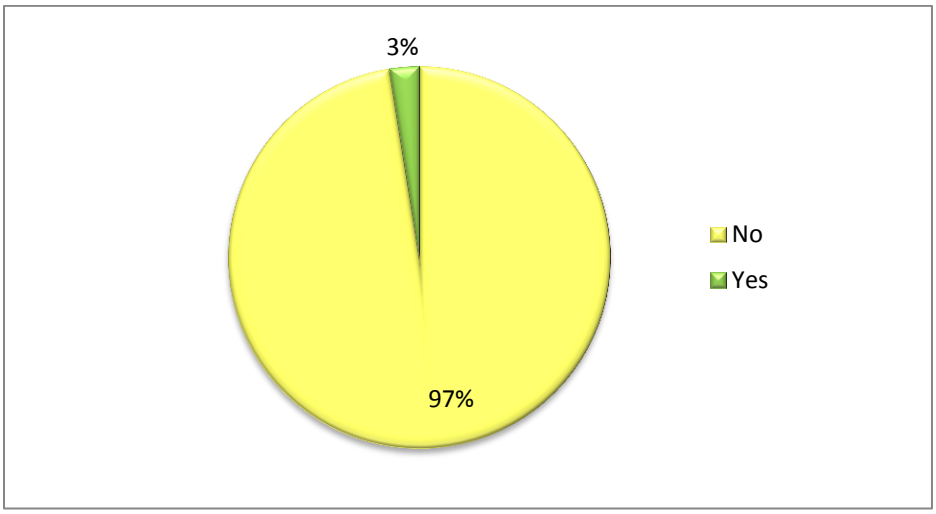


TABLE 6 : PERCENTAGE DISTRIBUTION OF PATIENTS WITH ENDOMETRIUM SAMPLING

ENDOMETRIAL SAMPLING	NO OF PATIENTS	PERCENTAGE
ASYNCHRONUS ENDOMETRIUM	1	2.5
DISORDERED PROLIFERATIVE ENDOMETRIUM	3	7.5
NO OPINION POSSIBLE	1	2.5
NORMAL	1	2.5
PROLIFERATIVE PHASE	27	67.5
SECRETORY ENDOMETRIUM	2	5.0
SIMPLE ENDOMETRIAL HYPERPLASIA WITH META	1	2.5
SIMPLE ENDOMETRIAL HYPERPLASIA WITHOUT A	4	10.0
Total	40	100.0

The most common endometrial histopathological pattern was proliferative phase. Other patients mainly had simple endometrial hyperplasia, and secretory endometrium, and none of the patients had compex hyperplasia.

COMMENT: This rules out the cases of malignancies and gynecological disorders associated with the case.

Graph 5 : Endometrial samples

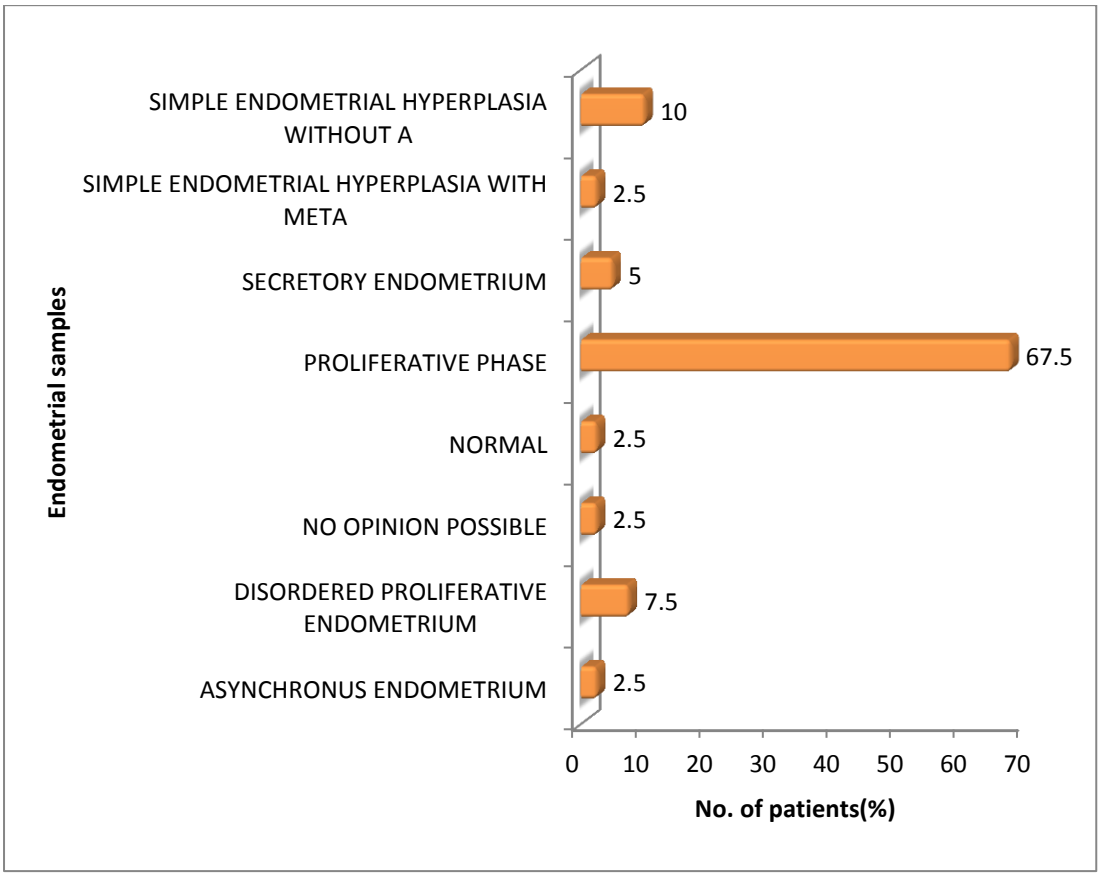
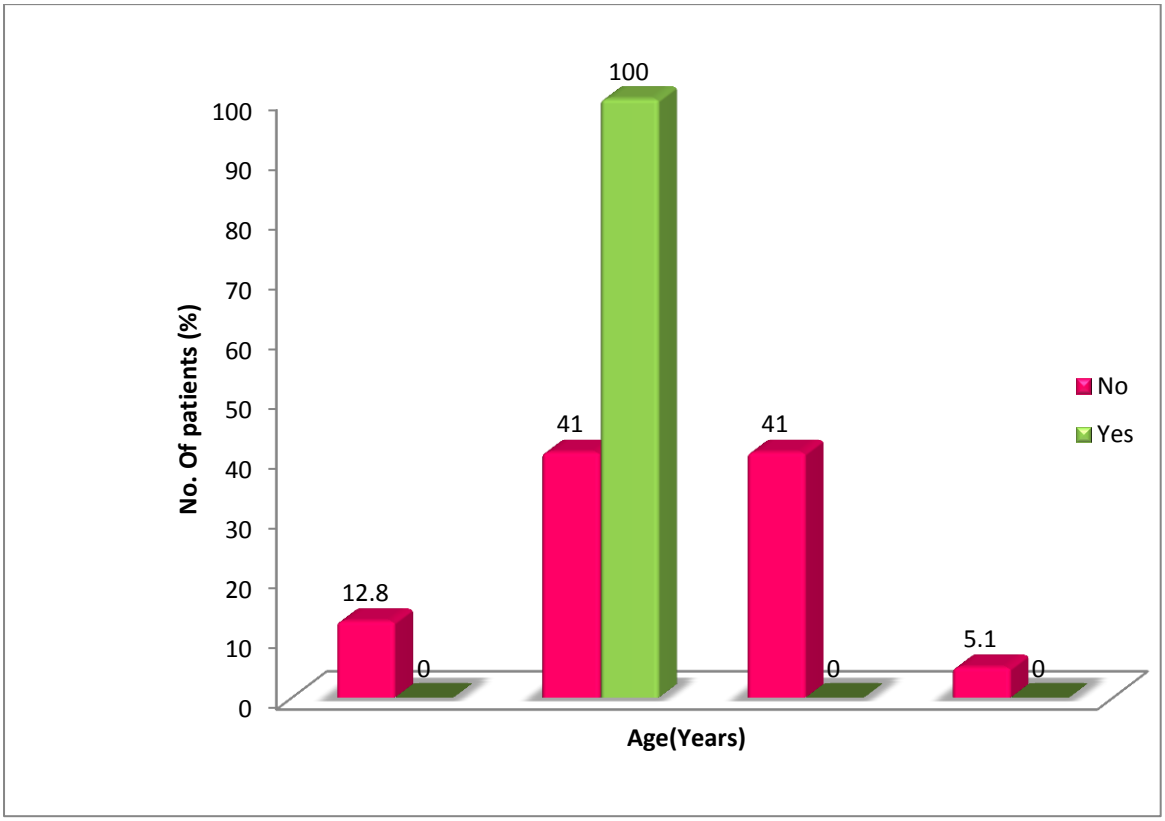


TABLE 7 : PERCENTAGEDISTRIBUTION OF CASES IN ASSOCIATION WITH AGE AND HYSTERECTOMY

Age(Years)	HYSTRECTOMY		Total	Chi square test
	No	Yes		
< 30	5	0	5	
	12.8%	.0%	12.5%	
30 - 39	16	1	17	
	41.0%	100.0%	42.5%	P=0.78
40 - 49	16	0	16	NS
	41.0%	.0%	40.0%	
50+	2	0	2	
	5.1%	.0%	5.0%	
Total	39	1	40	
	100.0%	100.0%	100.0%	

NS - There is no association between age and Hysterectomy (p=0.78) 40 patients are divided into 4 groups.< 30,30-39,40-49 and 50 +, where 1 patient underwent hysterectomy in age group between 30 -39. Rest all patients with other group are satisfied with LNG-IUS.P value 0.78 there is no association between age and hysterectomy.

Graph 6 : Association between age and Hysterectomy of patients



DISCUSSION

This is a prospective and observational study about the role of levonorgestrel intra uterine system as an alternative to hysterectomy for the treatment of abnormal uterine bleeding.40 patients with dysfunctional uterine bleeding were taken for the study.It provides a non surgical alternativecontinuation rate of 97.5% after one year shows high acceptance.

In abnormal uterine bleeding, their in significant reduction in menstrual blood loss with the use of LNG. This effect is based on the marked local action of intrauterine release of LNG on the endometrium.

A study by Taru G et al in 2013 conducted a study on the acceptability, efficacy, adverse effect and user satisfaction of levonorgestrel intrauterine system concluded that LNG IUS is a less invasive, effective treatment modality for menorrhagia.

This is an observational descriptive study where menstrual pattern, pictoral blood loss assessment, chart score, adverse effects and rate of acceptability and satisfaction were recorded over a period of one year after procedure, with the mean age of sample size 39.92years. After follow up of one year 33.87% were amenorrhic and 51.61% have regular period while 3.07% patients had irregular periods.

COMPARISON OF ADVERSE EFFECTS.

Study/sample size	Our study (40)	Kriplani et al(63)	Chattopdhya et al(42)
Irregular bleeding	7.1%	71%	28.5%
Perfortion	-		
Expulsion	2.5%		2.38%
Weight gain	-	30.5%	
Pain	-	38%	4.76%
Headache	-	13.3%	
Vaginitis	5.1%	33.3%	

A study conducted by Gupta .R et al. Reported good results with failure rate of only 3.4% i.e 1 out of 29 patients in DUB patients, comparitively higher in fibroid patients with 23.3%i.e 7 out of 30.

Haemoglobin and serum ferritin levels were significantly increases in both the groups with no major side effects. LNG-IUS is an excellent treatment moality for patients of dub, with good patient satisfaction. It is also a useful treatment option in sub mucosal fibroids for symptoms of menorrhagia.

Present study has a failure rate of 2.5%i.e 1out of 40.fibroid uterus were under the exclusion criteria.

Singh K et al found LNG IUS is highly effective in controlling bleeding and better alternative for hysterectomy with higher satisfaction in all age group of women.

Initially 37.5% of patients complained of irregular bleeding which was reduced after a year of follow up and 2nd most complaint was irregular spotting for

32.5% people which persisted in 7.4% patients at 1 year follow up. Preliminary endometrial biopsy was done to rule out malignancy.

In our study 7.1% patients had irregular spotting after follow up of one year, histopathologicalreport were considered.

Goni AZ et al conducted a prospective observational study where 82 were enrolled with mean age of 44.3., after 1 year follow up, progressive reduction in bleeding and no of sanitary measures was observed. Significant improvement in overall health related quality of life was achieved and contributed to decrease in the large number of hysterectomies.

In our study,97.5% were reported with patient satisfaction with LNG-IUS hysterectomies were reduced.no serious adverse effects were encountered.

A prospective observational study conducted by Lete. I et al with 225 women with one year follow up found significant reduction of bleeding, an improved quality of life with 98%satisfication.Here mainly QoL of women treated with the lNG-IUS is markedly improved, causing high levels of patient satisfaction. They regarded IUS as first choice therapy in idiopathic menorrhagia. This study had certain limitations, there was no control group for this study. Second limitation is that patient were followed up during only one year and further Analysis are required.

Roy k, conducted a prospective interventional comparative study conducted on women with abnormal uterine bleeding, found statistical improvement in the Hb level after insertion of LNG-IUS.

A observational study conducted by Tariq N et al to find out clinical response, side effects, and patients acceptability of levonorgestrel –releasing intrauterine system (LNG-IUS) . Adult women were enrolled, where two groups were enrolled where 57 women with abnormal uterine bleeding and 16 married woman for contraception.

In group A, at the end of one year 50.9% experienced normal cycle,8.8% wereoligomenorrhic 12.3% were amenorrhic.in group B menstrual pattern at the end of one year showed normal cycles in 52%,oligomenorrhea in 19% and amenorrhea in 10% women. Vaginal spotting was the main complaint in 10% at the end of an year.

Concluded with LNG-IUS is an effective and acceptable treatment for abnormal uterine bleeding as well as contraception .Vaginal spotting was most frequent side effect experienced by both groups.

Present study come up with minimal side effects and 97.5% success rate.

In the study conducted by Baxi A et al, which was a descriptive ,prospective and non comparative study here 44 women enrolled with complaints of menorrhagia after the medical therapies had failed .at the end of 2 year 88.6% of participants continued the use of LNG –IUD and found it acceptable. They found that LNG IUD is effective treatment and could be an alternative treatment for women with menorrhagia who are either contraindicated for or refuse hysterectomy or endometrial ablation.

A case controlled retrospective study conducted by Oliveira N, to identify the difference in levonorgestrel releasing intrauterine system efficacy or weight gain when used in HMB treatment between obese and non obese women. After 2 nd year followup there was a similar improvement in two groups regarding duration of menses, spotting and in analytic parameters of anaemia and menstral characteristics

without weight gain. Hence concluded that in obese women, the LNG-IUS is an effective treatment for HMB ,without being associated to weight gain.

A study conducted by Eralil J.G, a retrospective observational study of 70 women diagnosed with AUB and treated with LNG-IUS and usual medical treatment .baseline biopsies were done before insertion. primary outcome in the two treatment groups was significantly better among women assigned to LNG-IUS than among those assigned to usual treatment .this study concluded that leonorgestrel –IUS was more effective choice ,as assessed by the impact of bleeding on the women's quality of life.

A prospective, non randomized clinical study conducted by B.Chattopdhyay et al. aimed to evaluate the efficacy ,acceptability and side effects of levonorgestrel intrauterine system in patients with idiopathic menorrhagia .This study reported the reduction in mean blood loss was found to be stastically signigicant with a p value of <0.001 for all the follow up periods. They concluded that LNG –IUS as an effective friendly device with a high degree of compliance and worth considering as a viable alternative to surgery for menorrhagia due to dysfunctional uterine bleeding in developing countries like India.

CONCLUSION

LNG IUS can be a good alternative to the surgical treatment for abnormal uterine Bleeding with high acceptability rate and good efficacy. Present study, shows that LNG IUS is easy to insert has a sustained effect, cost effective, and well tolerated.

Present study brought out that LNG IUS appears equally effective as hysterectomy in improving quality of life in patients of DUB .It can serve to bring down the incidence of hysterectomies.

According to our study, LNG IUS meets the effectiveness and tolerability criteria for being considered as a first choice treatment option for women with abnormal uterine bleeding. LNG IUS can help to save uterus.

SUMMARY

Abnormal uterine bleeding is a common gynecological complaint affecting 10-30% of reproductive aged women. The abnormal bleeding patterns can be annoying and adversely affect the quality of woman's life .Heavy bleeding leads to anemia and its complications.

Abnormal uterine bleeding is one of the most frequent indication for hysterectomy. One of the better alternative treatment is levonorgestrel intrauterine system.

This is a prospective and observational study conducted in shri B. M. Patil Medical College, Vijayapura. 40 patients were included in the study with dysfunctional uterine Bleeding. Women diagnosed with dysfunctional uterine bleeding with an indication for hysterectomy were enrolled in the study and inserted LNG-IUS, followed up for a year.

Among 40 patients enrolled, a high degree of satisfaction reported by 97.5% with improvement in the symptoms of dysfunctional uterine bleeding. Patients with 2.5% only didn't resolve with LNG-IUS and underwent hysterectomy. There was a significant reduction in the amount of bleeding and haemoglobin levels with no major side effects. LNG-IUS is an excellent treatment modality for patients with DUB and contribute to decrease in large number of hysterectomies.

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ANNEXURE - I

ETHICAL CLEARANCE

B.L.D.E.UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR – 586103
INSTITUTIONAL ETHICAL COMMITTEE

No/58/2015
20/11/15

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 17-11-2015 *at* 03 pm *scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.*

Title "The levonorgestrel intrauterine system as an alternative to hysterectomy for treatment of abnormal uterine bleeding"

Name of P.G. Student : Dr Pallavi Hosamani
Dept of Obstetrics & Gynaecology

Name of Guide/Co-investigator : Dr. Mrs. Shailaja. R. Bidri
Professor

DR.TEJASWINI VALLABHA
CHAIRMAN

CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization:
1)Copy of Synopsis/Research Project
2)Copy of informed consent form.
3)Any other relevant documents.

INFORMED CONSENT

BLDE UNIVERSITY'S SRI BM PATIL MEDICAL

COLLEGE VIJAYAPUR-586103

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

INFORMED CONSENT FOR PARTICIPATION IN DISSERTATION/RESEARCH

I have been informed that this is a prospective study is to know the role of levonorgestrel intrauterine system in ABNORMAL UTERINE BLEEDING patients as an alternative to hysterectomy visiting to BLDE University's Shri B. M. Patil Medical College Hospital &Research Centre, Vijayapura.

PROCEDURE:

I understand that i will undergo detailed history and clinical examination and investigations.

RISKS AND DISCOMFORTS:

I/my ward understand that I/my ward would not have any discomfort with my study. I/my ward understand that necessary measures will be taken to reduce any kind of complications as and when they arise.

BENEFITS:

I/my ward understand that my participation in this study will help to know the role of levonorgestrel intra uterine system in DUB patients as an alternative to the hysterectomy.

CONFIDENTIALITY:

I/my ward understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of BLDE University's Shri B.M. Patil Medical College Hospital & Research Centre, Vijayapura. Information r n of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr. Pallavi hosamanis available to answer my questions or concerns. I/my ward understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I/my ward understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I/my ward also understand that Dr. Pallavi Hosamani will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

STUDY SUBJECT CONSENT STATEMENT:

I/my ward confirm that Dr. Pallavi Hosamani explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I/my ward have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(Witness to above signature) Date

PROFORMA

THE LEVONORGESTREL INTRAUTERINE SYSTEM AS AN ALTERNATIVE TO HYSTERECTOMY FOR TREATMENT OF ABNORMAL UTERINE BLEEDING"

Name:

Age/Sex:

O.P.No./I.P.NO

Occupation:

Case no:

DOA: DOD:

Address:

Chief complaints:

History of presenting complaints

Menstrual history

- Past menstrual cycle;
- LMP

Obstetric history

- Married life
- Obstetric score

Past history:

Family history:

Personal history:

GENERAL PHYSICAL EXAMNIATION:

Build & nourishment: P.R :

Height:B.P :

Weight: R.R :

Temp;

Breast:

Thyroid:

Spine

Pallor/ icterus/ cyanosis/clubbing/edema /lymphadenopathy.

SYSTEMIC EXAMINATION:

CVS:

RS:

PER ABDOMEN:

PER SPECULUM EXAMINATION:

PER VAGINAL EXAMINATION:

INVESTIGATIONS / INTERVENTIONS:

1. **BLOOD INVESTIGATIONS:**

- CBC:
- BLOOD GROUPING AND TYPING:
- BT:
- CT:
- HIV
- HBSAG
- USG
- URINE ROUTINE.
- THYROID PROFILE.
- GRBS.
- ENDOMETRIAL SAMPLING i.e DIAGNOSTIC DILATATION AND CURETTAGE

KEY TO MASTER CHART

Sl. No - Serial No

P - Parity

L - Living

D - Death

USG - Ultrasonography