A Prospective Study on Medical Management of Abnormal Uterine Bleeding Cases in Respect with Palm -Coein Classification.

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ABSTRACT:

Background:

Abnormal Uterine Bleeding (AUB) is a common gynaecological symptom in the women of reproductive age. The PALM - COEIN classification helps to practically ascertain the cause of AUB, and there by effectively adopt and plan for focused treatment of patients. In this research article we have found that AUB-O is the most common type of AUB followed by AUB-L and AUB-E. To avoid the morbidity associated with hysterectomy, medical management was mostly preferred. Tranexamic acid and mefenamic acid was found to be most commonly chosen medication to control abnormal menstrual blood loss and to control pain respectively. Among hormonal preparations, both Progesterone and OC Pills were found to be equally effective in reduction of blood loss in AUB and can be used in any PALM COEIN group of AUB.

Materials & Methods: A Prospective Observational study was conducted for 6 months (Aug-2023 to feb-2024) in department of Obstetrics and Gynaecology in Sri Balaji Medical College, Hospital & research Institute (SBMCH&RI), Renigunta. Data collection includes patient's information regarding laboratory data which includes CBP, TSH levels, RBS & PBAC score (pictorial blood loss assessment chart)used for each subject during their visit to the hospital.

Result: Based on our study, AUB can be treated by medical management without hysterectomy as most of the subjects i.e. out of 80 subjects, 74 subjects were returned to normal menses after the follow-up and only 6 subjects were hysterectomized during the course of study.

Conclusion: This study concludes, AUB-O is the most common type of AUB followed by AUB-L and AUB-E. Most of the study subjects had the complication of anaemia. To avoid the morbidity associated with hysterectomy, medical management was mostly preferred. AUB can be treated by medical management without hysterectomy as most of the subjects i.e. out of 80 subjects, 74 subjects were returned to normal menses after the follow-up and only 6 subjects were hysterectomized during the course of study.

Keywords: AUB, Hysterectomy, PALM-COEIN, anaemia, OC pills.

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I. INTRODUCTION:

Abnormal uterine bleeding is a broad term which is used to encompass a range of symptoms such as heavy menstrual bleed, inter menstrual bleed, combination of both heavy and prolonged menstrual bleed. It is also described as, any type of bleeding from uterus which is abnormal in flow, volume, regularity, frequency, and duration ^(1&2). The Royal College of Obstetrics and Gynaecology (RCOG) & American college of obstetrics and gynaecology (ACOG) defined AUB as heavy menstrual loss which interferes with women's physical, social, emotional quality of life.

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EPIDEMOLOGY: Menstrual disorders are a common indication for medical visits among women of reproductive age and the prevalence of menstrual disorders has been recorded as high as 87% ⁽⁴⁾. AUB is the most common reason for women to consult their general practitioner or gynaecologist and is responsible for as many as one-third of all outpatient visits to a gynaecologist ⁽⁵⁾.

ETIOLOGY: In the year 2011, The International Federation of Gynaecology and Obstetrics (FIGO) classification system for causes of AUB (PALM-COEIN) provides an excellent framework to approach the management of this condition. The structural anomalies causing abnormal bleeding that may be evaluated by imaging techniques and/ or histopathology is classified as PALM. The other categories causing abnormal bleeding that are unrelated to structural anomalies are classified as COEIN ^(6&7).

1. Structural causes:

- P- Polyp
- A- Adenomyosis
- L- Leiomyoma
- M- Malignancy and hyperplasia
- 2. Non structural causes:
- C- Coagulopathy
- O- Ovulatory dysfunction
- E- Endometrial
- I- Iatrogenic
- N- Not yet classified (8).

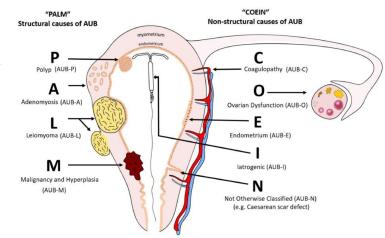


Fig: 1.1 PALM-COEIN classification of AUB

Clinical manifestations: Heavy menstrual bleeding, Abdominal pain, Abdominal cramps, Bleeding or spotting between periods, Shortness of breath, White discharge, Bleeding or spotting after sexual intercourse, Irregular periods in which cycle length varies more than 7-9 days (1&3).

MANAGEMENT OF AUB: The management of AUB is largely medical and surgery should be rarely required. The medical management is especially useful in all those women who wish to preserve their childbearing function and in those women whom a natural menopause is expected shortly ⁽⁹⁾.

- 1. Hormonal therapy
- i. combined oestrogen and progesterone
- ii. progestin's alone
- 2. Non Hormonal therapy
- i. Anti fibrinolytics
- ii. NSAIDS
- 3. Surgical management.

1. Hormonal Therapy

Hormonal management is considered the first line of medical therapy for patients with acute AUB without known or suspected bleeding disorders ⁽¹⁰⁾. More than 90% of the severe bleeding that occurs in adolescents is controlled with medical treatment. The choice of hormonal treatment very much depends on patients preferences. With regards to hormonal treatments, the combined oral pill is widely used to regulate bleeding and reduce blood loss ⁽¹¹⁾.

- AUB. Norethisterone acts by suppressing endometrial development through anti-proliferative endometrial effect, thereby correcting unpredictable bleeding patterns and reducing menstrual flow. Norethisterone is commonly prescribed at a dosage of 5 mg thrice daily from day 5 to day 26 of the menstrual cycle. The Gynae Endocrine Society of India (GESI) recommends norethisterone cyclically (for 21 days) as first-line therapy in acute episodes of bleeding associated with ovulatory AUB for 3 months (12).
- ii. Combined OCP's: Oral combination hormonal contraceptives reduce menstrual blood loss and result in consistent menstrual cycle interval. This could either be prescribed for three weeks (21 days) followed by one pill free week to allow withdrawal bleeding or be given in extended cycle regimen to reduce no. of withdrawal bleeding episodes. The possible but rare side-effects are breast tenderness, mood changes, headache, nausea and vomiting. The contraindication to COCPs use is women who are over 35yrs old having hypertension, cardiovascular diseases, migraine with aura, breast cancer, VTE (venous thromboembolism) (9&13).

2. Non-Hormonal Therapy

A. Antifibrinolytics

Tranexamic acid is an anti-fibrinolytic medication commonly used to counteract this aberration in women with heavy menstrual bleeding ^(9, 14&15). It works by preventing fibrin degradation and are effective treatments for patients with chronic AUB. They have been shown to reduce bleeding in these patients by 30–55%. Tranexamic acid effectively reduces intraoperative bleeding and the need for transfusion in surgical patients and is likely effective for patients with acute AUB, although it has not been studied for this indication ⁽¹⁰⁾. It is also acceptable to women who are trying to conceive, or those who experiencing significant side effects with hormonal preparation. The recommended tranexamic acid dosage is 1g orally 3-4 times daily during the day of heavy menstrual bleeding. The side effects are gastrointestinal symptoms, headache, nausea and vomiting ⁽⁹⁾.

B. Non-Steroidal Anti-Inflammatory Drugs (NSAIDS).

Inhibition of inflammatory medication can help to reduce the tissue damage at the time of menstruation. NSAIDS reduce the inflammatory process by inhibiting the cyclo-oxygenase enzyme that synthesizes prostaglandins. The most commonly used NSAIDs for heavy menstrual bleed are mefenamic acid, ibuprofen, naproxen etc. taken at the onset of menstruation. The side-effects are nausea, vomiting, abdominal pain and headache (9,14&15). Perhaps the most studied NSAID for this purpose is mefenamic acid, which provides 25 to 50% reduction in bleeding volume. It should be used during menstruation, and has the benefit of reducing dysmenorrhoea (16).

3. Surgical Management:

The surgical procedure is best suited for women who have no intention to become pregnant and is usually preceded by an unsuccessful clinical treatment ⁽¹⁷⁾. The decision to proceed with surgical treatment should be made after taking into account the fertility desire of the patient ⁽¹⁸⁾.

A. Total Abdominal Hysterectomy (TAH): The surgery in which the uterus is totally or partially removed, hysterectomy, can be done by abdominal, vaginal, laparoscopic, or robot-assisted laparoscopic surgery and abdominal hysterectomy is the most invasive approach ⁽¹⁷⁾. Hysterectomy represents the most common gynaecological procedure in the world. Its effectiveness in improving AUB symptoms being curative and definitive is well recognised ⁽¹⁹⁾. It is commonest major surgery in premenopausal women ⁽²⁰⁾.

B. Polypectomy:

Hysteroscopic polypectomy is a conservative surgical approach which an effective and safe therapeutic method, promoting symptomatic relief for 75 to 100% of patients ⁽²¹⁾. Dilation and curettage combined with the use of polypectomy forceps used to the standard method for investigating abnormalities ⁽²²⁾.

PBAC Score: Pictorial Blood Loss Assessment score, it is semi quantitative measurement tool validated for diagnosing. HMB Women are instructed to count their number of used towels or tampons each day and then divide them by level of soiling. The chart is scored using the scoring system. Scores are given according to soakage of pad/tampons details of which given. With the PBAC-Score the women can capture the number of pads or tampons and also state the intensity through the assessment of the drenching. The PBAC score is a simple and accurate tool for semi objective of MBL that can be used in clinical practice to aid the decision about treatment and follow-up (23).

II. METHODOLOGY

Study Design: Prospective Observational study.

Study Site: The study was conducted in the department of Obstetrics and Gynaecology at Sri Balaji Medical College, Hospital and Research Institute (SBMCH&RI) - Renigunta.

Study Duration: The study was conducted over a period of 6 months from August-2023 to february-2024

Study Sample Size: Total sample size = 80 subjects

Study Criteria: Inclusion Criteria

Women from reproductive age to menopausal period

- Symptomatic with irregular menstrual cycle
- Consent and compliance with all aspects of the study protocol, methods, providing data during follow-up contact

Exclusion Criteria

- Pregnant and lactating women.
- Patients who are not fully consent.
- Patient with severe complications.

Method of Study: Data collection includes patient's information regarding laboratory data which includes CBP, TSH levels, RBS. The diagnosis can be confirmed with the Ultrasonography (Usg). After the diagnosis of the subjects with AUB by the physician, the data of no. of pads changing per day for one complete menstrual cycle can be collected for calculating the PBAC score using pictorial blood loss assessment chart of the each subject during their visit to the hospital. By contacting the subjects every month through their phone numbers, we have calculated the PBAC score of the subjects as the follow up.

Results: A Prospective Observational study was conducted for 6 months (Aug-2023 to feb-2024) in department of Obstetrics and Gynaecology in Sri Balaji Medical College, Hospital & research Institute (SBMCH&RI), Renigunta. A total of 80 subjects with abnormal uterine bleeding were recruited into the study based on inclusion and exclusion criteria after the receival of ICF (informed consent form).

Table: 1 Distribution of Subjects on Type of AUB Based on Etiology:

S.No	Etiology of AUB	Type of AUB	No. of Subjects (N=80)	Percentage (%)	
1	Polyp	AUB-P	10	12	
2	Adenomyosis	AUB-A	2	3	
3	Leiomyoma	AUB-L	20	25	
4	Malignancy and Hyperplasia	AUB-M	0	0	
5	Coagulopathy	AUB-C	0	0	
6	Ovulatory dysfunction	AUB-O	35	44	
7	Endometrial dysfunction	AUB-E	13	16	
8	Iatrogenic	AUB-I	0	0	
9	Not yet classified	AUB-N	0	0	
		Total=	80	100	

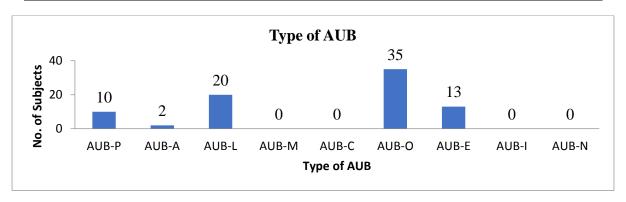
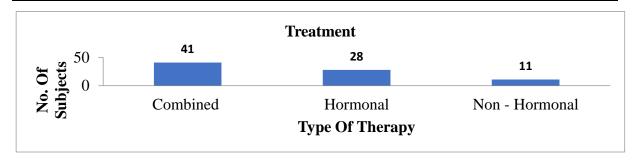


Table: 2 Distribution of Subjects Based on Treatment

S.NO	Type of Treatment (R _X)	Class of Drug	Drug Name	No. of Subjects	Total No. of Subjects (N=80)	Percentage (%)
1	Hormonal therapy	OCP's	Regesterone7 (Progesterone-5mg)	14	28	35
		OCP's	OVRAL-L (Progesterone + Estrogen)	14		
2	Non Hormonal therapy	Anti - Fibrinolytic	Tranexamic acid (500mg)	3	11	14
		NSAIDS	Mefenamic acid	8		
3	Combined therapy (Both Hormonal & Non Hormonal therapy)		Regesterone + Tranexamic acid	22	41	51
			Regesterone + mefenamic acid	5		
			OVRAL-L + Tranexamic acid	12	41	31
			OVRAL-L + Mefenamic acid	2		
			Total=		80	100



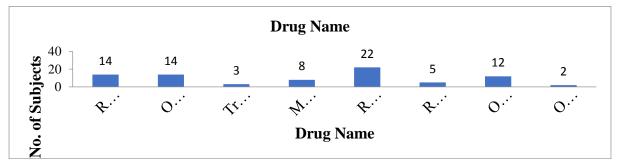
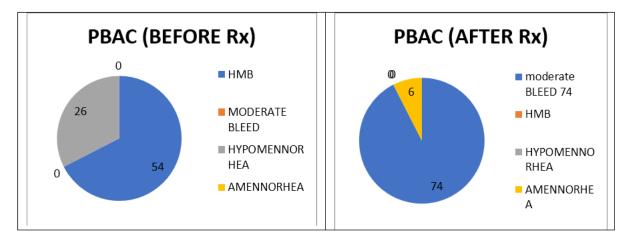


Table:3 Distribution of subjects based on PBAC score before and after therapy.

	Table: 5 Distribution of subjects based on 1 Dive score before and after therapy.								
BEFORE TREATMENT					AFTER TREATMENT				
s.no	Bleeding type	PBAC	No. of	Percentage	s.no	Bleeding type	PBAC	No. of	Percentage
		range	Subjects	(%)			range	Subjects	(%)
1	HMB	≥100	54	68	1	HMB	≥100	0	0
2	Moderate bleed	11-99	0	0	2	Moderate bleed	11-99	74	93
3	Hypomennorhea	≤10	26	32	3	Hypomennorhea	≤10	0	0
4	Amenorrhea	0	0	0	4	Amenorrhea	0	6	7
						(hysterectomized)			
_		Total=	80	100%			Total=	80	100%



III. DISCUSSION:

In this prospective observational study, 80 subjects were recruited. In our study AUB-O 35 (44%) was found in majority of subjects and same was reported by followed by 20 (25%) of subjects were with AUB-L, 13 (16%) of subjects were with AUB-E and same was reported by *Vimal H et al*, 10 (12%) of subjects were with AUB-P and the least no. of subjects 2 (3%) were with AUB-A and no cases were diagnosed with AUB-M, AUB-C, AUB-I & AUB-N and same was reported by *Burcu kisa karakaya et al*, study where no cases were diagnosed with AUB-C.

In our study, 41 (51%) subjects were treated with combined therapy which is combination of both hormonal and non- hormonal therapy on which regesterone + tranexamic acid was prescribed to 22 subjects, OVRAL-L + tranexamic acid was prescribed to 12 subjects, regesterone + mefenamic acid was to 5 subjects & OVRAL-L + mefenamic acid was prescribed to 2 subjects. 28 (35%) of subjects were prescribed with hormonal therapy out of which regesterone was prescribed to 14 subjects & OVRAL-L was prescribed to 14 subjects. and

finally 11 (14%) of subjects were given non – hormonal therapy out of which mefenamic acid was prescribed to 8 subjects & tranexamic acid was given to 3 subjects.

Follow-up was done on every month. Total PBAC score is taken in consideration which includes passage of clots along with number of pad soaked in a menstrual cycle, so improvement in PBAC score is calculated. However there was decreased or relieved of clots passage during treatment course. In our study the average PBAC score was 96.45 before treatment and 69.81 after 3 months of follow-up with significant p-value of 0.0025 (<0.05).

In this study, out of 80 subjects, 64 (80%) of subjects have achieved normal menses after the medical management for 3 months, 10 (13%) of subjects with AUB-P have undergone polypectomy and achieved normal menses during follow-up and 6 (7%) of subjects have failed in treating with drugs and opted for hysterectomy during the study same was reported by *Dr. Neethika et al* ⁽²³⁾.

IV. CONCLUSION

- AUB is a common gynaecological symptom in the women of reproductive age. The PALM COEIN
 classification helps to practically ascertain the cause of AUB, and there by effectively adopt and plan for
 focused treatment of patients.
- This study has found that AUB-O is the most common type of AUB followed by AUB-L and AUB-E. Most of the study subjects had the complication of anaemia. To avoid the morbidity associated with hysterectomy, medical management was mostly preferred.
- Tranexamic acid and mefenamic acid was found to be most commonly chosen medication to control abnormal menstrual blood loss and to control pain respectively. Among hormonal preparations, both Progesterone and OC Pills were found to be equally effective in reduction of blood loss in AUB and can be used in any PALM COEIN group of AUB.
- In our study on medical management of AUB, we concluded that AUB can be treated by medical management without hysterectomy as most of the subjects i.e. out of 80 subjects, 74 subjects were returned to normal menses after the follow-up and only 6 subjects were hysterectomized during the course of study.

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