Management of Abnormal Uterine Bleeding in Reproductive Period

Evidence-based Good Clinical Practice Recommendations for Indian women A Gynae Endocrine Society of India (GESI) initiative in collaboration with Endocrine Committee of Association of Obstetricians and Gynaecologists of Delhi

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INTRODUCTION

Abnormal uterine bleeding (AUB) is a common problem among women in the reproductive age. AUB may be accompanied by pain and discomfort, cause significant social embarrassment, and have a substantial effect on health-related quality of life. AUB leads to loss of productivity¹ and may result in surgical interventions including hysterectomy². Management of such common condition in a population with wide healthcare diversity requires uniform clinical practice guidelines. A unified practice guidance, based on scientific evidence helps in standardizing clinical management practices.

There is a remarkable inconsistency in the management of AUB in day to day clinical practice owing to lack of Good Clinical Practice (GCP) guidelines for diagnosis and management of AUB in India. Hence, there is an urgent need for the development of Indian guideline with recommendations on GCP to diagnose and manage AUB.

EPIDEMIOLOGY& NOMENCLATURE OF AUB

AUB is reported to occur in 9 to 14% women between menarche and menopause³. The prevalence varies in each country. In India, the reported prevalence of AUB is around 17.9%⁴. Descriptive terms that have been used to characterize AUB patterns include menorrhagia, metrorrhagia, polymenorrhea, dysfunctional uterine bleeding and heavy menstrual bleeding.

To standardize nomenclature of AUB, a new system known by the acronym PLAM-COEIN (Polyp; Adenomyosis; Leiomyoma; Malignancy and Hyperplasia; Coagulopathy; Ovulatory Disorders; Endometrial factors; Iatrogenic; and Not classified) was introduced in 2011 by the International Federation of Gynecology and Obstetrics (FIGO)⁵. However, the term 'amenorrhea', meaning absence of menstrual bleeding during a 6-month reference period, is retained. The PALM-COEIN system is etio-pathogenesis based, with PALM describing structural causes and COEIN demoting non- structural causes of AUB. Table 1 summarizes the PALM-COEIN system of classification. Further, FIGO nomenclature summarizes the parameters for characterization of normal and abnormal limits of menstruation (Table 2). Hence, FIGO nomenclature system will allow for standardization and uniformity while conducting future studies and can rectify the problem of inconsistency in AUB management.

METHODOLOGY FOR FRAMING RECOMMENDATIONS

A systemic review of literature was conducted to collect best evidence for the good clinical practice recommendations (GCPR). Existing guidelines, meta-analyses, cross sectional studies,

systemic reviews, and key cited articles related to AUB were reviewed by a group of experts. The expert committee considered the recommendations from the existing guidelines NICE (<u>http://www.nice.org.uk/guidance/QS47</u>)⁶, ACOG (ACOG, 2013)⁷, SOGC, 2013⁸, France 2010⁹ and identified variability in the reproductive profile of Indian women compared to the western countries. This variability may probably be due to the differences in the racial, socioeconomic, and cultural background of Indian and Western populations. Therefore there is a need to formulate recommendations in the Indian context.

The draft recommendations were framed by the committee and discussed during an Expert Panel meeting held in September 2015. The Expert panel discussed the draft recommendations on the basis of the clinical evidences, from India and abroad, and framed the final version. Where evidence is limited, the panel relied on their vast experience and clinical judgement.

Grading

The current consensus guidelines have been developed in accordance with the American association of clinical endocrinologists (AACE) protocol for standardized production of clinical practice guidelines¹⁰. Recommendations are organized aetiology-wise, according to the PALM-COEIN system. They are based on clinical importance and graded (A, B, C, and D), coupled with four intuitive levels of evidence (1, 2, 3, and 4) based on the quality of supporting evidence (**Table 3**).

DIAGNOSIS OF AUB

History and initial examinations

Recommendations regarding obtaining patient history and performing initial examination:

- 1. It is suggested to abandon the old overlapping terminology and to use PALM-COEIN classification for the diagnosis AUB. (Grade A; Level 4).
- 2. It is recommended to obtain a thorough history and to conduct a physical examination to direct the need for further investigations and treatment (Grade A; Level 4).
- 3. It is recommended to obtain information about the concomitant use of any medications, which may likely be the cause AUB (Grade B; Level 4).
- 4. In patients with AUB, any of the following criteria should be considered a positive screen for coagulopathies (Grade B; Level 4):
 - History of heavy bleeding starting at menarche
 - One of the following:
 - Postpartum haemorrhage

- Surgery-related bleeding
- Bleeding associated with dental work
- At least two of the following symptoms:
 - At least one episode of bruising per month
 - At least one episode of epistaxis per month
 - Frequent gum bleeding
 - Family history of bleeding symptoms
- Examination: Including assessment of weight, pallor, thyroid, breasts, acne, hirsutism scoring (if present), abdominal, P/S and P/V examination. (Grade A; Level 4).

Investigations

Laboratory Testing

Recommendations on Laboratory testing

- 1. A complete blood count (CBC) is recommended for women with AUB.
- 2. It is recommended to perform a sensitive urine pregnancy test whenever indicated, or if pregnancy is suspected.
- Bleeding time, platelet count, prothrombin time, and partial thromboplastin time are recommended in all adolescents and in adults with a positive screen for coagulopathies. Further testing for von Willebrand disease, ristocetin cofactor activity, factor VIII activity, and von Willebrand factor antigen is recommended in consultation with a hematologist.
- 4. TSH test is done when clinically indicated

Imaging

Recommendations on imaging

- 1. Ultrasonography is mandatory in AUB to evaluate uterus, adnexa and endometrial thickness (Grade A; Level 1)
- Doppler ultrasonography: In suspected arteriovenous malformation, malignancy cases and to differentiate between fibroid and adenomyomas (Grade B; Level 3) [upgraded as separate point]
- 3. 3D-USG:For evaluating intra myometrial lesion in selected patients for fibroid mapping (Grade B; Level 4)
- 4. SIS: If intracavitary lesion is suspected and hysteroscopy is not available (Grade A; Level 1)
- Hysteroscopy: For diagnosis and characterization of intrauterine abnormalities (Grade A; Level 1)

6. MRI: To differentiate between fibroids and adenomyomas and for mapping exact location of fibroids while planning conservative surgery and prior to therapeutic embolization for fibroids (Grade A; Level 3).

Endometrial Histopathology (HPE)

Recommendations

- 1. Endometrial histopathology is recommended in AUB
 - In women > 40 years (Grade A; Level 2).
 - In women < 40 years who have high risk factors for carcinoma endometrium such as irregular bleeding, obesity associated with hypertension, PCOS, diabetes, endometrial thickness > 12 mm, family history of malignancy of ovary/breast/endometrium/colon, use of tamoxifen for HRT or breast cancer, late menopause, HNPCC, AIB unresponsive to medical treatment (Grade A; Level 2)
- 2. Endometrial aspiration should be the preferred procedure for obtaining endometrial sample for histopathology. If endometrium is thick om imaging, but where HPE is inadequate or atrophic, hysteroscopy should be performed to rule out polyps (Grade A; Level 2).
- 3. Dilatation and curettage should not be the procedure of choice for endometrial assessment (Grade A; Level 3).

Common symptoms and imaging features of abnormal uterine bleeding aetiologies are presented in **Table 4**. A schematic diagram of diagnosis is depicted in **Figure 2**

MANAGEMENT OF PATIENTS WITH AUB AUB-P (Polyps)

Recommendations for management of AUB-P

- 1. Hysteroscopic polypectomy is recommended for younger women who wish to preserve fertility. (Grade A; Level 1).
- 2. In women multiple endometrial polyps and not desirous of continued fertility, it is suggested to perform hysteroscopic polypectomy followed by LNG- IUS insertion after confirmation of benign lesion on histopathology. (Grade A ; Level 2).
- 3. Polyp should be sent for histopathology. If histopathology suggests malignancy, further management should be as AUB-M.

AUB-A (Adenomyosis)

Recommendations for management of AUB-A

- 1. For managing adenomyosis-A, it is suggested to consider the age, symptomology (AUB, pain and infertility) and association with other conditions (leiomyomas, polyps and endometriosis)
- In women with AUB-A, desirous of preserving fertility but unwilling for immediate conception, progestogens especially LNG-IUS is recommended as first-line therapy (Grade A; Level 1).
- 3. In patients with AUB-A, desirous of preserving fertility and resistant to LNG-IUS/ unwilling to use LNG-IUS, gonadotropin releasing hormone (GnRH) agonists with add-back therapy is recommended as second-line therapy (Grade A; Level 1).
- 4. In patients with AUB-A, and not desirous of preserving fertility, medical management using long-term GnRH agonists and add-back therapy can be initiated.
- Combined oral contraceptives, danazol, NSAIDs, and progestogens can be offered for symptomatic relief where LNG-IUS and GnRH agonists cannot be indicated (Grade B; Level 4).
- 6. In case of failure/refusal for medical management, vaginal or laparoscopic hysterectomy is indicated (Grade A; Level 1).

AUB-L (Leiomyoma)

Recommendations for AUB-L

Treatment for AUB-L should be individualized because many variables such as age, parity, symptoms, fertility desires may affect the treatment preference. Various options can be generalized as follows:

- 1. Women with intramural or subserosal myomas (grade2-6), desirous of preserving fertility, can be managed with tranexamic acid or combined oral contraceptives (COCs) or NSAIDs as second-line therapy (Grade A; Level 2).
- 2. Women with intramural or subserosal myomas (grade2-6) and desirous of preserving fertility can be medically managed with LNG-IUS if other medical treatment fails and patient is not trying to conceive for at least 1 year. (Grade A; Level 1)
- If treatment fails, or if myoma is causing infertility, myomectomy is recommended by abdominal (open or laparoscopic)/ hysteroscopic route depending on myoma location. (Grade A; Level 3)

- For sub-mucosal myomas Grade 0-1, hysteroscopic resection (for <4 cm diameter) or abdominal myomectomy (for >4 cm diameter) is the recommended treatment. (Grade B; Level 4)
- In women above 40 years of age, not desirous of continued fertility, hysterectomy is the definitive treatment; however medical management including LNG-IUS may be tried in small fibroids (<4 cm diameter) before undergoing definitive surgery. (Grade B; Level 3)
- For short-term management (up to 6 months), GnRH agonists with add-back therapy is an option in peri-menopausal women, prior to myomectomy or for improving general condition. (Grade A; Level 1)
- 7. For long-term management of leiyomyomas, it is recommended to use LNG-IUS (except in AUB-L 0 and 1 grade, may be tried in selected cases of AUB-L 2) as first-line management. Newer promising options are progesterone receptor modulators such as ulipristal acetate and low dose mifepristone. (Grade A; Level 1), though these are presently not available in India.

AUB-M (Malignancy and Endometrial Hyperplasia)

Recommendations for AUB-M

- 1. In AUB-M with endometrial malignancy, standard protocol for management of malignancy should be followed (Grade B; Level 4).
- 2. In AUB-M with endometrial hyperplasia with atypia, hysterectomy is the standard treatment. (Grade B; Level 2).
- 3. In AUB-M with endometrial hyperplasia without atypia, LNG-IUS can be considered as first-line therapy; oral progestins can be used if LNG-IUS is contraindicated or if patient is unwilling for LNG-IUS(Grade A; Level 1).

AUB-C (Coagulopathy)

Recommendations specific to AUB-C

- 1. In patients with AUB-C, non-hormonal treatment with tranexamic acid as primary option and hormonal treatment with COCs/LNG-IUS as secondary option^{*} are recommended in consultation with a haematologist, with the following considerations (Grade A; Level 2)
 - a. For patients with uncontrolled uterine bleeding with above medical management, specific factor replacement where possible or desmopressin in refractory cases to be given
 - b. When surgical interventions are indicated, for appropriate pre-, intra- and post-operative management of bleeding

*NSAIDs are contraindicated as they can alter platelet function and interact with drugs that might affect liver function and production of clotting factors.

^{*} Injectables (GnRH agonists) are contraindicated, except in mild coagulation abnormalities. When administered, prolonged pressure should be applied at injection site (Singh et al 2013).

AUB-O (Ovulatory Dysfunction)

Recommendations specific to AUB-O

- In women not desiring conception presently, COCs can be used as first-line therapy for 6-12 months (Grade A; Level 1).
- 2. Cyclic luteal-phase progestins should not be used as a specific treatment in women with AUB-O (Grade A; Level 1)
- 3. Norethisterone cyclically (for 21 days) is given as initial therapy in acute episodes of bleeding for short-term management of 3 months (Grade B; Level 4).
- 4. It is suggested to assess response after 1 year of medical management and judge to continue/discontinue existing therapy (Grade B; Level 4).
- 5. Surgical intervention is not recommended unless, there is evidence of persistent AUB or failure of medical management to alleviate the condition (Grade A; Level 4).
- 6. If COCs are contraindicated or patient is unwilling for COCs, LNG-IUS is recommended if she wishes to use it for atleast 1 year (Grade A; Level 1).
- 7. In adolescents with AUB-O, both hormonal and non-hormonal therapies can be prescribed, (Grade A; Level 4).

AUB-E (Endometrial)

Recommendations specific to AUB-E

1. Management of AUB-E can be similar to the management of AUB-O (Grade A; Level 4).

AUB-I (Iatrogenic causes)

Recommendations specific to AUB -I

1. Whenever possible, medications causing AUB should be changed to other alternatives, if no alternatives are available, LNG-IUS is recommended (Grade A; Level 1).

AUB-N (Not defined)

Recommendations for AUB-N

- 1. In patients with idiopathic AUB and desire effective contraception, LNG-IUS is recommended as first-line therapy to reduce menstrual bleeding (Grade A; Level 1).
- 2. In patients with AUB-N desirous of continued fertility, in whom, LNG-IUS are contraindicated, use of COCs are recommended as second line therapy (Grade A; Level 1).
- 3. For the management of abnormal uterine bleeding that are mainly cyclic or predictable in timing, non-hormonal options such as NSAIDs and tranexamic acid are recommended (Grade A; Level 1).
- 4. When medical or conservative surgical treatments (such as ablation) have failed or are contraindicated, and GnRH agonists along with add-back hormone therapy are recommended to reduce idiopathic AUB, while hysterectomy is suggested as last resort (Grade B; Level 4).
- 5. Uterine Artery embolization is recommended for A-V malformations

AUB-COEIN: General management guidelines:

Recommendations of AUB-COEIN

- Tranexamic acid is first-line therapy. Other non-hormonal option is NSAIDs (Grade B; Level 1).
- 2. In women desiring effective contraception, LNG-IUS is recommended (Grade A; Level 1).
- 3. COCs are recommended as second line therapy in patients desiring effective contraception, but unwilling or unsuitable for LNG-IUS (Grade A; Level 4).
- 4. Cyclic oral progestins (from day 5 to 26), are recommended if COCs are contraindicated (Grade B; Level 1).
- 5. Centchroman is an option when steroidal hormones and other medical options are not suitable (Grade B; Level 3).
- 6. Use of cyclic luteal-phase progestins are not recommended for AUB (Grade A; Level 4).
- 7. GnRH agonists with add-back hormone therapy are recommended as a last resort when medical or surgical treatments for AUB have failed or are contraindicated (Grade B; Level 4).
- Role of conservative surgery such as ablation has decreased a lot due to availability of LNG-IUS which works like medical ablation.

A summary of recommendations for management of AUB is presented in Table 5.

Table 1: PALM-COEIN classification for the etiologies of abnormal uterine bleeding proposed

 by the International Federation of Gynaecology and Obstetrics (FIGO)

AUB causes	Subclass	Characteristics					
	Polyps	Present in endometrial and endocervical canal					
	(AUB-P)	 Categorized as absent or present 					
	Adenoma	> The genesis is controversial but minimal criterion					
	(AUB-A)	identification on ultrasound testing.					
Structural causes	Leiomyoma (AUB-L)	0:Submucosal types, do not impact endometrial cavity6:subserosal and < 50% intramuralOthres:7:subserosal and attached to serosa by stalk1: < 50% intramural					
	Malignancy &	May occur because of ovulatory disorder					
	hyperplasia	> Sub-classification according to the WHO or FIGO					
	(AUB-M)	system.					
	Coagulopathy	 Coagulopathy represents both inherited and acquired 					
	(AUB-C)	Most common is inherited von Willebrand disease					
Non- structural causes	Ovulatory dysfunction (AUB-O)	Can lead to amenorrhea or heavy menstrual bleeding.					
	Endometrial (AUB-E)	 Likely to occur when other abnormalities are excluded in the presence of normal ovulatory function. 					
	Iatrogenic (AUB-I)	breakthrough bleeding during use of single or combined gonadal steroid therapy, intrauterine systems, or devices, systemic agents that interfere with dopamine metabolism, or anticoagulant drugs					
	Not classified (AUB-N)	Rare or ill-defined conditions: Chronic endometritic arteriovenous malformations, and myometria hypertrophy.					

Clinical dimensions of menstruation and menstrual cycle	Descriptive term	Normal limits (5 th - 95 th percentiles)	
Frequency of menses, days	Frequent	<24	
	Normal	24-38	
	Infrequent	>38	
Regularity of menses: cycle-	Absent	No bleeding	
to-cycle Variation over 12	Regular	Variation $\pm 2-20$	
months, days	Irregular	Variation >20	
Duration of flow, days	Prolonged	>8.0	
	Normal	4.5-8.0	
	Shortened	<4.5	
Volume of monthly blood loss,	Heavy	>80	
mL	Normal	20-80	
	Light	<20	

Table 2.International Federation of Gynaecology and Obstetrics (FIGO) system for abnormaluterine bleeding: Suggested "normal" limits for menstrual parameters for uterine bleeding

Table 3. Grading system of current GCPR

Streng	th of Recommendation
Α	Strongly recommended
В	Intermediate
С	Weak
D	Not-Evidence based, Panel recommended
Scale o	f Scientific Support
1	Meta-analysis of randomized controlled trials and randomized controlled trials
2	Meta-analysis of non-randomized prospective or case-controlled trials, non-randomized
	controlled trials, prospective cohort study, and retrospective case-control studies
	Cross-sectional studies, surveillance studies (registries, surveys, epidemiologic studies,
3	retrospective chart reviews, mathematical modelling of database), consecutive case
	series, single case reports
4	Opinion/consensus by experts or preclinical study

	Symptoms	Signs	Imaging			
Polyp	Prolonged uncontrolled bleeding, Inter-menstrual bleeding, Pallor, Infertility	Uterus is usually normal in size, If big, cervical os may be patulous, Polyp extruding outside	Endometrium looks thickened Saline infusion sonography- echogenic smooth intracavitary mass outlined by fluid			
Adenomyosis	Heavy menstrual bleeding, Marked dysmenorrhea	Uterus enlarged up to 12 weeks Uniformly enlarged, globular May or may not be tender	Globular uterine enlargement up to 18 weeks (not due to leiomyoma) Thickening of uterine wall, which may be asymmetrical in focal disease Obscuring of endomyometrial junction; Multiple hypo-echoic halo zones of ≥ 12 mm thickness; heterogeneous texture of endometrium Echogenic			
Leiomyoma	Submucous- More prolonged un- controlled bleeding, Intramural- variable amount of HMB, Subserous- May be asymptomatic	Uterus irregularly enlarged Firm	Well-defined, solid masses with a whorled appearance; similar echogenicity to myometrium, occasionally hypoechoic alteration of the normal uterine contour of uterus 3D-USG –for exact location in selected patients MRI- fibroid mapping when indicated			
Malignancy	Postmenopausal bleeding, Irregular bleeding pattern at peri- menopause	Normal to mildly enlarged uterus Mobility may be restricted	US- Endometrial hyperplasia- Thickened endometrium >12mm at premenopausal age Endometrial carcinoma- Thickened endometrium, irregular endometrial lining, loss of endomyometrial junction			
Coagulopathy	Puberty menorrhagia, Heavy bleeding at menarche, History suggestive of bleeding diathesis, Family history	Uterus normal size Pallor Easy bruisability Petechiae	Normal scan Might have hemorrhagic cysts in ovary			

Table 4. Common symptoms and imaging features of abnormal uterine bleeding aetiologies

Ovulatory	Signs of	Uterus normal size	Polycystic ovaries on ultrasound			
Disorders	anovulation-		Thickened endometrium			
	Polycystic ovary syndrome Oligomenorrhea Signs of insulin resistance					
Endometrial	Inter-menstrual	Discharge per	Uterus normal size			
Linuomeenui	spotting	vaginum	Fluid in endometrial cavity			
	Prolonged spotting	Cervical erosion				
latrogenic	History of	No abnormality	Uterus normal size			
	medication intake		Copper T in situ			
	Copper T use					
Not Classified	HMB	Refer to PALM- COEIN	Ultrasound, Doppler, USG- for AVM			
	• 1 1/					

3D-USG: 3 dimensional ultrasonography; HMB: Heavy menstrual bleeding; MRI: Magnetic resonance imaging; AVM: Arterio venous malformation

 Table 5. Suggested treatment options for abnormal uterine bleeding based on PALM-COEIN etiology

Etiology	Treatment						
Polyp	Hysteroscopic surgical removal						
	Multiple polyps or polypoidal endometrium and fertility is not desired-						
	LNG-IUS can be combined with surgical removal						
Adenomyosis	LNG-IUS, if LNG IUS is not accepted– GnRH agonists with add back						
	therapy; if it fails OCP, NSAIDs, progestogens						
Leiomyoma	Intramural or sub-serosal myomas (grade 2-6)						
	Tranexamic acid or COCs or NSAIDs, LNG-IUS, if treatment fails						
	myomectomy depending on location						
	In women >40 years of age, fertility is not desired, for small fibroids (< 4-						
	5 cm)– medical management followed by hysterectomy						
	Short-term management (up to 6 months)– GnRH agonists with add back						
	therapy followed by myomectomy						
	Long-term management- LNG-IUS						
	Newer medical options: ulipristal acetate or low dose mifepristone,						
	currently not available in India						
	Sub mucosal myoma (grade 0-1)						
	hysteroscopic (< 4 cm) or abdominal(open or laparoscopic for > 4 cm)						
Malignancy	Atypical endometrial hyperplasia- surgical treatment						
	Continued fertility not desired-hysterectomy						
	Hyperplasia without atypia						
	LNG-IUS followed by oral progestins or PRMs						
COEIN	LNG-IUS or tranexamic acid, NSAIDs, followed by COCs or cyclic oral						
	progestins						
	Medical or surgical treatment failed or contraindicated: GnRH agonists						
	with add-back hormone therapy						
	When steroidal and other options unsuitable: Centchroman						

PALM: Polyp, Adenoma, Leiomyoma, Malignancy and hyperplasia; LNG-IUS: Levonorgestrel intrauterine system; NSAIDs: Non-steroidal anti-inflammatory drugs; COCs: Combined oral contraceptives; OCP: Oral contraceptive pill; PRMs: Progesterone receptor modulators; GnRH: Gonadotropin releasing hormone

			PBAC	SCORI	NG				•
Name of patient	ime of patient Days						Score		
Sanitary Pads	1	2	3	4	5	6	7		
\bigcirc									1= Lightly stained
2									5=Moderately stained
~									20= Completely stained
Tampons									
al De									1= Lightly stained
1									5=Moderately stained
_									10= Completely stained
Clots/Flooding									3
1 Point	For eac	For each small clot (Australian 5 cent coin)							
5 Points	For each largel clot (Australian 50 cent coin)								
5 Points	For each episode of flooding						12		

Figure 1. Pictorial Blood Assessment Chart (PBAC) scoring for uterine bleeding

Figure 2. Algorithm for the diagnosis of AUB



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