


Management Guidelines of Abnormal Uterine Bleeding in Reproductive Period

A Handbook of Evidence-based Good Clinical Practice
Recommendations- Indian Perspective



FOGSI Recommendations under aegis of Gynae Endocrine Society of India (GESI)





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Evidence-based Good Clinical Practice Recommendations for Indian women

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Chairpersons: Dr. Alka Kriplani, Dr. Nutan Agarwal

Coordinator: Dr. Prerna Gupta, Dr. Vidushi Kulshrestha, Dr. Sangeeta Gupta

Experts:

Dr. Atul Ganatra, Mumbai

Dr. Bharati Dhorepatil, Pune

Dr. Chandravati, Lucknow

Dr. Deepti Goswami, New Delhi

Dr. Dibyendu Banerjee, Kolkata

Dr. Garima Kachhawa, New Delhi

Dr. Hema Divakar, Bengaluru

Dr. Hrishikesh Pai, Mumbai

Dr. Jaishree Gajraj, Chennai

Dr. Krishnendu Gupta, Kolkata

Dr. Lila Vyas, Jaipur

Dr. Mahesh Gupta, Ahmedabad

Dr. Manjula Anagani, Hyderabad

Dr. Nalini Mishra, Raipur

Dr. P Das Mahapatra, Kolkata

Dr. P.C. Mahapatra, Cuttack,

Dr. Pratima Mittal, New Delhi

Dr. Revati Janaki Ram, Madurai

Dr. Rishma Pai, Mumbai

Dr. Sadhana Gupta, Gorakhpur

Dr. Sanjivni Khanna, New Delhi

Dr. Sunesh Kumar, New Delhi

Dr. Surender Mohan, New Delhi

Dr. Suvarna Khadilkar, Mumbai

Dr. Vidya Bhatt, Bengaluru

Dr. Vineet Mishra, Ahmedabad

Dr. Vinita Das, Lucknow

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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 PALM-COEIN (**P**olyp; **A**denomyosis; **L**eiomyoma; **M**alignancy and **H**yperplasia; **C**oagulopathy; **O**vulatory Disorders; **E**ndometrial factors; **I**atrogenic; and **N**ot 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 denoting 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 (<http://www.nice.org.uk/guidance/QS47>)⁶, ACOG 2013⁷, 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 examination

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 of 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
 - ▶ Bleeding associated with dental work
 - ▶ Surgery-related bleeding
 - 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, BMI pallor, thyroid, breasts, acne, FG score (if hirsutism is 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 all women with AUB.
2. It is recommended to perform a sensitive urine pregnancy test if pregnancy is suspected.
3. 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 investigations

1. Ultrasonography should be done in AUB to evaluate uterus, adnexa and endometrial thickness (Grade A; Level 1)
2. Doppler ultrasonography: In suspected arteriovenous malformation, malignancy and to differentiate between fibroid and adenomyomas (Grade B; Level 3)
3. 3D-USG: For evaluating intracavitary and myometrial lesions in selected patients and for mapping and typing of myomas. 3D-USG is a non-invasive alternative to hysteroscopy. (Grade B; Level 4)
4. SIS: If intra-cavitary lesion is suspected and hysteroscopy is not available (Grade A; Level 1)
5. Hysteroscopy: For diagnosis of intra-cavitary lesions and the type of myomas (Grade A; Level 1)
6. MRI: To differentiate between fibroids and adenomyoma, 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, hypertension, PCOS, diabetes, endometrial thickness > 12 mm, on ultrasound family history of malignancy of ovary/breast/endometrium/colon, use of tamoxifen for HRT or breast cancer, HNPCC, AUB 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 on 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 AUB 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 with multiple endometrial polyps and not desirous of continued fertility, it is suggested to perform hysteroscopic polypectomy may be 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)
2. In women with AUB-A, desirous of preserving fertility but not wishing 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, In such patients, 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 with LNG-IUS or GnRH agonists with add back therapy can be initiated.
5. 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. Adenomyomectomy is the conservative surgery that may be offered in selected cases presenting with infertility or with strong desire to retain uterus. Grade B; Level 2).
7. 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 as many variables such as age, parity, symptoms and fertility desire, may affect the treatment preference. Various options can be generalized as follows:

1. Women with intramural or subserosal myomas (type 2-6) causing symptoms and desirous of preserving fertility, can be managed with tranexamic acid, COCs or NSAIDs (Grade A; Level 2).
2. Women with symptomatic intramural or subserosal myomas (type 2-6) and desirous of preserving fertility/uterus, can be offered LNG-IUS if above medical treatment fails and patient is not planning to conceive for at least 1 year. (Grade A; Level 1)
3. If medical treatment fails, or if myoma is causing infertility, myomectomy is recommended by conventional laparotomic/ laparoscopic or hysteroscopic route depending on myoma location, size and number. (Grade A; Level 3)
4. For sub-mucosal myomas type 0-1, hysteroscopic resection (for <4 cm diameter myomas) or abdominal myomectomy (for >4 cm diameter) is the recommended treatment. (Grade B; Level 4)
5. In women above 40 years of age, with symptomatic leiomyomas, not desirous of continued fertility, hysterectomy is the definitive treatment; however medical management or LNG-IUS may be recommended in small fibroids (<4 cm diameter) before resorting to definitive surgery in case of failure of relief of. (Grade B; Level 3)
6. For short-term management (up to 6 months), GnRH agonists is an option in the following situations:
 - For improving general condition, anaemia
 - In selected patients prior to myomectomy
 - In younger patients to delay/avoid early surgical intervention
 - In selected perimenopausal women so that they can tide over to menopause (Grade A; Level 1)

- 
7. For long-term management of symptomatic leiomyomas, the LNG-IUS can be recommended except in AUB-L, type 0 & 1. LNG-IUS may also be advised in selected cases of AUB-L, type-2.
 8. Newer promising options are progesterone receptor modulators such as ulipristal acetate (Grade A; Level 1). Low dose mifepristone (daily 5-10 mg) although effective (Grade A; Level 1), is not available in India in tablets containing required strength.

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). Conservative treatment with high-dose progestins and close histological monitoring should only be considered in exceptional cases (when the patient wants to have children and compliance is satisfactory.)
3. In AUB-M with endometrial hyperplasia without atypia, LNG-IUS can be considered as first-line therapy; alternatively oral progestins can be used (Grade A; Level 1). Preventive hysterectomy should only be considered in exceptional cases (e.g., extreme obesity without any prospect of weight loss).

AUB-C (Coagulopathy)

Recommendations specific to AUB-C

1. In patients with AUB-C, non-hormonal treatment with tranexamic acid (1 g qid) 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 refractory patients of vWD with uncontrolled uterine bleeding with above medical management, specific factor replacement where possible or desmopressin to be given in refractory cases of von-willebrand disease in consultation with haematologist.
 - b. When surgical interventions are indicated, appropriate pre-, intra- and post-operative management of bleeding should be done.

*NSAIDs are contraindicated as they can alter platelet function and interact with drugs that might affect liver function and production of clotting factors [8, 106].

* Intramuscular injectable preparations are contraindicated, except in mild coagulation abnormalities. When administered, prolonged pressure should be applied at injection site

AUB-O (Ovulatory Dysfunction)

Recommendations specific to AUB-O

1. 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 (for 10-14 days) can 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 at least 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

Recommendations specific to AUB-I

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

AUB-N (Not defined)

Recommendations for AUB-N

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

AUB-COEIN:

General management guidelines:

Recommendations of AUB-COEIN

1. Tranexamic acid is the 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).




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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. For AUB-O, cyclic luteal-phase progestins (Day 15-25) are recommended (Grade A; Level 4).
 6. Centchroman (ormeloxifene) is an option when steroidal hormones and other medical options are not suitable (Grade B; Level 3).
 7. GnRH agonists with add-back hormone therapy are recommended as a last resort when medical or treatments for AUB have failed and surgical treatment is contra-indicated. (Grade B; Level 4).
 8. Role of conservative surgery such as ablation has decreased a lot due to availability of LNG-IUS which works like medical ablation.

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	
Structural causes	Polyps (AUB-P)	<ul style="list-style-type: none"> ▶ Present in endometrial and endocervical canal ▶ Categorized as absent or present 	
	Adenomyosis (AUB-A)	<ul style="list-style-type: none"> ▶ Endometrial tissue is present in the myometrium, atleast 2.5 mm beyond endo-myometrial junction. ▶ AUB with dysmenorrhea is the typical presentation 	
	Leiomyoma (AUB-L)	0: Submucosal types, do not impact endometrial cavity Others: 1: < 50% intramural 2: ≥ 50% intramural 3: totally extracavitary but lean on the endometrium, 100% intramural 4: intramural leiomyomas that are entirely within the myometrium 5: subserosal and atleast 50% intramural	6: subserosal and < 50% in tramural 7: subserosal and attached to serosa by stalk 8: do not involve the myometrium include cervical lesions, lesions that exist in the round or broad ligaments without direct attachment to the uterus, and parasitic lesions
	Malignancy & hyperplasia (AUB-M)	<ul style="list-style-type: none"> ▶ This includes premalignant hyperplastic lesions and malignant lesions ▶ Sub-classification according to the as with or without atypia WHO system. 	
Non-structural causes	Coagulopathy (AUB-C)	<ul style="list-style-type: none"> ▶ Coagulopathy represents both inherited and acquired ▶ Most common is inherited von Willebrand disease 	
	Ovulatory dysfunction (AUB-O)	<ul style="list-style-type: none"> ▶ Can lead to oligomenorrhea or heavy menstrual bleeding. 	
	Endometrial (AUB-E)	<ul style="list-style-type: none"> ▶ Likely to occur when other abnormalities are excluded in the presence of normal ovulatory function. 	
	Iatrogenic (AUB-I)	<ul style="list-style-type: none"> ▶ 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)	<ul style="list-style-type: none"> ▶ Rare or ill-defined conditions: Chronic endometritis, arteriovenous malformations, and myometrial hypertrophy. 	

Table 2:International Federation of Gynaecology and Obstetrics (FIGO) system for abnormal uterine bleeding: Suggested “normal” limits for menstrual parameters for uterine bleeding

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

Table 3: Grading system of current GCPR

Strength of Recommendation	
A	Strongly recommended
B	Intermediate
C	Weak
D	Not-Evidence based, Panel recommended
Scale of 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
3	Cross-sectional studies, surveillance studies (registries, surveys, epidemiologic studies, retrospective chart reviews, mathematical modelling of database), consecutive case series, single case reports
4	Opinion/consensus by experts or preclinical study

Table 4: Common symptoms and imaging features of AUB

	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 (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
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	USG- Endometrial hyperplasia- Thickened endometrium >12 mm 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



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

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 or contraindicated OCP, NSAIDs, progestogens for symptom relief. Conservative surgery (adenomyomectomy) in selected cases'Hysterectomy is the last resort
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: PRMs such as Ulipristal acetate or low dose mifepristone Sub mucosal myomectomy (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, alternatively oral progestins
COEIN	LNG-IUS or tranexamic acid, NSAIDs, COCs or cyclic (D5-25) oral progestins Luteal phase progestins (Day 15-25) only in AUB-O Medical or surgical treatment failed or contraindicated: GnRH agonists with add-back hormone therapy When steroidal and other options unsuitable: Centchroman

PALM: Polyp, Adenoma, Adenomyosis, 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

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

PBAC SCORING								
Name of Patient	Days							Score
Sanitary pads	1	2	3	4	5	6	7	
								
								
								
Tampons								
								
								
								
Clots/Flooding								
1 Point	For each small clot							
5 Point	For each large clot							
5 Point	For each episode of flooding							

1 = Lightly stained

5 = Moderatrly stained

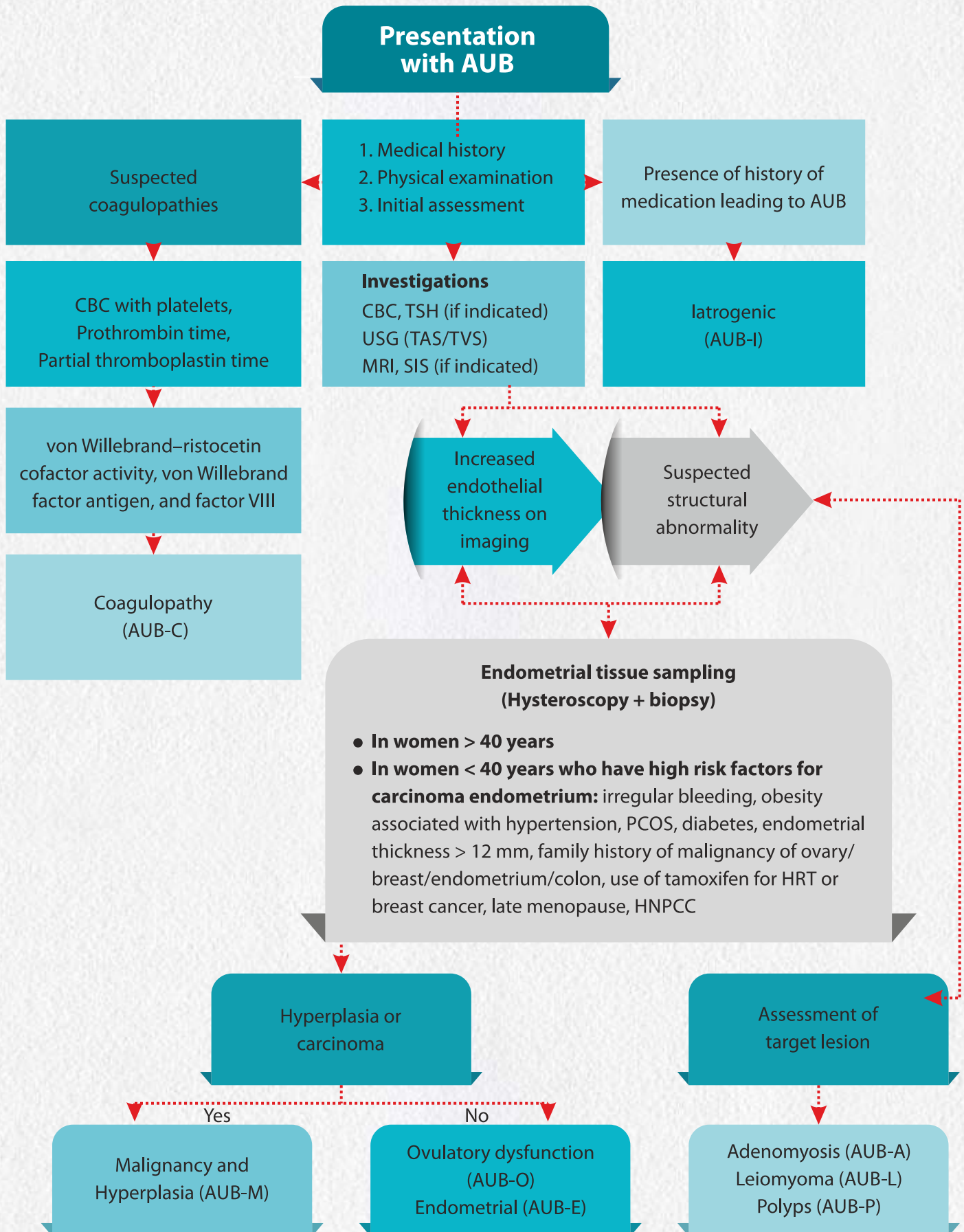
20 = Completely stained


1 = Lightly stained

5 = Moderatrly stained

10 = Completely stained

Figure 2:Algorithm for the diagnosis of AUB





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Bayer House, Central Avenue, Hiranadani Estate, Thane-400 607.
medicalinfo.india@bayerzyduspharma.com