Original Article

Applicability of PALM-COEIN Classification for Categorization of Abnormal Uterine Bleeding: A Clinico-Confirmatory Comparison in Women from South India

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Abstract

Background: Abnormal uterine bleeding (AUB) is a common gynecological complaint with varied etiologies that require systematic evaluation. PALM-COEIN classification provides a structured approach to diagnose the cause of AUB. Despite its widespread adoption, the correlation between clinical findings and histopathological diagnosis remains unexplored. This study evaluates the applicability of the PALM-COEIN classification and its concordance with histopathological outcomes in women with AUB.

Methods: A prospective observational study was carried out among women with AUB attending the gynecology outpatient department at Southern Railway Headquarters Hospital, Chennai from June 2017 to May 2019. All 205 women included in this study were categorized clinically using PALM-COEIN with the help of history, clinical examination and imaging. It was followed by appropriate laboratory testing and histopathological examination to obtain confirmatory diagnosis. The clinical and confirmatory diagnosis were compared using chi-square test.

Results: In clinical diagnosis, leiomyoma (38%, n=78) was the most common cause followed by ovulatory dysfunction (27.32%, n=56), but in the confirmatory diagnosis, adenomyosis (46.83%, n=96) contribute to most of the cases as it was underdiagnosed in 55 patients. The test was statistically significant ($p<0.05$) in the category of adenomyosis ($p<0.001$) and malignancy& endometrial hyperplasia ($p=0.04$), as histopathology examination could diagnose more cases.

Conclusion: PALM-COEIN classification helps in diagnosing all possible etiologies of AUB in a woman clinically. Consideration of laboratory testing and histopathological examination will establish a more accurate and consistent diagnosis.

Keywords:

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Introduction

Abnormal uterine bleeding (AUB) is a common problem among women of reproductive age group. Prevalence of AUB in India is 17.9%[1]. In India, AUB affects 9 to 14% of menstruating women[2]. "Abnormal uterine bleeding is defined as bleeding from uterine corpus that is abnormal in regularity, volume, frequency or duration and occurs in the absence of pregnancy[3]. Abnormal uterine bleeding may be acute or chronic. Acute AUB is defined as an episode of heavy menstrual bleeding that is of sufficient quantity to require immediate intervention to minimize or prevent further blood loss[3]. Chronic AUB is defined as bleeding from the uterine corpus that is abnormal in duration, volume, frequency, and/or regularity for the preceding 6 months[3]. AUB is associated with significant social and physical morbidities with serious underlying pathology. Impact of abnormal uterine bleeding are iron deficiency anemia, pain and premenstrual symptoms, decreased in work productivity, sickness absenteeism, cost of sanitary pads use, decrease in quality of life and psychological effects of women. In view of its huge disease burden, to standardize the categorization of AUB, the International Federation of Gynecology and Obstetrics have published the PALM-COEIN classification system in 2011 which was subjected to modifications in 2018. The FIGO AUB system 2018 introduced two systems, Definitions and Terminology of the bleeding pattern (FIGO AUB System 1) and the PALM-COEIN classification for causes of AUB (FIGO-AUB System 2).The PALM(Polyp, Adenomyosis, Leiomyoma, Malignancy and Hyperplasia) denotes the structural causes of AUB can be imaged and defined by histopathological examination. The COEIN (Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic, and Not yet classified) are non-structural causes as they cannot be diagnosed by imaging but need a detailed history, clinical examination and sometimes supporting laboratory investigations to diagnose them[4]. Hence, FIGO system 1 helps describe the specific bleeding patterns whereas system 2 helps pinpoint the underlying reasons for those patterns and helps in deciding therapy. Previous studies on the PALM-COEIN classification have primarily emphasized either clinical or histopathological aspects of abnormal uterine bleeding (AUB), with limited literature directly comparing the diagnostic accuracy of clinical evaluation against histopathological confirmation. This disconnect can lead to misclassification and suboptimal management decisions.

The present study was conducted with the aim to study the bleeding pattern of women presenting with AUB and to categorize them using PALM-COEIN classification. The comparison of structural causes (PALM) with histopathological examination and non-structural causes (COEIN) with appropriate testing and histopathological examination was studied.

Materials and methods

This is a prospective observational study was conducted in the department of obstetrics and Gynecology of a tertiary care center (Southern Railway Headquarters hospital) in Chennai, from June2017 toMay 2019. All women presented with abnormal uterine bleeding to the gynecology outpatient department who consent for the study were included. The women presented with postmenopausal bleeding, bleeding prior to menarche and pregnancy related bleeding were excluded from the study. The sample size was calculated assuming the expected proportion of any particular PALM-COEIN category as per previous study[5]as 50.23%. The other parameters considered for sample size calculation were 7% absolute precision and 95% confidence level. The required sample size as per the above-mentioned classification was 196 subjects. To account for a non-participation rate of 5% another 10 subjects will be included. Hence a total of 205 subjects will be sampled at the time of recruitment.

Approval was obtained from institutional ethical committee (Reference no: HQ/MD/156/I/EC/2017/02, 26.08.2017) and all participants gave written informed consent. All women included in this study have been asked about previous and current menstrual history, medical history, history of contraceptive use and family history of malignancy followed by clinical examination. Laboratory investigations like thyroid function test and serum prolactin were done (wherever required) to rule out ovulatory dysfunction. As per FIGO guidelines[3], Patients who were screen positive by history suggestive of coagulopathy (heavy menstrual bleeding since menarche, postpartum bleeding, surgery, or dental

work-related bleeding, two or more of bruising/ epistasis one or two times per month, family history of bleeding symptoms and frequent gum bleeding), coagulation profile was done. Patients with abnormal coagulation profile were further investigated for factor assay or von Willebr and factor in opinion with hematologist. Transabdominal and/or transvaginal ultrasonography was done by radiologist to assess Uterine size, endometrial thickness, presence of polyp, fibroids, adenomyosis and ovarian status. All women with abnormal uterine bleeding >40 years or < 40 years with risk factors for endometrial malignancy were subjected to endometrial aspiration biopsy (office pipelle biopsy) and sent for histopathology examination. Patients with inconclusive endometrial aspiration biopsy or transvaginal sonography suggestive of focal endometrial lesion or technical difficulty in obtaining sample due to obesity, previous surgery were subjected to diagnostic hysteroscopy and directed biopsy as a daycare procedure. Myomectomy/ Hysterectomy (vaginal or laparoscopic or abdominal) done only for indicated individuals and subjected to histopathology analysis to determine malignancy or premalignant lesions and to confirm the diagnosis obtained clinically using PALM-COEIN. Categorization of women was done as per FIGO PALM-COEIN recommendations 2018. All women included in this study, were categorized initially by detailed history, clinical examination and imaging (clinical diagnosis). This was followed by histopathological examination of endometrial sample or hysterectomy specimen wherever indicated to confirm the structural causes (PALM) and non-structural causes (AUB-O, AUB-E) whereas, appropriate laboratory testing like hormone assay, coagulation profile and factor assay were done to confirm AUB-C and AUB-I. Women who cannot be categorized by any of the above methods were categorized as AUB-N. The categorization by history, clinical examination and imaging (clinical diagnosis) was compared with histopathological examination and appropriate laboratory testing (confirmatory diagnosis) (Table 1).

Statistical analysis:

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Non-normally distributed quantitative variables were summarized by median and inter quartile range (IQR). The clinical diagnosis was compared with the confirmatory diagnosis using chi square test with the later as the gold standard. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

Results

Totally 205 subjects were included in the final analysis. In the study population, the mean age of the patients was 41.64 years (SD= 9.44), the minimum age was 15 years and maximum age was 55 years. Majority of them were aged between 40-49 years (n=119, 58.05%). Most of the patients were multiparous in which 55.61% had a parity of 2 (n=114) and 16.51% had a parity of 3 (n=40). The distribution of acute and chronic AUB was 28.29% (n=58) and 71.71% (n=147) respectively. The most common presenting complaints of the patients was heavy menstrual bleeding (38.05%, n=78) followed by heavy and prolonged menstrual bleeding (16.59%, n=34) (Table 2).

According to the clinical diagnosis, leiomyoma was the most common cause of AUB (38.05%, n=78) followed by ovulatory dysfunction (27.32%, n=56), but in the confirmatory diagnosis, adenomyosis (46.83%,n=96) contribute to most of the cases as it was underdiagnosed in 55 patients. In clinical diagnosis, 23 women had polyp and 78 women had leiomyoma while histopathology examination have found 2 and 4 additional cases with polyp and leiomyoma respectively. None of the patient had suspicion of malignancy in clinical diagnosis but histopathology found 4 women with pre-malignant lesions. Out of 4 patients assigned to AUB-C by clinical diagnosis, only 2 patients were categorized to the same by confirmatory diagnosis, while other 2 had normal coagulation profile and factor assay. The histopathological examination contributes to 3 additional cases of chronic endometritis and were recategorized to AUB-E. There is no much change in ovulatory dysfunction and iatrogenic cases of AUB. Women who cannot be categorized to any of the above category by clinical diagnosis were 9, was

reduced to 5 patients by confirmatory diagnosis. Multiple pathologies contribute to the causes of AUB in a single woman and each cause was categorized separately to compare the accuracy of the clinical diagnosis with confirmatory diagnosis. The test was statistically significant (≤ 0.05) in the category of adenomyosis and malignancy& endometrial hyperplasia, as histopathology examination could diagnose more cases of adenomyosis ($p<0.001$) and malignancy & endometrial hyperplasia ($p=0.04$) (Table 3).

Table 1: Methodology of clinical and confirmatory categorization:

PALM-COEIN	CLINICAL DIAGNOSIS	CONFIRMATORY DIAGNOSIS
AUB-P	History, clinical examination, presence of polyp in transvaginal ultrasonography, diagnostic hysteroscopy	Histopathology examination of endometrial aspiration biopsy or diagnostic hysteroscopy or hysterectomy specimen
AUB-A	Clinical examination, presence of adenomyosis according to transvaginal sonography criteria suggested by the morphological uterus sonographic assessment (MUSA) group[2]	Histopathology examination of hysterectomy specimen
AUB-L	Clinical examination, Transabdominal and transvaginal ultrasonography	Histopathology examination of hysterectomy/ myomectomy specimen
AUB-M	History, clinical examination, presence of risk factors for endometrial carcinoma, transvaginal ultrasonography.	Histopathology study of endometrial aspiration biopsy or diagnostic hysteroscopy with targeted biopsy or hysterectomy specimen suggestive of endometrial carcinoma, leiomyosarcoma, or atypical endometrial hyperplasia
AUB-C	Screening history positive for coagulopathy	Diagnosis of abnormal coagulation profile/ factor deficiency
AUB-O	History, clinical examination, hormone assay, ultrasonography	Hysterectomy specimen/Pre-menstrual endometrial sample showing proliferative endometrium or benign hyperplasia.
AUB-E	Presence of regular menstrual cycle with normal clinical examination and ultrasonographic feature	Hysterectomy/ premenstrual endometrial sample showing secretory phase endometrium or chronic endometritis.
AUB-I	Intrauterine contraceptive device, history of gonadal hormone therapy or anticoagulant	presence of intrauterine device, coagulation abnormality due to anticoagulant drug. Hormone assay disturbances such as hyperprolactinemia due to iatrogenic drugs.
AUB-N	Patients cannot be categorized by above category	Patients who cannot be categorized even after thorough structured history and detailed examination,investigationsand histopathological evaluation.

Table 2: Distribution of symptoms of AUB:

Menstrual History	Frequency(n=205)	Percentages
Heavy menstrual bleeding (HMB)	78	38.05%
Heavy and Prolonged Menstrual bleeding (HPMB)	34	16.59%
Intermenstrual bleeding (IMB)	15	7.32%
Frequent menstrual bleeding	25	12.20%
Infrequent menstrual bleeding	8	3.90%
Irregular bleeding	20	9.76%
Breakthrough bleeding	2	0.98%
Prolonged menstrual bleeding	17	8.29%
Shortened menstrual bleeding	3	1.46%
Amenorrhea	3	1.46%

Table 3: Comparison of clinical diagnosis and confirmatory diagnosis at different AUB levels (N=205)

Parameter	Clinical diagnosis	Histopathological Diagnosis	P value
AUB-P	23(11.2%)	25 (12.2%)	0.76
AUB-A	41(20%)	96 (46.8%)	<0.001
AUB-L	78 (38%)	80 (39%)	0.84
AUB-M	0 (0%)	4 (2%)	0.044
AUB-C	4 (2%)	2 (1%)	0.412
AUB-O	56 (27.3%)	55 (26.8%)	0.9124
AUB-E	12 (5.9%)	15 (7.3%)	0.55
AUB-I	13 (6.3%)	13 (6.3%)	1.00
AUB-N	9 (4.4%)	5 (2.4%)	0.275

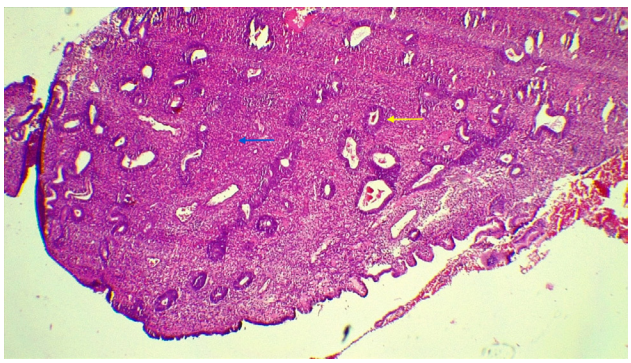

Figure 1: Localized polypoid projection of the endometrial tissue with dense, fibrous stroma (blue arrow) andglands (yellow arrow) embedded in it suggesting endometrial Polyp.

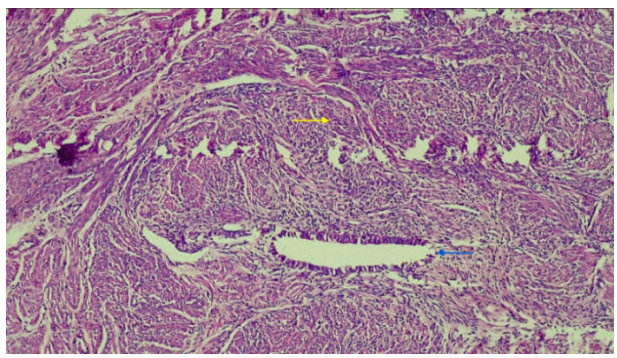

Figure 2: Glandular structures (blue arrow) embedded within the smooth muscle tissue (yellow arrow) suggesting Adenomyosis.

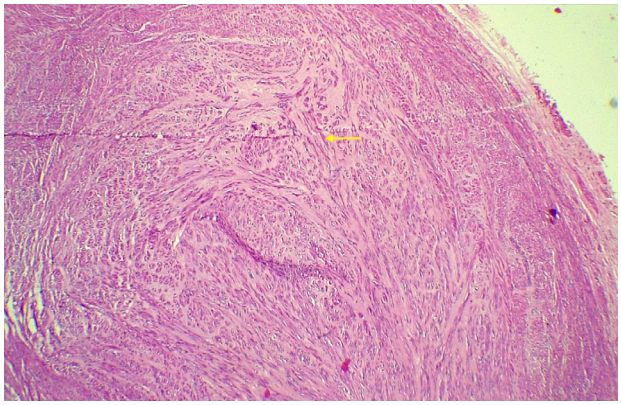

Figure 3: Bundles of elongated, spindle-shaped smooth muscle cells (yellow arrow) arranged in intersecting and whorled pattern consistent with Leiomyoma

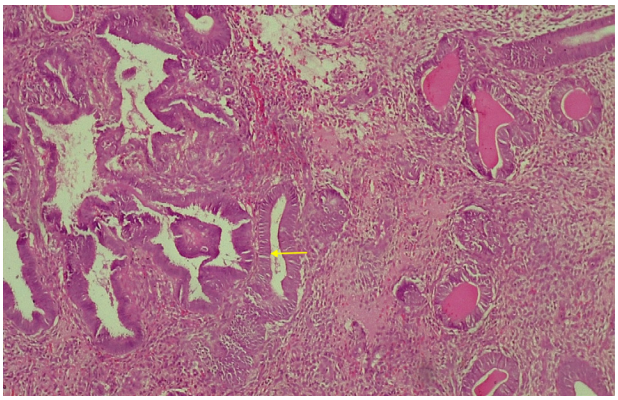

Figure 4: Endometrial glands are densely packed with altered epithelial cytology (yellow arrow) compared to the surrounding normal glandular arrangement revealing glandular crowding reflecting Endometrial Intraepithelial Neoplasia.

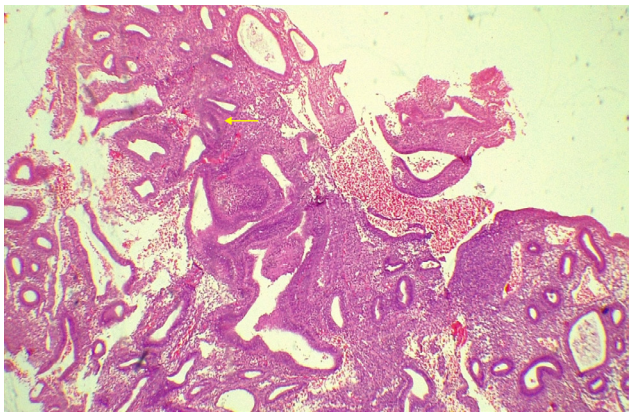

Figure 5: Proliferation of endometrial glands with reduced intervening stroma (yellow arrow). The glands exhibit irregular shapes, varying sizes and dilated suggesting Benign endometrial hyperplasia.

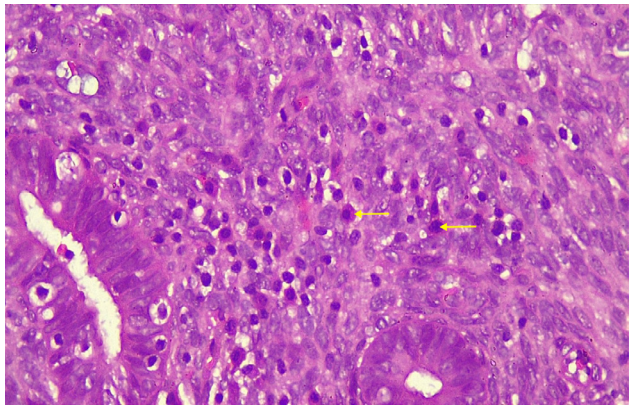

Figure 6: Presence of plasma cells (yellow arrow) within the endometrial stroma. The endometrial stromal cells showing increased density and spindled reflecting Chronic endometritis.

Discussion

The present study found that the PALM-COEIN classification helps in categorizing all causes of AUB methodically without missing any possible etiology. The structural causes contribute to most of the cases of AUB in reproductive age group. The difference in clinical and histopathological diagnosis was statistically significant in case of adenomyosis and endometrial hyperplasia & malignancy. The present study found HMB as the most common abnormal bleeding pattern (78 patients, 38.05%) which was in accordance with other descriptive observational study done in Indian population[6-8].

Several previous studies have studied the PALM-COEIN classification for categorization of AUB. In a retrospective study, leiomyoma and ovulatory dysfunction were the most common cause[9]. In another descriptive study on perimenopausal women, leiomyoma followed by ovulatory dysfunction and leiomyoma followed by adenomyosis were the most common clinical and histopathological diagnosis respectively[5]. However, these studies were done in a specific age group and analyzed only the accuracy of clinical and histopathological diagnosis. In the present study, women with AUB of reproductive age group were studied and each category of AUB have been compared between clinical and confirmatory diagnosis. In the present study, leiomyoma followed by ovulatory dysfunction and adenomyosis followed by leiomyoma were the most common clinical and confirmatory diagnosis respectively.

In AUB-P(polyp), the difference in clinical and histopathological diagnosis was not statistically significant (p value = 0.76), as most of the endocervical polyps were diagnosed by clinical examination and endometrial polyp were diagnosed by transvaginal ultrasonography. The histopathological diagnosis was slightly higher than the clinical diagnosis (12.2% vs 11.2%) due to the diagnosis of higher number of endometrial polyps in histopathological examination but not to significant proportion. Similar result was found in other study[5,9].

In AUB-A(adenomyosis), the difference in clinical and histopathological diagnosis was significant, p value < 0.001 (20% vs 46.8%), more cases were diagnosed by histopathology than clinical diagnosis. This is due to the fact that signs and symptoms of adenomyosis and leiomyoma are so similar that it is difficult to differentiate them clinically. As the clinical diagnosis of AUB-A needs a minimum requirement of transvaginal ultrasound criteria, the type of ultrasound machine used and expertise of the radiologist will have an effect on the likelihood of missing adenomyosis pre-operatively. MRI would have helped in better radiological diagnosis of adenomyosis but it is expensive and not readily available, so done in only patients who were in need of conservative management like myomectomy. The result is similar to another study, where adenomyosis was missed preoperatively in 37(46.3%) women[10].

In AUB-L(Leiomyoma), the difference in clinical and histopathological diagnosis was not significant, p value = 0.84 (38% vs 39%) as most of the leiomyoma causing abnormal uterine bleeding can be easily diagnosed by clinical examination and ultrasonography. So, leiomyoma is more of clinical diagnosis with histopathology plays a complementary role in confirmation of diagnosis.

In AUB-M (malignancy and endometrial hyperplasia) the difference in clinical and histopathological diagnosis was significant, p value=0.04 (0% vs 2%) and it was in accordance to another study done in Indian population[9]. No women were categorized under AUB-M clinically in this study due to the fact that clinical picture including menstrual history is not specific for AUB-M and endometrial thickness of perimenopausal women is highly variable. Endometrial hyperplasia with atypia was missed clinically in 4 cases. It emphasized the importance of histopathological examination in ruling out pre-malignant and malignant lesions.

AUB-C, the least common category in this study (2%). The difference in clinical and confirmatory diagnosis was not statistically significant, p value = 0.412 (2% vs 1%). Most of the cases of AUB-C could be diagnosed by structured history screen positive and laboratory investigation helped in the confirmation. Inclusion of coagulopathy (AUB-C) in categorization of AUB by FIGO is an eye-opener for clinicians as it is often missed in the differential diagnosis of women with HMB. AUB-O, accounted for the most important non-structural causes of AUB in this study. The difference in clinical and histopathological diagnosis was not statistically significant, p value=0.9124 (27.3 vs 26.8). Majority of women with ovulatory dysfunction were diagnosed with menstrual history of erratic and unpredictable bleeding. Hence, AUB-O is more of clinical diagnosis but histopathological confirmation by endometrial biopsy is essential in perimenopausal age group to rule out pre-malignant and malignant lesions.

In AUB-E, the difference in clinical and histopathological diagnosis was not statistically significant, p value = 0.55 (5.9% vs 7.3%). In other studies[5,10], clinical cases were more than histopathological diagnosis compared to present study as these studies follows FIGO 2011 recommendations where chronic endometritis included under category AUB-N. However, in FIGO 2018 recommendation it clearly states that chronic endometritis should be categorized as AUB-E [4]. In AUB-I, there is no change in clinical and confirmatory diagnosis (6.3% vs 6.3%), p value = 1.0. As most of the anticoagulant drugs and drugs to interfere with ovulation can be diagnosed by history and intrauterine device can be diagnosed by clinical examination and ultrasonography. In AUB-N, the difference in clinical and confirmatory diagnosis was not significant, p value = 0.275 (4.4% vs 2.4%). However, histopathology helps in the recategorization of some of the AUB-N to another specific category. The present study had limitation of not including subclassification of leiomyoma which would have helped further in the management of patient. The study was done in a tertiary care hospital and further study in low resource setting will reflect the exact applicability of PALM-COEIN classification.

Conclusion

PALM-COEIN classification helps in diagnosing all possible etiologies of AUB in a woman clinically. However, it should be followed by further investigations like laboratory testing and histopathological examination to rule out pre-malignant lesions & malignancy and to establish a more accurate and consistent diagnosis thereby improve the management and clinical care of the patient.

Author Contributions

Arthi Ekambaram conducted the study, collected and analysed the data, and prepared the initial manuscript draft. **K.S. Rajarajeswari** contributed to framing the manuscript and provided continuous guidance and supervision throughout the study.

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Conflicts of Interest: The authors declare no conflicts of interest.

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