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Assessment of the efficacy of Ashokarista syrup for the treatment of primary dysmenorrhea

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Abstract
The purpose of this article is to evaluate the effectiveness of Ashokarista syrup in treating primary dysmenorrhea. The study process was explained to the subjects, who were also directed to take 15 ml of Ashokarista Syrup orally in three divided dosages each day for 30 days along with regular water. Every participant in the study was made aware of the evaluation that will take place throughout that time. A common and sometimes ignored gynecological issue that affects women all around the world is dysmenorrhea, or unpleasant menstruation. The cramping pain that precedes or coincides with a menstrual cycle is called primary dysmenorrhea. Prostaglandins are naturally occurring substances produced in the uterine lining that are the source of this pain. The uterine muscles and blood vessels constrict as a result of prostaglandins. Prostaglandin levels are highest on the first day of menstruation. The level decreases when the bleeding keeps up and the uterine lining sheds. This explains why, after the first few days of a period, pain usually subsides. This study shows that the changed clinical symptoms from baseline to throughout the study in experimental groups. Improvement of painful means, lower abdominal pain, lower back pain, nausea, vomiting, headache, and irritability of different number of patients and also shows that hemoglobin concentration is significant increase. According to these numerical findings, Ashokarista Syrup medication is a useful method for managing primary dysmenorrhea and has been demonstrated to ease a variety of patient symptoms, including painful means, lower back and abdomen discomfort, headaches, nausea, and irritability.

Keywords: Syrup Ashokarista, primary dysmenorrhea, menstruation

1. Introduction
A severe, painful cramping sensation in the lower abdomen that is frequently accompanied by additional symptoms including sweating, headaches, nausea, vomiting, diarrhea, and tremulousness, all of which occur right before or during the menses is known as dysmenorrhea, or painful menstruation [1]. Dysmenorrhea is the greatest single cause of lost work and school hours in females [2]. It was surprised that 75% of menstruating women had the experiences of dysmenorrhea [3]. There are two types of dysmenorrhea: primary and secondary. Primary refers to pelvic pain in women under 20 years of age that lacks a clear pathogenic cause. Secondary is painful menses resulting from pelvic pathology like endometriosis, pelvic inflammatory disease, adenomyosis, fibroids and polyps. It is mostly seen in women older than 20 years of age. Prevalence of primary dysmenorrhea was 31% to 90% in Western countries and 44% to 70% of menstruating women in Asian countries has been identified to be affected [4]. Approximately 15% women missed work because the clinical manifestations were so severe to disrupt activities of daily living [3]. Primary dysmenorrhea can cause absenteeism and reduction in productivity at work. Regardless of whether dysmenorrhea occurs with each menstrual cycle or only with occasional cycles, the pain associated with menstruation can be a source of significant physical distress as well as inconvenience and activity limitations [5]. Dysmenorrhea is considered the most common symptom of all menstrual complaints and poses a greater burden of disease than any other gynecological complaint in developing countries. The prevalence of dysmenorrhea reported in the literature varies substantially. A greater prevalence was generally observed in young women, with estimates ranging from 67% to 90% for those aged 17–24 years [1]. Bangladeshi women suffer from menstrual problems such as dysmenorrhea, menorrhagia, light and heavy bleeding during menstruation, and irregular period etc. Gynecological problems such as those related to menstruation are a major concern among Bangladeshi women, but social stigma and shame stand as a barrier against seeking proper healthcare.

Often, they seek health advice from female relatives and unqualified health providers which in turn often leads to incorrect treatment and chronic menstrual related illnesses [6]. So it needs a better solution for the correction of this problem. Ayurveda can play a signification role for the management of this disease. Ashokarista is a polyherbal formulation that claim for the treatment of dysmenorrhea, but it needs scientific evidence. Besides this medicine is available all over the country and its very cost effective rather than other medicine. Dysmenorrhea, commonly referred to as menstrual cramps, is defined as cyclic pain directly related to menstruation. The pain begins just prior to or with onset of menstrual flow and resolves with menstruation. The pain may be experienced in the pelvis, lower back, or upper legs. The symptom can be severe enough to bother them in daily lives and work. The purpose of this article is to evaluate the effectiveness of Ashokarista syrup in treating primary dysmenorrhea**.**

2. Material and methods

Based on Hematological value and clinical improvements in painful menstruation, pain in the lower abdomen and suprapubic area, lower back pain, headache, nausea, and vomiting, Ashokarista Syrup's effectiveness was assessed. The study process was explained to the subjects, who were also directed to take 15 ml of Ashokarista Syrup orally in three divided dosages each day for 30 days along with regular water. Every participant in the study was made aware of the evaluation that was take place throughout that time.

2.1. Study design

Purposive sampling methods in single group was conducted those are sufferings from primary dysmenorrhea.

2.2. Study area

The whole study was done in the Shahjadpur slum Area.

2.3. Selection of cases

Total 30 numbers of patients were collected after following inclusion and exclusion criteria.

2.4. Inclusion criteria

1. Patients of female sex from age 13 to 30 years.
2. Pain begins before one or two days of menstruation and lasting for one to two days.
3. Pain in the lower abdomen and suprapubic region.
4. Pain radiating to the thigh and lower back. Sometimes associated with nausea, vomiting, headache, diarrhea, constipation, irritability, and faintness.

2.5. Exclusion criteria

1. Patients with other systemic disorders that interfere with the study.

2.6. Selection and collection of drugs

Ashokarista is an Ayurvedic traditional herbal formulation quoted in Bangladesh National Ayurvedic Formulary (B.N.A.F; 2011) (See Table 1.) for the treatment menstrual disorders [7]. The selected drug was collected from the Hamdard Laboratories (Waqf) Bangladesh.

Table 1: Contents of selected ayurvedic preparation of Ashokarista

Sl. No	Bengali name	Scientific name	Part uses	Each 5 ml contain
1	Ashoka	*Saraca indica*	Steam	1.52 gm
2	Dhaiful	*Woodfordia fruticose*	Flower	0.24 gm
3	Mutha	*Cyperus rotundus*	Rhizome	15.15 mg
4	Jira	*Cuminum cyminum*	Seed	15.15 mg
5	Sunth	*Zingiber officinale*	Rhizome	15.15 mg
6	Daruharidra	*Berberis aristata*	Stem	15.15 mg
7	Amlaki	*Phyllanthus emblica*	Fruit	15.15 mg
8	Harritaki	*Terminalia chebula*	Fruit	15.15 mg
9	Bohera	*Terminalia bellirica*	Fruit	15.15 mg
10	Basak	*Adhatoda vasica*	Bark	15.15 mg
11	Raktachandan	*Pterocarpus santalinus*	Stem	15.15 mg

2.7. Grouping and administration of drugs with duration: After taking the permission, 30 number of patients was grouped in a single group and was received syrup Ashokarista 15 ml daily in three divided doses along with normal water per orally for 30 days.

2.8. Assessment criteria

Patient's assessment was conducted at the day of baseline, 14 and 30 for the efficacy of treatment. Specific clinical symptoms were assessed separately at the day of baseline, 14 and 30. Total leucocytes count (TLC), Differential leucocytes count (DLC), Erythrocyte sedimentation rate (ESR) and Haemoglobin concentration (Hb %) concentration was performed at baseline day and the day of 30.

2.9. Data collection methods

The clinical data was collected through individual in-depth interviews, with questionnaires and followed particular assessment criteria and data of body weight, pulse rate, blood pressure was recorded with the help of digital weighing machine, wristwatch, and Sphygmomanometer. Blood samples for haematological examinations were collected directly from the vein of each patient. After collection blood samples, standard procedure was followed to evaluate all the investigations and report was collected in a hospital-based format.

2.10. Statistical analysis

The quantitative data was assessed by using paired student 't' test when compared before and after study in a single group. The value was expressed as mean ± SD (standard deviation). Probability level of less than 5% ($p<0.05$), 1% ($p<0.01$) and 0.1% ($p<0.001$) was considered for significant.

2.11. Ethical consideration

According to the instruction of Ethical Committee, every procedure was maintained throughout the study.

3. Result

This clinical trial was conducted to evaluate scientific basis of syrup Ashokarista for the treatment of the dysmenorrhea. A total of 30 participants were assigned to treatment in a single group.

3.1 Observations of Demographic of Selected Patients

3.1.1 Age group

Table 3.1 shows that total 18 (60.00%) numbers of patients were found as adolescence group, between the age of 13-18 years. It was the highest incidence of age groups in this study. Adulthood group (25-30 years) was observed 10 (33.33%) numbers of total subjects. Only 2 (6.66%) numbers of patients were 19-25 years group

Table 2: Age group of all patients of "Primary Dysmenorrhea"

Age Group	Number of Patients
13-18 (Adolescence)	18
19-25 (Young Adults)	02
25-30 (Adulthood)	10

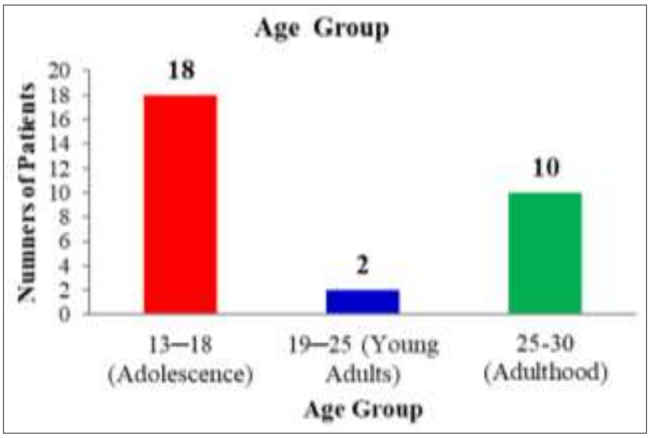

Fig 1: Age group of all selected patients

3.1.2 Marital status:

It is seen in table 3.2 the numbers of patients 18 (60.00%) were unmarried and married was found in 12 (40.00%) numbers of total patients.

Table 3: Marital status of all patients of "Primary Dysmenorrhea"

Sex	Number of Patients
Unmarried	18
Married	12

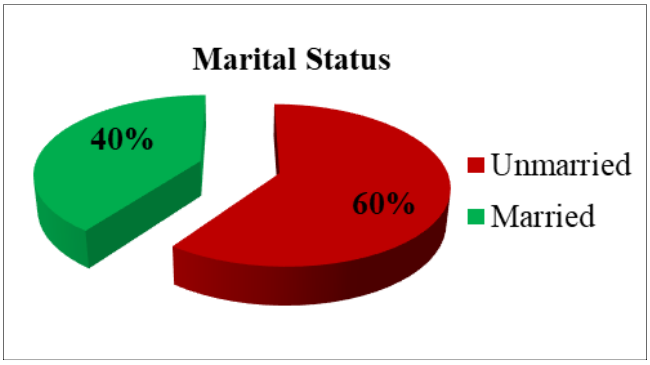

Fig 2: Marital status of all patients

3.1.3 Religion status

Table 3.3 shows that 29 (96.66%) number of patients were recorded from Islam religion. The Hindu was 1 (3.33%) number of patients, and no one accounted from other religion.

Table 3: Religions of all patients of "Primary Dysmenorrhea"

Religion	Number of Patients
Islam	29
Hindu	01
Others	00

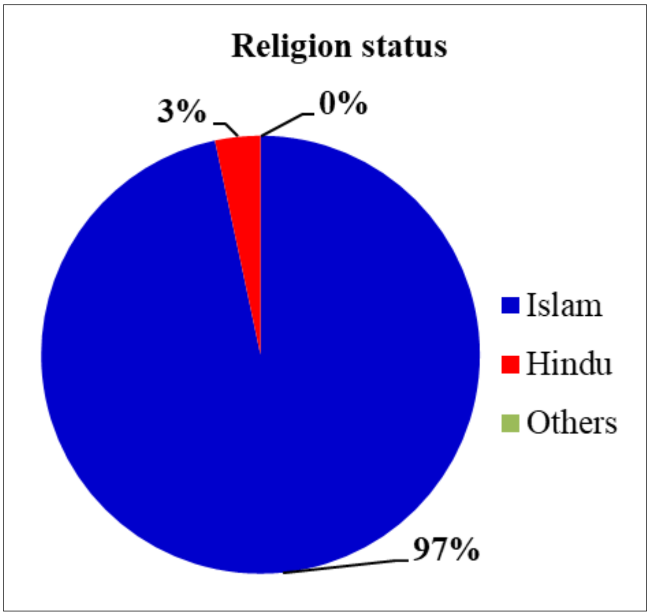

Fig 3: Religion status of All Selected Patients

3.1.4 Occupational status

The 17 (56.66%) numbers of patients were student. Housewife was found in 8 (26.66%) numbers of patients as a housewife. Only 05 (16.66%) numbers of patients were service holder according to table 3.4.

Table 4: Occupational statuses of all patients of "Primary Dysmenorrhea"

Occupational status	Number of Patients
Student	17
Housewife	08
Service Holder	05

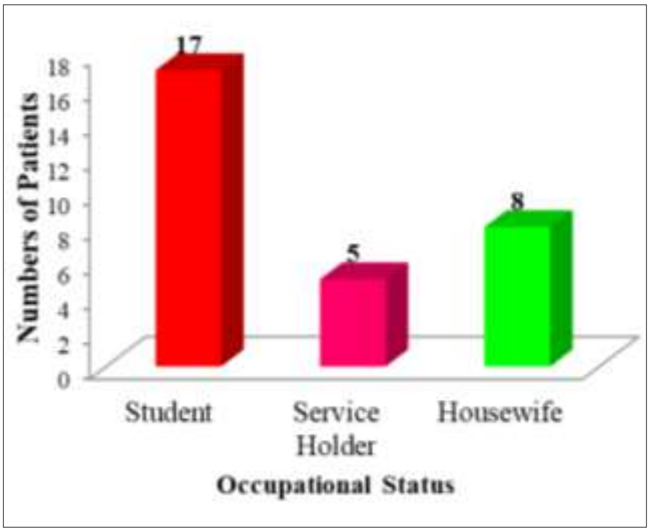

Fig 4: Occupational status of All Selected Patients

3.1.5 Socioeconomic status

Table 3.5 shows that total 30 (100.00%) numbers of patients came from lower class family and no one from other class socioeconomic status.

Table 5: Socioeconomic statuses of all patients of "Primary Dysmenorrhea"

Socioeconomic status	Number of Patients
Lower class	30
Middle class	00
Upper class	00

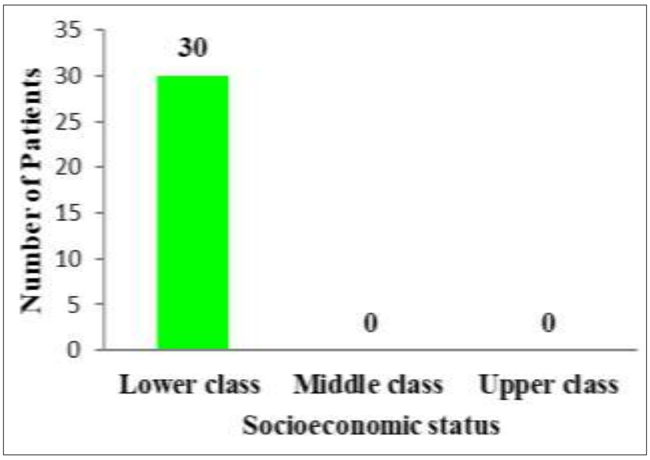

Fig 5: Socioeconomic statuses of All Selected Patients

3.1.6. Educational Status

Total 13 (43.33%) numbers of subjects were above 8th class, and 13 (43.33%) numbers of subjects were below the 8th class and remaining 4 (13.33%) numbers of patients were illiterate that shows in table 3.6.

Table 6: Educational statuses of all patients of "Primary Dysmenorrhea"

Educational status	Number of Patients
Above 8th Class	13
Below 8th Class	13
Illiterate	04

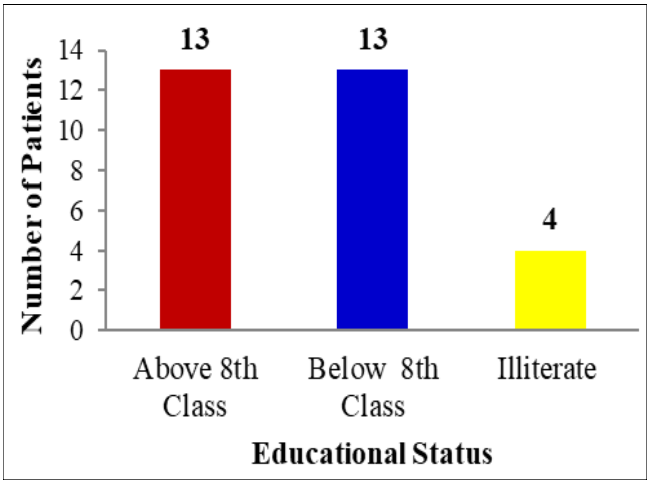

Fig 6: Educational Statuses of All Selected Patients

3.1.7 Dietary Habit

Total 23 (76.66%) numbers of subjects were mixed dietary habit and 5 (16.66%) numbers of patients were non vegetarian and only 2(6.66%) patients were vegetarian.

Table 7: Dietary habits of all patients of "Primary Dysmenorrhea"

Dietary Habit	Number of Patients
Vegetarian	02
Non-Vegetarian	05
Mixed	23

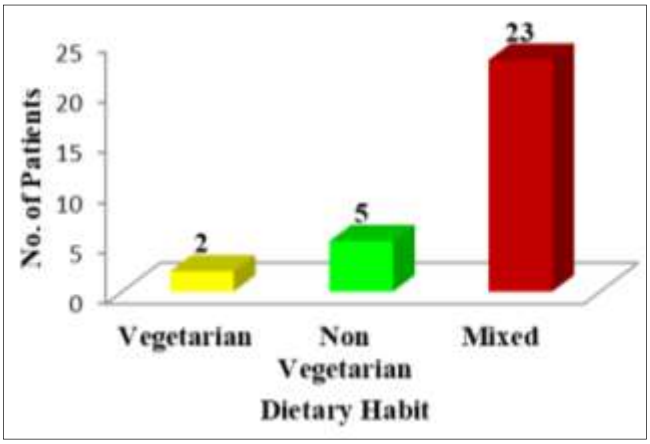

Fig 7: Dietary habits of All Selected Patients

3.1.8 History of any other illness

Total 29 (96.66%) numbers of subjects had no complaints on history of any other illness and 1 (3.33%) patient was the history of hypertension.

Table 8: History of any other illness of all patients of "Primary Dysmenorrhea"

Any other illness	Number of Patients
Yes	01
No	29

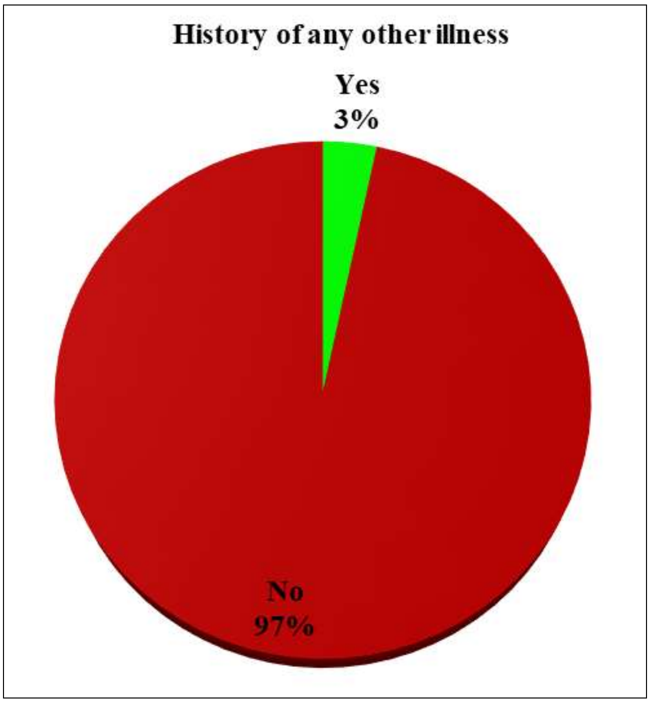

Fig 8: History of any other illness of all selected patients

3.1.9 Family history of any other illness

Total 27 (90.00%) numbers of subjects had no complaints of family history of any other illness, and 3 (10.00%) numbers patient was the history of hypertension.

Table 9: Family history of any other illness of all patients of "Primary Dysmenorrhea"

Any other illness	Number of Patients
Yes	03
No	27

3.2 Result of Clinical Symptoms of All Patients of Primary Dysmenorrhea

3.2.1 Clinical symptoms

Table 3.10 showed that the changed clinical symptoms from baseline to throughout the study in experimental groups. Pain begins before one or two days of menstruation and lasting for one to two days was found in 30 (100%), numbers of patient before study and after study it showed a significant change (<0.01) and symptoms having only in 04 (13.33%) number of patients. Before study the pain in the lower abdomen and suprapubic region was found in 29 (96.66%), numbers of patients but after study it showed in only 10 (33.33%) number of patients. Pain radiating to the thigh and lower back was found in 25 (83.33%) numbers of patients and after study it showed significant change (<0.01) in 02 (6.66%) number of patients. Nausea, vomiting showed in 11 (36.66%) numbers of patients, after study 03 (10.00%) number of patients had the complaints of nausea and vomiting. Before study headache and irritability was showed in 24 (80.00%) and 28 (93.33%) numbers of patients and after study it was found in significant changes (<0.01) and only 03 (10.00%) and 06 (20.00%) numbers of patients had those symptoms respectively.

Table 10: Clinical Symptoms of all patients of "Primary Dysmenorrhea"

Symptoms	Before study n (%)	After study n (%)	p value
Pain begins before one or two days of menstruation and lasting for one to two days	30 (100.00%)	04 (13.33%)	<0.01*
Pain in the lower abdomen and suprapubic region	29 (96.66%)	10 (33.33%)	<0.01*
Pain radiating to the thigh and lower back	25 (83.33%)	02 (6.66%)	<0.01*
Nausea, vomiting	11 (36.66%)	03 (10.00%)	<0.01*
Headache	24 (80.00%)	03 (10.00%)	<0.01*
Irritability	28 (93.33%)	06 (20.00%)	<0.01*

Note: n (%) represents number (percentage) of patients; *Wilcoxon t-test* was done at end of treatment when *$p<0.05$, **$p<0.01$, compared to baseline. ns= Not Significant

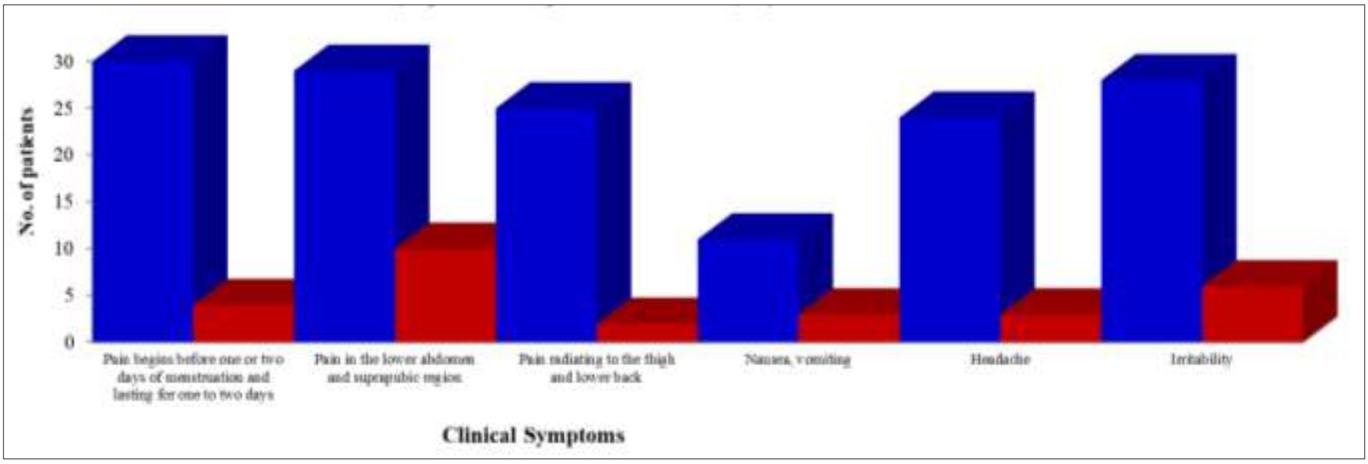

Fig 9: Symptoms of all patients of "Primary Dysmenorrhea"

3.3 Result of Hematological Values of All Patients of Primary Dysmenorrhea

Table 3.11 showed that only hemoglobin concentration was showed significant increase ($p<0.04$) after study. It is also showed that total leucocytes count (TLC) and neutrophils count was significantly increase at the end of treatment when compared to baseline study, but the monocyte count was decrease after 30 days of study. Total erythrocytes count (TEC), eosinophils, lymphocytes, and erythrocyte sedimentation rate (ESR) were not found significant changes at the end of treatment when compared to baseline study.

Table 11: Hematological Values of all patients of "Primary Dysmenorrhea"

Hematological Parameter	Before Study (Mean ±SD)	After Study (Mean ±SD)	t value	p value
Hemoglobin (gm/dl))	11.89±0.87	12.16 ±0.95	2.13	0.02*
Total Erythrocytes count (mm^3)	4.52±0.61	4.59 ±0.54	1.24	0.11^{NS}
Total Leucocytes count (1000/ m^3)	9.59 ±3.00	10.45 ±3.04	2.072	0.02*
Neutrophils	56.30±7.88	58.77±8.20	1.75	0.04*
Eosinophils	5.57±3.62	5.07 ±3.33	1.16	0.12^{NS}
Monocytes	2.97 ±0.89	2.13±0.81	5.00	< 0.01**
Lymphocytes	34.77±6.29	34.10 ±7.80	0.60	0.27^{NS}
Erythrocyte Sedimentation Rate (mm 1st hr.)	16.77±9.07	16.43 ±9.80	0.15	0.43^{NS}

Note: Each value represents the mean ± SD; P value was *$p<0.05$, **$p<0.01$, as compared to baseline. NS= Not Significant

4. Discussions
Ashokarista is an Ayurvedic traditional herbal formulation quoted in Bangladesh National Ayurvedic Formulary (B.N.A.F) for the treatment of menstrual disorders. The selected drug was collected from the Hamdard Laboratories Bangladesh. Trial duration was 30 days from baseline to end of treatment. Efficacy was evaluated by using clinical symptoms and haematological parameters.

4.1. Discussion of Demographic and Baseline Characteristics
4.1.1. Age group
There is a relationship between dysmenorrhoea and age group. The present study revealed that shows that total 18 (60.00%) numbers of patients was found as adolescence group, between the age of 13-18 years. It was the highest incidence of age groups in this study. Adulthood group (25-30 years) was observed 10 (33.33%) numbers of total subjects. Only 2 (6.66%) numbers of patients were 19-25 years group. Past studies also showed that dysmenorrhea mostly found in adolescence group [8].

4.1.2. Marital status
It was showed the 18 numbers of patients (60.00%) were unmarried and married was found in 12 (40.00%) numbers of total patients. Most previous research also explored the dysmenorrhea is more common in unmarried girl [9].

4.1.3. Religion status
This study found that most patients were from Islam religion. It might be the study area is dominated by Islam population.

4.1.4. Occupational status
The present study showed that total 17 (56.66%) numbers of patients were student. Housewife was found 8 (26.66%) numbers of patients. Only 05 (16.66%) numbers of patients were service holder. Past studies showed that the incidence of dysmenorrhea can be occurred both in employed and unemployed persons. Actually, its variability depends on many causes particularly personal lifestyle. As the students are always busy with their study and examination, so it creates a worrying situation in their mind it might the reason of highest reason in this study.

4.1.5. Socioeconomic status:
The present study shows that total 30 (100.00%) numbers of patients came from lower class family. It may cause their lower standard living status and unawareness regarding the knowledge of dysmenorrhea.

4.1.6. Educational status
Total 13 (43.33%) numbers of subjects were above 8th class, and 13 (43.33%) numbers of subjects were below the 8th class and only 4 (13.33%) numbers of patients were illiterate. The reason behind the cause is lack of knowledge regarding dysmenorrhea.

4.1.7. Dietary Habit
Total 23 (76.66%) numbers of subjects were mixed dietary habit and 5 (16.66%) numbers of patients were non vegetarian and only 2 (6.66%) patients were vegetarian. Past studies showed that low caloric diet causes the dysmenorrhea as the subjects were from lower socioeconomic condition, so their dietary habit is not so rich although they are mixed dietary habit.

4.2. Discussion of Clinical Symptoms of All Patients of Primary Dysmenorrhea
The main clinical symptoms pain begins before one or two days of menstruation and lasting for one to two days was found in 30 (100%), numbers of patient before study and after study it showed a significant changes and symptoms having only in 04 (13.33%) number of patients. Before study the pain in the lower abdomen and suprapubic region was found in 29 (96.66%), numbers of patients but after study it showed in only 10 (33.33%) number of patients. Pain radiating to the thigh and lower back was found in 25 (83.33%) numbers of patients and after study it showed significant change (<0.01) in only 02 (6.66%) number of patients. Because the syrup Ashokarista contains active ingredients *Saraca indica*, *Cyperus rotundus*, *Zingiber officinale*, *Berberis aristata*, *Phyllanthus emblica*, *Terminalia chebula* and *Pterocarpus santalinus* all have anti-inflammatory effects that might reduce pain after taking syrup Ashokarista. Before study nausea, vomiting showed in 10 (33.33%) numbers of patients, after study no patients had the complaints of nausea and vomiting. Probably these was reduced by the effects of *Zingiber officinalis* because past studies showed that ginger has the effect of nausea and vomiting [10-22]. Nausea, vomiting showed in 11 (36.66%) numbers of patients, after study 03 (10.00%) number of patients had the complaints of nausea and vomiting. Before study headache and irritability was showed in 24 (80.00%) and 28 (93.33%) numbers of patients and after study it was found in significant changes (<0.01) and only 03 (10.00%) and 06 (20.00%) numbers of patients had those symptoms respectively. It may have the anti-inflammatory effects of *Zingiber officinalis* and *Saraca indica* [10, 15].

4.3. Discussion of Hematological Values of All Patients of Primary Dysmenorrhea
In hematological parameters, the hemoglobin concentration was showed significant increase (p<0.04) after study when it was compared with baseline parameter. The syrup Ashokarista contains active ingredients *Saraca indica*. Past study showed that *Saraca indica* have strong antioxidant activity. The polyphenolic constituents of *Saraca indica* could play important roles in significantly increased ($p<0.04$) the hemoglobin concentration [23]. The other component of Ashokarista *is Phyllanthus emblica*. Different study and literature showed that this has a strong haemopoietic effects because this plant contains vitamin C and iron may help in synthesis of haemoglobin and formation of red blood corpuscles. Total leucocytes count (TLC) and neutrophils count was significantly increase at the end of treatment when compared to baseline study after 30 days of study. This may have the immunomodulatory effects of *Phyllanthus emblica* and *Saraca indica*. Recent studies also showed that *Phyllanthus emblica* and *Saraca indica* has significant role for increasing the number of neutrophils [19, 24-27]. Total erythrocytes count (TEC), eosinophils, lymphocytes, and erythrocyte sedimentation rate (ESR) was not found significant changes at the end of treatment when compared to baseline study.

5. Conclusions
Dysmenorrhea is common among the females which affect

daily activities leading to limitations of their social, academic, and recreational activities. In Bangladesh this is the most common gynecological problem among the female adolescent. Ashokarista is a polyherbal formulation that claims for the treatment of dysmenorrhea. This study suggests that syrup effective treatment for primary dysmenorrhea and it is also safe because no side effects showed during the treatment. Besides this medicine is available all over the country and its very cost effective rather than other medicine.

6. Recommendation
1. Sample size can be increased.
2. Treatment duration can be increased
3. More pathological parameters may be included to exclude other diseases.

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Author's Contribution
Not available

Conflict of Interest
The authors have no interest of conflict.

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