Menstruation occurs as a universal endometrial event following the withdrawal of estrogen and progesterone subsequent to a normal ovulatory cycle. Disruption of a regulated sequence of molecular, cellular and vascular events can lead to a range of menstrual disturbances.

Age of menarche varies globally, especially in the less developed countries. Menarche typically occurs within 2-3 years after thelarche (breast budding), at Tanner stage IV breast development, and is rare before Tanner stage III development.¹ The median menstrual cycle length is 28 ± 3 days and the average duration of menstrual flow is 5 ± 2 days with a blood loss averaging 130 ml.² This cyclical process is regulated in part by complex changes in the concentrations of five hormones: gonadotropin-releasing hormone (GnRH), follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol and progesterone. Menstrual cycles are often irregular through adolescence, particularly the interval from the first to the second cycle. Early menstrual life is characterized by anovulatory cycles and the ovulation frequency is related to time since menarche as well as age at menarche.

Menstrual irregularities can be caused by disturbance of the central GnRH pulse generator as well as by significant weight loss, strenuous exercise, substantial changes in sleeping or eating habits and severe stressors. Chronic diseases, such as poorly-controlled diabetes mellitus, genetic and congenital conditions, such as Turner syndrome and other forms of gonadal dysgenesis can also be a cause.³

Menorrhagia is menstrual bleeding longer than seven days or in an amount exceeding 80 ml from normal secretory endometrium after normal ovulation.⁴ It affects 10-30% of the menstruating women and may occur at some time during the perimenopause in upto 50% of the women. Metrorrhagia is uterine bleeding that occurs irregularly between menstrual periods. The bleeding is usually light, although it can range from staining to hemorrhage. Polymenorrhea is menstruation that occurs too frequently. Oligomenorrhea is an...
abnormally infrequent menstrual bleeding characterized by 3-6 menstrual cycles per year. When menstrual bleeding does occur, it can be profuse and prolonged or decreased in amount. Primary amenorrhea should be considered for any adolescent who has not reached menarche by the age of 15 years or has not done so within three years of thelarche.

There are three types of dysmenorrhea: Primary, secondary and membranous. Primary dysmenorrhea is characterized by the absence of an organic etiology, while secondary dysmenorrhea is associated with specific diseases or disorders, such as endometriosis, ovarian cysts, pelvic inflammatory disease, adenomyosis, cervical stenosis, fibroid polyps and possibly uterine displacement with fixation. Membranous dysmenorrhea (uterine cast) is rare and causes intense cramping pain due to the passage of the intact endometrial cast through an undilated cervix.

In women with dysmenorrhea, the concentrations of prostaglandins (PG), both PGF$_2$α and PGE$_2$, in menstrual blood are significantly increased compared to those in women without dysmenorrhea as a result of endometrial synthesis and release of PGs. It is, therefore, logical that in the clinical management of both primary and secondary dysmenorrhea, non-steroidal anti-inflammatory drugs (NSAIDs), which inhibit PG synthesis, offer a valid treatment. However, the treatment is less effective if the intake of the drug is delayed until the pain is more severe. Also side effects can occur, especially in women with asthma and allergic disorders and peptic ulcers. Oral contraceptives (OCs) are still used very often as treatment, especially in young women who also require contraception. They reduce uterine contractility, induce endometrial atrophy and reduce endometrial PG concentrations. But, side effects and potential of adverse drug reactions may limit their use in some women. Other treatments (e.g., danazol, GnRH agonists) have either too many side effects, are too invasive (e.g., surgical methods), or are ineffective for the treatment of an accompanying disorder, and cannot, therefore, be considered for routine treatment of dysmenorrhea.

Evecare Syrup is a polyherbal formulation and various clinical studies have observed the beneficial effect in the management of uterine disorders. This study was planned to evaluate the efficacy and safety Evecare Syrup in menstrual irregularities.

**AIM**

To evaluate the clinical efficacy and safety of Evecare Syrup in the treatment of menstrual irregularities.

**MATERIAL AND METHODS**

A multicentric, post marketing surveillance study was undertaken on 1,000 patients in the age group of 18-45 years presenting with history of irregular menstrual cycles. A written informed consent was obtained from all the study participants and they were informed of the voluntary nature of the trial. The study was conducted in accordance with regulatory standards of good clinical practice.

**Inclusion criteria:** Female patients aged between 18-45 years with menstrual irregularities and those willing to give informed consent.

**Exclusion criteria:** Patients who had systemic illness like hypertension, renal disease, tuberculosis, hepatic disease, diabetes, coagulation disorder, etc. and those who had any disorder of the reproductive tract, especially any benign or malignant growth, extensive cervical erosion, cervical polyps, endometriosis, tubercular endometritis and acute infective disorder, and patients with history of recent delivery or abortion, and those patients who refused to give informed consent. Women of childbearing age, who were not willing to follow the adequate contraceptive method and lactating women were also excluded from the trial.

**Study Procedure**

At the initial visit, a detailed medical history, symptomatic evaluation and gynecological evaluation was carried out in all the patients. Out of the 1,000 patients, 372 had dysmenorrhea, 388 had menorrhagia and 240 patients had oligomenorrhea (Table 1). Most of the patients with oligomenorrhea had scanty and irregular menstruation. There were only a few patients with primary dysmenorrhea and they were of the younger age group. Patients with complaints of menorrhagia had no organic cause and were thoroughly assessed before they were put on Evecare therapy. The blood flow loss was graded using a predefined symptom score scale from 0 to 2 (0-normal, 1-moderate, 2-profuse). The character of blood flow was graded from 0 to 2, where 0 was normal flow, 1 was passage of 1-4 clots and

<table>
<thead>
<tr>
<th>Clinical diagnosis</th>
<th>No. of patients</th>
<th>Age (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysmenorrhea</td>
<td>372</td>
<td>25.70 ± 6.43</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>388</td>
<td>28.24 ± 7.15</td>
</tr>
<tr>
<td>Oligomenorrhea</td>
<td>240</td>
<td>27.00 ± 2.28</td>
</tr>
</tbody>
</table>

Table 1. Distribution of Patients with Various Clinical Diagnoses of Menstrual Abnormalities (n = 1,000)
2 was >4 clots. Each patient was administered Evecare Syrup at a dose of 15 ml, twice-daily for a period of three months. All patients were followed up every month till the end of treatment. Symptomatic evaluation and clinical examination was done; any adverse events (AEs) were recorded. Complete blood count and ultrasound scans were done for all patients before and after treatment. The protocol of the study was as per the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines and the patients were free to withdraw from the study if they so desired. No other medication was allowed for these patients.

- Primary endpoint: Clinical recovery from the presenting symptoms of menstrual irregularities.

**Statistical Analysis**

Results were analyzed statistically by repeated measures of ANOVA and Friedman’s test followed by Dunnett’s multiple comparison test for evaluation of symptomatic scores. The minimum level of significance was fixed at 95% confidence limit and a 2-sided p value of <0.05 was considered significant. Statistical analysis was performed using GraphPad Prism Software, Version 4.03.

**Adverse Events**

All AEs, either reported or observed by patients, were recorded with information about severity, date of onset, duration and action taken regarding the study drug. Relation of AEs to the study medication was predefined as ‘Unrelated’ (follows a reasonable temporal sequence from the administration of the drug), ‘Possible’ (follows a known response pattern to the suspected drug, but could have been produced by the patient’s clinical state or other modes of therapy administered to the patient), and ‘Probable’ (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient’s clinical state). Patients were allowed to voluntarily withdraw from the study, if they so desired without assigning reasons. Efforts were made to ascertain the reason for dropout in such patients. Noncompliance (defined as failure to take <80% of the medication) was not regarded as treatment failure, and reasons for noncompliance were noted.

**RESULTS**

One thousand patients were enrolled into the trial and all the patients completed the study. The mean age of the patients in dysmenorrhea group was 25.70 ± 6.43; it was 28.24 ± 7.15 in menorrhagia group and 27.00 ± 2.28 in the oligomenorrhea.

**Effect of Evecare Syrup in Dysmenorrhea**

Three hundred seventy-two patients presented with clinical diagnosis of dysmenorrhea. The results of the study are shown in Table 2. A partial absence of symptoms was observed in 132 patients at second month and complete absence of symptoms in 14 patients. At the end of treatment, 14 had slight abdominal pain and 358 of them had total absence of symptoms (p < 0.001). No clinically significant adverse drug reactions were reported except for one patient who had nausea and it did not require additional treatment or withdrawal of drug.

**Effect of Evecare Syrup in Menorrhagia**

The clinical diagnosis of menorrhagia was made in 388 patients. The results of the study are shown in Table 3. Treatment with Evecare therapy showed a significant (p < 0.001) reduction in the mean score of duration of menstruation, quantity of blood loss (number of pads changed per day) and blood flow loss (graded as profuse to normal) at the end of treatment. Reduction in the symptoms was evident from the second month of therapy itself. Duration of menstruation was 12.80 ± 0.37 at baseline and significantly reduced to 6.77 ± 0.48 (p < 0.05) and 5.12 ± 0.76 (p < 0.001) at the end of second and third months of treatment, respectively. There was a significant change in the mean score of character of blood flow from clot to flow at the end of 3-month treatment with Evecare (p < 0.05). No adverse drug reactions were reported except for one patient who had symptoms of gaseous distension at third month of treatment and it did not require additional treatment or drug withdrawal.

**Effect of Evecare Syrup in Oligomenorrhea**

Two hundred forty patients had a clinical diagnosis of oligomenorrhea. The results of the study are shown in

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**Table 2. Effect of Evecare on Symptomatic Relief in Patients with Dysmenorrhea (n = 372)**

<table>
<thead>
<tr>
<th>Menstrual irregularity</th>
<th>Duration of treatment</th>
<th>No. of cases showing recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Complete</td>
<td>Partial</td>
</tr>
<tr>
<td>Dysmenorrhea 1st month</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>2nd month</td>
<td>14</td>
<td>132</td>
</tr>
<tr>
<td>3rd month</td>
<td>358*</td>
<td>14</td>
</tr>
</tbody>
</table>

*p < 0.001 as compared to at entry values.
Table 3. Effect of Evecare on Symptomatic Relief in Patients with Menorrhagia (n = 388)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Duration of treatment</th>
<th>Score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of menstruation</td>
<td>Baseline</td>
<td>12.80 ± 0.37</td>
<td>-</td>
</tr>
<tr>
<td>(No. of days)</td>
<td>1st month</td>
<td>9.80 ± 0.72</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2nd month</td>
<td>6.77 ± 0.48</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>3rd month</td>
<td>5.12 ± 0.76</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Quantity of blood loss</td>
<td>Baseline</td>
<td>6.76 ± 0.14</td>
<td>-</td>
</tr>
<tr>
<td>(No. of diapers changed/day)</td>
<td>1st month</td>
<td>5.35 ± 0.20</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2nd month</td>
<td>3.93 ± 0.12</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>3rd month</td>
<td>3.06 ± 0.32</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Blood flow loss</td>
<td>Baseline</td>
<td>1.62 ± 0.09</td>
<td>-</td>
</tr>
<tr>
<td>(Profuse to normal)</td>
<td>1st month</td>
<td>1.14 ± 0.04</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2nd month</td>
<td>0.86 ± 0.06</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>3rd month</td>
<td>0.72 ± 0.02</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Character of blood flow</td>
<td>Baseline</td>
<td>1.08 ± 0.12</td>
<td>-</td>
</tr>
<tr>
<td>(Clot or Flow)</td>
<td>1st month</td>
<td>0.88 ± 0.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2nd month</td>
<td>0.64 ± 0.14</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>3rd month</td>
<td>0.58 ± 0.08</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>

Statistical analysis was carried out using repeated ANOVA test, and Friedman test followed by Dunnett’s multiple comparison test.

NS: Not significant.

Table 4. Effect of Evecare on Symptomatic Relief in Patients with Oligomenorrhea (n = 240)

<table>
<thead>
<tr>
<th>Menstrual irregularity</th>
<th>Duration of treatment</th>
<th>No. of cases showing recovery</th>
<th>Complete</th>
<th>Partial</th>
<th>Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oligomenorrhea</td>
<td>1st month</td>
<td>21</td>
<td>34</td>
<td>185</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2nd month</td>
<td>156</td>
<td>79</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3rd month</td>
<td>238*</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*p < 0.001 as compared to at entry values.

Table 4. At the end of one month, a partial response was seen in 34 patients; they had moderate flow. In 21 patients there was total restoration of normal menstrual flow. At the end of two months, 156 patients had normal flow and 79 patients had moderate flow. At the end of three months, 238 patients had normal menstruation, normal duration and flow with significance of p < 0.001 as compared to at entry values. No adverse drug reactions were reported.

**DISCUSSION**

An extensive review of literature on herbal formulations has provided a list of natural remedies for symptoms related to hormonal and physiological imbalances. Several plants are known to be effective in treating hypogonadism, irregular menses, amenorrhea and other menstrual problems. Evecare Syrup is a polyherbal formulation that comprises extracts of Saraca indica, Boerhaavia diffusa, Symlocos racemosa, Tinospora cordifolia, Solanum nigrum, Asparagus racemosus, Aloe vera, Cocos nucifera, Santalum album, Cyperus rotundus, Acacia arabica, Hemidesmus indicus, Adhatoda vasica, Rubia cordifolia, Triphala, Dashamoola, Trikatu, Bombax malabaricum and Shilajeet. The beneficial results observed in this study could be due to synergistic actions of these herbs in Evecare Syrup.

S. indica is rich in tannins, and glycosides, which make it useful in different uterine affections like menorrhagia, dysmenorrhea, postpartum hemorrhage and leukorrhea. Dashamoola is an aequous extract of a combination of 10 plant roots known to be clinically beneficial in various disorders, which may be helpful in variety of conditions related to menstruation. Several plants are known to be effective in treating hormonal and physiological imbalances. Many plants are known to be effective in treating hypogonadism, irregular menses, amenorrhea and other menstrual problems. Evecare Syrup is a polyherbal formulation that comprises extracts of Saraca indica, Boerhaavia diffusa, Symlocos racemosa, Tinospora cordifolia, Solanum nigrum, Asparagus racemosus, Aloe vera, Cocos nucifera, Santalum album, Cyperus rotundus, Acacia arabica, Hemidesmus indicus, Adhatoda vasica, Rubia cordifolia, Triphala, Dashamoola, Trikatu, Bombax malabaricum and Shilajeet. The beneficial results observed in this study could be due to synergistic actions of these herbs in Evecare Syrup.

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S. nigrum has analgesic, anti-inflammatory, antispasmodic, central depressant and vasodilator activities, all of which are helpful in premenstrual syndrome, and other painful menstrual conditions. B. diffusa is a potent antifibrinoloytic and anti-inflammatory; hence, it is used in menstrual disorders like menorrhagia, including dysmenorrhea. Use of A. racemosus has been reported in menorrhagia, and threatened abortion. The extract blocks the uterine contraction and spontaneous motility and may also block the pitocin sensitive receptors. This action suggests its use as uterine sedative and in different menstrual problems like dysmenorrhea. C. nucifera has estrogen-like activity and may be helpful in various menstrual irregularities. It also has antinociceptive and anti-inflammatory activities.
which confirm the popular use of this plant in several inflammatory disorders and thus is of help in dysmenorrhoea. A. vera is used in spasmodic dysmenorrhoea due to its antispasmodic activity. Intragastric administration of A. vera powder at 60 mg/kg improved fertility rate in rabbits; it is used to improve fertility in women, which establishes the use of Evecare in assisted conception. It's additional anti-inflammatory activity is useful in various gynecological disorders.

Extract of S. album has antioxidant activity and is also used as adaptogenic activity. It may be helpful in debilitating conditions that may occur due to excessive menstrual bleeding. The extract of A. arabica has antioxidant activity and helps to re-normalize the hormonal imbalances in the body leading to a regular menstrual cycle. The rhizomes of C. rotundus have been used in traditional medicine as an estrogenic and anti-inflammatory agent for the treatment of women's diseases. The extract of the rhizomes of C. rotundus L. have shown acetylcholinesterase inhibitory activity as well as inhibition of nitric oxide and superoxide production activity. A saponin from H. indicus is found to have anti-inflammatory and antinociceptive activities in both acute and subacute condition, which may ameliorate the menstrual discomforts.

Triphala is a homogenous mixture of three fruits: Emblica officinalis, Terminalia chebula and T. bellerica. It is a rich source of vitamin C, ellagic acid, gallic acid, chebulinic acid, etc. Studies confirm its anti-inflammatory and antimicrobial activities, which may be helpful in various gynecological inflammatory disorders. The phenolic compounds present in Triphala extract are mostly responsible for their radical scavenging activity, and may be helpful in controlling various hormonal influences resulting in menstrual irregularities. The extract of A. vasica has anti-inflammatory activity is certainly of help in managing various inflammatory changes of the genitourinary system. Vasicine initiated rhythmic contractions of human myometrial strips from both pregnant and nonpregnant uteri. The effect is comparable to that of oxytocin and mephergin. Various ethnopharmacology approaches show its styptic activities and use in various bleeding disorders.

R. cordifolia has antioxidant and antimicrobial activities making it useful in various gynecological disorders. Trikatu is an Ayurvedic preparation containing black pepper, long pepper and ginger, which is prescribed routinely for a variety of diseases as part of a multidrug prescription may be due to its bioavailability enhancer activity. Mangiferin extracted from B. malabaricum shows antioxidant and analgesic activities and certainly may be helpful in various gynecological disorders.

Shilajeeet has been demonstrated as a prospective modifier of analgesic tolerance. All these activities are beneficial in menstrual disorders.

**CONCLUSION**

The results of this multicentric, post marketing surveillance 3-month study show that the clinical benefits of Evecare Syrup appear promising in the management of menstrual irregularities. In menorrhagia, significant reduction was observed in the mean score of duration of menstruation, quantity of blood loss, blood flow loss and character of blood flow changed from clot to flow after treatment with Evecare Syrup. Similarly, patients with oligomenorrhea had normal menstruation, normal duration and flow. No clinically significant adverse drug reactions were reported except for nausea, and gaseous distension, which did not require additional treatment or the withdrawal of drug. The beneficial results observed in this study therefore could be due to synergistic actions of the herbs present in Evecare Syrup.

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