Evecare (U-3107) as a Uterine Tonic - Pilot Study

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ABSTRACT
Menstrual disorders are a common manifestation. Since they often have a multifactorial aetiology, they pose a problem in effective treatment. Hormonal imbalances can be rectified by hormonal therapy but this is not devoid of side-effects. Moreover, this form of treatment is not well tolerated in some cases. Concurrently, vast research has been conducted on the usefulness of herbal formulations in menstrual disorders as a result of which the efficacy of certain herbs has been proven. With this in view, a herbal preparation, Evecare (U-3107), a uterine tonic was formulated using herbs whose potency was confirmed in this disorder. The effect of this uterine tonic was studied through experimental models. An open clinical trial was then conducted to further substantiate its use as a safe and effective remedy in menstrual disorders. (The Ind. Practit. (1998): (51), 269-272)

KEY WORDS: Uterine tonic, menorrhagia, dysmenorrhoea

INTRODUCTION
Abnormal uterine bleeding is a manifestation commonly encountered during a woman’s reproductive phase and approximately 20% of the female patients visiting a general gynaecologist are women with this problem. About one half of all patients who experience this problem are over 40 years of age and about 20% are adolescents. Among adolescents presenting with menstrual problems, about 50% constitute abnormal uterine bleeding and dysmenorrhoea. When administering treatment to a patient with abnormal uterine bleeding, it should be borne in mind that menstruation is not a purely physical phenomenon – the awareness of its onset, regularity and associated discomfort are strongly influenced by psychologic and cultural factors. Because menstruation is a normal process, it does have the ability to readjust itself after abnormal bleeding. For this reason, many therapies in the past have been considered to be successful when, in fact, they may have no scientific basis and are empirically instituted.

Evecare (U-3107) is a herbal uterine tonic formulated by The Himalaya Drug Co., Bangalore, India. A literature survey showed that the herbs used in this tonic are effective in various menstrual disorders. After confirming the safety of this formulation through animal studies, a clinical trial was conducted to evaluate its efficacy in menstrual disorders.

MATERIAL AND METHODS
An open clinical trial was conducted at different gynaecological centres. Thirty five female patients in the reproductive age group of 19-45 years with a history of abnormal uterine bleeding were enrolled. Their records showed that they encountered these symptoms consistently for the past 6 months. These patients were not on any hormonal therapy during and one month prior to the trial. Written informed consent was obtained from each patient. History taking consisted of detailed information with due importance on psychogenic, emotional factors, family history and drug intake. The patients were subjected to a thorough physical examination, which also included per speculum visual examination to rule out any underlying uterine pathology.
The objective of the study was to evaluate whether Evecare (U-3107)  
- Re-establishes cyclical bleeding  
- Controls excess bleeding occurring in the menstrual cycle  
- Prevents dysmenorrhoea  
- Controls physiologic leucorrhoea

Each patient enrolled in the trial was administered 1 tablespoonful of Evecare (U-3107) Uterine Tonic t.i.d. for a duration of 3 months. They were followed up at regular intervals to evaluate the effect of the drug and to rule out any side effects.

The selected patients were divided into the following groups:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menorrhagia</td>
<td>6</td>
</tr>
<tr>
<td>Metrorrhagia</td>
<td>12</td>
</tr>
<tr>
<td>Dysmenorrhoea</td>
<td>3</td>
</tr>
<tr>
<td>Dysmenorrhoea + menorrhagia</td>
<td>10</td>
</tr>
<tr>
<td>Physiologic leucorrhoea</td>
<td>4</td>
</tr>
</tbody>
</table>

**RESULTS**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Before treatment</th>
<th>After 1 month</th>
<th>After 2 months</th>
<th>After 3 months</th>
<th>Drop-outs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painful menstruation</td>
<td>13</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Increased duration of cycle and quantity of flow</td>
<td>28</td>
<td>24</td>
<td>4</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Irregular cyclical bleeding</td>
<td>12</td>
<td>12</td>
<td>8</td>
<td>-</td>
<td>2</td>
</tr>
</tbody>
</table>

Patients in the menorrhagia group had a history of bleeding per vagina lasting for 12-14 days.

Though they had a regular menstrual cycle, bleeding was profuse and in clots. After one month of treatment with Evecare (U-3107), they reported a slight decline in bleeding. By the end of 3 months of the study, all the subjects noticed a significant decrease in bleeding and the duration of flow had reduced to 6-8 days.

In the group of patients with metrorrhagia, irregular cycles occurred at a mean interval of 20-24 days. Ten subjects reported that they had bleeding for 8-10 days. After 3 months of treatment, it was observed that the bleeding decreased to 4-7 days and the interval between 2 cycles increased by 4-5 days. Two patients discontinued without prior information.

Only 3 patients were enrolled in the dysmenorrhoea group, as the others had associated dysfunctional uterine bleeding. These patients complained of pain in the abdomen which started on the first day of the cycle and lasted for 2 days. The pain was severe and required antispasmodics; however, they were advised to discontinue all other medication during the period of treatment with Evecare (U-3107). Within one month of treatment, patients reported complete regression of symptoms, which did not recur during the subsequent months of the trial.

Four patients had a history of white discharge per vagina. There was no significant effect on physiologic leucorrhoea.
In 10 patients of dysmenorrhoea + menorrhagia, dysmenorrhoea was completely cured in all patients while menorrhagia was normalised in 8 patients. In 2 others, there was no satisfactory improvement.

By the end of the trial, none of the subjects reported any side effects.

**DISCUSSION**

Menorrhagia or metrorrhagia may be a symptom of an underlying organic disease such as adenomyosis, thrombocytopenia, cancer etc., but in many cases, the origin of dysfunctional bleeding is unknown. The knowledge of haemostasis in menstrual endometrium has been reviewed\(^6\). Various factors have been put forth as a cause for this. Reports state that the decidual endometrium cells produce PGE\(_2\) and PGF\(_2\) as well as anticoagulating agents\(^7\). These prostaglandins have vasodilating and constricting properties and a stimulating action on the motility of the uterus. In women with DUB, it has been demonstrated that their Pg levels in the uterus are higher than those of controls\(^8\).

With the above in view, Evecare (U-3107) was formulated using the following potent herbs with properties which are favourable in these disorders. *Saraca indica* has been well proven for its effectiveness in menorrhagia and dysmenorrhoea\(^9,10,11\). It also has a stimulatory effect on the ovarian tissue\(^12\) which may produce an oestrogen-like activity that enhances the repair of the endometrium and stops bleeding. *Symplocos racemosa* has been reported to be useful in the treatment of menorrhagia and other uterine disorders\(^13,14,15,16\). The ethanolic extract of *Boerhavia diffusa* was found to stop intra-uterine-contraceptive-device-induced bleeding in monkeys\(^17,18\). This herb is also known for its anti-inflammatory and analgesic property which is comparable to that of ibuprofen\(^19\). The drug has also proved useful as a haematinic. *Cyperus rotundus* has been utilized in the treatment of anaemia and general weakness\(^20\) which are common manifestations of this disorder. These herbs acting alone and in combination, are responsible for the efficacy of the drug in dysmenorrhoea, menorrhagia and other uterine disorders.

**CONCLUSION**

Taking into consideration the results of the trial and the proven reports of the herbs used in the formulation, it can be concluded that Evecare (U-3107) can effectively avert the multifactorial aetiology of dysmenorrhoea and menorrhagia, without producing any undesirable side effects. Some of its ingredients render a holistic approach to the treatment of the disorder, because of their ability to improve anaemia and general weakness. However, a larger trial is proposed to ensure the exact mechanism of action of the drug and to evaluate its efficacy in a larger perspective.

**REFERENCES**


