

Clinical Evaluation of M2 Tone in Adolescent Menstrual Disorders

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Objective: To evaluate the effect of a non-hormonal menstrual modulator (M2 Tone) with proven estrogenic activity in teenaged girls with commonly encountered menstrual complaints.

Materials and methods: a randomized open study involving 112 girls aged between 11-19 years. Subjects complaining of the following menstrual disorders of sufficient intensity so as to necessitate treatment (decided by the examining gynecologist): oligomenorrhoea, hypomenorrhoea, polymenorrhoea, metrorrhagia, menorrhagia, irregular menses, dysfunctional uterine bleeding (D.U.B.), dysmenorrhoea. Subjects were excluded from the trial if they had received any hormonal treatment in the preceding two months of the study. The patients were then put on tablet M2 Tone (two tablespoonfuls) three times a day for a period of 3 to 6 months. Regularity of menses (frequency and duration), pain, blood flow, investigators assessment, and patient satisfaction were evaluated.

Results: Almost 80% of the patients were relieved of their symptoms within three months of treatment with M2 Tone, whereas the response rate increased to near 100% by the end of the 6-month study period. In the investigators assessment for the improvement in the patient condition at the end of the study period on a 7-point scale, 94.6% of the patients in the M2 Tone group showed a significant improvement in their condition. The patients were asked to grade the relief obtained by them on an increasing scale of 10. At the end of the 3 month treatment period the average scale given by the patients was 7.68 while at the end of the six month period the patient satisfaction level had reached the level of 9.43, which indicates that the patients perceived M2 Tone as extremely effective in relieving their complaints.

Conclusion: Thus, it can be concluded that M2 Tone could be valuable and safe alternative to the conventional hormonal therapy in managing functional menstrual disorders of the adolescents.

Introduction:

India has one of the largest populations of adolescents. Adolescence is a period of life when a carefree child becomes a responsible adult (1). World Health Organisation (WHO) has defined adolescence as:(2)

- Progression from appearance of secondary sex characteristics (puberty) to sexual and reproductive maturity.
- Development of adult mental process and adult identity.
- Transition from total socioeconomic dependence to relative dependence.

The age range may vary from individual to individual, but generally it is considered between 13 to 18 years. Menstrual irregularities, dysmenorrhea, excessive vaginal discharge, breast problems, STD's pregnancies, abortion and growth disorders are some of the health

problems among adolescents. Menstrual disorders accounted for upto 75% of new patients attending one such clinic (1).

Various treatments are prescribed in conventional form of therapeutics like contraceptive pills, prostaglandin synthetase inhibitors, anti-fibrinolytic agents, gonadotropins. These medications have their antecedent drawbacks. However, numerous herbs have been documented in standard Indian Ayurvedic texts for their efficacy and safety in various menstrual disorders. One such comprehensive herbal formulation M2 Tone has been reported for its efficacy in various menstrual disorders and infertility (3-7). Hence, a scientific evaluation was undertaken to evaluate the efficacy and safety of M2 Tone in functional menstrual disorders during adolescence.

Aim of the Study:

In this study we have tried to evaluate the effect of the non-hormonal menstrual modulator (M2 Tone) with proven estrogenic activity in teenaged girls with commonly encountered menstrual complaints. This is a herbomineral preparation researched and pioneered by Charak Research Foundation.

Materials and Methods: This was randomized open study involving 112 girls aged between 11-19 years. Parents or Guardians of all the subjects provided written informed consent before enrolment. Subjects: One hundred and twelve healthy girls were included in the study after they satisfied the following inclusion criteria.

Inclusion Criteria: Subjects complaining of the following menstrual disorders of sufficient intensity so as to necessitate treatment (decided by the examining gynecologist):

- Oligomenorrhoea-infrequent menses occurring at intervals longer than 35 days.
- Hypomenorrhoea-scanty menses less in duration (<3 days as well as in amount (<30 ml blood loss per cycle)
- Polymenorrhoea-frequent menstruation at regular intervals of two weeks but less than three weeks.
- Metrorrhagia-inter-menstrual irregular bleeding per vagina.
- Menorrhagia-excessive menses in amount (>80 ml. Blood loss per cycle) as well as duration (>5 days).
- Irregular menses-Menstrual cycles not occurring regularly (i.e. within a period of 28-30 days).
- Dysfunctional Uterine Bleeding (D.U.B.) – excessive uterine bleeding where the cause cannot be detected.
The nature of bleeding may reflect any of the above mentioned conditions.
- Dymenorrhoea-menstruation associated with severe pain.
- Other associated symptoms-low backache, pelvic discomfort, leucorrhoea etc.

Exclusion Criteria:

- Subjects were excluded from the trial if they had received any hormonal treatment in the preceding 2 months of the trial.

Method of Study:

Patients selected were subjected to detailed clinical history taking with regard to their menstrual disorder. This was followed by general systemic and pelvic examination. Routine pathological investigation, like complete blood count and urine analysis were done.

The patients were then put on Tablet M2 Tone (two tablets) or Syrup M2 Tone (two tablespoonful) three times a day for a period of 3 to 6 months. This was to be taken irrespective of the menstrual disturbances. The patients were called for follow up every month for evaluation of the symptoms and the observation of any side-effects. The patients were asked to report earlier if they experienced disturbing side effects while taking the drug at any point of time during the study period.

Data interpretation:

1. Patient Characteristics

Patients were classified on the basis of their age, socio-economic background, educational status and whether they hailed from an urban or rural area.

2. Symptomatology

An attempt was made to study the common symptoms in the sample population. This was done by analyzing the chief complaints of the selected population.

A. Regularity of Menses (Frequency and Duration)

The first criterion taken into account was the regularity of menses. Subjects were questioned about the frequency of menstruation and the duration of bleeding each month. Data was recorded each month by the investigator.

B. Pain

Patients were also divided into those complaining of Dysmenorrhoea and others who did not complain of any pain associated with menstruation.

C. Blood flow

The next criterion of efficacy was the blood flow, which was categorized into 3 sub-headings i.e. heavy, scanty or normal.

3. Investigators Assessment

The investigator assessed the patient's condition at the end of the treatment period as compared to her condition at baseline on a 7-point scale as follows:

1. Very much improved
2. Much improved
3. Minimally improved

4. Unchanged
5. Minimally worsened
6. Much worsened
7. Very much worsened

4. Patient Satisfaction

Patient Evaluation: The patient was asked to scale her improvement achieved on an increasing scale of 10.

Results

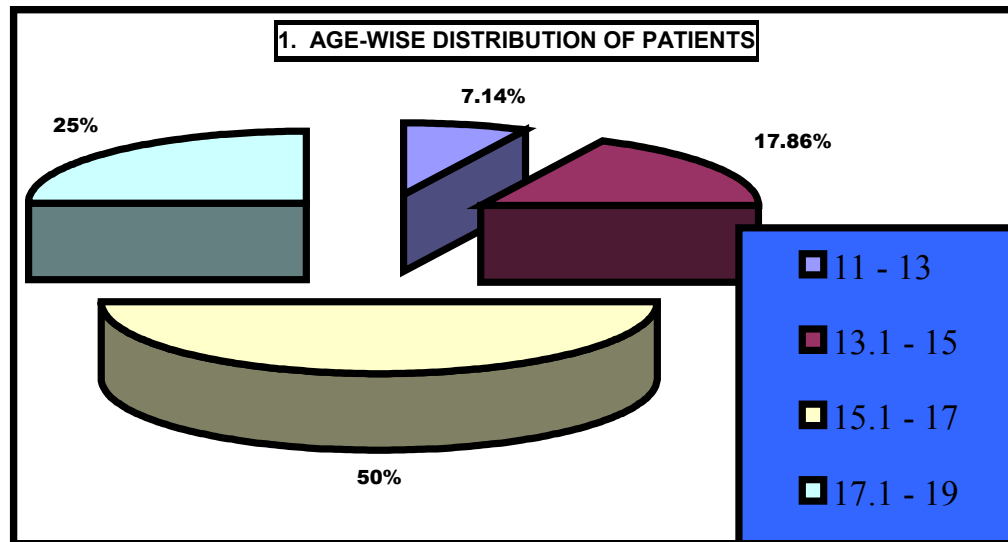
1. Patient Characteristics

1. Age

The mean age of adolescent girls included in the study was 15.86 ± 3.3 years.

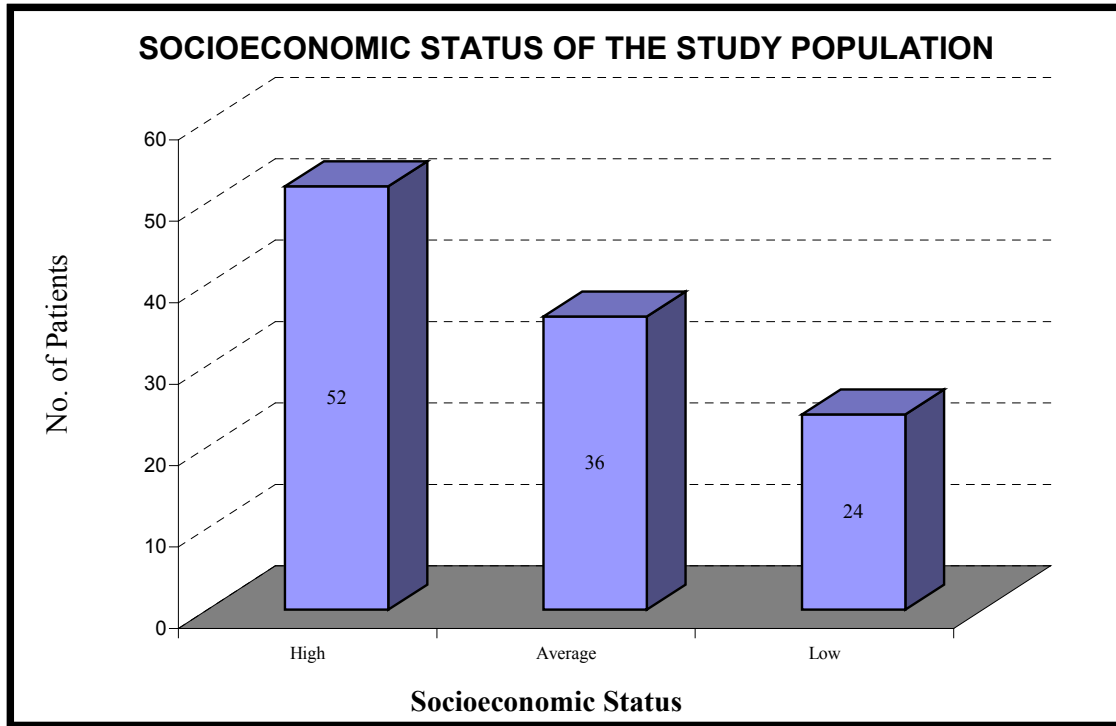
1. Age-Wise Distribution of Patients

Age in Yrs.	No. of Patients	% of Study Group
11 - 13	8	7.14
13.1 - 15	20	17.86
15.1 - 17	56	50
17.1 - 19	28	25



II. Socioeconomic Status

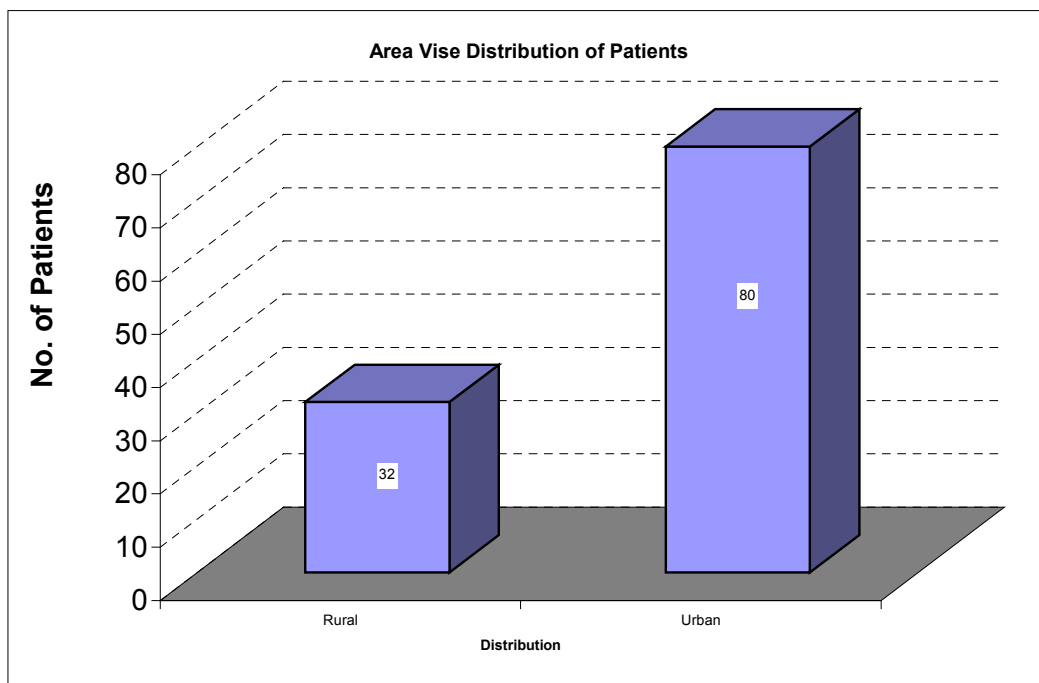
Socioeconomic Status of Patients		
Status	No. of Patients	% of Study Group
High	52	46.42
Average	36	32.14
Low	24	21.42



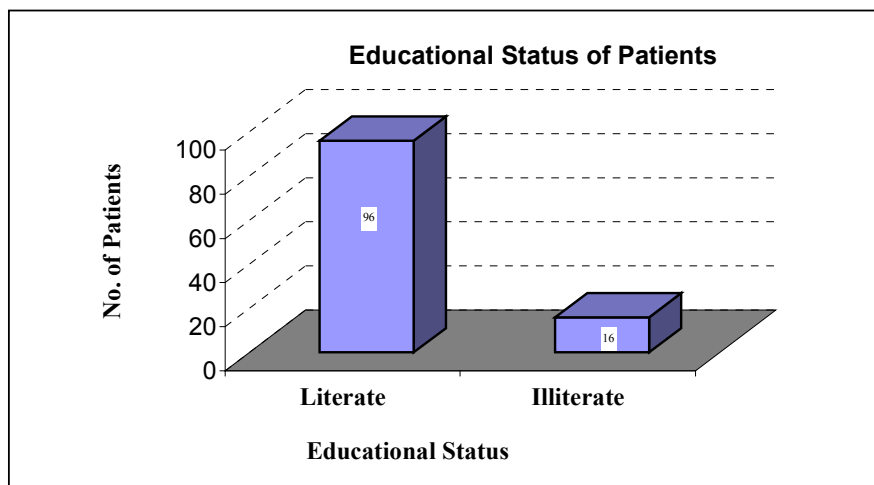
III. Area Wise Distribution

Area Wise Distribution of Patients

Area	No. of Patients	% of Study Group
Rural	32	28.6
Urban	80	71.4



Educational Status of Patients		
Status	No. of Patients	% of Study Group
Literate	96	85.8
Illiterate	16	14.2

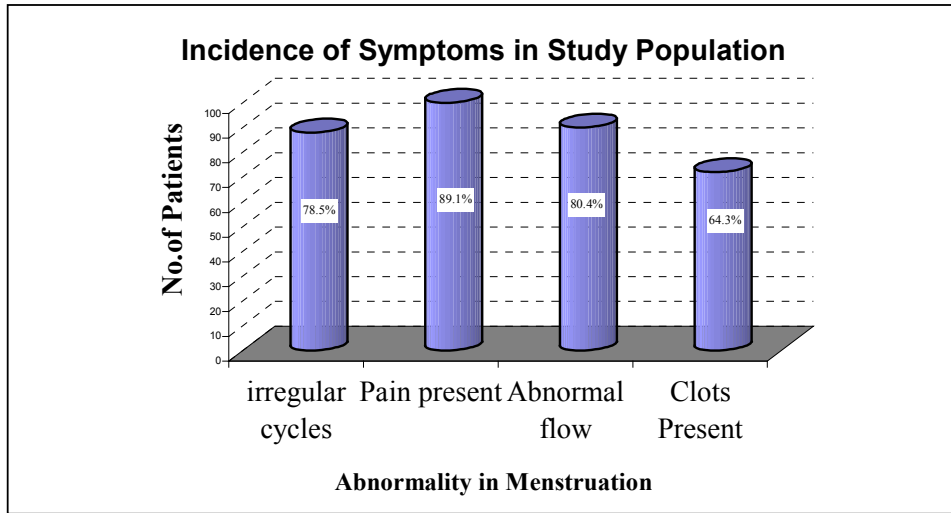


2. Symptomatology

The commonest symptoms presented by the patients and the number of patients complaining about them were as depicted in the table below. Almost 78% of patients complained of menstrual irregularities and 89% complained of dysmenorrhoea.

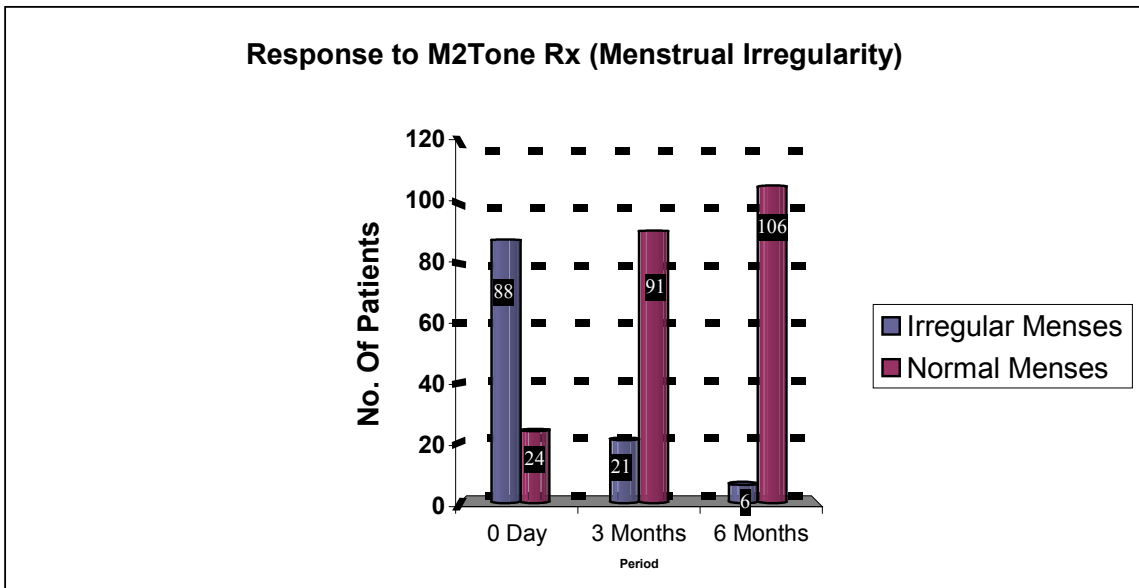
Chief Complaints	No. of Patients n = 112	% of Study Group
Irregular Cycles	48	42.9
Prolonged Cycles	16	14.2
Short Cycles	24	21.4
Average Cycles	24	21.4
< 2 days	16	14.3
3 - 5 days	28	25
6 - 7 days	68	60.7

Pain present	100	89.1
Pain absent	12	10.9
Heavy flow	74	66.1
Scanty flow	16	14.3
Normal flow	22	19.6
Clots Present	72	64.3
Clots Absent	40	35.7



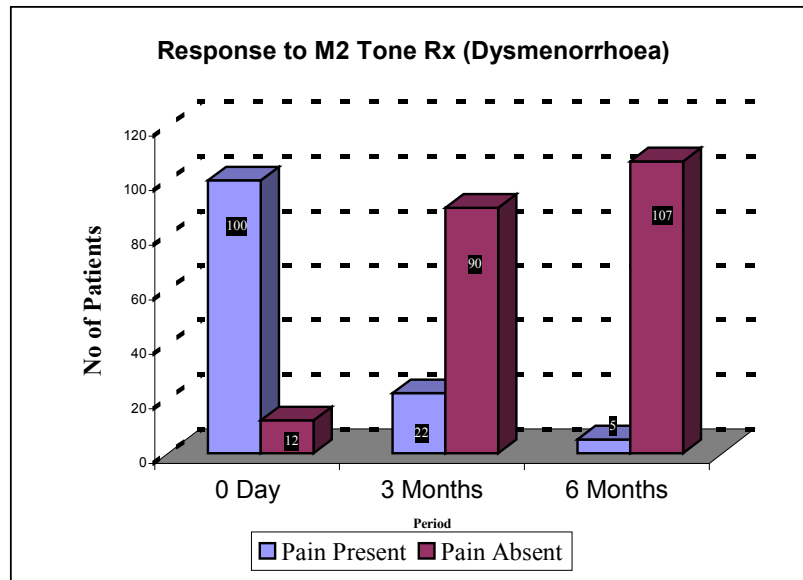
A. Regularity of Menses

Period	0 Day n = 112	3 Months n = 112	6 Months n = 112
Irregular Menses	88	21	6
Normal Menses	24	91	106



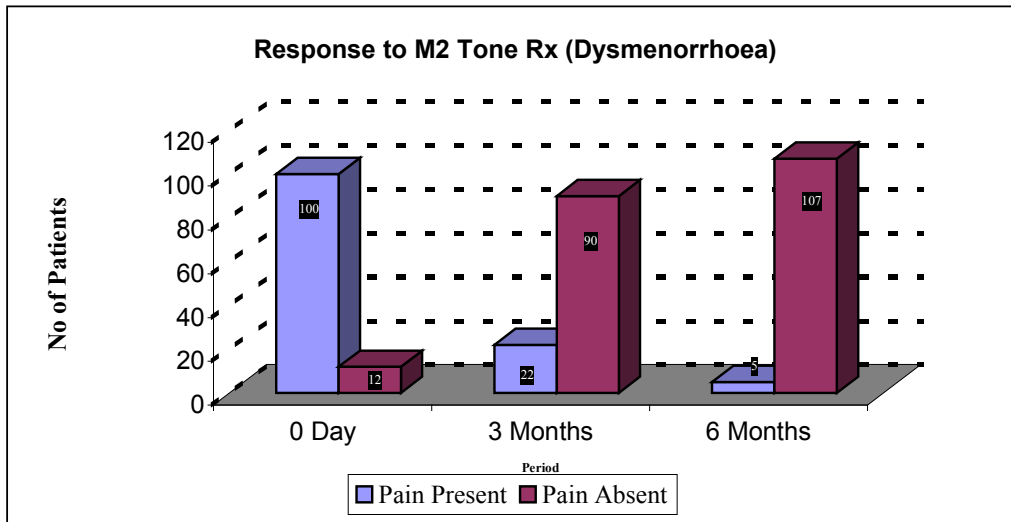
B. Pain

Period	0 Day	3 Months	6 Months
	n = 112	n = 112	n = 112
Pain Present	100	22	5
Pain Absent	12	90	107



C. Menstrual Blood Flow

Period	0 Day	3 Months	6 Months
Heavy Flow	100	18	8
Scanty Flow	12	2	0
Normal Flow	0	92	104

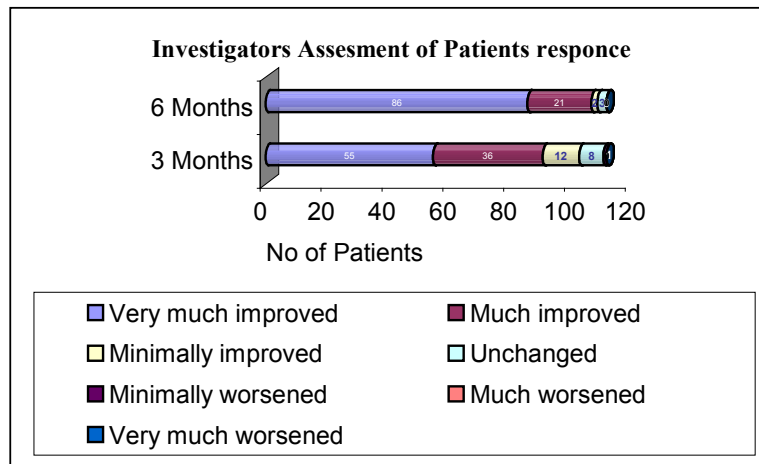


As seen in the figures almost 80% of the patients were relieved of their symptoms in 3 months of treatment with M2 Tone whereas the cure rate increased to near 100% by the end of the 6 month study period.

3. Investigators Assessment

The investigators assessed the improvement in the patient condition at the end of the study period on a 7-point scale as mentioned above. As seen in the following tables 94.6% of the patients in the M2 Tone group showed a significant improvement in their condition.

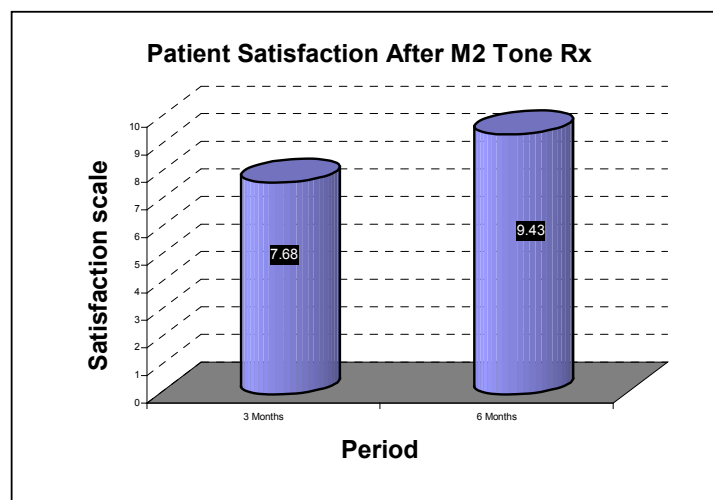
Investigators Assessment of Patients Response			
Improvement	Grade	3 Months	6 Months
	n = 112	n = 112	n = 112
Very much improved	1	55	86
Much improved	2	36	21
Minimally improved	3	12	2
Unchanged	4	8	3
Minimally worsened	5	1	0
Much worsened	6	0	0
Very much worsened	7	0	0



4. Patient Satisfaction

The patients were asked to grade the relief obtained by them on an increasing scale of 10. At the end of the 3 month treatment period the average scale given by the patients was 7.68 while at the end of the 6 month period the patient satisfaction level had reached the level of 9.43, which indicates that the patients perceived M2 Tone as extremely effective in relieving their complaints.

Patient Satisfaction (Scale of 10)		
	n = 112	n = 112
	3 Months	6 Months
	Treatment	Treatment
Average Grade	7.68	9.43



DISCUSSION :-

The results demonstrate the therapeutic efficacy of M2 Tone in the commonly encountered menstrual disorders during adolescence. These benefits could be attributed to the various herbal ingredients well documented in standard Indian Ayurvedic texts for their use in such conditions.

Saraca indica (Ashok chaal) has been well documented for its efficacy in menorrhagia and dysmenorrhea. The tannins, catechols and flavonoid principles present, have been found to exert a stimulating effect on the ovarian tissue. Thus providing an oestrogen-like activity that improves the repair of the endometrium and arrests bleeding. Furthermore, this oestrogen-like action of M2 Tone (10) could possibly assist in inducing ovulation by supplementing the necessary oestrogen required for the critical preovulatory LH surge (5). This activity would benefit in relieving menorrhagia due to anovulation, besides regularizing the cycles as a result of ovulation.

Additionally, in about 95% of dysfunction uterine bleeding is caused by the slow maturation of the hypothalamo-pituitary-ovarian (HPO) axis, in the adolescent leading to anovulatory cycles M2 Tone by regularizing the HPO axis could assist in inducing ovulation, thereby normalizing the menstrual cycles.

One of the most common cause of hypothalamic suppression, leading to either amenorrhoea or anovulation, is stress and inadequate nutrition. The antistress, antianxiety properties of *Withania somnifera* could possibly assist in alleviating these menstrual disorders.

Dysmenorrhoea, which is frequently present, is effectively tackled by the anti-inflammatory and analgesic properties of *Boerhaavia diffusa*. Additionally, the anti-spasmodic, uterine relaxant properties of *Symplocos racemosa*, assists in relieving the spasmodic-dysmenorrhoea.

CONCLUSION

It can be concluded that M2 Tone could be valuable and safe alternative to the conventional hormonal therapy in managing functional menstrual disorders of the adolescents.

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