

OBSERVATIONAL CLINICAL STUDY OF AN AYURVEDIC COMPOUND (ESTEEMO FORTE) IN THE MANAGEMENT OF SHAYYAMUTRATA (BED WETTING OR ENURESIS), STAMMERING AND BEHAVIOURAL CHANGES

*¹Dr. Ravi Raj M.D Ayurveda and ²Dr. Anupam Chaturvedi (D.C.H)

¹Associate Professor P.G Department of Rasa Shastra Evam Bhaishajya Kalpana, Shri Krishna Govt. Ayurvedic College Kurukshetra, 136118 Haryana.

²General Hospital Nahan Director G D Children Hospital Pinjore Haryana.

Article Received on
04 January 2023,
Revised on 24 Jan. 2024,
Accepted on 14 Feb. 2024
DOI: 10. 20959/wjpr20244-31478



*Corresponding Author

Dr. Ravi Raj M.D

Ayurveda

Associate Professor P.G
Department of Rasa Shastra
Evam Bhaishajya Kalpana,
Shri Krishna Govt.
Ayurvedic College
Kurukshetra, 136118
Haryana.

ABSTRACT

Child health has gained significant importance worldwide, increasingly recognized by both paediatricians and the general public in both developing and developed nations. Enuresis is characterized by the repeated discharge of urine into clothes or bed, whether voluntary or involuntary, after reaching an age when bladder control should typically be established. This clinical study aimed to assess the impact of ESTEEMO FORTE in managing Shayyamutrata (Bed wetting) (enuresis) stammering and behavioural changes. Twenty Five selected cases were taken in each Guroup of Indication. ESTEEMO FORTE was administered at a dose of 2.5 ml to 5 ml twice a day with lukewarm water. The study's results revealed highly significant outcomes in each groups.

KEYWORDS: Nocturnal enuresis, *Shayyamutrata* (Bed wetting), Stammering, ESTEEMO FORTE, Psychotherapy.

INTRODUCTION

Child health holds immense importance worldwide, with paediatricians and the general public increasingly recognizing its significance in both developing and developed countries. Health, in this context, refers to being physically and emotionally well-rounded, as organic illnesses often lead to emotional disturbances and vice versa.

Ayurvedic classical texts such as Sharangadhara and Vangasena Samhita offer concise insights into Shayyamutrata (bed wetting). This condition primarily arises from the derangement of Vata (Apan Vayu), Pitta (Pachaka), Kapha (Tarpaka), and the mental dosha, Tama. The affected tissue (Dushya) is Rasa (Ambu) dhatu, leading to disturbances in Mutravaha and Manovaha srotas, resulting in untimely and increased nocturnal urination.

Enuresis and Stammering is a behavioral problem and one of the most common chronic issues in childhood, second only to allergic disorders. Children are not labeled as enuretic until they reach 5 years of age, and the behavior is clinically significant, either with a frequency of at least twice a week for three consecutive months or the presence of distress in social, academic, or other important areas of the child's functioning. The prevalence of enuresis is approximately 15-25% in 5-year-old children, 8% in 12-year-old boys, and 4% in 12-year-old girls. Only 1-3% of adolescents still experience bedwetting, with boys being more affected than girls due to differences in achieving developmental milestones.

Sattvavajaya Chikitsa in *Shayyamutrata (Bed wetting)*

1. Complaints not be discussed in front of other people.
2. Appreciate (mental boost up) if bedwetting frequency decreased for e.g. from 3 to 1 etc.
3. Mental and physical stress shouldn't be given to child on bedwetting.
4. To console the child that it is psychological process and can be cured easily.

AIMS AND OBJECTIVES

The present work was undertaken with the following aims and objectives

1. Conceptual and hypothetical evaluation of enuresis and to study the prevalence of *Shayyamutrata (Bed wetting)* in children according to mental and physical personality (*prakriti*) types described in *Ayurveda*.
2. Assuring and educating the parents regarding the disorder and development of the child (Parent counselling).
3. Clinical evaluation of an *Ayurvedic* compound “**Esteemo Forte**” in the management of *Shayyamutrata (Bed wetting)* (Enuresis).
4. To study the role of counselling formulated in controlling the disorder.
5. Evaluation of the side effects of the study drug.

MATERIAL AND METHODS

Selection of Cases: Patients with repeated voiding of urine into bed or clothes involuntarily were selected randomly from OPD and IPD of P.G Department of Rasa Shastra evum Bhaishajya Kalpana, Shri Krishna Govt. Ayurvedic College Kurukshetra.

Age group: Children between 5 to 16 years were considered for the study.

Number of cases: Total 50 enuretic were selected from above said sources out of which 18 children discontinued the treatment.

Inclusion criteria

Individuals aged 5 to 16 years of either gender, exhibiting a history of bedwetting at least twice a week for a continuous three-month period, as per the criteria outlined in the DSM-IV-TR (Fourth Edition of the Diagnostic and Statistical Manual for Mental Disorders).

Exclusion criteria

Patients below 5 years and above 16 years of age.

Patients with congenital anomalies of the genito urinary tract especially of the urethral valves. Enuresis due to disease of CNS, epilepsy, spina bifida, and diabetes mellitus and diabetes insipidus.

Urinary tract infections.

Chemical urethritis.

Assessment criteria

Effect of the therapy will be assessed on the basis of improved status in the number of dry nights.

Laboratory procedure: The laboratory investigations were done at the pathology laboratory of Shri Krishna Govt Ayurvedic College and Hospital Kurukshetra. Complete urine analysis was done to rule out any pathological conditions.

Grouping of patients: Selected children registered for the study, were randomly divided into two groups keeping in mind that all the two groups had children from various grades (classes), schools and socio-economics status.

Group A: This group of children were given the trial drug Esteemo Forte with counseling.

Cases were randomly selected for classification, and the coded medication was administered following guidelines. An impartial individual, not associated with the study, conducted the coding the study drug. The coded document was securely sealed and stored. The envelope containing the coded information was opened after the study's completion to decipher it for the purpose of interpretation, observation, and documentation. The gathered data during the study underwent statistical analysis to assess and affirm the effectiveness of the interventions

Drug, Dose & Duration

Ingredients of “Esteemo Forte” (Table 1)

Hindi or Sanskrit Name of Herb	Latin or English Name	Morpho-logical Part	Each 10 ml Contains	Form Used
BRAHAMI	Bacopa monnieri	Leaves	200 mg	C. Powder
SHANKHPUSHPI	Convolvulus prostratus	Leaves	200 mg	C. Powder
DHANIYA	Coriandrum sativum	Fruit	200 mg	C. Powder
SHITALCHINI	Piper Cubeba.	Bark	200 mg	C. Powder
VIDANG	Embelia ribes	Fruit	100 mg	C. Powder
KADALI MOOL	Musa paradisiaca	Root	100 mg	C. Powder
UDUMBER	Ficus racemosa	Fruit	100 mg	C. Powder
SHALMALI	Bombax ceiba	Leaves	100 mg	C. Powder
JATAMANSI	<i>Nardostachys jatamansi</i>	RHIZOMES	100 mg	C. Powder
YASTIMADHU	<i>Glycyrrhiza glabra</i>	Stem	100 mg	C. Powder
VACHA	Acorus calamus	Root	50 mg	C. Powder

The **Esteemo Forte** is an Ayurvedic Patent Medicine Duly Approved by AYUSH Department of Haryana and prepared in the Mediwin Research & Healthcare, located at 13 & 14 Vita Enclave Near Sena Nagar, Dhulkot, Ambala, Haryana, India - 134002.

The ingredients of **Esteemo Forte** are BRAHAMI SHANKHPUSHPI DHANIYA SHITALCHINI VIDANG KADALI MOOL UDUMBER SHALMALI JATAMANSI YASTIMADHU VACHA and are explained briefly below.

Here are the properties of the mentioned herbs as useful in promoting intellect and helpful in treating bedwetting in children, according to the Bhav Prakash Nighantu.

Brahmi (*Bacopa monnieri*)

Nervine tonic, supports the nervous system

Enhances cognitive function and memory

Adaptogenic properties, helps in stress management

Shankhpushpi (*Convolvulus pluricaulis*)

Brain tonic, improves memory and concentration

Calming and anti-anxiety effects

Supports overall cognitive function

Dhaniya (*Coriandrum sativum*)

Cooling and calming properties

May help in reducing anxiety and stress

Supports digestive health

Shitalchini (*Cinnamomum tamala*)

Cooling and soothing effects

Supports respiratory health

May have calming properties

Vidang (*Embelia ribes*)

Anthelmintic properties, useful in deworming

Supports digestive health

May have neuroprotective effects

Kadali Mool (Banana Root)

Nutrient-rich

May have a soothing effect on the nervous system

Supports overall health

Udumber (*Ficus racemosa*)

Cooling and calming properties

Supports the digestive system

May have a soothing effect on the nervous system

Shalmali (*Bombax malabaricum*)

Cooling and demulcent properties

Supports respiratory health

May have calming effects

Jatamansi (*Nardostachys jatamansi*)

Calming and relaxing properties

Supports mental clarity and focus

May help in reducing stress and anxiety

Yastimadhu (*Glycyrrhiza glabra*)

Anti-inflammatory and soothing effects

Supports the respiratory and digestive systems

May have adaptogenic properties.

Vacha (*Acorus calamus*)

Nervine tonic, supports the nervous system

Enhances cognitive function

May have calming and antispasmodic effects

Dose: 10-15 ml according to age and severity of disease.

Duration of trial: 1 month.

Follow-up: 2 month after treatment.

Analytical Study

Esteemo Forte is a hypothetical drug formulated for the treatment of Shayyamutrata (Bed wetting). The present study deals for their determination of quality and their standardization through the following parameters.

OBSERVATION AND RESULTS

The predominant age group among patients in this study was 5-7 years, followed by children aged 8-10 years. The research revealed a higher incidence of Shayyamutrata (bed wetting) in male children compared to their female counterparts. The majority of cases were observed in the lower-middle-class demographic, followed by the middle class. Additionally, a significant number of children belonged to the second birth order, with a smaller percentage from the first birth order. A noteworthy portion of the patients had a positive family history of bed wetting.

The study found that most patients experienced bedwetting between 1-3 years, with a subsequent group reporting occurrences between 4-6 years. A significant portion of the patients exhibited a tendency towards deep sleep. Poor school performance was commonly

observed among the participants. The majority of cases fell under the category of primary nocturnal enuresis, and parental punishment for bedwetting was most prevalent among the subjects. Lastly, the majority of patients demonstrated a Kapha Vataja physical constitution and a Sattvic-Rajasic mental constitution.

Status of Bedwetting Before and After Treatment (3 months) and After 2 months Follow-up:
Discussion (Effect of therapy)

As already mentioned that, the study was conducted under Group.

Group A received *Esteemo* Forte along with counseling (psychological intervention). The effect of the therapy was assessed on the basis of improved status in the number of dry nights. For the purpose of making comparison between pre and post treatment, the history of bedwetting in last one week was documented.

Last one week history had shown that maximum patients, i.e 60% of the group (n=20) had no dry night (all wet night), out of 50 patients, 55% patients had no dry night. The 15% patients of the group had 2 dry nights. The 10% patients of the group had 3 dry nights and same percentage of the group patients had 4 dry nights.

The 5% patients of the group had single dry night, 5% patients of the group had 5 dry nights.

Before treatment the status of bedwetting incidence once per night was in 45% of patients of the Group. The 40% patients of the Group had 2 incidences / night; 15% patients of the Group had 3 incidences/night. It means before treatment 50% of total patients had incidence 2-3 times/night.

Effect of therapy according to weeks.

Although the patients were followed up every fortnightly but the improvement in dry night status recorded weekly.

After 1st week treatment it was observed that slight changes in dry nights status and incidence/night occur in both groups. Shifting of few patients towards increased dry nights and reduction in incidences was noticed of both group but improvement in group A was more than Group B.

After 1st week treatment statistically the Group showed significant ($p < 0.01$ in the Group) result. But according to the percentage of improvement.

After 2nd week treatment decrease in zero dry nights of the Group and 2 dry night of the Group but increase of percentage 1 dry night of the Group was seen.

In the Group the result revealed statistically significant after 2nd week treatment ($p < 0.005$).

After 3rd week treatment no patients of the Group had zero dry nights in 3rd week. Three incidence/night was found absent in the Group. In the Group, the result was observed highly significant ($p < 0.001$) after 3rd week treatment. Percentage of improvement was found 51.79% in the Group.

After 4th week treatment no patient had 3 incidence/night was found. The Group ($p < 0.001$) was statistically highly significant and percentage gain of the Group was 62.70%.

Study revealed that after completion of drug trial (after 1 month of treatment) 62.70 % of patients of the Group achieved all (7) dry nights; 30% patients of the Group. Only 5% patients had 4 dry nights and only 5% patients had zero dry nights in the Group.

As far as incidence / night is concerned 60% patients of the Group achieved no incidence/night, 50% patients had one incidence/night in the Group.

After a month of treatment the Group (counselling along with *Esteemo Forte*). But according to percentage of improvement in the Group showed good result (79.60%)

Various precious studies indicate that after discontinuation of therapy incidence of relapse increased remarkably. Most of the modern drugs have such tendency. To observe the relapse status of trial drug, monthly follow-up continued up to 2 month after treatment was performed. Observation have shown that 10% patients of the Group showed remission of disease.

After 2 month follow-up (after 3 month treatment the Group showed statistically insignificant ($p > 0.1$) result.

Effect of therapy on Associated Symptoms

Effect on Fear: The relief obtained from fear was statistically highly significant ($p < 0.001$) of the Group after treatment. The gain percentage was 62.96% in the Group. On follow-up 2 months after stopping treatment study revealed insignificant ($p < 0.1$) result in recurrence of fear.

Effect on Aggressiveness: After treatment highly significant ($p < 0.001$) relief was observed in the Group. The gain percentage was 60.87% in the Group. On follow-up after 2 month stopping the treatment result shows insignificance in recurrence of both the groups.

Effect on Shamefulness: Statistically highly significant relief from shamefulness at the level of $p < 0.001$ was observed at the end of 1 month therapy with the Group i.e. *Esteemo Forte* along with counseling. The percentage gain was 61.90% of the Group. On follow-up 2 month after stopping the treatment shamefulness was found statistically insignificant of both the groups.

Effect on Irritability: After the treatment of 3 months irritability in bedwetting patients was reduced with the highly significant at the level of $p < 0.001$. On follow-up the recurrence in this symptom was found insignificant in both the groups.

Effect on sleep: Statistically highly significant result was found after the 3 month of treatment sleep of the Group patients. On follow-up Group A showed insignificant result but Group B showed no change.

Effect on constipation: After 3 month of treatment the therapy was highly significant in the relief of constipation of the Group. On follow-up, the Group showed insignificant ($p > 0.1$) result.

Effect on activity: The therapy was able to yield statistically highly significant at the level of $p < 0.001$ on activity of the Group. On follow-up the result showed insignificant ($p < 0.1$) in the Group.

After discontinuation of therapy incidence of relapse was found markedly through various previous studies.

To observe the relapse status of this trial drug monthly follow-up continued up to 2 month.

The remission was not found significant in the Group. It indicates the drug compound is effective in the treatment of disease but counseling too plays vital role in preventing the disease.

The trial drug compound *Esteemo forte* possess multiple properties like *Balya*, *rasayana*, *Medhya*, *Srotoshodhaka*, *Mutrasamgrahana* and *Krimighna* etc.

CONCLUSION

Shayyamutrata (Bed wetting) is a common socially disruptive problem. *Ayurvedic* literature has very brief description of *Shayyamutrata* (Bed wetting). *Srotovarodha* and vitiation of *Sadhaka*, *Tarpaka Kapha*, *Pachaka Pitta*, *Manovaha Srotas* and *Atinidra* are the factors responsible for development of *Shayyamutrata* (Bed wetting). *Kapha - Vataja* Trait of *Shareerika* and *Sattvika - Rajasa* trait of *Manasika Prakriti* can render a child more prone to *Shayyamutrata* (Bed wetting).

Counselling along with drug therapy proved to be more effective in this study. As this research was a time bound project, hence further studies are necessary to evaluate the effect of counseling (*sattvavajaya chikitsa*) with more techniques for long duration.

However, the study was conducted on a small scale sample, even then all over results were found to enthusiastic, further to come out for better conclusion this should be progressed involving work psycho-neuro-pharmacological study.

REFERENCES

1. Tripathi Brhmanand., Dr. 188. Vol. 7. Varanasi, Tikakar: Chaukhambha Surbharti Prakashana. Sarangdhara Samhita. Purva khand. [Google Scholar], 2001.
2. Vang Sen Samhita, 70: 26–27. [Google Scholar]
3. *IAP text book of Pediatrics*. 2nd edition. New Delhi: Jaypee Brothers, Medical Publishers (P) Ltd, 484. [Google Scholar]
4. Ghai O. P. *Essential pediatric*. 6th ed. New Delhi: CBS Publishers and Distributors. revised. [Google Scholar], 2004.
5. Pandey G.S Dr, editor. *Bhavaprakash Nighantu of Shri Bhava Mishra, Commentary by K.C. Chuneekar*. Varanasi (India): Chaukhambha Bharti Academy; Reprint. [Google Scholar], 2004.

6. Nighantu Dhanvantari, Sharma P.V. 1st ed. Varanasi (India): Chaukhambha Orientalia, 1982. [Google Scholar]
7. Nighantu Madanpal, Gangavishnu Ram Prasad. 1st ed. Bombay (India): Shri Krishna Das Stream Press, 1854. [Google Scholar]
8. Nighantu Adarsha, Vaidya Bapalal G. 2nd ed. 1 and 2. Varanasi (India): Chaukhambha Bharti Academy, 1999. [Google Scholar]
9. Nighantu Raj, Tripathi Indradeva. 1st ed. Varanasi (India): Krishnadas Acaedemy, 1982. [Google Scholar]
10. *A Dictionary of Indian raw materials and Individuals Products*. New Delhi: Council of Scietific and Industrial Research, 1959. The wealth of India. [Google Scholar]
11. Elizabeth Williamson., editor. *Major Herbs of Ayurveda* London: Churchill Living stone, 2003. [Google Scholar]
12. Warriar P.S. In: *Indian medicinal Plants, a compendium pf 500 species*. Warriar P.K, Nambiar V.P.K, Raman Kutty C, editors. S. Hydrabad: Orient Longman; [Google Scholar]