Clinical Researches

Clinical Study of An Ayurvedic Compound (Divyadi Yoga) in the Management of Shayyamutrata (enuresis)

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Abstract

Child health has assumed great significance in all over world. Its importance is being realized more and more by pediatricians and general public in developing as well as developed countries. Enuresis is defined as the voluntary or involuntary repeated discharge of urine into clothes or bed after a developmental age when bladder control should be established. The present clinical study was planned to evaluate the effect of Divyadi Yoga along with counseling in the management of Shayyamutra. Total 40 selected cases were divided into two groups, i.e. 20 in each group. One group of children were given the trial drug Divyadi Yoga (D1) with counseling and other group of children were given placebo Divyadi Yoga (D2) with counseling. Divyadi Yoga was given in the dose of 3-6 gms. twice a day with lukewarm water. The result of the study showed that groups provided a highly significant.

Key words: Nocturnal enuresis, Shayyamutrata, Divyadi Yoga, Psychotherapy.

Introduction

Child health has assumed great significance in all over world. Its importance is being realized more and more by pediatricians and general public in developing as well as developed countries. Here the health means, should be physically and emotionally fit in all directions, because almost every organic illness results in some degree of emotional disturbance and vice versa.

In Ayurvedic classics, the brief description regarding Shayyamutra is found in Sharangadhara1 and Vangaseh Samhita2. In this disease mainly Vata (Apan Vayu), Pitta (Pachaka), Kapha (Tarpaka), alonga with Manasika dosha tama are involved (vitiated). Dushya involved is Rasa (Ambu) dhatu. Vitiation of Mutravaha and Manovaha srotas is found in the form of untimely and increased frequency of urine at night.

Enuresis is a behavioural problem and the most common chronic problem in childhood next to allergic disorders. Children are not considered enuresis until they have reached 5 years of age and this behaviour is clinically significant as manifested by either a frequency of at least twice a week for three consecutive months or the presence of clinically significant distress in social academic or other important areas of child's functioning. The prevalence of enuresis is about 15-25% of children at 5 years of age, 8% of 12 years old boys and 4% of 12 years old girls, only 1-3% of adolescent are still wetting their bed. Boys suffer more often than girls because girls typically achieve each milestones before boys3,4.

Sattvavajaya Chikitsa in Shayyamutra

- Complaints not be discussed in front of other people.
- Appreciate (mental boost up) if bedwetting frequency decreased for e.g. from 3 to 1 etc.
- Mental and physical stress shouldn't be given to child on bedwetting.
- 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

- Conceptual and hypothetical evaluation of enuresis and to study the prevalence of Shayyamutra in children according to mental and physical personality (prakriti) types described in Ayurveda.
• Assuring and educating the parents regarding the disorder and development of the child (Parent counseling).
• Clinical evaluation of an Ayurvedic compound “Divyadi yoga” in the management of Shayyamutra (Enuresis).
• To study the role of counseling formulated in controlling the disorder.
• Evaluation of the side effects of the study drug.

Material & Methods

Selection of Cases: Patients with repeated voiding of urine into bed or clothes involuntarily were selected randomly from OPD and IPD of Kaumarbhritya, Department of National Institute of Ayurveda, Jaipur.

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

Number of cases: Total 58 enuretics were selected from above said sources out of which 18 children discontinued the treatment.

Inclusion criteria

Subject aged 5-16 years of either sex with history of bed wetting at least twice in a week for 3 consecutive months according to the DSM-IV-TR (Fourth edition of 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 N. I. A. Jaipur. 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 Divyadi Yoga (D₁) with counseling.

Group B: This group of children were administered placebo Divyadi Yoga (D₂) with counseling.

Grouping of the cases was done by random selection. The coded medicine (study drug / placebo) was given as per instructions. Another person not related with the study did coding of study drug and placebo. Coded document was sealed and kept under safe custody. The envelope was opened after completing the study to decode it for interpretation, observation and documentation during the study which were analyzed and findings were evaluated by using statistical analysis to establish the efficacy.

Drug, Dose & Duration

Ingredients of Divyadi Yoga (Table 1)

The ingredients of Divyadi Yoga are Ashwagandha, Ashwattha, Bala, Bhallataka, Brahmi, Haritaki, Kamala, Kharjura, Mandookaparni, Tila, Vacha, Vata, Vidanga⁵,¹².

Dose: 3 - 6 gm according to age and severity of disease.

Duration of trial: 3 months.

Follow-up: 2 month after treatment.

Placebo: The placebo containing starch, sugar, edible colour and mango flavour was also prepared in similar way to that of study drug.

Analytical Study

Divyadi yoga is a hypothetical drug formulated for the treatment of Shayyamutra. The present study deals for their determination of quality and their standardization through the following parameters.

Observation and Results

Maximum patients were of 5-7 years followed by 8-10 years children.In this study, Male children were found higher incidence of Shayyamutra as compared to female children. Maximum number of cases belonged to lower middle class followed by middle class. Maximum children were of second birth order followed by 1st birth order. Maximum patients had positive family history of Shayyamutra.

Maximum patients were suffering from 1-3 years of bedwetting followed by 4-6 years. Maximum patients having deep sleep. Maximum patients showed poor school performance. Maximum patients were of primary nocturnal enuresis. Maximum patients showed parental punishment for wetting the bed. Maximum patients were of Kapha Vataja shareerika prakriti and Sattavika Rajasa trait of manasika prakriti.
Table 1: Ingredients of **Divyadi yoga**

| S. No. | Sanskrit name | Botanical name          | Part used      | Quantity       |
|--------|---------------|-------------------------|----------------|----------------|
| 1.     | Ashwagandha   | *Withania somnifera*    | Root           | (1.2 kg.) 1 part |
| 2.     | Ashwattha     | *Ficus religiosa*       | Stem, bark     | (1.2 kg.) 1 part |
| 3.     | Bala          | *Sida cordifolia*       | Root           | (1.2 kg.) 1 part |
| 4.     | Bhallataka (Godombi) | *Semicarpus anacardium* | Phalasthi majja (Kernel) | (1.2 kg.) 1 part |
| 5.     | Brahmi        | *Bacopa monnieri*       | Whole plant    | (1.2 kg.) 1 part |
| 6.     | Bal Haritaki  | *Terminalia chebula*    | Fruit          | (1.2 kg.) 1 part |
| 7.     | Kamal         | *Nelumbium speciosum*   | Beej           | (1.2 kg.) 1 part |
| 8.     | Kharjura      | *Phoenix dactylifera*   | Fruit (dry)    | (1.2 kg.) 1 part |
| 9.     | Mandookpurni  | *Centella asiatica*     | Whole plant    | (1.2 kg.) 1 Part |
| 10.    | *Tila (Krishna)* | *Sesamum indicum*       | Seed           | (1.2 kg.) 1 part |
| 11.    | Vacha         | *Acorus calamus*        | Root           | (0.850 kg.)  |
| 12.    | Vata          | *Ficus bengalensis*     | Shunga         | (1.2 kg.) 1 part |
| 13.    | Vidanga       | *Embelia ribes*         | Fruit          | (1.2 kg.) 1 part |

Table 2: Study of physical characteristics (Analysis Report in House) of sample prepared by **Divyadi Yoga** (D.) P. G. & Ph. D. Drug Mfg. Unit

| Specified test                                                                 | Result                  | Specification |
|-------------------------------------------------------------------------------|-------------------------|---------------|
| 1. Physiochemical                                                             |                         |               |
| a) Description                                                               | Deep Brown thick pest with characteristic odour |               |
| b) Organoleptic test                                                        | Sweet taste             |               |
| c) Extractives (taking 5 gm sample, dissolved in 100 ml solvent, kept for 24 hrs.) |                         |               |
| i) In water                                                                  | 60% w/w                 | In House      |
| ii) In 45% Alcohol                                                          | 55% w/w                 | In House      |
| d) Ash (taking 1 gm sample, ignition up to 740°C)                            |                         |               |
| i) Total ash                                                                 | 9.02% w/w               | In House      |
| ii) Acid insoluble ash                                                      | 1.05% w/w               | In House      |
| e) Foreign matter                                                           | Nil                     | -             |
| f) pH of W. S. E. (10 % w/v)                                                 | 5.328                   | In House      |
| g) Moisture content/Loss on drying                                           | 19.07% w/w              | -             |
| 2. Microbiological test (B. P. 2005)                                         |                         |               |
| a) Total Plate count                                                        | 400 C. F. U/GM          | Not More than 10^2 Bacteria / gm / ml |
| b) Total Yeast Mould                                                        | 30 C. F. U/GM           | Not More than 10^5 Fungi / gm / ml   |
| c) E. Coli                                                                  | Absent                  | Absent        |
| d) Salmonella                                                               | Absent                  | Absent        |

Table 3: Improvement in dry nights after 3 months treatment

| Dry night / week | Group A (n=20) | Group B (n=20) |
|------------------|----------------|----------------|
|                  | B.T. A.T.      | B.T. A.T.      |
|                  | No. %          | No. %          | No. %          | No. %          |
| 0                | 12 60          | 01 05          | 10 50          | 00 00          |
| 1                | 01 05          | 00 00          | 01 05          | 00 00          |
| 2                | 03 15          | 00 00          | 02 10          | 07 35          |
| 3                | 02 10          | 00 00          | 03 15          | 04 20          |
| 4                | 02 10          | 01 05          | 03 15          | 04 20          |
| 5                | 00 00          | 05 25          | 01 05          | 03 15          |
| 6                | 00 00          | 01 05          | 00 00          | 02 10          |
| 7                | 00 00          | 12 60          | 00 00          | 00 00          |
| Total            | 20 100         | 20 100         | 20 100         | 20 100         |
### Table 4: Improvement in incidence/night after 3 months treatment

| Incidence/night | Group A (n=20) | Group B (n=20) |
|-----------------|----------------|----------------|
|                 | B.T.           | A.T.           | B.T.           | A.T.           |
|                 | No. %          | No. %          | No. %          | No. %          |
| None            | 00 00          | 12 60          | 00 00          | 00 00          |
| Once            | 09 45          | 08 40          | 11 55          | 17 85          |
| Twice           | 08 40          | 00 00          | 08 40          | 03 15          |
| Thrice          | 03 15          | 00 00          | 01 05          | 00 00          |
| Total           | 20 100         | 20 100         | 20 100         | 20 100         |

### Table 5: Effect of *Divyadi Yoga* on Bedwetting after 3 months Treatment

| Groups        | Mean ± SD   | % Improvement | n    | S.E. | t     | p     | Interpretation |
|---------------|-------------|---------------|------|------|-------|-------|----------------|
|                | B.T.        | AT.           | Dif. |      |       |       |                |
| Group A        | 10.10 ± 4.91| 1.05 ± 1.73   | 9.05 ± 5.29 | 89.60 | 20 | 1.18 | < 0.001 | H.S.          |
| Group B        | 7.80 ± 3.38 | 4.00 ± 1.72   | 3.80 ± 2.57 | 48.72 | 20 | 0.57 | < 0.001 | H.S.          |

### Table 6: Effect of *Divyadi Yoga* on bedwetting (after 3 months treatment) on associated symptom with bedwetting in Group A

| Associated Symptoms | Mean ± SD   | % Improvement | n    | S.E. | t     | p     | Interpretation |
|---------------------|-------------|---------------|------|------|-------|-------|----------------|
|                     | B.T.        | AT.           | Dif. |      |       |       |                |
| Fear                | 1.93 ± 0.73 | 0.71 ± 0.73   | 1.21 ± 0.43 | 62.96 | 14 | 0.11 | 10.67 < 0.001 | H.S.          |
| Aggressiveness      | 1.92 ± 0.67 | 0.75 ± 0.75   | 1.17 ± 0.39 | 60.87 | 12 | 0.11 | 10.38 < 0.001 | H.S.          |
| Irritability        | 2.10 ± 0.99 | 0.90 ± 0.88   | 1.20 ± 0.42 | 57.14 | 10 | 0.13 | 9.00 < 0.001  | H.S.          |
| Shamefulness        | 1.75 ± 0.62 | 0.67 ± 0.65   | 1.08 ± 0.29 | 61.90 | 12 | 0.08 | 13.00 < 0.001 | H.S.          |
| Sleep               | 1.25 ± 0.91 | 0.55 ± 0.51   | 0.70 ± 0.57 | 56.00 | 20 | 0.13 | 5.48 < 0.001  | H.S.          |
| Constipation        | 1.63 ± 0.74 | 0.75 ± 0.89   | 0.88 ± 0.35 | 53.85 | 8  | 0.13 | 7.00 < 0.001  | H.S.          |
| Activity            | 2.13 ± 0.83 | 0.88 ± 0.83   | 1.25 ± 0.46 | 58.82 | 8  | 0.16 | 7.64 < 0.001  | H.S.          |

### Table 7: Effect of *Divyadi Yoga* (after 3 month treatment) on associated symptom with bedwetting in Group B

| Associated Symptoms | Mean ± SD   | % Improvement | n    | S.E. | t     | p     | Interpretation |
|---------------------|-------------|---------------|------|------|-------|-------|----------------|
|                     | B.T.        | AT.           | Dif. |      |       |       |                |
| Fear                | 1.63 ± 0.52 | 1.38 ± 0.52   | 0.25 ± 0.46 | 15.38 | 8  | 0.16 | 153 > 0.1     | I.S.          |
| Aggressiveness      | 1.67 ± 0.52 | 1.17 ± 0.75   | 0.50 ± 0.55 | 30.00 | 6  | 0.22 | 2.24 < 0.1    | I.S.          |
| Irritability        | 1.88 ± 0.64 | 1.38 ± 1.06   | 0.50 ± 0.53 | 26.67 | 8  | 0.19 | 2.65 < 0.050  | S.            |
| Shamefulness        | 1.88 ± 0.35 | 1.50 ± 0.51   | 0.38 ± 0.92 | 20.00 | 8  | 0.32 | 1.16 > 0.1    | I.S.          |
| Sleep               | 1.10 ± 0.97 | 1.00 ± 0.97   | 0.10 ± 0.31 | 9.09  | 20 | 0.07 | 1.45 > 0.1    | I.S.          |
| Constipation        | 1.50 ± 0.55 | 1.33 ± 0.52   | 0.17 ± 0.41 | 11.11 | 6  | 0.17 | 1.00 > 0.1    | I.S.          |
| Activity            | 1.83 ± 0.75 | 1.33 ± 0.82   | 0.50 ± 0.55 | 27.27 | 6  | 0.22 | 2.24 < 0.1    | I.S.          |

### Table 8: Effect of weekly improvement of 3 month treatment in Group A

| Weeks | Mean ± SD   | % Improvement | n    | S.E. | t     | p     | Interpretation |
|-------|-------------|---------------|------|------|-------|-------|----------------|
|       | B.T.        | AT.           | Dif. |      |       |       |                |
| 1     | 10.10 ± 4.91| 9.35 ± 4.37   | 0.75 ± 1.12 | 7.43  | 20 | 0.25 | 3.00 < 0.010  | S.            |
| 2     | 10.10 ± 4.91| 8.55 ± 3.75   | 1.55 ± 2.04 | 15.35 | 20 | 0.46 | 3.40 < 0.005  | H.S.          |
| 3     | 10.10 ± 4.91| 8.00 ± 3.68   | 2.10 ± 1.89 | 20.79 | 20 | 0.42 | 4.97 < 0.001  | H.S.          |
| 4     | 10.10 ± 4.91| 7.10 ± 3.40   | 3.00 ± 2.43 | 29.70 | 20 | 0.54 | 5.53 < 0.001  | H.S.          |
| 5     | 10.10 ± 4.91| 6.20 ± 2.82   | 3.90 ± 2.57 | 38.61 | 20 | 0.58 | 6.78 < 0.001  | H.S.          |
| 6     | 10.10 ± 4.91| 5.60 ± 2.58   | 4.50 ± 2.69 | 44.55 | 20 | 0.60 | 7.49 < 0.001  | H.S.          |
| 7     | 10.10 ± 4.91| 4.80 ± 2.31   | 5.30 ± 3.03 | 52.48 | 20 | 0.68 | 7.83 < 0.001  | H.S.          |
| 8     | 10.10 ± 4.91| 3.90 ± 1.70   | 6.60 ± 3.72 | 65.35 | 20 | 0.83 | 7.94 < 0.001  | H.S.          |
| 9     | 10.10 ± 4.91| 2.65 ± 1.46   | 7.75 ± 4.87 | 76.73 | 20 | 1.09 | 7.12 < 0.001  | H.S.          |
| 10    | 10.10 ± 4.91| 1.40 ± 1.70   | 8.70 ± 5.05 | 86.14 | 20 | 1.13 | 7.71 < 0.001  | H.S.          |
| 11    | 10.10 ± 4.91| 1.05 ± 1.73   | 9.05 ± 5.29 | 89.60 | 20 | 1.18 | 7.66 < 0.001  | H.S.          |
| 12    | 10.10 ± 4.91| 1.05 ± 1.73   | 9.05 ± 5.29 | 89.60 | 20 | 1.18 | 7.66 < 0.001  | H.S.          |
Table 9: Effect of weekly improvement of 3 month treatment in group B

| Weeks | B.T. Mean ± SD | AT. Mean ± SD | % Improvement | n | S.E. | t | p | Interpretation |
|-------|----------------|---------------|---------------|---|------|---|---|----------------|
| 1     | 7.80 ± 3.38    | 7.40 ± 3.55   | 0.40 ± 0.60   | 20| 0.13 | 2.99 | < 0.010 | S.            |
| 2     | 7.80 ± 3.38    | 6.80 ± 3.07   | 1.00 ± 0.92   | 20| 0.21 | 4.87 | < 0.001 | H.S.          |
| 3     | 7.80 ± 3.38    | 6.35 ± 2.89   | 1.45 ± 1.79   | 20| 0.40 | 3.62 | < 0.005 | H.S.          |
| 4     | 7.80 ± 3.38    | 6.20 ± 2.89   | 1.60 ± 1.73   | 20| 0.39 | 4.14 | < 0.001 | H.S.          |
| 5     | 7.80 ± 3.38    | 6.30 ± 3.21   | 1.50 ± 1.24   | 20| 0.28 | 5.43 | < 0.001 | H.S.          |
| 6     | 7.80 ± 3.38    | 5.55 ± 2.35   | 2.25 ± 2.00   | 20| 0.45 | 5.04 | < 0.001 | H.S.          |
| 7     | 7.80 ± 3.38    | 4.65 ± 1.90   | 3.15 ± 2.39   | 20| 0.53 | 5.89 | < 0.001 | H.S.          |
| 8     | 7.80 ± 3.38    | 4.45 ± 2.11   | 3.35 ± 2.43   | 20| 0.54 | 6.16 | < 0.001 | H.S.          |
| 9     | 7.80 ± 3.38    | 4.00 ± 1.72   | 3.80 ± 2.57   | 20| 0.57 | 6.62 | < 0.001 | H.S.          |
| 10    | 7.80 ± 3.38    | 4.00 ± 1.72   | 3.80 ± 2.57   | 20| 0.57 | 6.62 | < 0.001 | H.S.          |
| 11    | 7.80 ± 3.38    | 4.00 ± 1.72   | 3.80 ± 2.57   | 20| 0.57 | 6.62 | < 0.001 | H.S.          |
| 12    | 7.80 ± 3.38    | 4.00 ± 1.72   | 3.80 ± 2.57   | 20| 0.57 | 6.62 | < 0.001 | H.S.          |

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

Table 10: Number of dry nights / week, before treatment after 3 months treatment and after 2 months follow-up (Group A, n=20)

| Dry Night | Before treatment | After treatment (3 months) | After follow-up (2 months) |
|-----------|------------------|-----------------------------|-----------------------------|
|           | No. | %   | No. | %   | No. | %   |
| 0         | 12  | 60  | 01  | 05  | 01  | 05  |
| 1         | 01  | 05  |     |     |     |     |
| 2         | 03  | 15  |     |     |     |     |
| 3         | 02  | 10  |     |     |     |     |
| 4         | 02  | 10  | 01  | 05  | 01  | 05  |
| 5         | 00  | 00  | 05  | 25  | 07  | 35  |
| 6         | 00  | 00  | 01  | 05  | 01  | 05  |
| 7         | 00  | 00  | 12  | 60  | 10  | 50  |
| Total     | 20  | 100 | 20  | 100 | 20  | 100 |

Table 11: Number of dry nights / week, before treatment, after 3 months treatment and after 2 months follow-up (Group A)

| Incidence / night | Before treatment | After treatment (3 months) | After follow-up (2 months) |
|-------------------|------------------|-----------------------------|-----------------------------|
|                   | No. | %   | No. | %   | No. | %   |
| None              | 00  | 00  | 12  | 60  | 10  | 50  |
| Once              | 09  | 45  | 08  | 40  | 10  | 50  |
| Twice             | 08  | 40  | 00  | 00  | 00  | 00  |
| Thrice            | 03  | 15  | 00  | 00  | 00  | 00  |
| Total             | 20  | 100 | 20  | 100 | 20  | 100 |

Table 12 : Number of dry nights / week, before treatment after 3 months treatment and after 2 months follow-up (Group B, n=20)

| Dry Night | Before treatment | After treatment (3 months) | After follow-up (2 months) |
|-----------|------------------|-----------------------------|-----------------------------|
|           | No. | %   | No. | %   | No. | %   |
| 0         | 10  | 50  |     |     |     |     |
| 1         | 01  | 05  |     |     |     |     |
| 2         | 02  | 10  |     |     |     |     |
| 3         | 03  | 15  |     |     |     |     |
| 4         | 03  | 15  |     |     |     |     |
| 5         | 01  | 05  |     |     |     |     |
| 6         | 00  | 00  |     |     |     |     |
| 7         | 00  | 00  |     |     |     |     |
| Total     | 20  | 100 | 20  | 100 | 20  | 100 |
Table 13: Number of dry nights / week, before treatment, after 3 months treatment and after 2 months follow-up (Group B)

| Incidence / night | Before treatment | After treatment (3 months) | After follow-up (2 months) |
|-------------------|------------------|-----------------------------|---------------------------|
|                   | No.   | %    | No.   | %    | No.   | %    |
| None              | 00    | 00   | 00    | 00   | 00    | 00   |
| Once              | 11    | 55   | 17    | 85   | 17    | 85   |
| Twice             | 08    | 40   | 03    | 15   | 03    | 15   |
| Thrice            | 01    | 05   | 00    | 00   | 00    | 00   |
| Total             | 20    | 100  | 20    | 100  | 20    | 100  |

Status of Recurrence of Bedwetting After Completion of Drug Trial (3 months) + Next 2 months Follow-up:

Table 14: Status of recurrence after follow-up (2 months after stopping the treatment)

| Status of recurrence | Group A (n=20) | Group B (n=20) |
|----------------------|----------------|----------------|
|                      | No. | %    | No. | %    |
| Recurrence           | 02  | 10   | 05  | 25   |
| No recurrence        | 18  | 90   | 15  | 75   |
| Total                | 20  | 100  | 20  | 100  |

Table 15: Status of recurrence of bedwetting after 3 month treatment and after 2 month follow-up

| Groups                  | Mean ± SD | % Improvement | n | S.E. | t    | p    | Interpretation |
|-------------------------|-----------|----------------|---|------|------|------|----------------|
|                         | B.T.      | AT.            |   |      |      |      |                |
| Group A                 | 1.05 ± 1.73| 1.25 ± 1.71    | 0.20 ± 0.52 | 19.05 | 20 | 0.12 | 1.71           | > 0.10 | I.S.            |
| Group B                 | 4.00 ± 1.72| 5.00 ± 1.75    | 1.00 ± 0.83 | 25.00 | 20 | 0.19 | 5.21           | < 0.001| H.S.            |

Table 16: Status of associated symptom with enuresis after 5 month of treatment (2 months after stopping the treatment) (Group A):

| Associated Symptoms | Mean ± SD | % Improvement | n | S.E. | t    | p    | Interpretation |
|---------------------|-----------|----------------|---|------|------|------|----------------|
|                     | B.T.      | AT.            |   |      |      |      |                |
| Fear                | 0.71 ± 0.73| 0.50 ± 0.65    | 0.21 ± 0.43 | 30.00 | 14 | 0.11 | 1.88           | < 0.1  | I.S.            |
| Aggressiveness      | 0.75 ± 0.75| 0.67 ± 0.78    | 0.08 ± 0.29 | 11.11 | 12 | 0.08 | 1.00           | > 0.1  | I.S.            |
| Irritability        | 0.90 ± 0.88| 0.70 ± 0.82    | 0.20 ± 0.42 | 22.22 | 10 | 0.13 | 1.50           | > 0.1  | I.S.            |
| Shamefulness        | 0.67 ± 0.65| 0.50 ± 0.52    | 0.17 ± 0.39 | 25.00 | 12 | 0.11 | 1.48           | > 0.1  | I.S.            |
| Sleep               | 0.55 ± 0.51| 0.40 ± 0.50    | 0.15 ± 0.37 | 27.27 | 20 | 0.08 | 1.83           | > 0.1  | I.S.            |
| Constipation        | 0.75 ± 0.89| 0.75 ± 0.71    | 0.00 ± 0.76 | 0.00  | 8  | 0.27 | 0.00           | > 0.1  | I.S.            |
| Activity            | 0.71 ± 0.73| 0.50 ± 0.65    | 0.21 ± 0.43 | 30.00 | 14 | 0.11 | 1.88           | < 0.1  | I.S.            |

Table 17: Status of associated symptom with enuresis after 5 month of treatment (2 months after stopping the treatment) (Group B):

| Associated Symptoms | Mean ± SD | % Improvement | n | S.E. | t    | p    | Interpretation |
|---------------------|-----------|----------------|---|------|------|------|----------------|
|                     | B.T.      | AT.            |   |      |      |      |                |
| Fear                | 1.38 ± 0.52| 1.13 ± 0.64    | 0.25 ± 0.46 | 18.18 | 8  | 0.16 | 1.53           | > 0.1  | I.S.            |
| Aggressiveness      | 1.17 ± 0.75| 1.00 ± 0.63    | 0.17 ± 0.41 | 14.29 | 6  | 0.17 | 1.00           | > 0.1  | I.S.            |
| Irritability        | 1.38 ± 1.05| 1.25 ± 1.04    | 0.13 ± 0.35 | 9.09  | 8  | 0.13 | 1.00           | > 0.1  | I.S.            |
| Shamefulness        | 1.50 ± 1.07| 1.25 ± 1.04    | 0.25 ± 0.46 | 16.67 | 8  | 0.16 | 1.53           | > 0.1  | I.S.            |
| Sleep               | 1.00 ± 0.97| 1.00 ± 0.97    | 0.00 ± 0.00 | 0.00  | 6  | -    | -              | -      | -               |
| Constipation        | 1.33 ± 0.52| 1.33 ± 0.52    | 0.00 ± 0.00 | 0.00  | 6  | -    | -              | -      | -               |
| Activity            | 1.33 ± 0.82| 1.17 ± 0.75    | 0.17 ± 0.41 | 12.50 | 6  | 0.17 | 1.00           | > 0.1  | I.S.            |


Table 18: overall results of Shayyamutra on the basis of improvement after follow-up (5 months 3+2 months):

| Improvement | Group A (n=20) | | Group B (n=20) | |
|-------------|----------------|----------------|----------------|---|
|              | No. | %  | No. | %  |
| Complete     | 11  | 55 | 00  | 00  |
| Marked       | 08  | 40 | 04  | 20  |
| Moderate     | 00  | 00 | 14  | 70  |
| Mild         | 01  | 05 | 02  | 10  |

**Discussion**

Effect of therapy
As already mentioned that, the study was conducted under two groups. Group A received Divyadi yoga (D1) along with counseling (psychological intervention) and group B received counseling along with Divyadi yoga (D2, Placebo).

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 group A (n=20) and 50% of group B (n=20) had no dry night (all wet night), out of 40 patients, 55% patients had no dry night. The 15% patients of group A and 10% patients of group B had 2 dry nights. The 10% patients of group A and 15% patients of group B had 3 dry nights and same percentage of both group patients had 4 dry nights. The 5% patients of group A and same percentage of group B had single dry night, 5% patients of group B had 5 dry nights (Table 3).

Before treatment the status of bedwetting incidence once per night was in 45% of patients of Group A and 55% patients of Group B. The 40% patients of group A and 40% patients of Group B had 2 incidences/ night; 15% patients of Group A and 5% patients of Group B had 3 incidences/ night. It means before treatment 50% of total patients had incidence 2-3 times/night (Table 4).

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 both the groups A and B showed significant (p< 0.01 in Group A and p< 0.01 in Group B) result. But according to the percentage of improvement, Group A showed better result (7.43%) in comparison to Group B (5.13%). After 2nd week treatment decrease in zero dry nights of both groups and 2 dry night of Group A and 3 dry nights of Group B but increase of percentage 1 dry night of both groups and 2, 4 dry nights of group B was seen. Status of incidence/night showed increase of both incidence of both groups (more in Group B) but decrease of 3 incidences/night and Group B showed decrease in 2 incidence /night. In both Group A and B the result revealed statistically significant after 2nd week treatment (p<0.005 - Group A and p< 0.001 - Group B).

After 3rd week treatment no patients of Group A had zero dry nights in 3rd week, while in Group B 25% patient had zero dry nights in comparison to before treatment. Three incidence/night was found absent in both groups, increase of one incidence in both groups, increase patients of 2 incidences/night of group A and decrease patients of Group B. In Group A, the result was observed highly significant (p< 0.001) after 3rd week treatment, while in Group B it was significant (p<0.005). Percentage of improvement was found 20.79% in Group A and 19.59% in Group B.

After 4th week treatment no patient had 3 incidence/ night was found. Both the Group A and B (p<0.001) were statistically highly significant and percentage gain of Group A was 29.70% and in Group B was 20.51%.

After 5th week, 10% patients of Group A and 10% patients of Group B achieved 5 dry nights. Percentage of patients was found decreased in 2 incidence/night of both group and increased in 1 incidence of both groups. The result showed improvement of 38.61% in Group A and 19.23% in Group B and both groups showed statistically highly significant results.

As evident that after 6th week treatment both groups showed highly significant (p<0.001) percentage improvement of Group A was found 44.55% and Group B was found 28.85%. Study revealed that after 7th week treatment statistically highly significant results were observed in both the groups with percentage improvement of 52.48% of Group A and 37.82% of Group B. After 8th week treatment, statistically highly significant (p< 0.001) result was observed in both the groups. The percentage gain was 65.35% in Group A and 40.38% in Group B. After 9th week treatment highly significant (p< 0.001) relief in bedwetting was obtained in Group A and Group
B, while the percentage improvement was more in group A (76.73%) than the Group B (42.95%). After 10th week treatment result showed statistically highly significant (p< 0.001) in both the groups with gain percentage of 86.14% in Group A and 48.72% in Group B. After 11th week treatment it was observed highly significant (p< 0.001) results in both the group but the gain percentage more in Group A was 80.60% as compared to Group B (48.72%).

Study revealed that after completion of drug trial (after 3 months of treatment) 60% of patients of Group A achieved all (7) dry nights but no patients of Group B achieved all (7) dry nights; 50% patients of Group A and 25% patients of Group B achieved 5-6 dry nights. Only 5% patients had 4 dry nights and only 5% patients had zero dry nights in Group A. The 20% patients had 3 dry nights and 35% patients had 2 dry nights in Group B. As far as incidence / night is concerned 60% patients of Group A achieved no incidence/night, 40% patients had one incidence/night in Group A; 15% patients had 2 incidence/night and 85% patients had one incidence/night of Group B.

After 3 months treatment both groups (Group A - counseling along with Divyadi Yoga (D1), Group B-counseling with Placebo) showed highly significant (p<0.001) results. But according to percentage of improvement Group A showed better result (89.60%) in comparison to Group B (48.72%).

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 months after treatment was performed. Observation have shown that 10% patients of Group A and 25% patients of Group B showed remission of disease.

After 2 month follow-up (after 3 month treatment Group A showed statistically insignificant (p> 0.1) result. In Group B the result was statistically highly significant.

**Effect of therapy on Associated Symptoms**

**Effect on Fear:** The relief obtained from fear was statistically highly significant (p < 0.001) of Group A after treatment but insignificant (p> 0.1) in Group B. The gain percentage was 62.96% in Group A as compared to 15.38% in Group B; 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 Group A but insignificant in group B. The gain percentage was 60.87% in Group A but 30% in Group B. 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 3 months therapy with the Group A i.e. Divyadi yoga D1 along with counseling; Whereas insignificant results (p> 0.1) was obtained by the Group B. The percentage gain was 61.90% of Group A, but 20% of Group B. 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, but insignificant in Group B. 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 Group A patients but insignificant in Group B. 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 Group A, but insignificant in Group B. On follow-up, Group A showed insignificant (p> 0.1) result, but Group B remain unchanged in symptom as constipation.

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

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. Observation have shown that recurrence was observed more in Group B than Group A. The recurrence was statistically insignificant at the level of p> 0.1 of group a but highly significant (p< 0.001) of Group B.

The remission was found higher in Group B as compared to Group A. It indicates the drug compound is effective in the treatment of disease but counseling too plays vital role in preventing the disease. There by Group B shows more chances of remission in which placebo and counseling was used for the treatment.

The trial drug compound Divyadi Yoga possess multiple properties like Balya, rasayana, Medhya, Srotoshodhaka, Mutrasamgrahana and Krimighna etc.

**Conclusion**

Shayyamutra is a common socially disruptive problem. Ayurvedic literature has very brief description of Shayyamutra. Srotovarodha and vitiation of Sadhaka,
Tarpaka Kapha, Pachaka Pitta, Manovaha Srotas and Atinidra are the factors responsible for development of Shayyamutra. Kapha - Vataja Trait of Shareerika and Sattvika - Rajasa trait of Manasika Prakriti can render a child more prone to Shayyamutra. Counseling 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. For better palatability the trial drug should be in granule form rather than Avaleha. 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.

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हिन्दी सारांश

शय्यामूत्र की चिकित्सा में दिव्यादि योग के प्रभाव का अध्ययन

सी. एम. जैन एवं अंजु गुप्ता

पूरे दिव्श में बच्चे का स्वास्थ्य अधिक महत्वपूर्ण है। इसके महत्व को विकसित देश तथा विकासशील देशों में बालस्थिती विशेषता तथा सामान्य जनता भी अधिक से अधिक समझ चुकी है। एक निश्चित अवस्था में बच्चे का मूत्रश्वास पर पूर्णरूप से नियन्त्रण हो जाना चाहिए, उसके बाद बार-बार ऐल्क्सिक या अनैल्क्सिक रूप से कपड़े या बिस्तर में मूत्रयाग हो जाना ‘शय्यामूत्रा’ कहलाता है। यह अध्ययन शय्यामूत्रा पर दिव्यादि योग तथा सत्त्ववाय चिकित्सा के प्रभाव का निरीक्षण करने के लिए किया गया है। इसमें कुल ४० रोगी होने जो दो समूह में विभाजित किये गये। एक समूह के रोगियों को दिव्यादि योग (D1) तथा सत्त्ववाय चिकित्सा दी गई तथा दूसरे समूह के रोगी को दाबमूत्रतय तथा सत्त्ववाय चिकित्सा दी गई। दिव्यादि योग रोगी को दिन में दो बार कोष्ठ जल के साथ दिया गया। अध्ययन के पश्चात दोनों समूहों का परिणाम अत्यधिक महत्वपूर्ण पाया गया।