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A STUDY ON SEDATIVE EFFECT OF AN INDIGENOUS DRUG IN PAEDIATRIC PRACTICE

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ABSTRACT

In paediatric practice, most commonly observed symptoms are cry, irritability, restlessness, convulsions, hyperactivity, difficult to console & handle which many times becomes a hurdle in treatment. These symptoms are effectively managed with the judicious use of sedative drugs in modern medicine, to carry on main treatment schedule without hindrance. Present study aimed to find out the sedative effect an Ayurvedic drug which can be used in such conditions of clinical practice. Objective: To study the sedative effect of an indigenous drug (*Kolasthimajja)* in paediatric practice. Methodology: The present study was conducted in children presented with the symptoms such as cry, irritability, restlessness, hyperactivity, convulsion, difficulty to control and handle. Children in the age group of 1-16 years, irrespective of their sex, religion, socio-economic status, developmental milestones were selected randomly from OPD and IPD of SDMCA & H, Hassan. Total 120 patients were registered and divided in two groups of 60 patients each. Group A was given *Kolasthimajja churna* where as Group B was given Phenobarbitone diluted in lukewarm water through rectal route. The dosage of the treated group was 1 gram/kg body weight diluted with 20ml of luke warm water as per dosage schedule given by Yoga Ratnakara in children, and administered only once. The cases were registered as per the proforma and observations were recorded as per the gradation chart prepared followed by comparison of both the groups. Results: The time taken by the child to become calm and quiet ,time taken by the child to appear drowsy , time taken for induction of sleep ,effect on increasing the length of sleep, depth of sleep , was more in group B , in comparison to treated group A. The overall effect of the drug in Group A,. 20% patients showed moderate effect and 50% showed mild effect. While in Group B, 25% of patients showed marked effect, 55% of patients showed moderate effect and 20% of patients showed mild effect. Conclusion: *Kolasthimajja* has shown mild sedative effect when administered through rectal route in comparison to Phenobarbitone and was proved for its mild sedative effect, and can be used as per the need.

Keywords: *Kolasthimajja, Nidrajanaka,* Sleep, Phenobarbitone, Sedation, Rectal route,

INTRODUCTION

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Ayurveda always emphasizes both on physical and psychological health of an individual; hence global approach of treatment has been its greatness. As most of the disorders are proved as to be of psychosomatic, and remedies that keep tranquillity of mind are need of the hour. Rightly childhood clinical practice demands, sedation of

varied degree in management of irritable, restless child, convulsive disorders, infantile spasms, anxiety, hyperactivity disorders etc[1]. However sedation is not the main stay of treatment, its judicious use as an adjuvant helps for speedy recovery and reduces the anxiety of parents.

In Ayurvedic paediatric practice too we come across with similar situations like irritable child, difficult to handle, difficult to control, restless, jittery, crying, convulsions, etc, which necessitates the make the baby cool and calm[2]. So there is a need of a mild sedative drug, which is cost effective, induces sedation without apparently disturbing body functions and free from side effects.

We find enough references in Chinese traditional medicine where drug *Kola* or Zizyphus jujube has been extensively used to treat insomnia due to fatigue, thereby relaying additive effects in nourishing heart, liver and relaxing muscles[3]. Various research works have also been done internationally to evaluate the sedative effect of the constituents extracted from Jujube seeds. So far, to the best of our knowledge, no study has been done to evaluate the sedative effect of any Ayurvedic drug particularly in children; hence the present study was aimed to study the sedative effect of *Kolasthimajja* (Zizyphus jujuba seed) in common paediatric problems requiring effective sedation.

AIMS AND OBJECTIVES

To evaluate the Sedative Effect of *Kola-Asthimajja* in paediatric practice.

MATERIAL AND METHODS

For the present clinical study 120 children of various disorders presented with excess cry, irritability, difficult to console, convulsions were randomly selected from the OPD and IPD of Department of *Kaumarabhritya,* SDMCA & Hospital, Hassan.

Diagnostic methods: For diagnosis, detail medical history was taken and physical examination was done to establish the diagnosis of particular disorder. A detailed interview was conducted to elucidate various somatic disorders, behavioural disorders, sleep disorders, stress disorders; seizure disorders etc. A special Proforma was prepared with gradation of symptoms and scoring was done according to severity.

Plan of study: Totally 120 screened patients were distributed in Group A and Group B containing 60 patients each to know the effects of each drug separately and this was a single blind ,interventional comparative study

1) **Group A (Treated group)**: In Group A patients were administered with *Kola-asthimajja* powder in the dose of 1gram/kg diluted with 20 ml of lukewarm water respectively through rectal route of administration[4]. *(Dosage was fixed Classical reference given by Yoga Ratanakara)*
2) **Group B (Control group)**: In group B patients were given Phenobarbitone an established sedative[5] and anticonvulsant drug in a dose of 2mg/kg body weight diluted in required quantity of water.

Inclusion Criteria:

- Patients in paediatric age of either sex.
- Patients who were not recently exposed to long term modern sedative or Anti-epileptic drugs or similar group of drugs like Antihistaminic etc.
- Patients irrespective of underlying disorder, presented with irritability, restless, jitteriness, cry, difficult to handle, difficult to console, febrile, convulsions, certain behavioral disorders, sleep disorders etc were included in the study.

Exclusion Criteria:

- Patients with serious structural and inflammatory disorders of the CNS were excluded.
- Children with Grand mal epileptic seizures and status epileptics were excluded.
- Patients of Mental retardation with associated convulsions were excluded.
- Patients with chronic use of Anti-epileptic drugs, drug abuse, drug dependency, etc. were excluded.
- Cerebral malaria. Encephalitis, Meningitis, Brain tumours, metabolic errors, etc. was excluded from the study.

- Restless child due to hunger and severe cough were excluded.

Preparation of the drug:

Fresh fruits of Zizyphus jujuba (*Kola)* was identified and purchased from the market. The fruits were dried and the seed were obtained. The seed were further dried and roasted over fire in a vessel to make them easily crushable. After cooling, the fine powder of the seeds was made and stored in air tight container and kept ready for instant use.

Criteria for Assessment:

The assessment of the effect was done after administration of drug. To give some objectivity to the observations, each observation was assigned to definite scores. To know any post sedation effect different criteria was made and scoring was done. The scoring adopted for this study is as follows:

- Time taken to become calm and quite
- Time taken to appear drowsy
- Time taken for inducing sleep
- Length of sleep before awakening on its own
- Depth of Sleep
- Overall effect of treatment on induction of sleep
- Post Sedation effect: Status 15 min after awakening

Statistical analysis

In this study for the sake of statistical analysis of the above said parameters, paired‘t’ test method was adopted and S.D, S.E,‘t’ and ‘p’ values were calculated accordingly.

Observation and results

Table No. 1. Effect of both drugs to make calm & quite

Calm & quite	MEAN		% of effect	SD (±)	SE (±)	‘t’ value	‘p’ value
	BT	**AT**					
Group A	2.7	1.5	44.44	0.81	0.10	11.34	<0.001
Group B	2.7	1.1	59.25	0.82	0.10	14.97	<0.001

Table No. 2. Effect of both drugs to make drowsy

Drowsy	MEAN		% of effect	SD (±)	SE (±)	‘t’ value	‘p’ value
	BT	**AT**					
Group A	2.7	1.6	40.70	0.72	0.09	11.67	<0.001
Group B	2.7	0.8	70.37	0.70	0.09	20.84	<0.001

Table No. 3. Effect of both drugs on induction of sleep

Induction of sleep	MEAN		% of effect	SD (±)	SE (±)	‘t’ value	‘p’ value
	BT	**AT**					
Group A	2.6	1.8	30.76	0.63	0.08	9.79	<0.001
Group B	2.6	1.0	61.53	0.78	0.10	15.77	<0.001

Table No. 4. Effect of both drugs on length of sleep

Length of sleep	MEAN		% of effect	SD (±)	SE (±)	‘t’ value	‘p’ value
	BT	**AT**					
Group A	1.75	1.13	35.40	0.61	0.07	7.79	<0.001
Group B	1.75	0.65	62.85	0.91	0.11	9.31	<0.001

Table No. 5. Effect of both drugs on depth of sleep

Depth of sleep	MEAN		% of effect	SD (±)	SE (±)	‘t’ value	‘p’ value
	BT	**AT**					

Group A	1.25	0.70	44.00	0.64	0.08	6.56	<0.001
Group B	1.25	0.50	60.00	0.77	0.09	7.51	<0.001

Table No. 6. Overall effect of Drugs

Criteria	**Assessment**	**No. of Patients**				**Total**	**%**
		Group A	**%**	**Group B**	**%**		
Complete effect	100%	0	0	0	0	0	0
Marked effect	76% - 99%	0	0	15	25	15	12.5
Moderate effect	51% - 75%	12	20	33	55	45	37.5
Mild effect	26% - 50%	30	50	12	20	42	35
Unchanged	25%	18	30	0	0	18	15

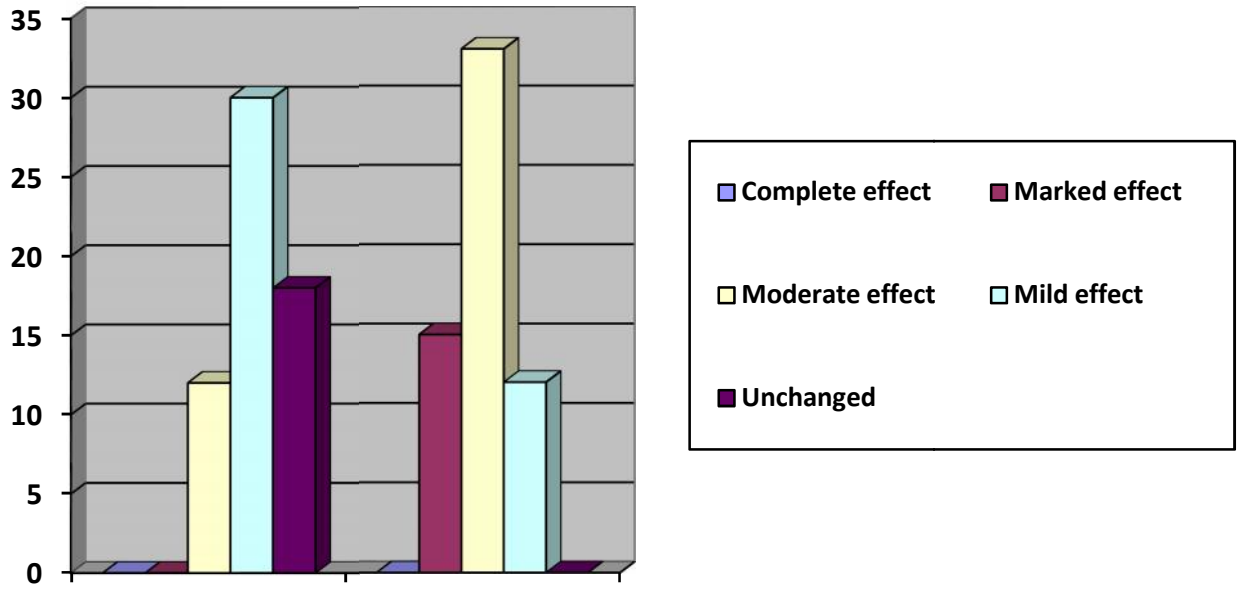

Table No. 7. Post sedation effect of both drugs

Post sedation effect	MEAN		% of effect	SD (±)	SE (±)	't' value	'p' value
	BT	**AT**					
Group A	0.50	0.61	22.00	0.53	0.06	8.52	<0.001
Group B	0.50	0.70	40.00	0.66	0.08	7.39	<0.001

DISCUSSION ON RESULTS:

The effect of drugs on time taken by the child to become calm and quite after administration of drug was improved significantly in group B (59.92%) as compared with group A (44.07%). This corresponds to higher efficacy of Phenobarbitone than *Kolasthimajja*. Both the groups have shown highly significant improvement in result with 'p' value of <0.001. This result is supported by the previous study done by, which proves the sedative action of flavonoids and Saponins in Zizyphus jujuba seeds[6]. (Shin et.al, Mar 2006)

The improvement in the time taken by the child to appear drowsy was seen more in group B (70.37%) as compared with group A (40.70%) which supports the more potent action of control group drug than the drug used in trial group. Both the results showed highly significant improvement with the 'p' value of <0.001. This is supported by

the result of previous study done which confirms the sedative and hypnotic effects of flavonoids, saponins and polysaccharides extracted from seeds of Ziziphus jujuba.[7] (by Jian-Guo et.al, Feb 2007),

The improvement in the time taken for induction of sleep was more in group B (61.53%) than compared with group A (30.76%) which supports the greater efficacy of Phenobarbitone in induction of sleep. Both the values showed highly significant results with the 'p' value of <0.001. This result is supported by the previous study done, which confirmed the action of flavonoids and saponins from Zizyphus jujuba seeds in inducing sleep[8]. (By Shin et.al, Mar 2006)

The improvement in the length of time of sleep was observed more in group B (62.85%) as compared with group A (35.40.%) which favours the Phenobarbitone for its more potent action as compared with *Kolasthimajja.* Both the groups showed highly significant results with the 'p' value of <0.001. This result is supported by the previous study done, which confirmed that the alkaloids present in seeds of Ziziphus jujuba like sanjoinine, zizyphusine and nuciferine prolonged the sleeping time produced by Hexobarbital. [9](by Han et.al in 1989)

Effect of drugs on the depth of sleep showed more improvement in group B (60.00%) as compared with group A (44.47%). favouring Phenobarbitone for its more potent action than *Kolasthimajja.* The result on overall effect of the drug in induction of sleep proved the mild sedative effect of *Kolasthimajja* (50%) as compared with that of Phenobarbitone (20%). The moderate sedative effect was observed more in Phenobarbitone treated group (55%) than that of *Kolasthimajja* (20%), proving *Kolasthimajja* as a mild sedative drug in comparison with the Phenobarbitone. At times phenobarbitone although a proved long acting sedative drug has not significantly shown complete effect due to early assessment of the results as it take long time to take plasma half life value.

The result on post sedation effects showed more sedative effect of drug in group B (22.00%) than in group A (40.00%) with 'p' value of <0.01 showing significant result in both groups. This signifies that the post sedative effects of *Kolasthimajja* are less as compared with Phenobarbitone making the former a safest drug for sedation in paediatric practice.

However the deficit of not having a reliable sedative drug in Ayurveda is partly fulfilled by *Kolasthimajja* as it showed an overall mild sedative efficacy in the study. Further the cheap cost, easily availability and negligible post sedation effect are considered to be the added advantages ahead of Phenobarbitone.

Probable action of *Kolasthimajja*

Madhura Rasa, Shita Virya and *Madhura Vipaka* of *Kolasthimajja* cause production of *Kapha.* [10]This increased *Kapha* up fills the *Hridaya* and produces sleep. *Hridaya* is responsible for awakened state of a person, perception of knowledge and onset of sleep and when *Kolasthimajja* is administered it produces excess increase in *Kapha* which gets lodged in *Hridaya* and probably hampers these functions producing obstacles in the path of perception of *Jyana* and *Samgya* (Consciousness) thereby decreasing the level of consciousness in a child by making calm, quite and drowsy[11]. *Kashaya Rasa* does *Stambana* and probably decreases *Satwa Guna* which reduces the excitement and awakened state and makes a child calm and quite.[12]

Kolasthimajja when administered to a child through rectal route gets absorbed quickly and probably shows *Madakari* effect[13], producing *Mada* (Stage Ist of decreasing level of consciousness) by virtue of its *Tamo Guna* producing *Avarana in Hridaya*. The movement of *Manas* gets partially blocked and the child gets *Jrumbha, Tandra, Glani & Sangya Daurbalya*.[14] The child appears calm, quite, and drowsy, likes to be on the bed and is not active. There is no complete loss of consciousness in this stage. Child is drowsy, awake able and is able to localize pain.

As the dose is increased, it probably increases *Tamo guna* which fills up *Sangyavahi Srotus*, completely blocks the movement of *Manas* and may produce *Murcha* (Stage 2nd of decreasing level of consciousness)[15.] In this stage child is asleep and is not able to verbalise, communicate

and localize pain. Further with an increase in dose it may produces excessive *Tamo guna* which may probably lodge in *Pranayatan*s including *Shiras t*here by producing loss of *Vaka, Deha, Manas, Cheshta* (vital functions) and *Samgja (*consciousness) producing more deeper level of unconsciousness i.e *Sanyasa* (Stage 3 of decreasing level of consciousness). As *Kolasthimajja* is *Vata-Pitta Shamaka* it reduces *Satwa & Rajo Guna* thereby reducing the excitement in the person.[16]The seed of Zizyphus jujube has Terpenoides like Jujubisoides which reduces CNS excitement and produces sedation.[17]

CONCLUSION

In the present study, the observed effect showed significant reduction in the time taken by the child to become calm, quite and drowsy. Further the length of sleep time and depth of sleep showed significant improvement with the negligible post sedation effect. The drug is more effective in making the child calm, quite and drowsy which confirms more of its sedative action rather than hypnotic effect seen by the induction of sleep.

Further, rectal route is concluded as easy, safe and effective route for administration of drug in children to get early absorption and immediate effect. Present study partly fulfilled the requirement of potent sedative drug in Ayurveda. Hence, *Kolasthimajja* is concluded as a safe, cheap, mild sedative drug, without any adverse effects and to be used in paediatric practice requiring effective sedation. However further studies to get better efficacy of *Kolasthimajja* may be done with alcoholic extract of the drug and increase in dose and also in relation with *Prakruti* of chid

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