

CLINICAL EVALUATION OF TAGARA (VALERIANA JATAMANSI JONES) AS A PREMEDICATION AGENT IN DISSOCIATIVE ANESTHESIA

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Article Received on
29 Jan. 2019,

Revised on 19 Feb. 2019,
Accepted on 12 March 2019

DOI: 10.20959/wjpr20194-14566

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ABSTRACT

Preoperative anxiety is a challenging concept in the preoperative care of patients. Most patients awaiting elective surgery experience anxiety and it is widely accepted as an expected response. So it becomes the duty of anesthesiologist to treat preoperative anxiety. Various drugs have been used to control preoperative anxiety but none is free from side effects. Few drugs are mentioned in *Ayurvedic* literature which may be useful and may full fill today's need of premedication. Keeping all these views, present study was undertaken to explore about preoperative anxiety in *Ayurvedic* parlance and then to formulate proper management. After the scrutiny of the various ancient texts, the drug *Tagara* was selected for the assessment of its adjuvant properties of premedication in this research work.

KEYWORDS: Anxiety, preoperative, surgery, anaesthologist, *tagara*.

INTRODUCTION

Management of anesthesia begins with preoperative psychological preparation of the patient and administration of a drug or drugs selected to elicit specific pharmacological responses. This initial psychological and pharmacological component of anesthetic management is referred to as Premedication. There are no specific references available for pre-medication agents across all *Ayurvedic* texts, but references related to use of anesthetic drug can be traced in various ancient texts in scattered form. *Sushruta Samhita* has described three types of *karmas*, in which *Poorva karma* can be correlated with the pre-operative preparation of the

patient. *Poorva karma* can be divided into *Rogi Smbandhita* (patient preparation), *Chikitsa Sambandhita* (plan of treatment), *Upakarana Sambandhita* (instrumental preparation) and *Shalya Kaksha Sambandhita* (preparation of operation theatre). *Rogi Sambandhita Poorva Karma* can be compared with preoperative preparation of the patient. The main purpose of pre-anesthetic or premedication is to facilitate the smooth induction and maintenance of anesthesia during operation. This is only possible by administration of drugs which relieve the patient's anxiety, apprehension and fear about the operation as well as it helps to relieve emotional tension, lowers metabolism, reduces salivary and respiratory tract secretions, prevents undesirable autonomic reflex responses to stimuli and decreases the side-effects of the anesthetic agents.^[1] The root of this drug is used for the purpose of premedication. It has been categorized as *Vedanasathapana* (Analgesic) and *Nidrajanana* (sedative), anticonvulsant, anti anxiety in stress and strain, having the action on central nervous system.^[2] It is also used in nervous disorders like epilepsy hysteria etc. It is having the active principle mainly Valeric acid. There is a clear reference of the use of strong alcohol (*TeekshnaMadya*) before surgical procedure.^[3] This was the most commonly used substance at the time of *Acharya Sushruta*. Probably use of alcohol before surgical intervention would have rendered the patient unconscious. The person who was addicted to alcohol was advised to take strong wines prior to operation. All these references showed that our ancient *Acharyas* were well aware about pre-operative preparation of the patient for making surgery uneventful.

AIMS AND OBJECTIVES

1. To evaluate the effect of *Tagara* as pre medication agent.
2. To come up with an effective, safe and *Ayurvedic* alternative to conventional treatment with minimal side effects.

RESEARCH PROTOCOL

After careful examination 20 patients were selected from OPD/IPD of Deptt of *Shalya Tantra*, *Shalakya Tantra* and *Prasuti Tantra avum Stree Roga* of R.G.G.P.G. Ayurvedic College and Hospital Paprola, undergoing surgery under Dissociative anesthesia. Separate Performa was prepared for complete assessment of patients. Selected patients were divided randomly into 2 groups (10 patients in each group):-

Group 1 - Patients of this group will be given *Tagara* capsule (hydro alcoholic extract) of 250 mg and 500 mg for children (up to 13 years) and adults respectively day before surgery at bed time (10 pm) and in the morning (6 am) on day of surgery with a sip of water.

Group 2- Patients of this group will be given Tab. Diazepam 10 mg HS and 5 mg morning in adults and 5 mg HS and 2 mg morning in children with a sip of water.

SELECTION CRITERIA

A) Inclusion Criteria

1. Patients ready to give informed consent.
2. Patients falling under the ASA grade-I.
3. Age group 10yrs to 30yrs irrespective of sex.
4. Patients undergoing surgery under Dissociative anesthesia.

B) Exclusion Criteria

1. Patients not falling under the ASA grade-I.
2. Patients who have undergone any surgical procedure before and who may be well aware of pre and post anesthetic consequences.
3. Contraindication to Dissociative anesthesia
4. Mentally retarded patients.

INVESTIGATIONS –Hb%, TLC, DLC, ESR, BT, CT,FBS, B. urea, S. creatinine, ECG and Chest X-ray

SCORING

1. Sedation Scoring

- 0 - Patient asleep.
- 1 - Patient drowsy, quiet but easily arousal.
- 2 - Patient awake but silent.
- 3 - Patient awake and talkative

2. Anxiety Scoring

- 0 - Patient quiet and comfortable.
- 1 - Patient feels uneasy.
- 2 - Patient worried or anxious.
- 3 - Patient frightened or terrified

3. SBP Grading

- 0 - < 120
- 1 - 121 – 130
- 2 - 131 – 140
- 3 - 141 – 150
- 4 - >150

4. DBP Grading

- 0 - < 60
- 1 - 61 – 70
- 2 - 71 – 80
- 3 - 81 – 90
- 4 - >90

5. PR Grading

- 0 - <80
- 1 - 81 – 90
- 2 - 91 – 100
- 3 - > 100

6. RR Grading

- 0 - < 12
- 1 - 13 – 15
- 2 - 16 – 18
- 3 - >18

Adverse Drug Reaction (ADR) Present / Absent

- i. Headache
- ii. Nausea
- iii. Vomiting
- iv. Dizziness
- v. Dyspepsia
- vi. Dyspnea

RESULT

1. 76-100% Effective (Patient is quiet, comfortable and asleep with no ADR)
2. 51-75% Effective (Patient is drowsy, quiet but easily arousal feels uneasy with few or no ADR).
3. 26-50% Effective (Patient is awake but silent, looks worried and anxious with few or no ADR).
4. 0-25% Effective (Patient is awake and talkative, frightened or terrified with few or no ADR).

Overall assessment Criteria

76-100 %	- Highly Effective
51-75%	- Moderately Effective
26-50%	- Mildly Effective
0-25%	- Not Effective

RESULT**On Sedation**

Effect of therapy on both the groups shows statistically significant results ($t=2.67$, $p<0.05$ in trial group, while $t= 2.51$, $p<0.05$ in standard group). Trial group showed 11.66% while standard group showed only 8.47%. On inter group comparison results were found to be non-significant. This shows that both the drugs have similar effect on sedation.

On Anxiety

In this study, group-I where *Tagara* was administered showed statistically significant result ($t=7.285$, $p<0.001$ with 46.0% reduction) which denoted anxiolytic action of *Tagara*. Standard group also showed statistically significant results with 't' value of 12.365 and $p<0.05$. with 59.0% reduction. Inter group comparison showed statistically highly significant results ($p< 0.001$), which showed that standard drug is more effective in reducing anxiety than the trial drug.

On SBP

The efficacy of drugs on blood pressure was found to be statistically non-significant in both the Groups ($t=1.371$, $p>0.05$ in trial group and $t=2.349$, $p>0.05$ in standard group). Trial group showed 8.57% reduction in SBP while standard drugs showed 12.19% reduction. Intergroup

comparison also showed non-significant results. This showed that there was almost same effect of both the drugs, on systolic blood pressure.

On DBP

Both the groups showed statistically non-significant results on the effect of treatment ($P>0.05$) on DBP. On inter group comparison, no significant difference was noted between the groups. This showed that both the drugs have same effect on diastolic blood pressure.

On Pulse Rate

Analysis of pulse rate showed significant result in both the groups. In trial group significant reduction in pulse rate was observed with 't' value of 3.249 and $p<0.001$. Trial group shows percentage reduction of 38.46%. This was statistically highly significant ($p<0.001$). In Standard group 't' value was 2.666 and $p<0.05$. which shows percentage reduction of 25.0%. This was statistically significant ($p<0.05$). Inter group comparison showed non-significant results. This showed that both the drugs have significant effect on reduction in pulse rate.

On Respiration Rate

Effect of therapy on respiration rate showed statistically significant results in both the groups. Trial group showed percentage reduction of 30.0%. This was statistically Significant ($p>0.05$). Standard group showed percentage reduction of 25.0%. This was statistically significant ($p<0.05$). On intergroup comparison, non-significant results were obtained. Hence it can be said that both the drugs have same effect on the respiration rate.

Overall effect of Therapy in both the Groups

In group I, 10% of patients showed moderate effect while 30% of patients showed mild effect of therapy. In 60% of the patients there was no effect of the treatment. In group II, 30% of patients showed mild effect of treatment while 70% of patients showed no effect of treatment.

Sr. No.	Assessment	Group I		Group II	
		No. of patients	%age	No. of patients	%age
1.	Highly Effective (76-100%)	0	0	0	0
2.	Moderately Effective (51-75%)	01	10	0	0
3.	Mildly Effective (26-50%)	03	30	03	30
4.	Not effective (0-25%)	06	60	07	70

Mode of action of the Drug

The trial drug tested in this study was well-known for its action on nervous system. Neurological and psychiatric functions in the body are seems to be governed by the *Vata Dosha* which is mainly responsible for motor as well as sensory activities carried out in the body, along with other functions. In Ayurveda *Tagara* has been described under *Vednasthapnagana*. *Vedna* is mainly due to *Vatadosha* hence, *Tagara* help in alleviation of *Vatadosha*. *Tagara* also possesses *Snigdha Guna* which is facilitated to control *Vatadosha*^[4]. So trial drug works by controlling *Vatadosha* which is one of chief factor in the pathogenesis of *Chittodvega*. *Tagara* possesses *Kashaya*, *Tikta* and *Katu Rasas* and possess *Snigdha Gun*^[5]. According to *Vagbhatta*, *kleidshoshana* property of *Tikta* and *Kashaya rasa* is helpful to reduce secretions in the body which is extremely needed during any surgical procedures to minimize the operative complications^[6]. Preoperative anxiety and tension increases the release of catecholamines from the adrenal medulla. A possible mechanism by which a valerian may act is increasing the amount of GABA, an inhibitory neurotransmitter available in synaptic cleft. Results from an in vitro study suggests that valerian extract may cause GABA to be released from brain nerve endings and then block GABA from being taken back into nerve cell^[7]. In addition, valerenic acid inhibits an enzyme that destroys GABA^[8]. Valerian extracts contain GABA in quantities sufficient to cause a sedative effect, but whether GABA can cross the blood-brain barrier to contribute to valerian's sedative effects is not known. Glutamine is present in aqueous but not in alcohol extracts and may cross the blood-brain barrier and be converted to GABA^[9]. Levels of these constituents vary significantly among plants depending on when the plants are harvested, resulting in marked variability in the amounts found in valerian preparations^[10]. Valerian extracts contain GABA in quantities sufficient to cause a sedative effect, but whether GABA can cross the blood-brain barrier to contribute to valerian's sedative effects is not known. Glutamine is present in aqueous but not in alcohol extracts and may cross the blood-brain barrier and be converted to GABA. Levels of these constituents vary significantly among plants depending on when the plants are harvested, resulting in marked variability in the amounts found in valerian preparations. The therapeutic properties of Diazepam are similar to other benzodiazepines and include anxiolytic, anticonvulsant, and muscle relaxant, hypnotic and amnesic properties. *Tagara* (valerian) is believed to work in ways similar but weaker than BZDs.

SUMMARY AND CONCLUSION

Effect of therapy in Trial group

Trial group showed statistically highly significant result ($p < 0.001$) on anxiety level (with 46.0% reduction), while it showed statistically significant result ($p < 0.05$ with 11.66% reduction) on sedation, respiratory rate (30.0% reduction) and on pulse rate (with 38.46% reduction). Trial drug showed no significant results on SBP and DBP with percentage reduction of 8.75 and 11.62 respectively.

Effect of therapy in Standard Group

Standard group showed statistically highly significant result on anxiety level ($p < 0.001$, with 59.09% reduction), while it showed statistically significant result on sedation ($p < 0.05$ with 11.66% reduction), pulse rate and respiratory rate with the percentage reduction of 8.97, 25% and 25% respectively. Standard drug showed non significant results on SBP and DBP with percentage reduction of 12.19 and 11.36 respectively.

Overall effect of the therapy

In Group 1, 10% of patients showed moderate effect while 30% of patients showed mild effect of therapy. In 60% of the patients there was no effect of the treatment. In Group 2, 30% of patients showed mild effect while 70% of patients showed no effect of therapy.

Hence it can be said that *Tagara* can be used as a premedication agent as Diazepam.

CONCLUSION

Anxiety is physiological and at times pathological entity also. The term *Chittodvega* can be correlated with anxiety. Preoperative anxiety is a clinical condition which requires pharmacological management apart from reassurance. Although the relief of anxiety was found better with Diazepam than the trial drug, but the trial drug also possesses significant anxiolytic properties, with significant reduction in pulse rate and respiratory rate. The drug did not produce any variant in blood pressure. No undesirable and adverse effects were observed. Therefore, *Tagara* the trial drug, is proven effective and safe premedication drug which can be used safely as a premedication agent before surgery particularly in those cases where patients are anxious and apprehensive.

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