AYUSHDHARA
ISSN: 2393-9583 (P)/ 2393-9591 (O)
An International Journal of Research in AYUSH and Allied Systems

Research Article

A CLINICAL EVALUATION OF *HARITAKI KASHAYA* AND *MADHU* AS *KAWALA* IN THE MANAGEMENT OF POST OPERATIVE SORE THROAT DUE TO TRACHEAL INTUBATION UNDER GENERAL ANAESTHESIA

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Article info

Article History:

Received: 29-03-2022

Revised: 14-04-2022

Accepted: 28-04-2022

KEYWORDS:

POST (Post Operative Sore Throat), Coughing, Difficulty in swallowing, Hoarseness of voice, VAS (Verbal Analog Scale), General Anaesthesia, Tracheal Intubation, *Haritaki Kashaya, Madhu, Kawala*.

ABSTRACT

A sore throat is pain or irritation in the throat. It is usually caused by acute pharyngitis (inflammation of the pharynx). Although it can also appear as a result of trauma, diphtheria or other conditions. Post Operative Sore Throat is a common complaint in patients undergoing general anaesthesia following orotracheal intubation, with reported incidence of 21-65%. POST ranks among the most frequent subjective complaint after tracheal intubation under general anaesthesia. Post operative sore throat, cough and hoarseness of voice though minor sequel, but they may cause significant post operative morbidity and patient dissatisfaction. Various pharmacological and non-pharmacological trials have been used for attenuating POST with no single proven modality in modern medicine. Keeping this in mind, a thorough study was planned to search out for an ideal Ayurvedic preparation for the management of Post Operative Sore Throat due to tracheal intubation under general anaesthesia. As *Haritaki* has anti-inflammatory and anti-septic properties and *Madhu* has anti-microbial and wound healing properties, A planned study was done on *"Haritaki Kashaya* and *Madhu* as *Kawala"* to evaluate its importance in treating post operative sore throat caused by tracheal intubation and the results were compared with the patients receiving normal saline gargles. Total effect of drug was evaluated on the basis of signs and symptoms relieved after completion of the trial. The data obtained in clinical study before and after the trial was expressed in terms of Mean, Standard Deviation (SD±) and Standard Error (SE±). Group-II (trial group) revealed better results than Group-I (control group) over total criteria of assessment. The trial drug was found to be efficient to relieve the symptoms like coughing, pain in throat and post operative sore throat in the patients who undergo orotracheal intubation after general anaesthesia.

INTRODUCTION

Tracheal intubation provokes a transitory irritation of laryngo-pharyngeal mucosa, resulting in undesirable effects at emergence and sore throat, dysphagia and dysphonia are reported in approximately 50% of cases. Injury to the tracheal mucosa either due to laryngoscope or high intra cuff pressure is thought to be the cause for these problems. The pain can vary from mild to severe and is extremely distressing to the patients.

After general anaesthesia with tracheal tube, the risk of developing a sore throat is estimated to be 1 in every 5 patients[1]. Some of the common causes which lead to the development of sore throat due to tracheal intubation under general anaesthesia include:

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https://doi.org/10.47070/ayushdhara.v9i2.932

1. **Trauma to the tonsillar fauces and pharynx:** Damage and inflammation of the pharynx (pharyngitis) and tonsillar fauces (tonsillitis) may be caused by the laryngoscope blades.
2. **Trauma to the larynx:** This is more likely if the tube has been forced through the vocal cords. A poorly stabilized tube causes more frictional damage to the larynx than one which is securely stabilized[2].
3. **Trauma to the pharynx[3]:** This usually occurs during passage of a nasogastric (NG) tube or insertion of an oropharyngeal airway and is particularly common when a throat pack has been used. Occasionally, the pharynx or upper esophagus may get perforated during insertion of a nasogastric tube or during difficult tracheal intubation and severe pain in the throat is often the first symptom. Sore throat is likely if a NG tube remains in situ during the post- operative period[4].
4. **Other factors:** The mucous membranes of the mouth, pharynx and upper airway are sensitive to the effects of unhumidified gases used during general anesthesia. The drying effects of anaesthetic gases may cause Post Operative Sore Throat (POST). The antisialogogue effect of anti-cholinergic drugs. (e.g. atropine, glycopyrrolate etc.) may also contribute to these symptoms.

   In Ayurvedic texts, various numbers of drugs and preparations have been mentioned under the section of for the above mentioned complaint.

   Therefore, a thorough and planned study was done on *"Haritaki Kashaya* and *Madhu* as *Kawala"* to search out for an ideal Ayurvedic preparation for the management of post operative sore throat due to tracheal intubation. *Haritaki* is *Tikta, Kashaya*, *Tridosha Hara* and *Vrana Ropaka. Madhu* is *Vrana Shodhak* and *Ropaka*. All these properties make them potential "*Vrana Ropka"* as being told in *Kantha Rog Chikitsa Prakarnam[5].*

Pharmacological Actions of *Haritaki* (Terminalia chebula)

Acharya Bhavprakash described *Haritaki* as first drug in *Bhaprakash Nighantu*. *Haritaki* has five *Rasa* (taste) i.e., *Madhur, Amla, Katu, Tikta* and *Kashaya*, its *Vipaka* (taste after digestion) is *Madhura* and *Veerya* (potency) is *Ushna* (hot). Due to these virtues the plant has various pharmacological actions such as *Rasayana* (rejuvenating), *Medhya* (brain tonic), *Deepana* (appetizer), *Aampachana* (digest toxins) and *Srotas Shodhana* (detoxifying).

Haritaki, if chewed leads to *Agnivardhana*, if took by *Peshana Karma* leads to *Malashodhana*, if we give *Swedana* procedure to *Haritaki* then it do *Sangrahana Karma* and if we do *Bhrushta Karma* it helps to maintain equilibrium state in body regarding *Vata*, *Pitta* and *Kapha*[6].

The fruit has anti-inflammatory, astringent, digestive, anti-helminthic, cardiotonic, aphrodisiac and restorative properties. Along with it, it has been found to have anti-pyretic, anti-septic, anti-emetic and expectorant action.

Pharmacological Actions of *Madhu*

The medicinal properties of honey have been known since ancient times. There are eight types of bee's honey mentioned in Ayurveda. Their actions differ and *Makshika* is considered medicinally the best. Honey has been used internally and externally since many ages. Honey has been useful in the treatment of *Tamaka Shwasa, Krimi, Arsha, Kshya Roga, Netra Roga, Trishna* etc. Application of *Madhu* is one among the *Shashti Upkrama* described by *Sushruta*, for *Vrana Ropana*. It has properties like *Lekhana* (scrapping), *Sandhana* (union), *Shodhana* (purification) and *Tridoshaghana* (pacifying all three *Doshas: Vata, Pitta* and *Kapha*)

Science has confirmed the efficacy of *Madhu* (honey) as an effective anti-microbial agent (inhibiting the growth of certain bacteria, yeast and moulds). Commenting on the recent interest in the medicinal value of honey, 'Honey has been found to reduce inflammation and promote the growth of healthy tissues'.

Method of Study

Atkins (1966) in his presidential address to the Royal College of Surgeons of England said that, "There are many paths which lead to the acquisition of clinical knowledge that might profitably be explored but there is only one high road to increase the therapeutic knowledge and that is the controlled clinical trial."

Selection Criteria

Inclusion Criteria for the Clinical Trial

a. Patients willing for the trial.
b. Patients of age group 18-40 years.
c. Patients undergoing surgical procedures under GA with tracheal intubation.
d. Patients fit for surgery.

Exclusion Criteria for the Clinical Trial

a. Patients not willing for the trial.
b. Patients not falling under ASA Grade-I and II.
c. Patients not fit for general anaesthesia.

This includes:

1. Any known allergies to the agents being used for general anaesthesia.
2. Patients at increased risk of pulmonary aspiration.
3. Patients with known/documented difficulties to tracheal intubation.

- Cervical spine pathology
- Patients unable to cooperate with airway assessment.
- Tumors, polyps or foreign bodies in the upper airway.
- *Mallampati* Grade IV.
- Thyromental distance less than 5cm.

After obtaining the approval of DRC and patient's informed consent, 40 patients of both sexes with narrow age and weight distribution scheduled for elective surgeries under general anaesthesia with tracheal intubation were enrolled in this study. There were no restrictions on recruiting the patients by type of surgery. Patients with a history of reaction to herbs, upper respiratory tract disease or gastro-esophageal reflux or regurgitation were excluded from this study. The relevant routine investigations which were essential prerequisite for the conduct of anaesthesia were got done.

All the screened and selected cases were divided randomly into two groups as Group-I and Group-II. Patients of Group-I were considered as Control Group and the patients of Group-II were considered as Trial Group.

Group-I (Control Group)- Total 20 patients were included in this group and they had normal saline gargles (80 ml) four times a day for 3 days.

Group-II (Trial Group)- Total 20 patients were included in this group and they had *Haritaki Kashaya* (80ml) and *Madhu* (5ml) as *Kawala* (gargles) four times a day for 3 days.

Assessment Criteria

Clinical assessment of this study consisted of evaluation of the drug as a '*Kawala*' in the management of Post Operative Sore Throat due to tracheal intubation based upon the following criteria:

Subjective Criteria: Pain on Verbal Analog Scale (VAS).

The patients with Post Operative Sore Throat (POST) were evaluated using a Verbal Analog Pain Scale (VAS) after extubation.

Scheme of Verbal Analog Scale (VAS) pain score

1- No pain
2- No pain, slightly strange*
3- No pain, strange
4- Slight pain
5- Pain (+)
6- Pain (++)
7- Pain (+++)

* When a patient did not complained of a sore throat but felt uncomfortable or unusual, it was defined as "strange."

The other assessment criteria included

- Age
- Sex

Total intubation time period (i.e., time duration between intubation and extubation)

No. of intubation attempts

Also, the patient's response to the trial drug was assessed based upon changes in the following criteria:

- Incidence of coughing.
- Hoarseness of voice.
- Difficulty in swallowing.

Post Operative Sore Throat (POST) was graded after extubation on a four point scale (0-3).

G_0- No sore throat
G_1- Mild sore throat
G_2- Moderate sore throat
G_3- Severe sore throat

Assessment of Result

Following recovery of anaesthesia, response of the preparation under trial was assessed based on the criteria mentioned above. Patients were asked to gargle the preparation four times a day and the effects were evaluated in relation to the patient group receiving the conventional treatment (saline gargle). The response to the preparation under trial was assessed based upon the improvement in the symptoms/signs as follows:

For no symptoms/signs- G_0
For mild symptoms/signs- G_1
For moderate symptoms/signs- G_2
For severe symptoms/signs- G_3

1- Cured: Patient was considered cured

Total remission of signs and symptoms observed at the time of inclusion to the trial.

Patient was able to do routine work without any problem (G_0)

2- Markedly improved: Patient was considered markedly improved

a. If the patient had 50% relief of signs and symptoms noted at the time of inclusion into the trial.

b. If patient had slight difficult in work. (G_1)

3- Improved: Patient was considered improved

If patient had a 30-50% relief in signs and symptoms.

If patient had more difficulty in doing routine work (G_2)

4- Unimproved: Patient was considered unimproved

a. If patient had no relief or had increase in signs and symptoms observed at the time of inclusion into the trial.

b. Unable to perform routine work (G_3).

OBSERVATIONS AND RESULTS

Incidence of Coughing

Group	Mean Score		% relief	SD±	SE±	't'	p
	BT	AT					
Group-I	1.1	0.25	77.27	0.489	0.109	7.768	<0.001
Group-II	1.5	0.35	76.66	0.587	0.131	8.759	<0.001

- In control group (Gr-I) 77.27% relief in the symptom of coughing was observed.
- In trial group (Gr-II) 76.66% relief was observed.

Hoarseness of Voice

Group	Mean Score		% relief	SD±	SE±	't'	p
	BT	AT					
Group-I	1.05	0.2	80.95	0.489	0.109	7.768	<0.001
Group-II	1.5	0.25	83.33	0.716	0.160	7.804	<0.001

- In control group (Gr-I) 80.95% relief was observed in the above symptom.
- In trial group (Gr-II) 83.33% relief was observed.

Difficulty in Swallowing

Group	Mean Score		% relief	SD±	SE±	't'	p
	BT	AT					
Group-I	1.25	0.4	68	0.587	0.131	6.474	<0.001
Group-II	1.35	0.2	85.18	0.587	0.131	8.759	<0.001

- In control group (Gr-I) 68% relief was reported.
- In trial group (Gr-II) 85.18% relief was observed in the above symptom.

Pain (VAS)

Group	Mean Score		% relief	SD±	SE±	't'	p
	BT	AT					
Group-I	4.1	1.45	64.63	1.182	0.264	10.025	<0.001
Group-II	4.45	2.1	52.80	1.309	0.293	8.029	<0.001

- In control trial (Gr-I) 64.63% relief was observed.
- In trial group (Gr-II) 52.80% relief was observed in the symptoms of pain.

Post Operative Sore Throat (POST)

Group	Mean Score		% relief	SD±	SE±	't'	p
	BT	AT					
Group-I	1.4	0.6	57.14	0.523	0.117	6.839	<0.001
Group-II	1.7	0.2	88.23	0.607	0.136	11.052	<0.001

- In control group (Gr-I) 57.14% relief was observed.
- In trial group (Gr-II) 88.23% relief was observed in the symptom of sore throat.

Overall result

In control group (Gr-I), 15% i.e. 3 patients were cured and 85% i.e. 17 patients showed marked improvement.

In trial group (Gr-II), 50% i.e. 10 patients were cured and 50% i.e. 10 patients showed marked improvement.

CONCLUSION

On the basis of observations made in both groups of patients we can conclude that:

1. The trial drug (*Haritaki Kashaya+Madhu)* as a *'Kawala'* shows marked improvement in relieving the symptom of Post Operative Sore Throat (POST).
2. The trial drug delivers improvement in relieving the symptoms of hoarseness of voice, difficulty in swallowing and coughing.
3. The Trial drug was effective in relieving the symptom of pain but was of not that much efficacy. Thus it can be concluded the *'Haritaki Kashaya + Madhu'* as a *'Kawala'* (gargle) is a better alternative in the management of Post Operative Sore Throat when compared to its modern counterpart.

However, this is a very preliminary study and requires more comprehensive observation and assessment to reach the final conclusion.

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Cite this article as:
Sneha Pal, Anil Dutt, Pradeep Awasthi. A Clinical Evaluation of Haritaki Kashaya and Madhu as Kawala in the Management of Post Operative Sore Throat due to Tracheal Intubation Under General Anaesthesia. AYUSHDHARA, 2022;9(2):85-89.
https://doi.org/10.47070/ayushdhara.v9i2.932
Source of support: Nil, Conflict of interest: None Declared

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