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Clinical Evaluation of *Khadira Kshaya* as *Kawala* in the management of POST (Post-operative sore throat) Due to Tracheal Intubation under General Anesthesia

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ABSTRACT

Introduction:- POST (post operative sore throat) is a common complaint in patients receiving General anesthesia following Orotracheal intubation, with reported incidences of 21-65 %. Sore throat ranks the most frequent subjective complaint under General anesthesia and is reported between 30% and 70% of patients after tracheal intubation. Though considered as a minor complication, but it may cause significant post operative morbidity and patient dissatisfaction. Various non pharmacological and pharmacological trials have been done for attenuating POST with no single proven modality in modern medicine. In Ayurvedic texts, various number of drugs and preparations have been mentioned under the section of "*Kantha Roga Chikitsa Prakaranam''* for the above complaint. Keeping all in mind, a thorough study was planned to search out for an ideal *Ayurvedic* preparation for the management of Post Operative Sore Throat (POST) due to tracheal intubation under General anesthesia. A planned study was done on "*Khadira Kshaya*" to evaluate its importance in treating sore throat caused by tracheal intubation. **Materials and methods:-** The plan of study was undertaken to evaluate the effect of an ayurvedic preparation consisting of '*Khadira Kshaya'* as '*Kawala*' and its potential for use on subjects suffering from **'**Sore throat' due to tracheal intubation under General anesthesia. In this study we undertook an investigation to find out whether gargling with the trial drug reduces the '*Post Operative Sore Throat' (POST*) after tracheal intubation. For this proposed work, 20 patients of both sexes with narrow age and weight distribution under ASA Grade-I were selected. The patients were randomly divided into two groups, Group-I and Group-II. Group-I was considered as Control Group and the patients of this group were given 'saline gargle' (80ml) post operatively for the management of sore throat. The Group-II patients were considered as Trial group and were provided with *Khadira Kshaya* (80ml) as a gargle for the post operative management of sore throat.After extubation, patients were assessed for sore throat along with incidence of coughing, hoarsness of voice, pain, difficulty

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in swallowing etc. and their response towards the trial was also evaluated. **Results:-** It was clearly observed that In Control Group (Gr.-I), 65.5% relief was observed and in Trial group (Gr.-II), 82.6% relief was observed.

KEYWORDS

POST (*post operative sore throat*), *Kantha roga*, *Khadira kshaya*

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INTRODUCTION

'Post Operative Sore Throat' (POST) though a minor complication, has been a matter of concern among the patients undergoing surgical procedures under General Anesthesia through endotracheal intubation with reported incidences of 30-70 %.[1] Hoarsness of voice, pain and difficulty in swallowing can be very distressing to the patient and may affect his satisfaction after surgery. Unfortunately, Endotracheal intubation is necessary for administering General Anesthesia in most of the surgeries and still no effective method has been discovered to protect the patient from the minor injuries caused due to intubation.[2] The conventional treatment proposed in modern perspective usually consists of a 'saline gargle' which does provide relief, but tends to be short lived as it does nothing to eradicate the cause of sore throat.[3] Also, if the saline preparation is overdone (i.e. making the gargle salty enough), it can even lead to a greater irritation of the throat[4].Keeping all this in mind, a thorough study was planned to search out for an ideal *Ayurvedic* preparation for the management of Post Operative Sore Throat (POST) due to Tracheal intubation under General Anesthesia. A planned study was done on *Khadira Kshaya* to evaluate its importance in treating sore throat caused by tracheal intubation. *Khadira* is *Tikta, Shita* and *Pittakapha Shamka*. All these properties make it potential "*Vrana Ropka*" as being told in *Raj Nighantu*, and various *Ayurvedic* texts[5]. So the main idea behind taking up the *Khadiradi Kshaya* as *Kavala* was to come up with safe, effective measure for the POST (post operative sore throat) due to its *Vrana Ropaka* property.

Objectives - The prime objective of the research is to study the efficacy of *Khadira Kshaya* in POST(Post operative sore throat).

MATERIAL AND METHODS

Ethical Committee Approval no. IEC/2015/1019

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[6]:-

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) immediately and 1st, 2nd and 3rd day after tracheal 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.
- Hoarsness of voice.
- Difficulty in swallowing.

Post operative Sore throat (POST) was graded at 0,1st,2nd and 3rd after extubation on a four point scale (0-3)[7].

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 anesthesia, response of the preparation under trial was assessed based on the criteria mentioned above. Patients were asked to gargle the preparation for four times a day. 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 :- Patients 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 -

- If the patient had 50% relief of signs and symptoms .
- If patient had slight difficulty 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 -

- If patient had no relief or had increase in signs and symptoms observed at the time of inclusion into the trial.
- Unable to perform routine work (G_3).

Drugs and Doses:-

Different time duration period for different forms of medicines have been mentioned by the ancient *Ayurvedic* Schools regarding the stability period of the preparations.

The texts of *Ayurveda* recommended for *'Aushadha'* and '*Ahara Kalpanas*' and their '*Saviryata avadhi'* (diet and medicinal formulae and their expiry dates i.e. the period for which they can retain potency) signify *Kawala* as *'Sadyosevana'* (to be used readily or within 24 hrs.).

So the preparation in the present trial was self made after proper identification of raw materials under the supervision of highly specialized faculty of *Rasashatra* and *Dravyaguna.*

After collection, the drug was cleansed, perfectly dried and then made into a coarse powder '(*Kasaya churna*)' with the help of a pestle and mortar.

One *'pala'* (=40gm) of coarsely powdered drug was then boiled with 8 parts of water in an open earthen pot over a medium fire till liquid was reduced to one fourth of the original quantity.

The whole preparation was carried out as per guidelines mentioned in *Sarangdhar Samhita.*

Drug Presentation:-

The drug was presented in the form of a '*Kawala*' (gargle) in a bottle containing 80ml *Khadira Kshaya*

Dose of the drug:-

80ml of *Khadira Kshaya*

Inclusion criteria[8]:-

- Patient willing for trial.
- All the patients undergone GA except patients fall in exclusion criteria.

Exclusion criteria for the clinical trial:

- Patients not willing for the trial.
- Patients not falling under ASA Grade-I
- Patients not fit for General Anesthesia. This includes:-

a)Any known allergies to the agents being used for General Anesthesia.

b)Patients at increased risk of pulmonary aspiration

c)Patients with known/documented difficulties to tracheal intubation.

d)Cervical spine pathology

e)Patients unable to cooperate with airway assessment.

f)Poor dentition.

g)Tumors, polyps or foreign bodies in the upper airway.

h)Mallampati Grade IV.

i)Thyromental distance less than 5 cm.

After obtaining the approval of DRC and patient's informed consent, 20 patients which were divided into two groups , scheduled for elective surgeries under General Anesthesia 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 anesthesia were got done.

After pre-medication with Atropine, pre-oxygenation was followed by induction of anesthesia with an intravenous anesthetic agent and then administration of a short acting muscle relaxant was done to facilitate endotracheal intubation, followed by maintenance of anesthesia and muscle relaxation through inhalational agents and neuromuscular blockers respectively.

After emergence from anesthesia, patients were tracheally extubated after neuromuscular reversal through gentle approach.

The patients with 'Post Operative Sore Throat' (POST) were counted and assessed using a Verbal Analog Scale (VAS) for pain score and also other symptoms assessed at 0, 1st, 2nd and 3rdday after the extubation.

Finally, the response of the patients to the drug in their respective groups was assessed and evaluated based upon the following symptoms.[9]

Incidence of coughing.

Hoarsness of voice.

Difficulty in swallowing.

Verbal Analog Scale (VAS).

The patients were assessed before treatment and after giving control and trial drugs at the interval of 0, 1, 2 and 3days after Entotraceal tubation.

OBSERVATION

The patients of ASA-Grade-I of either sex selected for the present study undergoing various surgical procedures with tracheal inhibition under General Anesthesia were randomly divided into Control and Trial Group, 10 patients in each group.

Age:- Overall distribution of patients in both groups was 25% (5 out of 20 patients) were in the age group of 16-20 yrs and 51-60 yrs, 15% (3 out of 20 patients) were in the age group of 21-30 yrs, 30% (6 out of 20 patients) were in the age group of 31-40 yrs and 5% (1 out of 20 patients) in the age group of 41-50yrs respectively.

Sex :-Overall percentage of male and female in both the groups was found to be 40% and 60%, respectively.

Time duration:-Overall 55% (11 out of 20 cases) were enrolled in both groups with time duration of 50-80 min, 35% (7 out of 20 cases) with time duration of 81-110 min and 10% (1 out of 20 case) with time duration of 110-140min .

Intubation attempts:-Distribution of patients based upon intubation attempts showed that 40% (4 patients) were intubated in the 1st attempt while 60% (6 patients) were intubated in the 2nd attempt of the Control group (Gr.-I), respectively. Similarly, 50% (5 patients) of the trial group (Gr.-II) were intubated in their 1st attempt whereas 50% (5 patients) got intubated in their 2nd attempt.

Sore throat complaint in patients at different time intervals: Assessment of 'Post-Operative Sore Throat' (POST) at different time intervals showed 100% (10 patients) with sore throat were taken just after extubation in Grp 1(Control group) . 100% (10 patients) had the same complaint after 1st and 2nd day. 80% (8 patients) reported sore throat after 3rd day of extubation. In Trial group (Gr.-II), immediately after extubation 100% (10 patients) with sore throat complaint were taken .100%(10 patients) had same complaint after 1st day , 90%(9 patients) had same complaint after 2nd day and 40%(4 patients) had same complaint after 3rd day.

Based on grading system:-Observation based upon grading system revealed that in present trial, maximum patients, 70% (14 out of 20) developed sore throat of Grade 3 nature, 40% (4 out of 20 patients) developed sore throat of Grade 2 nature, 10%(2 out of 20 patients) developed sore throat of Grade 1 nature .

RESULTS

Effect on incidence of coughing:-In Group-I (Control Group) mean score of incidence of coughing before treatment was 0.6 which was reduced to 0.1 after the treatment i.e. there was 83% relief in the Control group in the incidence of coughing with SD± of 0.52,SE± of 0.16. .It was statistically significant with p <0.05. In Group-II (Trial Group), mean score of incidence of coughing before treatment was 0.3 which reduced to 0.0 after treatment, giving a relief of 100% with SD± 0.483, SE± 0.153. It was not significant statistically with a 'p' value of 0.081 (p>0.05). Table no.1

Effect on hoarsness of voice:-In Control Group (Gr.-I) hoarsness gf of voice before treatment had a mean score of 0.4 which was reduced to 0.14 after the treatment giving a relief of 25% with SD± 0.66, SE±

0.211. It was significant statistically with value of 'P'= 0.001. In Trial group (Gr.-II) the mean score of hoarsness of voice before treatment was 1.2 which reduced to 0.0 after the treatment giving a relief of 100% with a SD± 0.789, SE ± 0.249. It was highly significant statistically with 'p' value < 0.001.Table no.2

Effect on difficulty in swallowing:-In Control Group (Gr.-I) mean score of 'Difficulty in swallowing' before treatment was 2.0 which reduced to 0.6 after treatment giving a relief of 70% with SD± 0.69, SE± 0.22. It was highly significant statistically with a 'p' value < 0.001. In Trial Group (Gr.-II), mean score of difficulty in swallowing before treatment was 1.4 which reduced to 0.1 after treatment giving a relief of 92.8% with SD± 0.675, SE± 0.213. It was highly significant statistically with a value of 'p' <0.001.Table no.3

Effect on VAS:-In Control Group(Gr.-I) mean score of pain based on Verbal Analog Scale (VAS) was 5.7 before treatment which reduced to 2.3 after the treatment giving a relief of 59.6% with SD± 0.966, SE± 0.306. It was highly significant statistically with value of 'p' < 0.001. In Trial group (Gr.-II) mean score of pain based on Verbal Analog Scale (VAS) was 5.4 before treatment and it reduced to 1.7 after the treatment giving a relief of 68.5% with SD± 0.675, SE± 0.213. It was highly significant statistically with value of p<0.001. Table no.4

Effect on POST:-In Control Group (Gr.-I) mean score of POST was 2.9 before treatment which reduced to 1.0 after treatment giving a relief of 65.5% with SD± 0.738, SE± 0.233. It was highly significant statistically with value of 'p'<0.001. In Trial group (Gr.-II) mean score of POST was 2.3 before treatment and it reduced to 0.4 after treatment giving a relief of 82.6% in the above symptom with SD± 0.568, SE± 0.180. It was highly significant statistically with value of p<0.001.Table no.5

DISCUSSION

1) Age wise distribution :The maximum incidence of sore throat (i.e. 50%) reported in the age group of 31-40yrs may be due to the fact that most healthy patients with strong immune system belonged to this group which resulted in strong and acute inflammatory response in form of 'sore throat' because of trauma during intubation.

2) Total Intubation Time Period (TITP): Maximum cases presented during the trial, 55% (11 out of 20 cases) were of duration 50-80min. Observation of sore throat in this distribution revealed no direct link with duration of the operation but chance of injury with long duration is likely to ocur as

it expose the mucosa for longer time ultimately leading to Sore throat.

3) Incidence of Coughing:

The treatment gave 83% relief in Control group and gave 100% relief in the Trial group. This relief can be attributed to the *Tikta, Shita, Pitta Kapha Shamaka* and *Vrana Ropaka* properties of *Khadira Kshaya* healing the trauma causing the cough and sooth the throat and prevent dryness of throat thereby avoiding the ruptured mucous membranes from irritation.

4) Hoarsness of Voice:

Hoarsness of voice before treatment had a mean score of 0.4 and 1.2 in Group-I and II, respectively which reduced to 0.14 and 0.0 after treatment giving a relief of 25% and 100% in Group-I and II, respectively. Group-II with the trial drug was found more effective in relieving the above symptom. This may be due to the 'anti inflammatory' action of *Khadira Kshaya* which reduces the bruising and swelling of vocal cord structures thereby improving the symptoms

8) Difficulty in Swallowing:

'Difficulty in Swallowing' before treatment had a mean score of 2.0 and 1.4 in Group I and Group –II respectively which was reduced to 0.6 and 0.1 giving a relief of 70% and 92.8% in Group–I and II, respectively. More relief in above symptom was observed in the Trial group. Healing properties of *Khadira* due *to Shita ,Tikta ,Kshaya Guna* help in relieving above symptom caused during tracheal tube intubation under GA.

6) Pain Score (VAS):

The reduction in pain was more in the Trial group giving a relief of 68.5% as compared to the control group with 59.6% relief in pain. *Khadira* predominantly is 'Pitta Kapha Shamaka' . Pain specifically occurs due to injury during intubation. *Khadir*a due to its *Shita, Tikta* and *Kshaya* properties heal the wound ultimately causing a relief in pain.

7) Post-Operative Sore Throat (POST) :

POST before treatment had a mean score of 2.9 and 2.3 in Group-I and II, respectively which came down to 1.0 and 0.4 after the trial, giving a relief of 65.5% and 82.6% in Group-I and II respectively. The effect of relief was more predominant in the Trial group which may be attributed to the 'anti inflammatory, purifying and healing capacity' of *Khadira Kshaya* thus providing relief in the symptoms of sore throat. *Khadira*, by virtue of its *Sita guna, Kashaya* and *Tikta rasa* acts as a '*Tridoshaghana*' predominately *Pitta Kapha Shamaka* with dominating above all thereby relieving the symptoms of sore throat.

CONCLUSION

On the basis of observation made we can conclude that[14]:

The Trial drug *Khadira Kshaya as a 'kawala'* shows marked improvement in relieving the symptom of Post Operative Sore Throat (POST).

The Trial drug delivers improvement in relieving the symptoms of pain, hoarsness of voice and difficulty in swallowing.

The Trial drug was effective in improving the symptom of coughing.

Thus it can be concluded the *'Khadira Kashaya' 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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