RESEARCH ARTICLE

The Effect of Single Dose of Harpagophytum Capsule (Teltonal) on Post Tracheal Intubation Sore Throat after General Anesthesia

Hassan Mohammadi Poor Anvari[1], Jafar Rahimi Panahi[1], Maarouf Ansari[2]*, Masoumeh Iraji[3], Nasser Ghorbanian[2], Abbasali Dehghani[1]

Background: Sore throat is one of the major complications of tracheal intubation after general anesthesia. Harpagophytum is an herbal medicine, the anti-inflammatory and analgesic effects of which have been demonstrated in various studies. We studied the effects of single dose Harpagophytum one hour before tracheal intubation, to prevent the sore throat after extubation.

Methods: In a randomized clinical trial, 60 patients who had undergone general and urologic surgeries at Imam Reza hospital in Tabriz, Iran, since March to July 2015 that required tracheal intubation, were included in the study. The patients were randomly divided into two groups (case group 30 patients and control group 30 patients). In the case group, one hour before anesthesia, one Teltonal capsule (480 mg) was given to the patients. For the control group of patients, the empty capsule of Teltonal was given. After patients regained consciousness, the severity of sore throat was scaled and recorded by VAS scale after 2, 6 and 24 hours of the surgery.

Results: Severity and incidence of sore throat after tracheal intubation were not significantly different between case and control groups. Also, no side effects of Harpagophytum were observed in the case group.

Conclusion: Administration of Harpagophytum with the single dose of 480 mg one hour before the anesthesia and intubation did not decrease the sore throat severity and incidence.

Keywords: harpagophytum; tracheal intubation; sore throat

Endotracheal intubation during general anesthesia is done in order to achieve two major objectives: first, creating safety airway and second, prevention of aspiration during surgery.

Endotracheal intubation is performed in various ways, including intubation through the mouth and nasal intubation, as well as the use of laryngeal mask. Endotracheal intubation using direct laryngoscopy is done through the mouth, except in special circumstances such as surgery or a need for an endotracheal tube in the mouth for a long time [1]. Postoperative sore throat is a common and unpleasant complication in patients who undergo surgery with general anesthesia with endotracheal intubation or laryngeal mask. Postoperative sore throat has been reported to be 14/4% - 57% in patients who had endotracheal intubation and 3/5%-34% in patients with laryngeal mask [2-4]. Several factors are involved in causing the complication including age over 60 years, use of a pharyngeal pack, appropriate size of endotracheal tubes, high pressure of the laryngeal masks and endotracheal tube cuff, duration of surgery, the patient's position during surgery and the degree of difficulty of intubation. These factors cause airway irritation and inflammation and pain [3-5]. However, the pain in some patients is so severe that it results in the patient's discomfort. The different drug and Non-drug preventative methods are recommended to reduce the incidence and severity of pain and improve the quality of post-operative care [3-4, 6]. Non-drug approaches include: the use of small endotracheal tube, lubricating endotracheal tube with a lubricant that is insoluble in water, and careful techniques of suction of patient's throat and extubation when the tracheal tube cuff is completely empty [6]. Drug preventative methods include the use of magnesium tablets, benzydamine hydrochloride spray, 10% and 2% lidocaine spray on the endotracheal tube cuff, the use of lidocaine 2% gel, and the use of inhaled beclomethasone and dexamethasone [2-3, 6-7]. Given the prevalence of this complication it seems that extensive research needs to be done. The use of certain drugs in the postoperative period may cause undesirable side effects. For example, nonsteroidal anti-inflammatory drug (NSAID) has such side effects as platelet dysfunction, stress ulcer, etc. The routine use of them has not dealt well in controlling sore

From the [1]Department of Anesthesiology, School of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran.
[2]Department of Anesthesiology, Faculty of Paramedical, Tabriz University of Medical Sciences, Tabriz, Iran.
[3]Medical Student, School of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran.
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The authors declare no conflicts of interest.
*Corresponding author: Maarouf Ansari, MSc, Department of Anesthesiology, Faculty of Medicine and Paramedicine, Tabriz University of Medical Sciences, Tabriz, Iran. E-mail: marof.ansari@gmail.com

throat. The use of a variety of analgesics seems acceptable for which there aren't any side effects. The use of a variety of analgesics is useful that have not these complications [8]. Perhaps the use of herbal anti-inflammatory is useful which has properties similar to COX 2 inhibitor. Harpagophytum or Devil's claw currently available with the name Teltonal has good anti-inflammatory effects, but doesn't have complications of nonsteroidal anti-inflammatory drugs [9]. In the long - term use of Harpagophytum the complications that have been reported include headache, loss of appetite, allergic reactions, nausea and vomiting, diarrhea, and tinnitus [10]. In a systematic study by J.E.Chrubasik et al, strong anti-inflammatory effects of Harpagophytum have been reported in osteoarthritis. This drug is made from Harpagophytum Procumbent roots and has no gastrointestinal side effects [11]. Several studies have shown low toxicity and side effects of the drug in moderate doses [9]. In another study Dider Leblan and colleagues have reported NSAID-like anti-inflammatory effects of this herb [12].

As one of the components of sore throat after tracheal intubation is an inflammatory component, we decided in a comparative study to investigate the effect of a single dose Teltonal with placebo to reduce postoperative pain throat. Due to the fact that no study with this drug on postoperative sore throat is performed, this study could be valuable.

Methods

In a randomized double-blind clinical trial, 60 patients who were scheduled to undergo general surgery and urological surgery with general anesthesia and tracheal intubation at Imam Reza Hospital, Tabriz, Iran from March 2015 to July 2015 were included in the study. After ethics committee approval of all the patients' written consent to the use of Harpagophytum, this drug was used to control postoperative sore throat. The patients were trained on the measurement of pain to manner visual analog scale (VAS). All were divided into two groups with simple random sampling. Group A received one capsule Harpagophytum (Teltonal 480 mg capsule) with 50 ml of water one hour before anesthesia and intubation, and group B received placebo instead of Teltonal capsule 480 mg. The patients in both groups had similar premedication with fentanyl (1µg/kg) and midazolam (0.02 mg/kg), and were similarly inducted with propofol (2-2.5 mg/kg), atracurium (0.5 mg/kg). The patients were slowly intubated with cuffed oral endotracheal tube with a diameter of 7-8 mm by an anesthesiologist. Anesthesia was continued with a continuous infusion of propofol 100 µg/kg/min, and remifentanil 0.0625-0.25 µg/kg/min. After completion of the operation the patient's throat was gently suctioned, and then endotracheal tube was extubated after deflation of cuff. The postoperative analgesic regimen was similarly chosen in the ward. The patients' sore throats were recorded after awareness of patients by one medical student who was unaware of the group of patients, 2-6 and 24 hours after surgery, and data were collected by questionnaires. In order to study qualitative variables X2, and quantitative variables t- test were employed. For data analysis, SPSS version 15 was used. If P=0.05 or less then it was considered statistically significant. Data obtained from the study by descriptive statistics (frequency-percentage - Mean and standard deviation) were analyzed and the mean difference test for independent groups was employed. For normality of distribution of data Kolmogorov-Smirnov test and Q-Q charts was used.

Results

60 patients were included in this study. Among them, 29 patients (48.3%) were males and 31 (51.7%) were female. The gender of patients in the group A and B was 17 males and 13 females and 12 males and 18 females, respectively. The minimum and maximum age of the patients in the groups A and B was 20 years and 64 years. Information (demographic) related to the patients' general characteristics are presented in (Table 1).

The patients in the groups A and B were ASA of physical status classification I and II, no statistically significant difference was found between the physical conditions (P=0.17).

Prevalence of postoperative sore throat in patients of both groups was measured by a medical student and using a VAS in the hours of 2-6 - 24 postoperative (after surgery). There was no statistically significant difference in prevalence of pain at different times after surgery (Table 2).

Prevalence of postoperative sore throat severity and pain intensity according to VAS was measured in the hours of 2-6-24 postoperative (after surgery) and was recorded There was no statistically significant difference in pain severity average at different times after surgery (Table 3).

Table 1- Demographic characteristics of patients in both groups

Parameters	Group A	Group B	P values
Patients (number)	30	30	
Female (number)	13	18	
Male (number)	17	12	
Mean age (years)	35.5±12.2	42.4±12.8	P=0.3

Table 2- Prevalence of sore throat among patients in both groups

Time (Hours)	patients in Group A(number)	patients in Group B(number)	P values
2	23	17	P=0.1
6	19	15	P=0.19
24	4	6	P=0.45

Table 3- Prevalence of postoperative sore throat severity and pain intensity in both groups

Time	Pain in group A					Pain in Group B					P value
hour	Without	mild	moderate	acute	severity average	Without	mild	moderate	acute	severity average	
2	7	6	13	4	3.9±2.9	13	2	9	5	3.2±3.3	P=0.41
6	11	16	3	1	1.7±1.8	15	9	4	1	1.5±2	P=0.59
24	26	4	0	0	0.5±1.7	24	3	1	2	0.7±1.6	P=0.67

Discussion

The present study assessed preventive effect of a single dose of Harpagophytum on the sore throat at two, six and twenty-four hours after intubation, and the results obtained from the two groups who had received single dose of Harpagophytum (experimental group) and placebo (control group) were compared. In our study, the frequency of sore throat in two, six and twenty-four hours after intubation had no significant difference between the two groups. The severity of sore throat was not significantly different in two, six and twenty-four hours after intubation in two groups, and no adverse effects were observed in this study related to Harpagophytum.

Few studies have been done on the analgesic effect of preoperative single dose of Harpagophytum. In another study by Lim and colleagues on mice, analgesic effects of Harpagophytum were assessed after plantar incision on spared nerve damage using mechanical withdrawal threshold. In the acute phase after incision, Harpagophytum was able to significantly reduce pain criteria. Also, after 21 days of continuous treatment, the drug reduced chronic neuropathic pain significantly [13]. Several studies have shown the effects of various drugs on the sore throat after general anesthesia and intubation. However, no study has yet investigated the effects of Harpagophytum on the sore throat.

Another study by Canbay and colleagues on 46 patients who were scheduled for septorhinoplasty showed that ketamine gargle with a dose of 40 mg, 5 minutes before induction of anesthesia, reduce the frequency and severity of postoperative sore throat significantly. However, in this study, ketamine failed at all times up to 24 hours after surgery to reduce the frequency and severity of sore throat. In our study, unlike this research the intensity of sore throat did not decrease with the use of Harpagophytum [14]. In a review study that was conducted by Lam and colleagues on nineteen trails which the intra cuff lidocaine versus air or saline was compared in patients receiving endotracheal tube intubation general anesthesia. Investigating the outcome of 1566 patients, it found that the use of both alkalinized and non-alkalinized lidocaine tube can significantly decrease sore throat (post), coughing, hoarseness, agitation and dysphonia [15]. But in our study the use of single-dose Harpagophytum could not reduce sore throat after intubation. Klemola and colleagues' study on 94 patients showed that the comparison between lidocaine spray and gel, alone and in combination on postoperative sore throat, increased sore throat and hoarseness in patients [16]. In placebo-controlled clinical trial conducted by Thang and colleagues on 42 patients undergoing laparoscopy, single dose of intravenous diclofenac was studied in the prevention of sore throat after extubation. There was no significant difference between the intervention and control groups after 2, 6, and 18 hours [17]. In our study the highest incidence of throat pain was 76.7% in the intervention group and 56.7% in the control group 2 hours after surgery.

The lowest incidence of throat pain was 13.3% in the intervention group and 20% in the control group 24 hours after surgery. Zhao and colleagues in a systematic review and meta-analysis study on 480 patients, showed that prophylactic use of intravenous dexamethasone before surgery reduces the sore throat significantly 1 hour and 24 hours after extubation. This method could also reduce hoarseness 1 hour after extubation, but was not successful 24 hours after extubation [18]. A study done by Safavi et al. showed to reduce the frequency and severity of sore throat, at all times up to 24 hours after surgery, simultaneous use of ketamine gargle with intravenous dexamethasone is more effective than using any of these drugs alone. The use of these two drugs together (gargling of ketamine and intravenous dexamethasone) reduces the frequency and severity of hoarseness at all times up to 24 hours after extubation rather than the use of saline [19]. Ansari and colleagues' study showed that dexamethasone and magnesium sulfate into inside the endotracheal tube cuff has no significant effect on decreasing incidence of sore throat after tracheal intubation, but found that the severity of sore throat is significantly less after receiving the endotracheal tube cuff dexamethasone compared to control group and the group receiving magnesium sulfate into the endotracheal tube cuff in the morning after surgery. They have suggested that if these results with larger population was confirmed, injection of dexamethasone into the endotracheal tube cuff can be used as an effective way to reduce the severity of sore throat after intubation. Thus, it can be used as an alternative manner to intravenous administration of dexamethasone in patients who do not receive IV corticosteroids [20]. Maruyama and colleagues' study revealed that the use of oral clonidine does not decrease sore throat after intubation immediately and one day after surgery [21].

Conclusion

The results of this study show that a single dose of 480 mg Harpagophytum an hour before anesthesia and intubation did not decrease the severity and incidence of sore throat after extubation in the intervention group in comparison with the control group, also in our study any adverse effects of Harpagophytum was not observed.

Suggestions

According to various studies and long-term administration of Harpagophytum in the prevention of inflammatory and noninflammatory pain, and the minimal side effects of this

drug compared with other drugs used to prevent sore throat, the effects of this drug in long-term administration can be evaluated. This study can also be used in a larger population in order to evaluate the effect of Harpagophytum on sore throat after tracheal intubation.

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