Effectiveness of Lubrication of Endotracheal Tube Cuff with Chamomile-Extract for Prevention of Postoperative Sore Throat and Hoarseness

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Purpose of the study : *To determine the efficacy of lubrication of the endotracheal tube cuff with Chamomile extract (Kamillosan®M) before intubation on postoperative sore throat and hoarseness.*
Material and Method : *The authors randomly assigned 161 patients ASA (American Society of Anesthesiologists) physical status I, II elective surgical, orthopedic, gynecological or urological into 2 groups. The study group received 10 puffs of total 370 mg of Chamomile extract (Kamillosan®M spray) lubricated at cuff of endotracheal tube while the control group did not receive any lubrication before intubation. Standard general anesthesia with tracheal intubation was given in both groups. Sore throat and hoarseness were recorded in post anesthetic care unit and at 24 h after operation.*
Results : *One hundred and sixty-one ASA physical status I, II elective surgical patients were recruited. Forty one out of 81 patients (50.6%) in the Chamomile group, scored no postoperative sore throat in the post-anesthesia care unit compared with 45 out of 80 patients (56.3%) in the control group p=0.386. Postoperative sore throat and hoarseness both in the postanesthesia care unit and at 24 h postoperation were not statistically different. There was no statistically significant relationship between sore throat or hoarseness and postoperative nausea or vomiting, ASA physical status, gender, history of smoking, grade of laryngoscopic view, number of intubation attempts, condition during intubation, use of oral airway and couching during extubation.*
Conclusion : *Lubrication of endotracheal tube cuff with Chamomile extract spray before intubation can not prevent post operative sore throat and hoarseness.*

Keywords : *Sore throat, Hoarseness, Chamomile, Lubrication, Tracheal intubation*

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Healthcare quality can be improved by eliciting patient preference and customizing cares to meet the needs of patients under safety. Sore throat is one of the most common postoperative complaints, the incidence of sore throat varies from 14.4% to 90 percent [1-8]. The highest incidence of sore throat and other airway related symptoms tends to occur in patients who have undergone tracheal intubation. The wide variation in these incidences is presumably due to different skills and techniques among anesthesiologists and differences between individual anesthesiologists and patients in the definition of a sore throat. It is well recognized that the method of questioning is an important determinant of the incidence of a sore throat [2]. After indirect questioning of 129 patients, only two complained of a sore throat, whereas after direct questioning of 113 patients, 28 complained of a sore throat [2]. This difference may be due to the fact that patients concentrate on symptoms directly related to the operative site and do not immediately associate a sore throat with anesthesia and surgery. The mechanism of postoperative sore throat after tracheal intubation is thought to be due to trauma of the airway mucosa [9]. Methods to avoid this airway symptoms have been sought.

Topical local anesthetic to the respiratory passage has been used to reduce the intensity of the tracheal reflex and cough following intubation [10]. There seems, on the other hand, to be general agreement that local anesthetic solutions, either instilled or sprayed into the larynx, have no adventageous effect on the incidence of sore throat [3,10,11]. The benefit of topical 1 percent hydrocortisone ointment as a specific anti-

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inflammatory agent for the prevention of post-operative sore throat has been suggested [12]. Beclomethasone inhaler, another glucocorticoid anti-inflammatory agent, has also been shown to be effective in prevention of post-operative sore throat [13]. Chamomile, an anti-inflammatory natural extract is commonly used for sore throat and respiratory symptoms. The active anti-inflammatory properties of chamomile together with the anti-bacterial effect of the essential oils are commercially prepared in the form of Kamillosan®M spray (ASTA Medica AG, Frankfurt, Germany). This randomized double-blind control study was performed to assess the effectiveness of lubrication of endctracheal tube cuff with Chamomile spray on the incidence of sore throat and hoarseness after tracheal intubation for general anesthesia.

Table 1. Grading of condition during intubation

Grade	Condition during intubation
1 = Excellent	Visualization of larynx easy, vocal cords relaxed and open, easy passage of the endotracheal tube without bucking or coughing.
2 = Good	Visualization of larynx easy, vocal cords relaxed and open, easy passage of the endotracheal tube with mild bucking or coughing.
3 = Poor	Visualization of larynx difficult, vocal cord moving, reaction of vocal cords on intubation with moderate bucking or coughing.
4 = Not possible	Visualization of larynx difficult, vocal cords closed, intubation possible.

Method

After the study protocol had been approved by the institutional ethics committee, informed consent was obtained from 161 patients aged between 15 and 65 years. The ASA physical status I, II, patients undergoing elective general, surgical, orthopedic, gynecological or urological procedures were recruited. Patients who had head and neck surgery or had preoperative upper respiratory tract infection within 7 days, or those in whom a nasogastric tube or esophageal stethoscope would be passed and those who had anticipated difficult intubation were excluded from the study. The study patients were randomly allocated by random number table into 2 groups: group I, endotracheal tube cuff was lubricated with 10 puffs of total 370 mg of Chamomile extract (Kamillosan®M spray) spray and group II, endotracheal tube cuff was not lubricated before intubation. The allocated number was kept in concealed envelopes. All patients were anesthetised by staff anesthesiologists or residents with more than 6 months experience. Fentanyl 1 $\mu g.kg^{-1}$ was given intravenously before induction. Anesthesia was induced 3 min later with a dose of propofol 2 $mg.kg^{-1}$ followed by vecuronium bromide 1 $mg.kg^{-1}$ to facilitate endotracheal intubation. Standard Mallinckrodt tubes, size 8.5 mm inner diameter for males and 7.5 mm inner diameter for females were used, unless the anesthesiologist judged that the trachea was too small and required a smaller tube. The cuff was inflated until cuff pressure was 25 mm.Hg. Plastic oral airway was used according to the attending anesthesiologist and was also recorded. Anesthesia was then continued with N_2O, O_2, isoflurane or balanced anesthesia with morphine or pethidine. Before extubation, atropine 0.02 $mg.kg^{-1}$ and neostigmine 0.05 $mg.kg^{-1}$ were given intravenously to reverse the muscle relaxant effect. The anesthesiologists completed the questionnaire to allow comparison between the groups regarding ASA physical status, history of smoking, grade of laryngoscopic view, frequency of attempts at endotracheal intubation, duration of intubation, grade of condition during intubation as shown in Table 1, use of oral airway and condition during extubation (1=no coughing, 2=mild coughing, 3=moderate coughing, 4=severe coughing). All patients were interviewed in the post-anesthesia care unit by trained nurse anesthetists and at 24 hours postoperatively by the residents who were unaware of the study drugs used. Standardized questionnaire was employed to help control observer bias. Sore throat was grade on a 0-3 scale: 0=none, 1=less severe than with a cold, 2= similar to that noted with a cold, 3=more severe than with a cold. Hoarseness was graded on 0-3 scale: 0=none, 1=noted by patient, 2=obvious to observer, 3=aphonia. Postoperative nausea or vomiting was also recorded.

Power analysis was performed to determine the size of the treatment groups, on the basis of previous clinical observations that 50 per cent of the presented patients had postoperative sore throat. Allowing for probability of a type I error of 0.05, type II error of 0.1 and assuming a reduction in the incidence of sore throat by half to be clinically important, a sample size of 80 in each group was calculated as being required. Statistical analysis was performed by using SPSS program version 11. Comparison of continuous, categorical and ordinal data between groups were analysed by student's t-test, chi-square test and Mann-Whitney U test respectively. P value less than 0.05 was considered significant.

Results

One hundred and sixty one patients were

recruited into the study. There was no significant difference between the groups regarding age, weight, sex, ASA physical status and smoking habit as shown in Table 2. Duration of anesthesia, duration of intubation, intubating condition, number of attempts of intubation, extubating condition, use of oral airway were comparable between the groups as shown in Table 3.

The number of patients with no postoperative sore throat in the chamomile group and control group were not significantly different: 45(56.3%) vs 41(50.6%), p=0.386. Post operative sore throat, hoarseness, nausea or vomiting in the post-anesthesia care unit and at 24 h postoperatively were not different between groups as shown in Table 4. There was no statistically significant relationship between sore throat, hoarseness and ASA physical status, gender, history of smoking, grade of laryngoscopic view, frequency of attempts of endotracheal intubation, condition during intubation, use of oral airway, condition during extubation post-operative nausea or vomiting both in the post-anesthesia care unit and at 24 hour after operation.

Table 2. Patients' characteristics

	Group 1 Chamomile n = 81	Group 2 Control n = 80
Age (yr)	41.9 (12.7)	45.0 (12.2)
Weight (kg)	56.9 (8.3)	56.0 (11.1)
Sex F : M	58 : 23	60 : 20
ASA physical status I : II	60 : 21	56 : 24
Cigarette smokers (%)	17.0 (21.0%)	17.0 (21.3%)

Values are expressed as mean (SD) and number of patients (%)

Discussion

Sore throat is a common complication after surgery. It affects patient satisfaction and can affect the patient's activities after leaving hospital [14-16]. In the present study, the authors attempted to compare the incidence and severity of postoperative sore throat and hoarseness following endotracheal intubation under clinical routine conditions. Data on the incidence of laryngopharyngeal complaints vary extensively in the literature and in analyzing the data it must be considered that the variety of results may have been affected by the interview method used to collect the data. It

Table 3. Peri-operative data

	Group 1 (Chamomile)	Group 2 (Control)	P-value
Laryngoscopic view grade 1 : 2 : 3	72 : 7 : 2	72 : 8 : 0	0.528
Number of attempts of intubation 1 : 2	78 : 3	76 : 4	0.987
Condition of intubation excellent : good : poor	67 : 13 : 1	66 : 13 : 1	0.972
Duration of intubation (sec)	22.0 (7.1)	23.3 (8.4)	0.290
Use of oral airway (%)	24 (29.6%)	24 (30.0%)	1.000
Coughing during extubation no : mild : moderate : servere	35 : 35 : 9 : 2	45 : 28 : 6: 1	0.097
Duration of anesthesia (min)	109.9 (41.4)	102.9 (34.5)	0.249

Table 4. Post-operative sore throat, hoarseness and PONV

Score			
At PACU			
Sore throat score 0 : 1 : 2 : 3	45 / 20 / 7 / 8	41 / 19 / 12 / 9	0.386
Percent of patients with no sore throat	56.3	50.6	
Hoarseness score 0 : 1 : 2 : 3	29 / 20 / 31 / 1	36 / 20 / 24 / 0	0.150
Percent of patients with no hoarseness	35.8	45.0	
PONV (%)	22 (27.2%)	16 (20.0%)	0.286
At 24 hr after operation			
Sore throat score 0 : 1 : 2 : 3	42 / 30 / 9 / 0	48 / 24 / 6 / 2	0.548
Percent of patients with no sore throat	51.9	60.0	
Hoarseness score 0 : 1 : 2 : 3	50 / 16 / 14 / 1	42 / 23 / 15 / 0	0.513
Percent of patients with no hoarseness	61.7	52.5	
PONV (%)	26 (32.5%)	21 (26.3%)	0.416

PACU = postanesthetic care, PONV = post-operative nausea and vomiting
Values are expressed as number of patients (%)

has been shown that direct questioning results in a significantly higher incidence of sore throat than indirect questioning [2]. In the present study a standardized questionaire with direct questions was used, the data were obtained by independent observers who were not informed about the group of patients and standardised anesthetic technique was performed.

It has been clearly demonstrated that the use of a smaller tracheal tube reduces the incidence of sore throat, presumably because of decreased pressure at the tube mucosal interface [6]. Therefore, the authors chose an endotracheal tube of 8.5 mm internal diameter for men and 7.5 mm internal diameter for women to be intubated in the present study. A study of blood flow in rabbit tracheal mucosa demonstrated that when the endotracheal tube cuff was inflated to high pressure, the mucosa in contact with the cuff became ischemic [17]. In the present study the authors inflated the initial intracuff pressure to 25 cmH_2O according to the recommendation that intracuff pressure should be maintained at <20mmHg (26 cmH_2O) [6].

Topical glucocorticoid anti-inflammatory agents have previously been used to present post-operative sore throat. Hamelberg et al studied the effect of applying lidocaine ointment that contained 1 percent hydrocortisone to red rubber tubes before intubation [18]. He reported an insignificant decrease in the incidence of sore throat from 35 percent to 26 percent. He relied on symptoms related to intubation which were volunteered by the patients [18]. Details of the anesthetic technique and agent in the present study were not shown. Valentine et al found that a higher incidence of sore throat was associated with the use of anticholinergic premedication compared with oral temazepam 1 hour before operation (67% vs 19%) [19]. Monroe et al found that the incidence of sore throat was higher when blood was noted on the airway instruments as evidence of pharyngeal trauma compared when it was not (64.5% vs 30.9%) [20]. Capan et al have demonstrated that a sore throat is more frequent after the use of suxamethonium (86% vs 10%) [21]. However, the number of patients in Capan's study was small n=20-22 and the method of questioning patients was not standardized; therefore these data are inconclusive. In 1990, Stride used the same method as Hamelberg, together with standardized anesthesia without suxamethonium and a direct questioning technique. He found that hydrocortisone ointment was ineffective in the prevention of sore throat [7]. However, Hakkim showed that 90 percent of patients who received beclomethasone inhaler scored no postoperative sore throat compared with 45 percent in the lidocaine spray group [22]. There is a general agreement that local anesthetic agents, either applied or sprayed into the larynx, have no clear benefit in the prevention of sore throat [23-26]. Many other factors including types, duration of surgery, the use of lubricants, movement of head during surgery, straining on the tracheal tube and prone position have been implicated [24].

In the present study, the patients' characteristics, smoking habit, intubating conditions, use of oral airway, incidence of coughing during extubation and duration of anesthesia were comparable between the groups. The result of the present study indicated that tracheal tube cuff lubrication with Chamomile 10 puffs spray before intubation provided no advantage. In terms of postoperative sore throat and hoarseness, there was also no statistically significant relationship between sore throat or hoarseness both at post aneshtesia care unit and at 24 hr after operation and ASA physical status, gender, history of smoking, grade of laryngoscopic view, frequency of attempts at intubation, condition during intubation, use of oral airway, and coughing during extubation. This confirms the finding of the authors' recent study that Chamomile spray over the laryngeal outlet could not prevent post-operative sore throat or hoarreness [26]. Although in this study, the authors increased the dose of chamomile to 10 puffs (370 mg) which was considered a much higher dose than a previous study, the incidence of sore throat was 43.7% compared with 47.3% in previous study.

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ประสิทธิภาพของการหล่อลื่นถุงลมของท่อหายใจด้วยสารคาร์โมไมล์สกัดสำหรับการป้องกันอาการเจ็บคอและเสียงแหบภายหลังการผ่าตัด

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วัตถุประสงค์ *: เพื่อศึกษาผลของการหล่อลื่นถุงลมของท่อหายใจด้วยสารคาร์โมไมล์สกัดก่อนใส่ท่อหายใจที่มีต่อการเกิดอาการเจ็บคอและเสียงแหบก่อนการผ่าตัด*

วิธีการศึกษา *: แบ่งผู้ป่วย 161 ราย ที่มี ASA physical status I, II ที่มาผ่าตัดแบบไม่ฉุกเฉินในแผนกศัลยกรรม ศัลยกรรมกระดูก นรีเวช หรือ ผ่าตัดศัลยกรรมระบบทางเดินปัสสาวะออกเป็น 2 กลุ่ม กลุ่มที่ทำการศึกษาจะได้รับการพ่น 370 มก. ของสารสกัดคาร์โมไมล์ (พ่น 10 ครั้ง) ที่บริเวณถุงลมของท่อหายใจ สำหรับกลุ่มควบคุมไม่ได้รับการหล่อลื่นบริเวณถุงลมด้วยสารใด ๆ ทำการให้ยาระงับความรู้สึกแบบทั้งตัวด้วยวิธีมาตรฐาน แล้วทำการประเมินอาการเจ็บคอ และเสียงแหบที่ห้องพักฟื้น และที่ 24 ชั่วโมงหลังการผ่าตัด*

ผลการศึกษา *: ผู้ป่วย 41 ใน 81 ราย (50.6%) ในกลุ่มคาร์โมไมล์ และ 45 ใน 80 ราย (56.3%) ในกลุ่มควบคุมไม่มีอาการเจ็บคอที่ห้องพักฟื้น (p = 0.386) ที่ 24 ชั่วโมงหลังการผ่าตัดอาการเจ็บคอ และเสียงแหบไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ไม่พบความสัมพันธ์อย่างมีนัยสำคัญทางสถิติระหว่างอาการเจ็บคอ หรือเสียงแหบกับภาวะคลื่นไส้ หรืออาเจียน, ASA physical status, เพศ, ประวัติการสูบบุหรี่, สภาวะการส่องกล้องลาริงโคสโคป, จำนวนครั้งของการใส่ท่อหายใจ, สภาวะขณะใส่ท่อหายใจ, การใส่ oral airway และอาการไอขณะถอดท่อหายใจ*

สรุป *: การหล่อลื่นถุงลมของท่อหายใจด้วยสารสกัดคาร์โมไมล์ก่อนใส่ท่อหายใจไม่สามารถป้องกันอาการเจ็บคอและเสียงแหบภายหลังการผ่าตัด*