Effectiveness and safety of the routinely use of throat packs in ENT surgery

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Abstract

Introduction. Throat packs are routinely placed in (para)nasal surgery, based on the assumption they prevent postoperative nausea and/or vomiting (PONV) by preventing blood and wound debris to run into the hypopharynx and being swallowed. Literature suggests a throat pack does not lower the incidence of PONV, but does cause more postoperative throat pain. In addition a throat pack bares possible dangers, such as postoperative asphyxia.

Objective. The aim of the study was to evaluate the influence of a throat pack on the incidence and severity of postoperative throat pain. Influence of insertion mode (manual vs. under direct vision) was also addressed. Lastly, incidence and severity of PONV were evaluated to get an impression of the effectiveness of throat packs.

Methods. We designed an observational prospective trial comparing the research group of (para)nasal surgery patients in whom a throat pack is used with a control group of diverse surgery patients, also operated under general anaesthesia and endotracheal intubated. Incidence and severity of throat pain and PONV were recorded directly postoperative and 24 hours postoperative.

Results. A throat pack increases the chance on suffering from throat pain (OR 2.4) due to a higher incidence directly postoperative. Throat pain was severe both directly postoperative and 24 hours postoperative when a throat pack was placed. No statistical significant differences were found in incidence and severity of PONV, neither between research and control group nor between modes of inserting the throat pack.

Conclusion. A throat pack causes significantly more and severe postoperative throat pain than endotracheal intubation alone. Insertion mode does not influence the effectiveness of hypopharyngeal packing. PONV incidence and severity after (para)nasal surgery with a routinely placed throat pack does not differ from a general surgery population, suggesting the throat pack is effective in preventing PONV evoked by blood in the stomach.
Samenvatting

Introductie. Routinematig wordt een keeltampon geplaatst tijdens operaties aan neus en neusbijholten, met het idee postoperatieve misselijkheid en/of braken (POMB) te voorkomen doordat een keeltampon voorkomt dat bloed en debris in de hypofarynx lopen en worden ingeslikt. Er zijn aanwijzingen in de literatuur dat een keeltampon de incidentie van POMB niet beïnvloedt, maar wel leidt tot meer keelpijn postoperatief. Daar komt bij dat een keeltampon potentiële gevaren heeft, zoals postoperatieve asfyxie.

Doel. Het doel van de studie was de invloed van een keeltampon op incidentie en ernst van postoperatieve keelpijn te evalueren. Daarbij werd ook de manier waarop een keeltampon wordt ingebracht (manueel of à vue) meegenomen. Tot slot werden incidentie en ernst van POMB geregistreerd om een idee te krijgen van de effectiviteit van de keeltampon.

Methode. Een observationele prospectieve studie waarin de onderzoeksgroep, bestaande uit patiënten geopereerd aan neus en neusbijholten waarbij een keeltampon wordt gebruikt, werd vergeleken met een controlegroep, bestaande uit diverse chirurgische patiënten die ook onder algehele anesthesie geopereerd en endotracheaal geïntubeerd werden. Incidentie en ernst van de keelpijn en POMB werden direct postoperatief en 24 uur postoperatief geregistreerd.

Resultaten. Een keeltampon vergroot de kans om postoperatief keelpijn te krijgen (OR 2,4). Deze hogere incidentie wordt veroorzaakt door de hogere incidentie direct postoperatief. Bovendien zijn de pijnsscores hoger na gebruik van een keeltampon, zowel direct postoperatief als na 24 uur. In incidentie en ernst van POMB vonden we geen statistisch significante verschillen, niet tussen onderzoeksgroep en controlegroep en niet tussen de manier waarop de keeltampon werd ingebracht.

Conclusie. Plaatsing van een keeltampon veroorzaakt significant meer en ernstigere postoperatieve keelpijn dan alleen endotracheale intubatie. De manier waarop een keeltampon wordt ingebracht beïnvloedt de effectiviteit van de keeltampon niet. Incidentie en ernst van POMB na neus- en neusbijholtechirurgie waarbij routinematig een keeltampon is geplaatst, verschilt niet van de incidentie en ernst in een algemeen chirurgische populatie. Dit suggereert dat de keeltampon effectief is in het voorkomen van POMB uitgelokt door bloed in de maag.
1. Introduction

During nasal and paranasal surgery, most anesthesiologists routinely place a throat pack in the hypopharynx. Every once in a while, ENT surgeons face one of those patients suffering from severe pain in the throat and raise the question whether there could be a causal relationship with the throat pack. To answer this question we decided to review the safety and effectiveness of the routinely use of a throat pack in ENT surgery.

1.1. Risks of throat packs
Placement of a pharyngeal throat pack might come with complications. Cases of pharyngeal plexus injury after use of a throat pack and impaired venous drainage of the tongue resulting in cyanosis and edema have been described. Erkalp et al concluded a throat pack is a predisposing factor for postoperative aphthous stomatitis in nasal surgery and states the use of throat packs should be discussed. The oral lesions postoperatively observed at the patients in whom a throat pack was used, were mainly localized on the mucosa of the soft palate, uvula and on the lateral surface of the tongue and thus could be attributed to the effect of the pack on those surfaces. Thereby the potential risk of a forgotten throat pack should be considered, as this may lead to severe postoperative asphyxia.

Two case reports describe forgotten throat packs being swallowed during surgery or extubation. One of these patients vomited the throat pack, while the other needed endoscopic removal of the pack after identification on the chest X-ray (figure 1).

1.2. Throat packs and postoperative sore throat
The complications described above can be quite disturbing and threatening, but fortunately are quite rare. Evidence indicates placing a throat pack raises the incidence of postoperative sore throat, troubling a considerable part of the patients.

After every surgery under general anesthesia part of the patients suffers from a sore throat. Obviously, incidence is higher after endotracheal intubation than when a laryngeal mask or Guedel airway was used, and is reported between 14% and 50%. Mucosal erosion from the cuff of the endotracheal tube, intubation trauma and mucosal dehydration seem to contribute to the etiology of postoperative sore throat. Mucosal erosion results from bucking or coughing of the patient or friction between the tracheal mucosa and the endotracheal tube during
general anesthesia. The strong stimulus of laryngoscopy or moving the tube may excite sensory C fibers and produce secondary neuroplasticity that is associated with postoperative sore throat and cough.\textsuperscript{11–13}

Several studies show that the time under anesthesia, the size of the tube (and cuff) and gender (being female increases the risk) are risk factors for suffering from sore throat postoperatively.\textsuperscript{6,8,10} Prophylactic lidocaine, both topical (on the cuff) and systemic, seems to lower the incidence and severity of postoperative throat pain.\textsuperscript{11} This coincides the significant lowering of incidence and severity of postoperative throat pain reported with tenoxicam application on the throat pack.\textsuperscript{14}

A negative influence of the presence of a throat pack was found by research aiming to detect variables associated with postoperative sore throat after endotracheal intubation,\textsuperscript{15} namely increasing the incidence of throat pain from 35\% to 64\%. This correlates well with Conway et al who already in 1960 demonstrated a throat pack almost doubles the incidence of a sore throat postoperatively from 38\% to 61\%.\textsuperscript{16}

Several earlier randomized trials were designed to answer our question. Unfortunately these trials all consist of just a few samples, which could possibly mean that one has to face a β error (failing to reject a false null hypothesis due to lack of power). Evidence is not definite yet.

Marais et al\textsuperscript{17} performed a study designed to investigate the difference between gauze or a tampon used as a throat pack. Gauze means moist 50 mm gauze-roll throat packs, alternatively two dry tampons were slid down either side of the endotracheal tube. They concluded that moist gauze did more harm than the tampons; both resulted in higher incidence of throat pain (33\% for gauze, 48\% after tampon) than when no pack at all was used (25\%). A remarkable high incidence of postoperative sore throat was found by Basha et al,\textsuperscript{18} that was significantly higher after use of a throat pack: 71\% without a throat pack and 87\% when a throat pack was placed.

On the contrary, Piltcher et al\textsuperscript{19} reported the incidence of throat pain not to differ between patients with (40\%) or without (43.2\%) hypopharyngeal packing. This observation was confirmed by Fennessy et al\textsuperscript{20} who reported no difference in throat pain scores between patients with a wet, a dry or no throat pack at all during surgery. We need to remark they only report pain scores for the first six hours postoperatively, while surgeons and anesthesiologists report patients are generally complaining of throat pain a day after surgery.

All authors describe the throat pack is placed under direct vision. In the Deventer Hospital, however, the anesthesiologist chooses whether to place the throat pack in the hypopharynx under direct vision using a Magill forceps or to insert the pack manually without visual aid.

1.3. Postoperative nausea and vomiting

Postoperative nausea and/or vomiting (PONV) is still troubling a considerable part of the patients, although the diverse medicaments used by anesthesiologists have been investigated extensively and are being optimized. This influences a patient’s postoperative experience and satisfaction.

To understand PONV, one should understand the physiology of the vomiting reflex.\textsuperscript{21} The vomiting reflex (act of vomiting) is coordinated by the vomiting center (figure 2).
The chemoreceptor trigger zone (CTZ) is of great importance in the mechanism, and consequently the possible treatment, of PONV. The CTZ is easily activated by chemical stimuli like anesthetic agents received intravenous or intrathecal, since no blood-brain barrier exists here. Opioid, dopamine, histamine, cholinergic, and serotonin receptors are found in the CTZ (figure 3). Thus, vomiting after morphine is mediated by the CTZ. Subsequently opioid use postoperative is an important risk factor for PONV. Antiemetic drugs used as prophylaxis of PONV are serotonin and dopamine receptor antagonists, while antihistamines are primarily used for motion sickness. The general believe is that the effectiveness of dexamethasone in preventing PONV must be attributed to its anti-inflammatory effect; reason why it should be administered before the surgeon starts the first incision. The exact pathophysiological mechanism of PONV is not completely understood.

Figure 2 The vomiting center with chemoreceptor trigger zone

Figure 3 Chemoreceptor trigger zone with receptors
1.4. PONV in ENT surgery

The very reason throat packs are still commonly used is the presumption that a throat pack lowers the incidence of PONV in nasal and paranasal surgery by preventing blood and wound debris to enter the esophagus and stomach. Blood in the stomach is a potent emetic. Cuffed endotracheal tubes prevent aspiration by sealing the airway, but leave the esophagus unsealed (see figure 4).

![Figure 4 Anatomy of the pharynx and larynx and position of a cuffed endotracheal tube](image)

Over the years numerous studies on PONV have been published, amongst which multivariate analyses of large prospective trials that revealed that differences in the incidences of PONV are mainly caused by patient dependent risk factors and far less by the operation itself. The fact that diverse studies all identified other surgery types to be relevant, supports the conclusion that type of surgery is not relevant for the risk on PONV.

The reported incidence of PONV after ENT surgery differs from 13.5% to 65% and seems partly to depend on whether prophylaxis is given and the way PONV was measured. Thus a difference in incidence of PONV after ENT surgery compared to other types of surgery cannot be concluded.

It still remains unclear whether a throat pack indeed lowers the risk of PONV for nasal and paranasal surgery. In fact, the research performed on this topic does not show a significant rise in PONV when a throat pack is omitted. Therefore one could draw the conclusion that a routinely placed throat pack could do more harm than good. Yet few studies consider this practice and all address small sample sizes hindering to draw a reliable conclusion.

1.5. Risk on and prevention of PONV

In the Deventer Hospital the risk score developed by Apfel et al is used to predict the chance that a patient will suffer from PONV preoperatively. Based on this risk the anesthesiologist decides which prophylaxis to give. This widely accepted risk score (table 1) proved valid in more centers and could be simplified without significant loss of discriminating power.
Effectiveness and safety of the routinely use of throat packs in ENT surgery

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Points</th>
<th>Score</th>
<th>Risk on PONV</th>
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<tr>
<td>Female gender</td>
<td>1</td>
<td>0</td>
<td>10%</td>
</tr>
<tr>
<td>History of PONV or motion sickness</td>
<td>1</td>
<td>1</td>
<td>21%</td>
</tr>
<tr>
<td>Non smoker</td>
<td>1</td>
<td>2</td>
<td>39%</td>
</tr>
<tr>
<td>Postoperative use of opioids planned</td>
<td>1</td>
<td>3</td>
<td>61%</td>
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<tr>
<td></td>
<td>4</td>
<td>4</td>
<td>78%</td>
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Table 1 Apfel score

Despite the vast amount of studies addressing this issue, the incidence of PONV remains fairly constant with an average of 20-30%. The IMPACT study compared all possible combination of six prophylactic interventions in a randomized controlled trial. The antiemetic prophylactic drugs ondansetron, dexamethasone and droperidol all caused a relative risk reduction of 25-30%. Since they work independently their combined benefit can be derived from their single effects.

In the Deventer Hospital dexamethasone, haloperidol and promethazine are used as prophylaxis, while granisetron is given postoperatively when needed. The serotonin receptor antagonists are exchangeable both with respect to clinical outcome and side effects. Both droperidol and haloperidol are butyrophenoderivates antagonizing dopaminergic (D2) and α1-adrenergic receptors. Haloperidol is presumed to be effective against PONV by blocking the dopaminergic receptors in the chemoreceptor trigger zone. Haloperidol and droperidol seem to be comparable with respect to effectiveness and side-effects, which is reasonable reviewing their characteristics. Promethazine is a strong antihistaminic drug (H1 receptor blocker) with sedative, anticholinergic and antiemetic effects.

The IMPACT study also reported total intravenous anesthesia (TIVA) compared to volatile anesthesia lowers the risk on PONV to almost the same extent as a single antiemetic drug, with a risk reduction of approximately 18% when TIVA was used. This advantage of TIVA with propofol was also reported by earlier meta-analyses. Apfel et al proved an emetogenic effect of volatile anesthesia in the early postoperative period rather than antiemetic properties of propofol eliciting the difference in incidence of PONV. The predictive value of type of anesthesia used was not strong enough to be included in the Apfel score, making it a factor of indistinct value.

1.6. Summary

Recapitulating it appears PONV remains an issue of fairly constant severity although ample research has been performed on antiemetic prophylaxis. The chance on suffering from PONV is best predicted by the Apfel score. Duration of surgery and anesthetics used are of less importance, but evidence strongly suggests total intravenous anesthesia (TIVA) instead of inhalation or combined anesthesia lowers the risk on PONV regardless of patient factors.

The routinely use of throat packs needs revision as none of the published articles on this topic shows a reduction in PONV is reached by placing a throat pack, while those articles do suggest a throat pack results in more postoperative throat pain. Thereby a throat pack bares potential danger (asphyxia) and side-effects.

1.7. Study purpose

The aim of this study is to review the safety and effectiveness of the routinely use of a throat pack in ENT surgery. As no clear evidence exists that indicates just to omit the throat pack, we designed a prospective observational study.
The central research question is: “Does the insertion and presence of a throat pack peroperative affect the incidence and severity of postoperative sore throat?”

We hypothesized that the incidence and severity of sore throat are negatively influenced by the presence of a throat pack, as literature suggests a lower incidence of sore throat when a throat pack is omitted. One can easily imagine rough gauze damaging the fragile pharyngeal mucosa causing postoperative pain. To answer this question we compare the throat pain scores of (para)nasal surgery patients in whom a throat pack is routinely used with those of a control group, consisting of general surgery patients that are also endotracheal intubated and operated under general anesthesia.

Secondly, we address the mode of inserting the throat pack. In the Deventer Hospital, whether a throat pack is inserted manually or using Magill forceps depends solely on the preference of the anesthesiologist. We question whether the effectiveness of the throat pack in preventing PONV depends on the mode of insertion. Next, we wonder whether incidence and severity of postoperative sore throat vary with mode of insertion.

In addition to analyzing postoperative sore throat we will analyze the incidence and severity of PONV. For this we will use the control group consisting of patients undergoing other than nasal and paranasal surgery, the incidence predicted by the Apfel score and the prophylaxis used. Because an observational study is designed, it will not be possible to draw definite conclusions concerning the influence of a throat pack on the incidence of PONV. We expect the incidence and severity of PONV will not differ between the research group and control group, as long as the baseline risk (derived from Apfel score and prophylaxis given) for both groups is equal. We expect no difference, because none of the studies performed before showed a significant increase in PONV when a throat pack was omitted and the surgery type is not a risk factor for PONV.
2. Patients & methods

2.1. Inclusion & exclusion criteria
Included in this study were all patients scheduled for nasal and paranasal surgery in which a throat pack was routinely used from 4 March until 5 July 2013 in the Deventer Hospital, a non-academic teaching hospital. To compare the throat pain experienced by the patients in whom a throat pack was placed, a control group was selected. Patients were included when they were endotracheal intubated but a throat pack was not placed, with a comparable surgery time and not operated in oro-, hypopharynx or larynx. Patients were excluded if standardized anesthesia would not suit the patient (see “Methods”).

2.2. Calculation of the sample size
To estimate the number of patients needed to analyze the influence of a throat pack on postoperative throat pain 24 hours postoperative, the difference found by Basha et al\textsuperscript{18} was used to perform a power analysis. When estimating the minimal risk reduction to be 18% with a statistical power of 80% and an alpha error of 5% a minimum of 98 patients per group was necessary. Since other studies mentioned found a greater risk reduction,\textsuperscript{15–17} the sample size estimated using these data is smaller.

2.3. Methods
Although anesthetics used are not mentioned as a risk factor in the Apfel score, type of anesthesia seems to influence the incidence of PONV,\textsuperscript{23,50,51} mainly in the early postoperative period. Anesthesia was standardized to avoid introducing a possible confounder. All patients received total intravenous anesthesia (TIVA) with propofol and remifentanil since literature suggests TIVA lowers the risk on PONV.

All patients were endotracheal intubated using a laryngoscope with macintosh blade, with tube size 7 mm for female and 8 mm for male, while cuff pressure was controlled using a manometer. The throat pack used is gauze roll from the firm Lohmann & Rauscher (figure 5) moisturized with 200 ml saline.

![Figure 5](Image)

Figure 5 Throat pack used in the Deventer Hospital

The antiemetic protocol (appendix 1), based on the Apfel score, and the pain protocol of the Deventer Hospital were followed as usual. As PONV prophylaxis haloperidol 1 mg alone, in combination with dexamethasone 8 mg or in combination with both dexamethasone 8 mg and promethazine 12.5 mg peroperative is used. Postoperative patients receive granisetron 1 mg if needed. Premedication an hour preoperatively is acetaminophen 1000 mg, virtually always combined with celecoxib 200 or 400 mg. Additionally oxazepam 10 mg is given when needed and pantoprazole 20 mg when indicated. Postoperative analgesia consists of acetaminophen 1000 mg up to four times a day, combined with celecoxib 200 mg twice daily (if needed). Subsequently opioids can be added (Schedule postoperative pain protocol; appendix 2).
Directly postoperative and 24 hours postoperative the researcher took a record. The record directly postoperative was taken as soon as the patient was awake and responsive, which was most of the time between 1 and 2 hours postoperative. This record comprised throat pain, measured on a verbal numeric rating scale (NRS) ranging from 0 to 10, with 0 means no pain at all and 10 equals “pain as bad as you can imagine”, and whether the patient was facing nausea and/or vomiting. Thereby the administered medication was recorded. The record is enclosed (appendix 3).

Nausea is subjective and defined as a feeling of wanting to vomit. Vomiting is the expulsion of gastric contents through the mouth. The record resulted in three measurements: PONV directly (mostly 1-2 hours) postoperative – between 1-2 and 24 hours postoperative – 24 hours postoperative. These measurements were merged into one score on scale 0-3:
- 0: no nausea
- 1: mild nausea or short-term (<30 minutes) nausea or one mild or short-term emetic episode provoked by movement, eating or drinking
- 2: moderate - severe nausea
- 3: nausea and vomiting.

For pain assessment the verbal NRS-11 was used. Hjermstad et al reviewed 54 studies comparing Numerical Rating Scales, Verbal Rating Scales (VRS) and Visual Analogue Scales (VAS) and concluded the NRS-11, VRS-7 and VAS all work quite well. Besides, patients were interviewed by telephone if they were already sent home 24 hours postoperatively, necessitating using a verbal rating scale. To compare the severity of throat pain we subdivided the NRS scores in pain severity scores, based on what level of postoperative pain we consider acceptable:
- NRS 0-3: no or mild pain, to be accepted
- NRS 4-7: moderate pain, treatment needed
- NRS 8-10: severe pain, unacceptable.

Factors possibly influencing the incidence of throat pain and PONV were recorded. For throat pain those factors include gender, intubation grade, mode of placing the throat pack, analgesia, and time under anesthesia. For PONV the possible factors of importance are Apfel score (gender, smoking habit, history of PONV or motion sickness and postoperative opioids used), prophylaxis given and antiemetic drugs used postoperative. Thereby general patient characteristics were taken, including age, BMI and health status (American Society of Anesthesiologists (ASA) classification).

2.4. Ethical aspects

All patients were informed by the researcher about the purpose of the study and received a letter with further information and contact details (appendix 4) when the first questionnaire was taken directly postoperative. Informed consent was obtained when the questionnaire was taken 24 hours postoperative. A patient was not included if he or she did not understand the information provided by the researcher, for instance because of a language barrier.

2.5. Statistical analysis

The Statistical Package for Social Sciences (SPSS) version 19 was used for all statistical tests. The $\chi^2$ test was used to evaluate nominal variables, while the Mann-Whitney-U test was used to compare ordinal variables. The $t$ test for independent samples was used to evaluate averages. Before performing a $t$ test, normal curves were plotted on the histograms of the test variables to check for normal distribution. Univariate and multivariate binary logistic
regression analysis was used to test the influence of a variable on a dichotomous outcome variable, while correcting for other variables. Ordinal logistic regression analysis was used to test the influence of several variables on an ordinal outcome variable. Probabilities < 0.05 were regarded as significant.

Scaled variables are shown as mean ± standard deviation (SD), as mean and range (age) or as mean ± SD and range (BMI). For nominal and ordinal variables the percentage and/or the number per group is shown.
3. Results

From 4 March 2013 until 5 July 2013 215 patients were included in the study. Appendix 5 shows the number of excluded patients with reason of exclusion.

In the research group, eight patients received volatile anesthesia instead of total intravenous anesthesia with propofol. They were included in the analysis of postoperative throat pain, but excluded when analyzing PONV.

In the control group some patients received patient controlled analgesia (PCA) or epidural analgesia with opioids, while in the research group none received this, leading to a substantial difference in opioids usage. Patient controlled analgesia makes it difficult to find out the exact dosage of opioids received. Therefore we compared two groups, patients who received PCA or epidural analgesia and those without, on severity of throat pain and PONV, using Mann-Whitney-U tests. Severity of throat pain both directly postoperative and 24 hours postoperative did not differ significantly between the groups (P value > 0.32). The PONV scores however did differ significantly between the groups (P value <0.001), with 70% PONV score ≥ 1 in the PCA/epidural group versus 29% in the group without PCA/epidural analgesia. Thus patients with PCA or epidural analgesia postoperative were excluded when analyzing PONV.

### 3.1. Descriptive statistics

Table 2 shows the baseline characteristics of all patients. Significantly more women were included in the control group than in the research group and dosage opioids used was significantly higher in the control group. The risk factor for PONV however is whether opioids are used, yes or no, not the dosage of the opioids. All patients (except those mentioned above) received TIVA and one of three muscle relaxants: Esmeron, Mivacron or Nimbox. Dosage of anesthetic agents received did not differ between the groups.

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<tr>
<th></th>
<th>Research group (n=94)</th>
<th>Control group (n=121)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>Mean 44</td>
<td>Mean 46</td>
<td>0.87</td>
</tr>
<tr>
<td></td>
<td>Range 18-79</td>
<td>Range 19-81</td>
<td></td>
</tr>
<tr>
<td><strong>Gender (male/female)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>38/56</td>
<td>70/51</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>Mean 26.0 ± 4.33</td>
<td>Mean 26.4 ± 4.58</td>
<td>0.44</td>
</tr>
<tr>
<td></td>
<td>Range 16.7-37.6</td>
<td>Range 16.9-40.5</td>
<td></td>
</tr>
<tr>
<td><strong>ASA (class 1/2/3)</strong></td>
<td></td>
<td></td>
<td>0.62</td>
</tr>
<tr>
<td>Class 1</td>
<td>51/39/4</td>
<td>72/42/6</td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td>32/46/13</td>
<td>38/43/42</td>
<td></td>
</tr>
<tr>
<td><strong>Active smoker</strong></td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>Not active smoker</td>
<td>78/16/0</td>
<td>102/18/1</td>
<td></td>
</tr>
<tr>
<td><strong>Time under anesthesia (min)</strong></td>
<td>101.3 ± 44.32</td>
<td>93.1 ± 49.21</td>
<td>0.21</td>
</tr>
<tr>
<td><strong>Opioids used postoperative</strong></td>
<td>66 (70.2%)</td>
<td>94 (77.7%)</td>
<td>0.21</td>
</tr>
<tr>
<td><strong>Dosage postoperative opioids (mg morphine)</strong></td>
<td>5.10 ± 4.30</td>
<td>7.40 ± 6.02</td>
<td>0.001</td>
</tr>
<tr>
<td>– Patient controlled analgesia excluded</td>
<td>(n=101)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2 Baseline characteristics of the patients

The research group comprises all patients undergoing (para)nasal surgery with a throat pack placed during surgery. The control group consists of patients undergoing diverse surgical procedures. Table 3 shows the proportion of patients undergoing the diverse procedures or combinations of procedures for the research group. The percentage of patients included per specialism is showed for the control group. The category “other” comprises plastic surgery, urology and not-abdominal general surgery. Not all (para)nasal surgery patients received a throat pack during surgery, this is up to the surgeon performing the procedure. The six patients in whom a throat pack was omitted were included in the control group.
Effectiveness and safety of the routinely use of throat packs in ENT surgery

<table>
<thead>
<tr>
<th>Surgery type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septorhinoplasty</td>
<td>7 (8%)</td>
</tr>
<tr>
<td>Septoplasty (SP)</td>
<td>36 (38%)</td>
</tr>
<tr>
<td>SP</td>
<td>33 (35%)</td>
</tr>
<tr>
<td>SP+P</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>SP+adenotomy (A)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Functional Endoscopic Sinus Surgery (FESS)</td>
<td>46 (49%)</td>
</tr>
<tr>
<td>FESS</td>
<td>32 (34%)</td>
</tr>
<tr>
<td>FESS+SP</td>
<td>11 (12%)</td>
</tr>
<tr>
<td>FESS+SP+A</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>FESS+A</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Dacryocystorhinostomy</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Conchae inferior/media reduction</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Polypectomy</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

Table 3 Composition of research group (left) and of control group (right)

3.2. Postoperative throat pain

Gender, time under anesthesia and intubation grade possibly influence the incidence and severity of throat pain. Table 2 shows the groups do differ statistically on gender. Significantly more women in the control group would result in a higher incidence of throat pain than with proper randomization. Patients who reported throat pain before surgery were excluded before analysis (n=3). One patient was excluded, because a fibroma of the tonsil niche was removed in the same procedure.

In both research and control group for five patients a difficult intubation grade was reported. Performing the tests with or without those ten patients did not change the results, making us decide not to exclude them directly. Instead, we performed the Chi-square tests and Mann-Whitney-U tests as planned and extended our analysis with a multiple logistic regression analysis to evaluate the influence of both gender and intubation grade on our results.

Figure 6 Incidence of postoperative throat pain; throat pack vs. no throat pack
To compare the incidence of postoperative throat pain between the research group and control group, a Chi-square test was performed. Figure 6 shows the overall percentage of patients suffering from throat pain and the incidences directly postoperative and after 24 hours. A significant higher proportion of the research group patients suffered from throat pain. This is due to the higher incidence directly postoperative, as the incidence after 24 hours does not differ significantly (table 4).

Secondly, we compared the severity of throat pain, using a Mann-Whitney-U test. Table 4 shows the severity of throat pain was significantly higher in the research group both directly and 24 hours postoperative. Thereby it stands out barely anybody suffered from throat pain scored NRS 8 or higher.

Next to comparing the incidence of throat pain between research group and control group, we were also interested whether the mode of inserting the throat pack influenced the chance on suffering from postoperative throat pain. To answer this question we performed the same tests: a Chi-square test to compare the incidence and a Mann-Whitney-U test on severity, using the pain severity score explained above. Before we performed those tests, we checked whether the groups based on mode of inserting the throat pack were comparable on gender and time under anesthesia (P value > 0.36). Again, results did not change when patients with difficult intubation grade were excluded. Table 5 shows the incidence of postoperative throat pain does not differ significantly with mode of insertion. The severity of the throat pain does only differ significantly after 24 hours.

<table>
<thead>
<tr>
<th>Research group (n=91)</th>
<th>Control group (n=120)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directly postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS 0-3</td>
<td>77.7%</td>
<td>94.2%</td>
</tr>
<tr>
<td>NRS 4-7</td>
<td>17%</td>
<td>5.8%</td>
</tr>
<tr>
<td>NRS 8-10</td>
<td>2.1%</td>
<td>0</td>
</tr>
<tr>
<td>24 hours postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS 0-3</td>
<td>89.0%</td>
<td>97.5%</td>
</tr>
<tr>
<td>NRS 4-7</td>
<td>9.9%</td>
<td>1.7%</td>
</tr>
<tr>
<td>NRS 8-10</td>
<td>1.1%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Table 4 Incidence and severity of throat pain; throat pack vs. no throat pack

<table>
<thead>
<tr>
<th>Manual (n=56)</th>
<th>Magill forceps (n=33)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directly postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS 0-3</td>
<td>78.6%</td>
<td>81.8%</td>
</tr>
<tr>
<td>NRS 4-7</td>
<td>19.6%</td>
<td>15.2%</td>
</tr>
<tr>
<td>NRS 8-10</td>
<td>1.8%</td>
<td>3%</td>
</tr>
<tr>
<td>24 hours postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS 0-3</td>
<td>94.6%</td>
<td>78.8%</td>
</tr>
<tr>
<td>NRS 4-7</td>
<td>3.6%</td>
<td>21.2%</td>
</tr>
<tr>
<td>NRS 8-10</td>
<td>1.8%</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 5 Incidence and severity of throat pain; manual insertion vs. under direct vision

We saw the control group comprised significantly more women than the research group. However, the incidence of throat pain is significantly higher in the research group; since literature shows women suffer from postoperative throat pain more often than men, one would expect this to be the other way around. We conducted a logistic regression to evaluate the influence of known factors (gender, intubation grade, time under anesthesia) as well as the test variables (group (presence of a throat pack) and mode of inserting the throat pack) on the
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incidence of postoperative throat pain. Dosage opioids also is taken into account to avoid introducing a confounder. Firstly, we tested those variables independently. Thereafter we put the variables of significant influence in a multiple logistic regression; results are shown in table 6. We found both presence of a throat pack and female gender raise the risk on postoperative throat pain, with even lower P values in a multivariate logistic regression. Thus, when we correct for gender the incidence of throat pain is raised with a factor 2.4, approximately, by placing a throat pack.

<table>
<thead>
<tr>
<th></th>
<th>Univariate</th>
<th></th>
<th>Multivariate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P value</td>
<td>OR (95% C.I.)</td>
<td>P value</td>
<td>OR (95% C.I.)</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>0.004</td>
<td>2.24 (1.28-3.89)</td>
<td>0.001</td>
<td>2.72 (1.51-4.91)</td>
</tr>
<tr>
<td>Intubation grade</td>
<td>0.77</td>
<td>0.82 (0.23-3.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time under anesthesia</td>
<td>0.16</td>
<td>1.004 (0.998-1.01)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of throat pack</td>
<td>0.02</td>
<td>1.94 (1.12-3.38)</td>
<td>0.003</td>
<td>2.432 (1.35-4.40)</td>
</tr>
<tr>
<td>Mode of inserting throat pack</td>
<td>0.61</td>
<td>0.80 (0.34-1.89)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosage opioids used</td>
<td>0.21</td>
<td>0.98 (0.95-1.01)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OR = Odds ratio; C.I. = confidence interval of OR

Table 6 Logistic regression analysis; influence on incidence of throat pain

3.3. Postoperative nausea and vomiting

Before comparing the incidence of PONV between the research and control group, we need to make sure the groups have a similar baseline risk on PONV. As mentioned previously, patients with PCA or epidural analgesia postoperative are excluded in this part of the study. We performed Chi-square tests to compare the proportions of patients with a positive score on the risk factors of the Apfel score. Figure 7 shows the distribution of Apfel scores per group, which is compared using a Mann-Whitney-U test. Lastly, we performed a t test to evaluate the number of antiemetic drugs given as prophylaxis. We added this test because the antiemetic protocol was not always followed closely (patients did not always receive the number of antiemetic prophylactic drugs they should have, based on the Apfel score).

Significantly more patients in the control group have a history of motion sickness or PONV; on the other items of the Apfel score the groups do not differ significantly (table 7). Apfel scores in the control group are higher (figure 7), but the difference is not statistical significant (P value 0.06). The control group received significantly more prophylactic antiemetic drugs (P value 0.02) with mean 1.04 vs. mean 0.71 in the research group. So the groups do not differ significantly in baseline risk, based on the Apfel score. However, when we also take into account the difference in history of motion sickness and antiemetic prophylactic drugs received a tendency to a higher risk on PONV in the control group shows up.

<table>
<thead>
<tr>
<th></th>
<th>Research group (n=86)</th>
<th>Control group (n=101)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of motion sickness/PONV</td>
<td>21%</td>
<td>35%</td>
<td>0.04</td>
</tr>
<tr>
<td>Smoking habit (% non smoker)</td>
<td>72%</td>
<td>70%</td>
<td>0.79</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>41%</td>
<td>54%</td>
<td>0.08</td>
</tr>
<tr>
<td>Opioids postoperative used</td>
<td>71%</td>
<td>73%</td>
<td>0.72</td>
</tr>
</tbody>
</table>

Table 7 PONV risk factors
The percentage of patients suffering from PONV in both groups, compared using the Chi-square test, was equal (P value 0.68). 27.9% in the research group suffered from PONV vs. 30.7% of the control group patients. The severity of PONV (figure 8), tested using a Mann-Whitney-U test, did not differ significant either (P value 0.64).

Since we saw a tendency to a higher baseline risk in the control group, we also performed a multiple ordinal logistic regression analysis to evaluate the influence of the presence of a throat pack on severity of PONV while the Apfel score, antiemetic prophylaxis given and dosage opioids used are taken into account. Odds ratio with 95% confidence interval is calculated from “Parameter estimates”. We find the presence of a throat pack does not affect the severity of PONV, when tested alone nor when we correct for Apfel score, prophylaxis and dosage opioids used (table 8).
Effectiveness and safety of the routinely use of throat packs in ENT surgery

<table>
<thead>
<tr>
<th></th>
<th>Univariate P value</th>
<th>OR (95% C.I.)</th>
<th>Multivariate P value</th>
<th>OR (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Apfel score</strong></td>
<td>&lt;0.001</td>
<td>1.99 (1.45-2.73)</td>
<td>&lt;0.001</td>
<td>2.34 (1.49-3.67)</td>
</tr>
<tr>
<td><strong>Prophylaxis</strong></td>
<td>0.20</td>
<td>1.24 (0.89-1.73)</td>
<td>0.04</td>
<td>0.62 (0.39-0.99)</td>
</tr>
<tr>
<td><strong>Dosage opioids</strong></td>
<td>&lt;0.001</td>
<td>1.13 (1.07-1.20)</td>
<td>0.003</td>
<td>1.11 (1.03-1.18)</td>
</tr>
<tr>
<td><strong>Presence of throat pack</strong></td>
<td>0.64</td>
<td>1.16 (0.62-2.16)</td>
<td>0.44</td>
<td>0.76 (0.38-1.53)</td>
</tr>
</tbody>
</table>

OR = Odds ratio; C.I. = confidence interval of OR

Table 8 Ordinal logistic regression analysis; influence on severity of PONV

Lastly, we wondered whether the effectiveness of the throat pack differs with mode of insertion. Comparability of the groups was tested first: those with manual insertion vs. placement under direct vision did not differ in Apfel score, antiemetic prophylaxis given or dosage opioids used (P value ≥0.21). Incidence of PONV did not differ significantly with mode of insertion, compared using Chi-square test (P value 0.22) and was 24.1% for those with manual insertion and 36.7% after Magill forceps was used to place the throat pack. The severity of PONV for both groups is shown in figure 9 and did not differ significantly either (Mann-Whitney-U test; P value 0.18).

![Figure 9 PONV score manual vs. Magill forceps](image_url)
4. Discussion

4.1. Throat pain

The results show patients suffer significantly more from throat pain when a throat pack is placed, than when they only are endotracheal intubated. We found 54% of patients with a throat pack suffered from throat pain, whereas only 38% in the control group reported throat pain, achieving a risk reduction of 30% with omitting the throat pack. Since significantly more women were included in the control group, the risk reduction will be even greater and the logistic regression analysis gives us a more accurate outcome. The risk reduction however is the outcome measure used in other studies and it corresponds quite well with earlier research on the effect of a throat pack on operative throat pain.\(^\text{15--17}\) Only Basha et al\(^\text{18}\) reported a much higher incidence in both research and control group (87% and 71%) and a risk reduction of 18%.

Thereby, we saw the throat pain reported in the research group was more intense than in the control group, both directly and 24 hours postoperative. This corresponds with the differences in severity reported by Basha et al,\(^\text{18}\) who reported their results in the same way as we did. Since all factors described in literature that influence the occurrence of postoperative throat pain are taken into consideration in this study, we can draw the conclusion that a throat pack causes more and more intense throat pain; an odds ratio of 2.4 (95% C.I. 1.35-4.40) is found, indicating the chance on suffering from throat pain is multiplied by 2.4 by placing a throat pack.

The difference in incidence of throat pain between the groups arises from the significantly higher proportion of patients suffering from throat pain in the research group directly postoperative; after 24 hours the incidence is equal. We think the throat pain is caused by traumatic damage of the mucosa, instigated by the raw surface of the throat pack. This would explain the higher incidence directly postoperative. Intensity scores are higher on both points of time. However, pain scores are not extremely high (barely anyone above 7), to put the complaints in perspective.

4.2. Postoperative nausea and vomiting

We compared the incidence and severity of PONV in the (para)nasal surgery group with routinely placement of a throat pack with the incidence and severity of PONV in patients undergoing diverse surgical procedures. We tested for baseline risk and conducted multiple regression analysis to correct for possibly ruffling confounders, thus strengthening the conclusion the incidence and severity of PONV in (para)nasal surgery with routinely placement of a throat pack do not differ from the incidence in a general surgery group.

Finding no difference in PONV intensity suggests a throat pack that is functioning well: we can argue a higher incidence of PONV caused by blood and wound debris in the stomach is prevented. On the other hand, we cannot rule out the throat pack does not function at all. The amount of blood and wound debris being swallowed by our research patients is unknown, as is its causative role in PONV.

Previous randomized controlled trials comparing PONV in (para)nasal surgery with and without routine placement of a throat pack found no effect of the throat pack on occurrence of PONV.\(^\text{18--20,39,40}\) Our study on the contrary supports effectiveness of the throat pack, but was not designed to draw definite conclusions on the effect of the throat pack in prevention of PONV. Further research is indicated to answer the question on effectiveness.
4.3. Manual vs. Magill forceps

All other studies on this topic report the throat pack was inserted under direct vision. Part of the anaesthesiologists in the Deventer Hospital prefer manual insertion, while others prefer placing the throat pack under direct vision using Magill forceps and laryngoscope. Those with a preference of manual insertion state that a Magill forceps and laryngoscope would cause more mucosal damage, thus doing more harm. Those with a preference of direct vision are convinced that a throat pack manually inserted is not placed deep enough in the hypopharynx to function well.

Our results show the incidence and severity of PONV does not differ with the insertion mode used. We can conclude that the throat pack functions just as good or as bad in both situations. When the throat pack indeed prevents PONV caused by blood being swallowed, the pack is equal effective with both ways of placement. Perhaps a throat pack does not function at all, than the mode of insertion does not matter either.

The incidence of throat pain did not differ with the mode of insertion, but the intensity of throat pain 24 hours postoperative did. This suggests the damage caused by insertion with Magill forceps and laryngoscope takes longer to recover, making the throat pain last longer. As described before, we assume the throat pain is caused by traumatically damaged mucosa. The hypopharynx is narrower just above the cuff, where the throat pack is placed under direct vision, than on the level of oro-/hypopharynx that one reaches with manual insertion. This might result in higher pressure on the mucosa with placement under direct vision, causing deeper or more extensive mucosal damage.

4.4. Differences between (para)nasal surgical procedures

The effectiveness of the throat pack remains unclear, with our results suggesting effectiveness in spite of previous research. To what extent blood is prevented to run into the esophagus, is still unknown. The increased risk on throat pain supports ENT surgeons who already omit a throat pack in surgical procedures where mild blood loss is expected (for instance limited septoplasty).

We did not measure how much blood was taken up by the throat packs, what could have been done by weighing the throat pack after removal. If we would have, we would still not know if and how much blood ran into the esophagus. Besides, the size of the throat pack is not standard; when the hypopharynx is sufficiently packed, the gauze is cut.

If blood being swallowed during surgery is of influence on occurrence of PONV, gastric aspiration at the end of surgery could perhaps prevent this. Jones et al\(^5\)\(^5\) designed a randomized controlled trial to study the effectiveness of gastric aspiration in the prevention of PONV after tonsillectomy. They concluded the incidence of PONV after gastric aspiration was as high as the incidence without aspiration. Gastric aspiration also failed to result in any reduction of the postoperative length of stay. A study on the effectiveness of perioperative gastric aspiration to prevent PONV in outpatients from various disciplines found gastric aspiration did not decrease PONV.\(^5\)\(^6\) The incidence of nausea and vomiting after discharge was even higher when gastric aspiration was administered.

It is imaginable that vast endoscopic sinus surgery with nasal polyposis causes (much) more blood loss than limited submucosal septal surgery. Different bleeding potentials might lead to a recommendation to use a throat pack “on indication”. The results of Korkut et al\(^3\)\(^9\) however show the incidence and severity of PONV does not differ with type of (para)nasal surgery
with or without a throat pack. As this is the only study so far answering this question, further research is needed. No evidence of cartilage aspiration following septoplasty is found in literature, which might imply no proper indication for a throat pack exists in septoplasty.

4.5. Confounding factors

The surgeon, the anaesthesiologist and the person intubating and inserting the throat pack were not standardized. Intubation and throat pack insertion were also conducted by anaesthetic nurses and medical students, under supervision of an anaesthesiologist. This might introduce a confounder. Previous research however showed the person who intubates does not influence the incidence and intensity of postoperative throat pain.\textsuperscript{6,57}

Pain protocol and antiemetic protocol were followed as usual. We saw the antiemetic protocol was not always followed properly (table 9). This outcome should be taken into account when designing a new study on this topic. Since the number of antiemetic prophylactic drugs used influences the risk a patient will suffer from PONV significantly,\textsuperscript{44} this is an important factor to be taken into account when analyzing and interpreting the results. We eliminated those factors by multiple logistic regression analysis.

<table>
<thead>
<tr>
<th>Apfel score</th>
<th>Prophylaxis given</th>
<th>None</th>
<th>Haldol</th>
<th>Haldol + dexa</th>
<th>Haldol + dexa + promethazine</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6 (86%)</td>
<td>0</td>
<td>1 (14%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>37 (78%)</td>
<td>5 (11%)</td>
<td>5 (11%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>42 (58%)</td>
<td>17 (24%)</td>
<td>13 (18%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7 (14%)</td>
<td>10 (20%)</td>
<td>33 (66%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>5 (14%)</td>
<td>0</td>
<td>28 (78%)</td>
<td>3 (8%)</td>
<td></td>
</tr>
</tbody>
</table>

\textit{Haldol} = haloperidol 1 mg; \textit{dexa} = dexamethasone 8 mg; \textit{promethazine} = promethazine 12.5 mg; all intravenous.

Table 9 Antiemetic prophylaxis given per Apfel score

Premedication and analgesics differ amongst patients according to their needs and predisposition (for instance, being careful with non-steroidal anti-inflammatory drugs in elderly or adding prophylactic pantoprazole in patients with a history of pyrosis). This might introduce confounders; on the other hand, this gives us a better impression of the general patient population undergoing surgical procedures in our hospital.

Adenotomy was performed in a few patients adjacent to the main surgical procedure. This causes pain that can be differentiated from throat pain (which is felt lower), but may also lead to more blood loss, possibly causing PONV. Thereby the different surgeons use different methods for nasal packing. We did not evaluate this variable, so we cannot eliminate a difference in effectiveness of their packing.

4.6. Study design

An observational prospective study was chosen, because the results of studies that are performed on this question are ambiguous. Thereby no data were available on the incidences of throat pain and PONV in our hospital. This observational study was used to investigate if we should stop placing a throat pack routinely. It is obvious this study is not suitable to draw definite conclusions on the influence of a throat pack on PONV.

The standard anesthesia was not always given. We included those patients anyway, because the needed patient numbers – based on the power analysis – were not met. Although we prolonged inclusion with 4 weeks, still the desired number was not reached. Planning was
based on surgery numbers from last year and all surgical patients that met inclusion criteria were included, implying less productivity of the ENT surgeons compared to previous years.

4.7. Control group

The control group consists of patients undergoing diverse surgical procedures. The criteria for inclusion were the patients being operated under general anaesthesia, endotracheal intubation, and duration of anaesthesia not longer than approximately three-and-a-half hours. In the course of the study, however, we noticed the control group received significantly more opioids in a higher dosage than the research group. This is due to the fact that patients undergoing nasal and paranasal surgery receive more local analgesics during surgery, reducing the need for opioids. Therefore during inclusion we decided to further exclude patients receiving epidural or patient controlled analgesia with opioids and to include more patients that also received local analgesics intraoperative, like orthopaedic procedures with plexus blockade and ear surgery during which local infiltration is applied. We extended the inclusion period for ear surgery patients as to be able to create a reliable control group.

4.8. Conclusion

We conclude a throat pack does significantly influence both incidence and severity of postoperative sore throat. We found no difference in PONV intensity between (para)nasal surgery with routinely placement of a throat pack and a general surgery population. This suggests the throat pack is effective, contradicting the few studies published so far. Inserting the throat pack manual or under direct vision with Magill forceps does not affect the effectiveness of the throat pack. Further research is needed to confirm the effectiveness of the throat pack. The different surgery types with different bleeding potential should be taken into consideration in such a study, as theoretically a throat pack might be useful “on indication”.
5. Bibliography

Effectiveness and safety of the routinely use of throat packs in ENT surgery

larynx.jpg/151326099/Anatomy-of-the-larynx.jpg

27. Clark Medical Media [Internet]. Available from: http://www.clarkmedicalmedia.com/medical-ill-illustration/#prettyPhoto/gallery_142/0/


Acknowledgement

First of all I would like to thank my mentor, Jan-Hein Cobben, for his guidance. Secondly, I want to thank all the anaesthesiologists of the Deventer Hospital for their co-operation in the inclusion of patients. Without their support I would not have been able to conduct the study in this way. Besides, they introduced me in anaesthesiology in a pleasant way. The nurses of the post anaesthesia care unit have been of great help in questioning the patients directly postoperative when I was unable to attend. I would like to thank the ENT surgeons for their input and supportiveness of this study.

The statistical experts of the research institute of the Deventer Hospital helped me out with the statistical analyses; I owe them for their guidance. During the clerkship I have been in the pleasant company of colleagues, who I would like to thank for their thinking along, co-reading and for the regular coffee-breaks, which helped me work efficiently throughout the day.
Appendix 1 Antiemetic protocol Deventer Hospital

<table>
<thead>
<tr>
<th>Documenttype: Protocol (DZ)</th>
<th>Versie: 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code: Anesthesiologie</td>
<td></td>
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</tbody>
</table>

| Titel: Anti-emeticaprotocol voor volwassenen | Publicatiedatum: 6 maart 2012 |
|                                             | Herzieningsdatum: 6 maart 2014 |
|                                             | Autorisator: Ramaker, R.       |

1. TITEL * ................................................................. 1
2. DOEL * ................................................................. 1
3. TOEPASSINGSGEBIED * ........................................ 1
5. WERKWIJZE/UITVOERING* ........................................ 1
RISICO OP PONV ......................................................... 1
8. GERELATEERDE DOCUMENTEN * ................................ 2

1. Titel *

Anti-emeticaprotocol voor volwassenen
Auteur J.H. Cobben

2. Doel *

Pre-operatieve risicoanalyse PONV tijdens pre-operatieve screening anesthesiologie

3. Toepassingsgebied *

Anesthesiologen

5. Werkwijze/Utvoering*

Risicofactoren volgens Apfel
1. vrouwelijke geslacht
2. eerdere PONV of reis- wagenziekte
3. niet-roken
4. gebruik van opioiden postoperatief

Risico op PONV

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Risicofactoren</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 20%</td>
<td>geen risicofactoren</td>
</tr>
<tr>
<td>20 – 40%</td>
<td>1 risicofactor</td>
</tr>
<tr>
<td>40 – 60%</td>
<td>2 risicofactoren</td>
</tr>
<tr>
<td>60 – 80%</td>
<td>3 risicofactoren</td>
</tr>
<tr>
<td>&gt; 80%</td>
<td>4 risicofactoren</td>
</tr>
</tbody>
</table>

Situatie A/B: geen preventieve maatregelen. Indien PONV granisetron 1 mg iv.
Effectiveness and safety of the routinely use of throat packs in ENT surgery

Situatie C: haloperidol 0,5 – 1,0 mg preventief perioperatief. Indien PONV granisetron 1 mg i.v.

Situatie D: haloperidol 0,5 – 1,0 mg + DXM (Dexamethason) 8 mg i.v. preventief perioperatief. Indien PONV granisetron 1 mg i.v.

Situatie E: haloperidol 0,5 – 1,0 mg + DXM 8 mg + 12,5 mg promethazine i.v. preventief perioperatief

8. Gerelateerde documenten *
Welke artikelen hebben verband met het betreffend artikel

© Deventer Ziekenhuis
## Bijlage 1: Schema postoperatieve pijnbestrijding

### Schema Postoperatief Pijnprotocol Deventer Ziekenhuis

<table>
<thead>
<tr>
<th>Basisanalgectica</th>
<th>Opioiden</th>
<th>vakgroep anesthesiologie</th>
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</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>Morfine</td>
<td>Uurdosering, vervolgens pompstand met 1 ml/u verhogen tot max stand</td>
</tr>
<tr>
<td>Celebrex®</td>
<td>Piritramide (Dipidolor®)</td>
<td></td>
</tr>
<tr>
<td>Dolofoan®</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Epidurale analgesie</th>
<th>Perineurale analgesie</th>
<th>bolus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine 0,125%</td>
<td>Bupivacaine 0,25% (+ Clonidine 1 μg/ml)</td>
<td>Uurdosering, vervolgens pompstand met 1 ml/u verhogen tot max stand</td>
</tr>
<tr>
<td>Morfine 0,02 mg/ml pomppstand 2 tot 10 ml/u</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Doseringen</th>
<th>Doseringen</th>
<th>bolus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol tot 4 g/dag supp/po/iv</td>
<td>Morfine 0 – 10 mg sc/im/iv</td>
<td>volgens algoritme</td>
</tr>
<tr>
<td>Celebrex 2 dd 200-400 mg/ dag po</td>
<td>Piritramide 20 mg sc/im/iv</td>
<td></td>
</tr>
<tr>
<td>Dolofoan 3 dd 25 – 50 mg supp/po/iv</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Patiënt Controlled Analgesia (PCA)

Elektronisch (Braun-pomp)
Pompinstelling: bolus 1 ml, lockout 7 min.
De Braunpomp werkt met een 20 of 50 ml spuit.
Op indicatie kan een achtergronddosering worden gestart tot 2 ml/u.

Samenstelling:
- Morfine 1 mg/ml of Dipidolor® 2 mg/ml in NaCl 0,9%

### Piënscore

- 0: geen pijn
- 1: weinig pijn
- 2: veel pijn
- 3: ondraaglijke pijn

### Sedatiescore

- 0: wakker en helder
- 1: makkelijk wekbaar
- 2: moeilijk wekbaar
- 3: niet wekbaar

### Streefwaarde score 0 of 1

### Schaaf volgens Bromage

- 0: geen motorisch blok
- 1: kan gestrektbeen niet heffen
- 2: kan knie niet buigen
- 3: volledig motorisch blok

### Streefwaarde score 0 of 1

### Alarmsignalen tijdens PDA

1. toenemend blok zonder duidelijke verklaring
2. koorts en pijn in de rug
3. toenemende pijnklachten in de rug

### Voorwaarden bolustoeding en/of pompverhoging door verpleegkundige

Bij subcutane toediening opiodien
- piënscore 2 of 3
- sedatiescore 0 of 1
- geen hypotensie
- laatste bolus > 1 uur geleden

Bij epidurale analgesie
- piënscore 2 of 3
- sedatiescore 0 of 1
- geen hypotensie
- laatste bolus > 1 uur geleden

Bij PCA-morfine
- Soms is een extra oplaadosis noodzakelijk: in overleg met anesthesioloog.
Appendix 3 Record and questionnaire taken postoperative

<table>
<thead>
<tr>
<th>Patiënt</th>
<th>Datum</th>
<th>Ingreep</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
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<th>Duur anesthesie:</th>
<th>Eindtijd:</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Telefoonnummer</th>
<th>Intubatiegraad:</th>
<th>Wijze inbrengen keeltampon:</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Medicatieregistratie</th>
<th>Medicament+dosering</th>
<th>Tijd</th>
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<tbody>
<tr>
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</table>

**Premedicatie**

<p>| | | |</p>
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**Anaesthesie**

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</table>

**Peroperatief**

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<th></th>
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</thead>
</table>

**Postoperatief**

<p>| | | |</p>
<table>
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<tr>
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<th></th>
<th></th>
</tr>
</thead>
</table>

Vragenlijst postoperatieve keelpijn en PONV

**Tijdstip eerste meting:**

**KEELPIJN**

1. NRS:
2. NRS:
3. Tussen 1e en 2e meting:

**MISSELIJKHEID**

   Effect medicatie:
   Effect medicatie:
3. Tussen 1e en 2e meting:
   Effect medicatie:

Eerder PONV | JA / NEE
Bekend met reis-/wagensziekte | JA / NEE
Appendix 4 Patient information letter

Research group

Onderzoek naar misselijkheid en keelpijn na een operatie

Deventer, 4 maart 2013

Geachte heer/mevrouw,

Zojuist bent u geopereerd. Na de operatie is u gevraagd of u keelpijn heeft, hoe erg die pijn is en of u misselijk was. Deze vragen zijn u gesteld in het kader van medisch-wetenschappelijk onderzoek dat in het Deventer Ziekenhuis wordt verricht naar de mate waarin patiënten na een operatie aan de neus, traanbuis of de aangezichtshotel klachten hebben van misselijkheid of keelpijn. Wij vragen u vriendelijk en vrijblijvend deel te nemen aan dit onderzoek.

Wij kunnen ons voorstellen dat u het lastig vindt om zo vlak na de operatie een beslissing hierover te nemen. Daarom kunt u deze informatie nog eens rustig doorlezen en bespreken met uw naasten. Als u na het lezen van de informatie nog vragen heeft kunt u contact opnemen met de onderzoeker of haar begeleider. De contactgegevens vindt u onderaan deze brief.

Mocht u zich na het lezen van de informatie bedenken en wilt u liever toch niet dat uw gegevens gebruikt worden voor onderzoek, dan kunt u dat altijd laten weten. Uw gegevens zullen dan uit het onderzoek verwijderd worden. Dit heeft geen consequenties voor uw verdere behandeling in het Deventer Ziekenhuis.

Wat is het doel van het onderzoek?
Misselijkheid na een operatie komt regelmatig voor. Dit wordt soms veroorzaakt door de narcose, maar niet iedere patiënt heeft hier (evenveel) last van. Daarnaast bestaat bij patiënten die geopereerd worden aan de neus, traanbuis of aangezichtshotel de kans dat er wat bloed in de maag loopt afkomstig uit het operatiegebied. Hiervan kun je je ook misselijk gaan voelen. Om dit te voorkomen wordt tijdens de operatie gaas achter in de keel voor de ingang van de slokdarm geplaatst om te voorkomen dat bloed in de maag kan komen.

Daarnaast kunnen patiënten wat keelpijn hebben na de operatie als gevolg van een beademingsbuis die noodzakelijk is om tijdens de narcose te kunnen beademen. Het doel van het onderzoek is uit te zoeken of het gaas achter in de keel extra klachten geeft na de operatie. Daarnaast willen we graag zeker weten of dat gaas in de keel de kans op misselijkheid daadwerkelijk verminderd.

Wat wordt er van u verwacht als u deelneemt aan het onderzoek?
Aan uw behandeling verandert niets. U hebt voor en tijdens de operatie dezelfde medicijnen gekregen als iedere andere patiënt die in het Deventer Ziekenhuis geopereerd wordt. Ook krijgt u na de operatie de gebruikelijke medicijnen tegen misselijkheid en pijn, als u die nodig heeft. Wat we van u vragen, is om tweemaal de vragen te beantwoorden die de onderzoeker u zal stellen over misselijkheid en keelpijn die u eventueel kunt hebben.

Op de dag dat u naar huis gaat hoeft u niet te wachten tot de onderzoeker langs is geweest. Zij belt u dan na de operatie thuis op zodat u de vragen telefonisch kunt beantwoorden.

Wat zijn de voor- en nadelen van deelname voor u?
U heeft zelf geen voordeel van deelname aan het onderzoek. Het onderzoek levert mogelijk voordeel op voor toekomstige patiënten, doordat gekeken wordt hoe we ervoor kunnen zorgen dat patiënten zo min mogelijk last hebben van pijn en misselijkheid na een operatie. Een eventueel nadeel is dat er twee keer iemand bij u langs zal komen om u een aantal vragen te stellen over misselijkheid en keelpijn.
Effectiveness and safety of the routinely use of throat packs in ENT surgery

**Wat gebeurt er als u niet wenst deel te nemen aan het onderzoek?**
Deelname is vrijwillig. Als u besluit niet mee te doen, hoeft u verder niets te doen. U hoeft niet te zeggen waarom u niet mee wilt doen en hoeft niets te tekenen. Aan uw behandeling verandert dan niets, u krijgt de behandeling die u anders ook zou krijgen. Ook als u zich tussentijds of achteraf bedenkt, kunt u altijd stoppen. Uw gegevens zullen dan uit het onderzoek verwijderd worden.

**Wat gebeurt er met uw gegevens?**
Uw gegevens zijn vertrouwelijk en zullen anoniem worden verwerkt. Er wordt alleen gekeken naar informatie die van belang is voor het onderzoek. Uw medische gegevens en privacy worden volgens de geldende regels gerespecteerd. De antwoorden die u geeft op de vragenlijsten worden in een computerprogramma verwerkt, waarin ook de andere relevante informatie wordt opgenomen. Gegevens die u herkenbaar maken, zoals naam en geboortedatum, worden hier niet in gebruikt. In plaats daarvan krijgt u in het computerprogramma een codenummer dat gebruikt zal worden in documentatie over het onderzoek.

**Wilt u verder nog iets weten?**
Voor vragen kunt u altijd contact opnemen met de onderzoeker: Mw. A.J. Petri, te bereiken via e-mail (petria@dz.nl) of telefonisch (0570 – 53 53 53 doorverbinden met 2822) of haar begeleider JMG Cobben, anesthesioloog via de telefoniste van het ziekenhuis. Mocht u uw vragen aan een onafhankelijk arts willen stellen, dan kunt u zich wenden tot T. van der Laan, KNO-arts, te bereiken via de telefoniste van het ziekenhuis.

Heeft u klachten over iets dat met het onderzoek te maken heeft neemt u dan contact op met de onderzoeker of haar begeleider. U kunt natuurlijk ook contact opnemen met de klachtencommissie van het Deventer Ziekenhuis via telefoonnummer 0570 – 53 61 44.

Met vriendelijke groet,

Mw. A.J. Petri

Onderzoeker: A.J. Petri, BSc, afdeling Anesthesiologie
Deventer Ziekenhuis
Nico Bolkensteinlaan 75
7416 SE Deventer
Tel: 0570 – 53 53 53 intern 2822
E-mail: petria@dz.nl

Begeleider: drs. J.M.G. Cobben, Anesthesioloog
Deventer Ziekenhuis
Nico Bolkensteinlaan 75
7416 SE Deventer

**Control group**

**Onderzoek naar misselijkheid en keelpijn na een operatie**

Deventer, 4 maart 2013

Geachte heer/mevrouw,

Zojuist bent u geopereerd. Na de operatie is u gevraagd of u keelpijn heeft, hoe erg die pijn is en of u misselijk was. Deze vragen zijn u gesteld in het kader van medisch-wetenschappelijk onderzoek dat in het Deventer Ziekenhuis wordt verricht naar de mate waarin patiënten na een operatie klachten hebben van misselijkheid of keelpijn. Wij vragen u vriendelijk en vrijblijvend deel te nemen aan dit onderzoek.
Wij kunnen ons voorstellen dat u het lastig vindt om zo vlak na de operatie een beslissing hierover te nemen. Daarom kunt u deze informatie nog eens rustig doorlezen en bespreken met uw naasten. Als u na het lezen van de informatie nog vragen heeft kunt u contact opnemen met de onderzoeker of haar begeleider. De contactgegevens vindt u onderaan deze brief.

Mocht u zich na het lezen van de informatie bedenken en wilt u liever toch niet dat uw gegevens gebruikt worden voor onderzoek, dan kunt u dat altijd laten weten. Uw gegevens zullen dan uit het onderzoek verwijderd worden. Dit heeft geen consequenties voor uw verdere behandeling in het Deventer Ziekenhuis.

**Wat is het doel van het onderzoek?**
Dit onderzoek richt zich op patiënten geopereerd aan neus, aangezichtsholten of traanbuis. U zult zich afvragen waarom u dan bent benaderd, aangezien u vanwege een geheel andere reden geopereerd bent. U bent benaderd omdat we willen weten of misselijkheid en keelpijn vaker voorkomen bij patiënten die aan neus, aangezichtsholten of traanbuis geopereerd worden, dan bij patiënten die een andere operatie hebben ondergaan. Zoals u.

Misselijkheid na een operatie komt regelmatig voor. Dit wordt soms veroorzaakt door de narcose, maar niet iedere patiënt heeft hier (evenveel) last van. Daarnaast bestaat bij patiënten die geopereerd worden aan de neus, traanbuis of aangezichtsholten de kans dat er wat bloed in de maag loopt afkomstig uit het operatiegebied. Hiervan kun je je ook misselijk gaan voelen. Om dit te voorkomen wordt tijdens de operatie gaas achter in de keel voor de ingang van de slokdarm geplaatst om te voorkomen dat bloed in de maag kan komen.

Daarnaast kunnen patiënten wat keelpijn hebben na de operatie als gevolg van een beademingsbuis die noodzakelijk is om tijdens de narcose te kunnen beademen. Het doel van het onderzoek is uit te zoeken of het gaas achter in de keel extra klachten geeft na de operatie. Daarnaast willen we graag zeker weten of dat gaas in de keel de kans op misselijkheid daadwerkelijk verminderd.

U heeft tijdens de operatie een buisje in de keel gekregen om te kunnen worden beademd, maar u heeft geen gaas in de keel gehad. Daar was immers geen reden toe bij deze operatie. Om te kunnen beoordelen wat de invloed van dat gaas is op eventuele misselijkheid en pijnklachten in de keel, willen we u dezelfde vragen stellen als de patiënten die tijdens de operatie wél zo’n gaas in de keel hebben gekregen.

**Wat wordt er van u verwacht als u deelneemt aan het onderzoek?**
Aan uw behandeling verandert niets. U hebt voor en tijdens de operatie dezelfde medicijnen gekregen als iedere andere patiënt die in het Deventer Ziekenhuis geopereerd wordt. Ook krijgt u na de operatie de gebruikelijke medicijnen tegen misselijkheid en pijn, als u die nodig heeft. Wat we van u vragen, is om tweemaal de vragen te beantwoorden die de onderzoeker u zal stellen over misselijkheid en keelpijn die u eventueel kunt hebben.

Op de dag dat u naar huis gaat hoeft u niet te wachten tot de onderzoeker langs is geweest. Zij belt u dan na de operatie thuis op zodat u de vragen telefonisch kunt beantwoorden.

**Wat zijn de voor- en nadelen van deelname voor u?**
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**Wat gebeurt er als u niet wenst deel te nemen aan het onderzoek?**
Deelname is vrijwillig. Als u besluit niet mee te doen, hoeft u verder niets te doen. U hoeft niet te zeggen waarom u niet mee wilt doen en hoeft niets te tekenen. Aan uw behandeling verandert dan niets, u krijgt de behandeling die u anders ook zou krijgen. Ook als u zich tussentijds of achteraf bedenkt, kunt u altijd stoppen. Uw gegevens zullen dan uit het onderzoek verwijderd worden.
Wat gebeurt er met uw gegevens?
Uw gegevens zijn vertrouwelijk en zullen anoniem worden verwerkt. Er wordt alleen gekeken naar informatie die van belang is voor het onderzoek. Uw medische gegevens en privacy worden volgens de geldende regels gerespecteerd. De antwoorden die u geeft op de vragenlijsten worden in een computerprogramma verwerkt, waarin ook de andere relevante informatie wordt opgenomen. Gegevens die u herkenbaar maken, zoals naam en geboortedatum, worden hier niet in gebruikt. In plaats daarvan krijgt u in het computerprogramma een codenummer dat gebruikt zal worden in documentatie over het onderzoek.

Wilt u verder nog iets weten?
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Heeft u klachten over iets dat met het onderzoek te maken heeft neemt u dan contact op met de onderzoeker of haar begeleider. U kunt natuurlijk ook contact opnemen met de klachtencommissie van het Deventer Ziekenhuis via telefoonnummer 0570 – 53 61 44.

Met vriendelijke groet,

Mw. A.J. Petri

Onderzoeker: A.J. Petri, BSc, afdeling Anesthesiologie
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Nico Bolkensteinlaan 75
7416 SE Deventer
Tel: 0570 – 53 53 53 intern 2822
E-mail: petria@dz.nl

Begeleider: drs. J.M.G. Cobben, Anesthesioloog
Deventer Ziekenhuis
Nico Bolkensteinlaan 75
7416 SE Deventer
Appendix 5 Flow diagram excluded patients

All patients included n=215

Anesthesia other than TIVA
n=8 (research group)

PCA or epidural analgesia with opioids
n=20 (control group)

For analysis PONV:
- research group n=85
- control group n=101

Throat pain before surgery
n=3

Surgery also involved tonsil niche
n=1

For analysis throat pain:
- research group n=91
- control group n=120