Sharma et al. Ain-Shams Journal of Anesthesiology (2021) 13:26
https://doi.org/10.1186/s42077-021-00144-8

Ain-Shams Journal of Anesthesiology

ORIGINAL ARTICLE Open Access

Dexamethasone to decrease post-anesthesia sore throat (POST) and hoarseness-which is the most effective route: intravenous, topical, or nebulization? A prospective randomized trial

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Abstract

Background and Aims: Postoperative sore throat (POST) is common after endotracheal intubation making patients uncomfortable and anxious in postoperative period. The present study was undertaken to compare efficacy of equal dose of dexamethasone in preventing POST via three different routes, i.e., intravenous, topical, and nebulization before surgery.

Methods and Results: The present prospective double-blind randomized parallel group trial included 190 patients of either sex above 18 years, American Society of Anesthesiologists (ASA) physical status I–II posted for laparoscopic cholecystectomy. The patients were divided into three groups. Patients in group N were nebulized with 8 mg dexamethasone prior to surgery, patients in group I received intravenous dexamethasone (8 mg) before induction of anesthesia, while patients in group C were intubated with endotracheal tube which was pretreated (cuff soaked in dexamethasone 8 mg). The severity of POST and hoarseness of voice was determined by interviewing patients after 24-h of completion of surgery. Incidence of POST decreased in all patients with maximum decrease in group N (18%), while 30.8% in group I and 30.4% in group C. This decrease was not statistically significant when compared to group I (p 0.14) as well as group C (p 0.15). Incidence of hoarseness significantly decreased in group N (15.6%) as compared to group I (40.3%) as well as group C (39.1%). This decrease was statistically significant when compared to group I (p 0.005) as well as group C (p 0.009).

Conclusions: Topical dexamethasone (group C) is as effective as intravenous dexamethasone in decreasing incidence of POST, while both the techniques are not effective in decreasing hoarseness of voice. Nebulization is most effective method in decreasing POST as well as hoarseness.

Trial Registration: CTRI/2017/08/009524 dated 29 August 2017 prospectively.

Keywords: Cuff soaking in dexamethasone, Dexamethasone, Nebulization, Postoperative sore throat

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Background

Postoperative sore throat (POST) is a common complication after general anesthesia. Though considered to be a minor complication by most of the clinicians, it may be quite distressing for the patient. Postoperative sore throat results in cough. Cough after any surgery causes strain at the suture site increasing pain at site of surgery and thus further adding to the patient's discomfort and dissatisfaction. It also adds to patient morbidity and making postoperative period a bad memory for patient (Lee et al., 2017). Hoarseness is also known to occur after endotracheal intubation. This change in voice may range from mild hoarseness noted by the patient to complete aphonia.

The incidence of POST may be up to 90% (Saarnivaara & Grahne, 1981; Jensen et al., 1982; Stride, 1990) and that of hoarseness reported in different studies ranges from 4 to 43% (Winkel & Knudsen, 1971; Jones et al., 1992).

A lot of research work has been published in past for reducing POST and hoarseness of voice either as non-pharmacological or pharmacological methods. Non-pharmacological methods in the form of appropriate size of endotracheal tube, presence or absence of cuff or use of airway adjuncts like stylet or bougie, and pharmacological methods which includes various drugs administered intravenous or topically. These drugs include ketamine, lignocaine, aspirin, dexamethasone, and magnesium sulfate.

Use of drugs like ketamine can have adverse effects on hemodynamics or on central nervous system. Intracuff lidocaine decrease POST but may increase hoarseness due to nerve paresis (Rajan et al., 2018) while aspirin gargle may affect coagulation (Kalil et al., 2014).

Previous studies suggest that dexamethasone is effective in decreasing the incidence of POST when given via different routes, i.e., intravenous (Subedi et al., 2019; Thomas & Beevi, 2007; Jiang et al., 2018; Zhao et al., 2015; Kadar, 2015), nebulization (Salama & El-badawy, 2016), or topical (Lee et al., 2017). We assumed that by soaking cuff of endotracheal tube (ETT) in dexamethasone, we will deliver drug directly to the laryngeal wall (direct contact), while with nebulization the drug will be absorbed directly to upper airway mucosa.

When we searched the literature, there was no study comparing equal doses of dexamethasone when given via different routes, i.e., intravenous, after dipping endotracheal tube cuff and nebulization in preventing POST and hoarseness. So we took up the present study.

Methods

This study was designed as a prospective, double-blind randomized parallel group trial. After written informed consent, we included 190 adult patients of either sex with ASA physical status I–II and above the age of 18 years posted for elective laparoscopic cholecystectomy surgery over a period of 1 year in a tertiary care institute between August 2017 and 2018. Approval from institutional ethics committee was taken and the study was registered in CTRI.

Patients who were on steroids; had anticipated difficult intubation; required manipulation or instrumentation of airway (like oral airway, stylet, bougie, external laryngeal maneuver); needed 2nd attempt during ETT insertion; were with a sore throat, upper respiratory infection, or hoarseness of voice; and coughed on extubation were excluded from the study.

The patients were assessed a day prior to surgery in PAC (pre-anesthetic checkup) clinic and the patients to be taken up for the study were selected. The randomization was done using computer-generated random number table using opaque envelopes and the patients were divided into three groups. In the first group (group N), patients were nebulized with dexamethasone (8 mg in 6 ml), normal saline (6 ml) was given intravenously at the time of induction, and their ETT cuff was dipped in normal saline. In the second group (group I), patients were nebulized with normal saline (6 ml) half an hour prior to induction, dexamethasone (8 mg in 6 ml) was given intravenously at the time of induction, and their ETT cuff was dipped in normal saline. In the third group (group C), patients were nebulized with normal saline (6 ml), normal saline(6 ml) was given intravenously at the time of induction, and the ETT cuff was dipped in dexamethasone (8 mg in 6 ml).

All patients were given alprazolam 0.5 mg orally the night before surgery. On day of surgery, the patient was taken to the preoperative area where non-invasive blood pressure and pulse oximeter was attached. After securing intravenous line, the patient was nebulized with either normal saline or 8 mg dexamethasone (total volume 6 ml) according to randomization 30 min prior to the induction. The patient was then shifted to operation theater and monitors (electrocardiography, non-invasive blood pressure, and pulse oximeter) were attached. The patient was then administered either normal saline or 8 mg dexamethasone intravenously according to the group allocated. Anesthesia was induced by giving injection fentanyl 2 μg/kg, propofol 2 mg/kg, and atracurium 0.5 mg/kg. After 4 min of giving atracurium, laryngoscopy was done by the anesthesiologist with a minimum experience of 3 years with appropriate size MacIntosh blade. Airway was secured with pretreated single use disposable PVC Portex tubes with large volume low pressure cuff (size of 7-mm and 8-mm internal diameter for females and males, respectively). The ETT was pretreated by dipping in 10 ml syringe (after taking out the plunger and blocking the open end) either containing

dexamethasone 8 mg or normal saline for 10 min before intubation. The Cormack-Lehane grade was noted in all patients during laryngoscopy. The cuff was inflated with room air and cuff pressure was kept 20–25 cm of water. The ETT placement was confirmed with end-tidal carbon dioxide concentration. Anesthesia was maintained with isoflurane (1–1.2%) in oxygen-air mixture and atracurium. Mechanical ventilation was adjusted to maintain partial pressure of carbon dioxide between 30 and 35. Cuff pressure was monitored with cuff manometer every 15 min and after change in the position of patient and was kept between 20 and 25 cm of water. Paracetamol infusion (15 mg/kg) and ondansetron 4 mg were given intravenously for postoperative pain relief and postoperative nausea and vomiting. After surgery was over, gentle oral suctioning was done and anesthesia was reversed with glycopyrrolate (0.01 mg/kg) and neostigmine (0.05 mg/kg) by the same anesthesiologist who performed intubation. When the patient was able to obey verbal commands and ventilation was considered adequate, extubation was done. Any cough during extubation was noted. Institutional protocol for analgesics in the postoperative period was followed in form of 1 g paracetamol every 8 h and tramadol 50 mg on demand intravenously for incisional pain.

Patients were assessed for POST and hoarseness in postoperative period after 24 h. The anesthesiologist who did the scoring in the postoperative ward was blinded to the route of administration of dexamethasone. Sore throat (Canbay et al., 2008) was graded as 0 = no sore throat, 1 = mild sore throat (complains of sore throat only on asking), 2 = moderate sore throat (complains of sore throat on his/her own), and 3 = severe sore throat (change in voice or hoarseness, associated with throat pain). Hoarseness of voice (Kadar, 2015) was graded as 0, none; 1, noted by the patient; 2, obvious to observer; and 3, aphonia.

The primary objective of our study was to compare the efficacy and incidence of equal dose of dexamethasone in decreasing the incidence of POST and hoarseness when given via three different routes, i.e., intravenous, topical, and nebulization.

Statistical analysis and sample size

As data from previous studies was analyzed (Kadar, 2015), taking an incidence of 60% of POST with precision of 7% at confidence interval of 95%, the sample size was calculated to be 190 using software Epi Info Version 7. Statistical analysis was performed using Epi info Version 7. The results were expressed as the mean ± standard deviation (SD) or number of patients (%). Chi-square and Fisher exact test were used to compare proportions and a p value of less than 0.05 was considered to be statistically significant.

Results

A total of 190 ASA I–II patients were enrolled in this study out of which 41 patients were excluded from the analysis. These patients were excluded because either they required 2nd attempt for intubation or airway adjuncts like stylet or bougie were used. Two patients had Cormack-Lehane grade 4 during laryngoscopy while nine patients coughed on extubation were also excluded from the study so as to determine the true incidence of POST. The demographic profile of the patients has been described in Table 1. All patients were hemodynamically stable throughout the study period.

There was a difference in the incidence of POST among three groups with minimum incidence (18%) in the patients who were nebulized with dexamethasone (Fig. 1). Odds of having POST (Table 2) with intravenous dexamethasone as compared to the patients who were nebulized with dexamethasone was 1.82 (95% CI, confidence interval), while it was 1.79 when the patients in whom cuff soaked in dexamethasone was used were compared to the patients who were nebulized with dexamethasone, though the p value in both the cases was not found to be statistically significant.

Similarly, there was a difference in the incidence of hoarseness among three groups with minimum incidence (15.6%) in the patients who were nebulized with dexamethasone (Fig. 1). Odds of having POST (Table 2) with intravenous dexamethasone as compared to the patients who were nebulized with dexamethasone was 3.64 (95% CI), while it was 3.45 when the patients in whom cuff soaked in dexamethasone was used were compared with the patients who were nebulized with dexamethasone. p value in both the cases was found to be statistically significant (Table 2).

Two patients complained of severe sore throat in patients who received intravenous dexamethasone, while one patient had severe sore throat in the patients in whom pretreated cuff was used. None of the patients had severe sore throat when nebulized with dexamethasone. Hoarseness was mild in all cases who were nebulized with dexamethasone, while it was mild in all but one patient in whom dexamethasone was administered intravenous as well as the patients in whom pretreated cuff was used (Table 3).

Discussion

In an era of day care surgeries especially laparoscopic where hospital stay is kept minimum (24–48 h), all efforts are made to make the patient comfortable so that he can return to daily activities as soon as possible.

POST has been reported in literature after the use of endotracheal tube, supraglottic devices, or even face mask. The underlying cause might be trauma to oropharynx, base of tongue or posterior pharyngeal wall, or

Table 1 Demographic profile and duration of surgery

	Group I (n = 52)	Group C (n = 46)	Group N (n = 51)
Age (years)	44.35 ± 12.97	44.52 ± 12.19	43.02 ± 14.25
Gender (M/F)	12/40	10/36	14/37
BMI (kg/m^2)	22.76 ± 3.07	22.78 ± 3.53	22.74 ± 3.38
Duration of surgery (min)	56.54 ± 10.26	54.57 ± 12.05	55.78 ± 12.58

M/F male/female, *BMI* body mass index; duration of surgery in mean ± standard deviation (SD)

inflammation secondary to allergy to any component of the airway device used. Further trauma to epithelial or deeper layers of vocal cords may cause inflammation and edema which can affect the voice quality (Kotekar & Vyshnavi, 2019). Hoarseness usually resolves spontaneously (< 6 weeks) (Yamanaka et al., 2009).

Inflammatory reaction sets in after the initial insult. It is this early stage of inflammation that is inhibited by the corticosteroids (Patra & Nayak, 2008).

Dexamethasone is a potent corticosteroid which has 26.6 and 6.6 times stronger anti-inflammatory and immunosuppressant effects than cortisol and prednisone, respectively (Lee et al., 2017). It has anti-inflammatory property and is reported to be effective in treatment of sore throat (Zhao et al., 2015) and decreasing edema in airway after traumatic intubation. Further, it is used in perioperative period as an antiemetic (Patra & Nayak, 2008) and also to potentiate analgesic effects. It has rapid onset and short duration of action. It is cheap so can be considered as a good option.

It reduces the production of inflammatory mediators, prostaglandins, and leukotrienes. The mechanism behind this is inhibition of phospholipase-A_2 through production of calcium-dependent phospholipid-binding proteins known as annexins (Yao et al., 1999) and cyclooxygenase (Lubenow et al., n.d.). The mechanism of post-extubation laryngeal edema due to endotracheal intubation trauma is infiltration of fibrinous exudates and polymorph nuclear cells (Patra & Nayak, 2008).

Dexamethasone when used in treating POST by different routes is found to be effective (Rajan et al., 2018), intravenous being most commonly studied, but it has some undue side effects (Henzi et al., 2000). However, there are studies which show that single dose of dexamethasone has no systemic adverse effects (Meade et al., 2001) like adrenal suppression, gastritis, glucose intolerance, osteoporosis, and high blood pressure. Also, glucocorticoids do not increase risk of postoperative infection (Becker, 2013). It has also been reported that rapid intravenous infusion of dexamethasone in awake patients may cause genital or perineal burning or itch (Neff et al., 2002), and it is hence been recommend to administer them either in diluted form or after induction of general anesthesia.

Local therapy with dexamethasone, i.e., either nebulization or using the ETT with cuff soaked in dexamethasone, assures that maximum concentration of drug is delivered to the area of concern, i.e., upper airway and side effects are less. Local therapies allow the use of smaller doses and reduce systemic side effects as well (Ibrahim et al., 2015). We did not use topical dexamethasone preparation because lubricants made no difference to the incidence as shown in previous studies and also contain some amount of local anesthetic which may worsen the problem and may precipitate laryngospasm (Kadar, 2015). Also, we wanted to deliver equal doses of drug via all three routes though efficacy of absorption from every route is different.

We excluded all patients in whom airway trauma could possibly have occurred, i.e., anticipated difficult intubation, manipulation, or instrumentation of airway, 2nd attempt during ETT insertion, and in whom patient coughed on extubation. Further patients with sore throat, upper respiratory infection, or hoarseness of voice were also excluded. We also monitored the cuff pressure (kept < 30 cm of H_2O) in our study as cuff

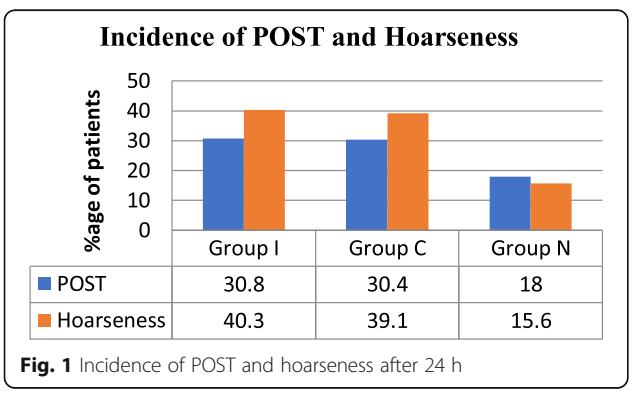

Fig. 1 Incidence of POST and hoarseness after 24 h

Table 2 Odds ratio with 95% confidence interval

	POST		Hoarseness	
	Odds ratio	p value	Odds ratio	p value
Group I vs C	1.01 (0.42–2.40)	0.57	1.05 (0.46–2.37)	0.532
Group C vs N	1.79 (0.70–4.56)	0.15	3.45 (1.32–9.01)	0.009*
Group I vs N	1.82 (0.73–4.51)	0.14	3.64 (1.42–9.28)	0.005*

*p value < 0.05 considered significant

Table 3 Grading and severity of POST and hoarseness of voice

	Severity of POST				Severity of hoarseness of voice			
	0	1	2	3	0	1	2	3
Group I	36 (69.2%)	13 (25%)	1 (1.9%)	2 (3.8%)	31 (38.4%)	20 (38.4%)	1 (1.9%)	0 (0)
Group C	32 (69.6%)	12 (26.1%)	1 (2.2%)	1 (2.2%)	28 (60.8%)	17 (36.9%)	1 (2.1%)	0 (0)
Group N	41 (80.3%)	9 (17.6%)	1 (1.9%)	0 (0)	43 (84.35%)	8 (15.6%)	0 (0)	0 (0)

*Values expressed in number (percentage)

pressure and volume are considered to be most crucial and essential factors that affect the vocal characteristics. Further, we avoided nitrous oxide during general anesthesia.

In our study, incidence of POST was 30.8% in patients who received intravenous dexamethasone. Subedi et al. (Subedi et al., 2019) administered dexamethasone 8 mg iv just before induction in one group and found the incidence of POST to be 36%, while Thomas et al. (Thomas & Beevi, 2007) administered a similar dose and found the incidence to be 20% at 24 h. Bagchi et al. (Bagchi et al., 2012) found the incidence of sore throat with intravenous dexamethasone (0.2 mg/kg) was 29.2% at the end of 24 h. In a study by Park et al. (Park et al., 2010), POST was found in 28% patients at the end of 24 h when prophylactic intravenous dexamethasone 10 mg was administered. In a meta-analysis by Jiang et al. (Jiang et al., 2018), authors concluded that prophylactic administration of dexamethasone ≥ 0.2 mg/kg intravenously within 30 min before or after induction of general anesthesia should be recommended as grade 1A evidence with safety and efficacy for patients without pregnancy, diabetes mellitus, or contraindications for corticosteroids.

Incidence of POST was 30.4% when the endotracheal tube cuff was soaked in dexamethasone. Similarly, Lee et al. (Lee et al., 2017) in their study found that the incidence of POST was 27% during the initial 24 h after surgery when the ETT cuff was soaked in dexamethasone (0.05% solution). They further found that gargling with dexamethasone reduced the incidence to 33%. It signifies that topical use of dexamethasone is as effective on POST as intravenous injection of dexamethasone.

The incidence of POST decreased to 18% when the patients were nebulized with dexamethasone. Hence, nebulization was found to be most effective method in decreasing POST. In a study by Salama et al. (Salama & El-badawy, 2016), the incidence and severity of POST were significantly reduced in the dexamethasone group than in the saline group at 2, 4, 8, and 12 h after extubation; however, there was no significant difference after 24 h. No complication was reported with dexamethasone nebulization. In a meta-analysis by Kuriyama et al. (Kuriyama et al., 2019), it was found that aerosolized corticosteroids may be superior to non-analgesic methods in preventing POST.

Incidence of hoarseness was found in 40.3% of patients who received intravenous dexamethasone. Bagchi et al. (Bagchi et al., 2012) found the incidence of hoarseness with intravenous dexamethasone (0.2 mg/kg) was 29.2% which was equal to the incidence of POST. Park et al. (Park et al., 2010) found hoarseness to be present in 56% patients at the end of 24 h when prophylactic intravenous dexamethasone 10 mg was administered.

Hoarseness was found to be present in 39.1% of patients in whom pretreated ETT was used. Lee et al. (Lee et al., 2017) found the incidence of hoarseness to be 13% when the ETT was dipped in 0.05% dexamethasone at 24 h.

Severity of hoarseness in our study was grade 1 (noted by the patient) in 38.4% patients in whom intravenous dexamethasone was administered. Again, it was grade I in 36.9% of patients in whom cuff soaked in dexamethasone was used, while it was 15.6% in the patients who were nebulized with dexamethasone.

Our findings suggested that isolated hoarseness can occur. This could be due to the fact that larger surface area of cuff is in contact with the airway mucosa though mechanisms can be multiple as quoted by researchers (Jones et al., 1992; Kotekar & Vyshnavi, 2019; Yamanaka et al., 2009). Many factors related to the general anesthesia can change voice quality like interviewing patient within 24 h of surgery, dehydration, use of narcotics, and position of cuff after intubation.

Limitation of our study was that we did not do the postoperative blood glucose levels which could substantiate whether the effect of dexamethasone was due local or systemic effect. There was no control group, so we could not compare overall decrease in incidence of POST and hoarseness. There is a difference in terms of bioavailability of dexamethasone depending on the administration route chosen which cannot be commented upon. There were more females in the study population which was only a matter of chance during sampling.

Conclusion

In conclusion, it can be said that topical dexamethasone (ETT cuff dipped in dexamethasone) is equally effective to intravenous dexamethasone in decreasing incidence

of POST while both the techniques have no effect in decreasing hoarseness of voice. Nebulization with 8 mg dexamethasone was found to be most effective method of reducing POST and hoarseness without causing much systemic side effects and hence can be a preferred route for decreasing POST and hoarseness.

We recommend further studies to verify and authenticate our results on larger population.

Abbreviations

POST: Postoperative sore throat; ASA: American Society of Anesthesiologists; ETT: Endotracheal tube; CTRI: Central Trials Registry-India; PAC: Pre-anesthetic checkup; CI: Confidence interval; SD: Standard deviation; BMI: Body mass index

Acknowledgements

Not applicable

Authors' contributions

SS, VB, and SjS done the concepts, design, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. SR done the concepts, design, literature search, clinical studies, experimental studies, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. SS is the guarantor. All authors have read and approved the manuscript.

Funding

None.

Availability of data and materials

The datasets used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Yes, written informed consent was taken from all the study participants. Details: Dr. Rajendra Prasad Government Medical College Kangra at Tanda, Himachal Pradesh, India, 176001, Institutional Ethics Committee with registration number ECR/490/Inst/HP/2013, and reference number of study is IEC/15/2017. Consent to participate has also been taken from all the study participants as per the approval by the committee.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 2 May 2020 Accepted: 15 March 2021
Published online: 26 March 2021

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