นิพนธ์ต้นฉบับ Original Article

ผลของยา Dexamethasone ในการลดอาการเจ็บคอและเสียงแหบหลังผ่าตัดที่มีการใส่ท่อช่วยหายใจใส่หลอดลมแขนงชนิดสองช่อง

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บทคัดย่อ

อาการเจ็บคอและเสียงแหบหลังผ่าตัดเป็นภาวะแทรกซ้อนที่พบได้ทั่วไปภายหลังการใส่ท่อช่วยหายใจใส่หลอดลมแขนงชนิดสองช่อง การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิภาพและความปลอดภัยของยา เดกซาเมทาโซน (dexamethasone) ในการป้องกันอาการเจ็บคอและเสียงแหบในผู้ป่วย 94 ราย ที่เข้ารับการผ่าตัดทรวงอกซึ่งต้องใช้ท่อช่วยหายใจใส่หลอดลมแขนงชนิดสองช่อง ณ โรงพยาบาลสกลนคร ระหว่างเดือน พฤศจิกายน พ.ศ. 2565 – พฤษภาคม พ.ศ. 2566 โดยผู้ป่วยถูกสุ่มแบ่งเป็นสองกลุ่ม กลุ่มแรกได้รับยาเดกซาเมทาโซนขนาด 0.2 มก./กก. กลุ่มควบคุมได้น้ำเกลือทางหลอดเลือดดำหลังการนำสลบ วัตถุประสงค์หลักของการศึกษา คือ อุบัติการณ์และความรุนแรงของอาการเจ็บคอและเสียงแหบที่เวลา 1 ชั่วโมง และ 24 ชั่วโมงหลังผ่าตัด วัตถุประสงค์รอง คือ ศึกษาถึงผลข้างเคียงจากการให้ยา

ผลการศึกษาพบว่า กลุ่มที่ได้รับเดกซาเมทาโซนพบอุบัติการณ์ของอาการเจ็บคอต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทั้งที่ 1 ชั่วโมง (ร้อยละ 2.17 เทียบกับ ร้อยละ 28.26, $p < 0.001$) และ 24 ชั่วโมง หลังผ่าตัด (ร้อยละ 15.22 เทียบกับ ร้อยละ 56.52, $p < 0.001$) โดยเฉพาะที่ 24 ชั่วโมง สามารถลดความเสี่ยงของอาการเจ็บคอได้ถึงร้อยละ 73.07 โดยมีจำนวนผู้ป่วยที่ต้องรักษาเพื่อป้องกันหนึ่งรายเท่ากับ 2.42 รวมถึงอาการเสียงแหบก็ลดลงอย่างมีนัยสำคัญที่ 24 ชั่วโมง (ร้อยละ 6.52 เทียบกับร้อยละ 30.43, $p = 0.003$) นอกจากนี้ยังไม่พบผลข้างเคียงที่มีนัยสำคัญระหว่างการติดตามผล 2 สัปดาห์ จากผลการศึกษานี้แนะนำได้ว่าควรให้ยาเดกซาเมทาโซนทางหลอดเลือดดำขนาด 0.2 มก./กก. เพื่อช่วยป้องกันอาการเจ็บคอและเสียงแหบในผู้ป่วยที่มีคุณสมบัติเหมาะสมที่เข้ารับการผ่าตัดทรวงอกโดยได้รับการใส่ท่อช่วยหายใจใส่หลอดลมแขนงชนิดสองช่อง

คำสำคัญ: เดกซาเมทาโซน อาการเจ็บคอหลังผ่าตัด เสียงแหบ ท่อช่วยหายใจใส่หลอดลมแขนงชนิดสองช่อง การผ่าตัดทรวงอก

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The Prophylactic Effects of Dexamethasone on Postoperative Sore Throat and Hoarseness after Double Lumen Endobronchial Tube Intubation: a Randomized Controlled Trial

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Abstract

Postoperative sore throat (POST) and hoarseness are common complications following double–lumen endobronchial tube (DLT) intubation. This randomized, double–blinded, controlled trial aimed to evaluate the efficacy and safety of prophylactic dexamethasone in 94 patients undergoing thoracic surgery requiring DLT intubation at Sakon Nakhon Hospital between November 2022 and May 2023. Patients were randomly allocated to receive either dexamethasone 0.2 mg/kg or normal saline intravenously after anesthesia induction. Primary outcomes were the incidence and severity of POST and hoarseness at 1 and 24 hours postoperatively. Secondary outcomes included adverse effects.

The dexamethasone group showed significantly lower incidence of POST at both 1 hour (2.17% vs 28.26%, $p < 0.001$) and 24 hours (15.22% vs 56.52%, $p < 0.001$) postoperatively. The relative risk reduction at 24 hours was 73.07%, with a number needed to treat of 2.42. Hoarseness was also significantly reduced at 24 hours (6.52% vs 30.43%, $p = 0.003$). No significant adverse effects were observed during the 2–week follow–up period. Given these findings and its favorable risk–benefit profile, prophylactic intravenous dexamethasone 0.2 mg/kg is recommended for routine use in eligible patients undergoing thoracic surgery with DLT intubation.

Keywords: Dexamethasone, Postoperative sore throat, Hoarseness, Double–lumen tube, Thoracic surgery

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Introduction

Postoperative sore throat (POST) and hoarseness are common complications in patients undergoing general anesthesia with tracheal intubation, causing significantly postoperative discomfort and patient dissatisfaction.[1] The reported incidence of POST varies from 30% to 70%[2,3,4,5,6,7], with higher rates associated with double–lumen endobronchial tube (DLT) intubation compared to standard endotracheal tubes.[8]

The pathophysiology primarily involves mechanical trauma during intubation and inflammation of the airway mucosa from pressure effects of the endotracheal tube (ETT).[9] Risk factors include patient demographics (age, female gender, smoking history), procedural factors (intubation time, surgical duration), and technical aspects such as tube size and cuff pressure.[2,8,9,10] The use of DLT for one–lung ventilation particularly increases the risk of these complications compared to bronchial blockers, likely due to its larger diameter and more complex insertion technique.[8]

Dexamethasone has emerged as a promising prophylactic intervention due to its potent anti–inflammatory and analgesic properties. When administered as a single dose, it effectively suppresses the inflammatory cascade triggered by tissue injury while maintaining a favorable safety profile.[10,11,12] Recent studies have demonstrated that low–dose dexamethasone can reduce the incidence of POST and hoarseness following DLT intubation.[13] However, comprehensive data regarding potential adverse effects of single low–dose dexamethasone in this context remains limited.

Therefore, this randomized controlled trial aimed to evaluate both the efficacy and safety of a single low–dose intravenous dexamethasone in preventing postoperative sore throat and hoarseness following DLT intubation.

Methods

Design

A randomized, double–blind, controlled trial was conducted at Sakon Nakhon Hospital between November 2022 and May 2023 after ethics committee approval (Ref No. COA/2 No.007/2565). All participants provided written informed consent before enrollment.

Participants

Eligible participants were patients aged 18–75 years with ASA physical status I–III undergoing thoracic surgery requiring double–lumen endobronchial intubation. Exclusion criteria: preexisting sore throat/hoarseness, corticosteroid contraindications, recent intubation, pregnancy, BMI >30 kg/m^2, poorly controlled diabetes, expected surgery > 4 hours, Mallampati grade > 2, Cormack–Lehane grade 3–4. Discontinuation criteria: > 3 intubation attempts, anticipated postoperative ventilation.

Randomization and Blinding

Using computer–generated randomization, patients were allocated to receive normal saline (Group C) or dexamethasone 0.2 mg/kg IV (Group D). Allocation concealment used sealed opaque envelopes. The patients, anesthesiologist and anesthetic nurse who attend the case will be blinded. Double–blinding was maintained with non–participating nurses preparing identical 4 mL study medications.

Intervention Protocol

Standard monitoring was applied upon arrival in the operating room. Anesthesia was induced with morphine 0.1–0.2 mg/kg or fentanyl 1–2 mcg/kg, propofol 1–2 mg/kg, and succinylcholine 1–1.5 mg/kg IV. The study medication was

administered after induction. A non–participating anesthesiologist or anesthetic nurse with more than 3 years of experience performed intubation using a Macintosh laryngoscope (blade size 3–4) and a left–sided DLT (Bronchocath; Rüsch, Kernen, Germany). DLT size selection was based on patient height: 35 French for females <160 cm, 37 French for females ≥160 cm or males <170 cm, and 39 French for males ≥170 cm. DLT position was confirmed by flexible fiberoptic bronchoscopy initially and after lateral positioning. Cuff pressure was maintained below 20 cmH_2O throughout the procedure. Anesthesia was maintained with 2% sevoflurane. Mechanical ventilation was set with tidal volumes of 6–8 mL/kg, and FiO_2 was titrated between 50–100% during one–lung ventilation to maintain adequate oxygenation. All patients were carefully extubated at the end of surgery. In addition, the following parameters were recorded:

– Cormack–Lehane grade: a widely used classification system in anesthesiology for describing the view of the larynx during direct laryngoscopy. It is graded into four distinct classes:

Grade I (Best View): The entire glottis is clearly visible, full view of vocal cords, represents an easy intubation

Grade II: Only the posterior part of the glottis is visible, anterior portion of vocal cords or arytenoids are obscured, partial view of the larynx, moderate difficulty in intubation

Grade III: Only the epiglottis is visible, no view of the vocal cords, significant difficulty in intubation

Grade IV (Worst View): Even the epiglottis cannot be seen, extremely challenging intubation, may require advanced airway management techniques

– number of intubation attempts

– intubation time (from laryngoscopy insertion to successful intubation)

– number of DLT position adjustments, and total duration of intubation.

Outcome Measurement

Primary outcome: Postoperative sore throat and hoarseness

A blinded investigator assessed postoperative sore throat and hoarseness at 1 and 24 hours after surgery. Sore throat severity was evaluated using a numerical rating scale (0–10): 0 = no sore throat, 1–3 = throat discomfort, 4–6 = mild to moderate sore throat, and 7–10 = severe sore throat. Hoarseness was defined as any change in voice quality compared to preoperative status.

Secondary outcome: Adverse events, including hyperglycemia (within 24 hours) and surgical site infection (up to 2 weeks postoperatively), were monitored.

Sample size Calculation

Sample size was calculated using the formula for comparing two proportions in a randomized controlled trial with binary outcome. According to Park et al.[14], the incidence of sore throat was 57% in the placebo group and 27% in the dexamethasone group. Using a two–sided type I error (α) of 0.05 and a power (1–β) of 80%, the required sample size was calculated to be 42 patients per group. To account for a potential 10% dropout rate, the final sample size was increased to 47 patients per group, for a total of 94 patients.

Randomization and Bias Control

Computer–generated randomization with sealed opaque envelopes ensured allocation concealment. Double–blinding was maintained by non–participating nurses preparing identical medications. All procedures, assessments, and documentation followed standardized protocols

and CONSORT guidelines.

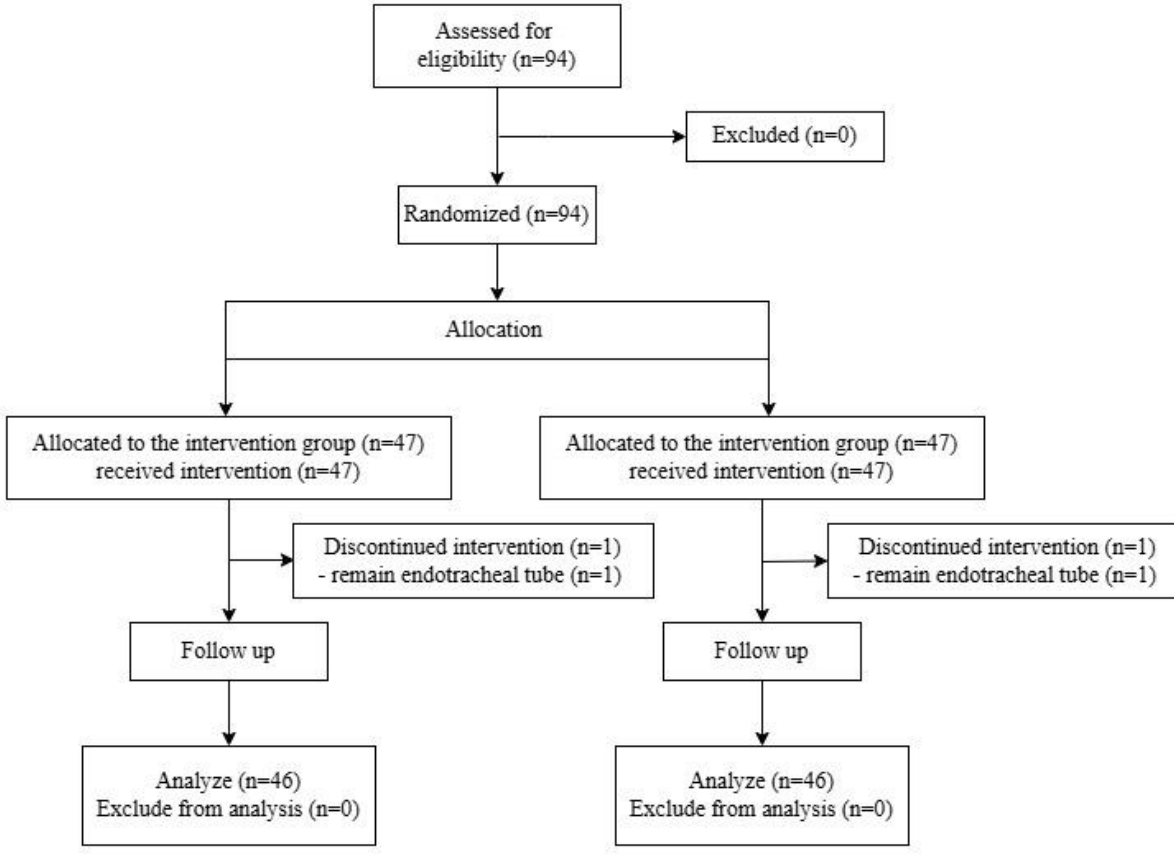
Statistical Methods

Analysis was performed using SPSS v26.0 (IBM Corporation, NY, USA). The Shapiro–Wilk test was used to assess normality of continuous variables. Continuous data are presented as mean ± SD and analyzed using independent t–test. Categorical data are shown as number (%) and analyzed using Fisher's exact test. Clinical effectiveness was evaluated using relative risk reduction and number needed to treat for POST and hoarseness outcomes. Statistical significance was set at $p < 0.05$. Per–protocol analysis was conducted for study completers. Multiple comparison was corrected by Bonferroni correction for secondary outcome (hoarseness) to avoid inflation of error.

Results

A total of 94 patients were assessed for eligibility and randomized into the study between November 2022 and May 2023. Forty–seven patients were allocated to each group. One patient in each group was discontinued from the study due to remaining endotracheal tube postoperatively. Final analysis included 46 patients in each group (Figure 1).

Figure 1 Consolidated standards of reporting trial diagram



The baseline demographic and clinical characteristics were comparable between groups (Table 1). There were no significant differences in age, gender distribution, weight, height, BMI, ASA physical status, smoking history, duration of intubation, number of intubation attempts, tube repositioning requirements, coughing during extubation, blood in suction, or perioperative opioid usage.

Table 1 Demographic data

Parameters	Treatment group (n = 46)	Control group (n = 46)	p
Gender (male/Female) (n)	34 / 12	28 / 18	0.182
Age (years, mean ± S.D.)	53.54 ± 2.01	51.32 ± 1.97	0.433
Weight (kg, mean ± S.D.)	62.17 ± 8.82	54.65 ± 1.39	0.402
Hight (cm, mean ± S.D.)	162.39 ± 1.13	160.63 ± 1.12	0.270
BMI (Kg/m^2, mean ± S.D.)	24.15 ± 3.98	21.14 ± 0.46	0.454
ASA (grade I/II/III) (n)	3 / 24 / 19	3 / 26 / 17	0.944
Smoking (smoke/non–smoke)	28 / 18	21 / 25	0.144
Intubate onset (min, mean ± S.D.)	20.11 ± 1.19	19.35 ± 1.40	0.679
Tube insertion (attempt, mean ± S.D.)	1.30 ± 0.07	1.30 ± 0.06	1.000
Re–position tube (time, 0/1/2) (n)	37 / 7 / 2	38 / 7 / 1	0.841
Cough (n, %)	7 (15.22)	5 (10.87)	0.536
Blood in suction (n, %)	2 (4.35)	1 (2.17)	1.000
Perioperative Opioid			
Morphine (mg., mean ± S.D.)	6.39 ± 0.45	6.11 ± 0.44	0.657
Fentanyl (n, %)	4 (8.70)	5 (10.87)	1.000
Post–operative Opioid			
Morphine (mg., mean ± S.D.)	7.30 (0.19)	7.39 (0.25)	0.785

ASA = American Society of Anesthesiologists

The incidence of postoperative sore throat at 1hour was significantly lower in the dexamethasone group compared to the control group (2.17% vs 28.26%, $p < 0.001$). This significant difference persisted at 24 hours postoperatively (15.22% vs 56.52%, $p < 0.001$) (Table 2).

Table 2 Incidence of Postoperative sore throat

Group	At 1st postoperative hour			At 24 postoperative hours		
	S/N	%	p	S/N	%	p
Treatment group (n = 46)	1/45	2.17	< 0.001*	7/39	15.22	< 0.001*
Control group (n = 46)	13/33	28.26		26/20	56.52	

S/N: sore throat /non–sore throat, % = percent of sore throat, *significant as p–value < 0.025 for global p–value after Bonferri correction, sore throat was defined as NRS score 4–10; non–sore throat was defined as NRS score 0–3

For postoperative hoarseness, while there was no significant difference between groups at 1 hour (dexamethasone: 2.17% vs control: 10.87%, $p = 0.203$), a significant reduction was observed in the dexamethasone group at 24 hours (6.52% vs 30.43%, $p = 0.003$) (Table 3).

Table 3 Incidence of Postoperative Hoarseness

Group	At 1st postoperative hour			At 24 postoperative hours		
	H/NH	%	p	H/NH	%	p
Treatment group (n = 46)	1 / 45	2.17	0.203	3 / 43	6.52	0.003*
Control group (n = 46)	5 / 41	10.87		14 / 32	30.43	

H/NH: Hoarseness/Non–Hoarseness, % = percent of Hoarseness, *significant as p–value < 0.025 for global p–value after Bonferri correction

The severity of sore throat, assessed using NRS scores, was significantly lower in the dexamethasone group at both 1 hour and 24 hours postoperatively ($p < 0.001$) (Table 4). At 24 hours, the relative risk reduction for sore throat was 73.07%, indicating that dexamethasone was 73.07% effective in preventing postoperative sore throat compared to placebo. The absolute risk reduction was 41.30%, and the number needed to treat was 2.42, indicating that approximately 3 patients would need to receive dexamethasone to prevent one case of sore throat (Table 5).

Table 4 Severity of sore throat

Group	NRS	Treatment group (n = 46)	Control group (n = 46)	p
At 1st postoperative hour (n (%))	0 – 3	45 (97.83)	33 (71.74)	
	4 – 6	1 (2.17)	11 (23.91)	0.001*
	7 – 10	0 (0.00)	2 (4.35)	
At 24 postoperative hours (n (%))	0 – 3	39 (84.78)	20 (43.48)	
	4 – 6	6 (13.04)	12 (26.09)	<0.001*
	7 – 10	1 (2.17)	14 (30.43)	

NRS = Numerical Rating Scale, *significant as p–value < 0.05

Table 5 Relative risk reduction at 24 postoperative hours

Sore throat treatment group (n = 46)	Sore throat control group (n = 46)	Relative risk reduction	Absolute risk reduction	Number needs to treat
15.22%	56.52%	73.07%	41.30%	2.42

Sore throat was defined as NRS score 4–10; Non–sore throat was defined as NRS score 0–3

Regarding complications, there were no significant differences between groups in the incidence of desaturation, laryngospasm, or bronchospasm (Table 6). No patients in either group experienced blood glucose levels >250 mg/dL or surgical site infections during the 2–week follow–up period.

Table 6 Complications

Parameters	Treatment group (n = 46)	Control group (n = 46)	p
Desaturation (n, %)	3 (6.52)	4 (8.70)	1.00
Laryngospasm (n, %)	0 (0.00)	0 (0.00)	NA
Bronchospasm (n, %)	0 (0.00)	0 (0.00)	NA

NA = Not applicable due to zero events in both groups

Discussion

This randomized controlled trial demonstrated that prophylactic intravenous dexamethasone 0.2 mg/kg significantly reduced both the incidence and severity of postoperative sore throat (POST) and hoarseness following double–lumen endobronchial tube (DLT) intubation.

The timing of maximum effectiveness at 24 hours aligns with dexamethasone's known pharmacodynamics. As a long–acting glucocorticoid with a biological half–life of 36–54 hours, dexamethasone's peak anti–inflammatory effect typically occurs between 24–36 hours after administration.[11] This explains the sustained benefit observed in our study, particularly at the 24–hour timepoint.

Our findings support previous research by Park et al.[14], reported similar efficacy using the same dosage. However, our study demonstrated a higher relative risk reduction (73.07% vs 52.6%), possibly due to more rigid exclusion criteria and standardized intubation techniques. The number needed to treat (NNT) of 2.42 in our study suggests superior clinical utility compared to other prophylactic measures reported in recent meta–analyses.[15]

The mechanism behind dexamethasone's effectiveness likely involves multiple pathways. Its potent anti–inflammatory properties include inhibition of phospholipase A2, prevention of arachidonic acid release, and suppression of various inflammatory mediators.[12] These effects are particularly relevant for DLT–related airway trauma, which typically causes more severe inflammation than standard endotracheal tubes due to its larger diameter and more complex insertion procedure.[3]

Regarding safety, our study found no significant increase in surgical site infections or clinically relevant hyperglycemia, consistent with recent systematic reviews of single–dose perioperative dexamethasone.[16] This favorable safety profile supports its routine prophylactic use, though careful patient selection remains important, particularly in diabetic patients.

Our findings have important clinical implications. With an NNT of 2.42, prophylactic dexamethasone represents an efficient intervention for preventing POST and hoarseness after DLT intubation. The simplicity of administration and low cost further support its integration into standard practice for thoracic surgeries requiring one–lung ventilation.

Several limitations should be acknowledged. First, as a single–center study, our results may not fully generalize to other settings. Second, the single–dose design doesn't address optimal timing or potential benefits of repeated dosing. Third, concomitant analgesic use may have influenced symptom reporting, though randomization should have balanced this effect between groups. Fourth, we did not collect data regarding the experience

level of anesthesiologists and anesthetic nurses performing the intubations. The technical expertise and experience of airway management providers could potentially influence the incidence and severity of postoperative sore throat and hoarseness. While our randomization process should have distributed any provider–dependent effects equally between groups, future studies might benefit from stratifying results based on provider experience levels to better understand this potential confounding factor.

Future research should focus on identifying optimal timing of administration, investigating potential benefits in high–risk populations, and evaluating long–term outcomes. Additionally, studies comparing dexamethasone with other prophylactic measures would help establish its relative position in airway management protocols.

Conclusion

The prophylactic intravenous dexamethasone 0.2 mg/kg is both effective and safe to prevent postoperative sore throat and hoarseness following double–lumen endobronchial tube intubation. Given its favorable risk–benefit ratio, low cost, and ease of administration, prophylactic dexamethasone should be considered as a standard preventive measure for patients undergoing thoracic surgery requiring one–lung ventilation with double–lumen endobronchial tube intubation, particularly in patients without contraindications to corticosteroids.

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