Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i2.4601

A COMPARISON OF EFFICACY OF BETAMETHASONE GEL V/S LIGNOCAINE JELLY APPLIED OVER ENDOTRACHEAL TUBE CUFF AS PROPHYLAXIS AGAINST INTUBATION ASSOCIATED THROAT COMPLICATIONS

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ABSTRACT

BACKGROUND: This study was undertaken to compare the effectiveness of application of an endotracheal tube cuff with betamethasone gel and lignocaine jelly in reducing the incidence and severity of postoperative sore throat,hoarseness and cough.

METHODS: After receiving approval from the institutional ethics committee and signed informed consent from the study participants, a prospective comparative study based in a hospital was carried out among 100 patients (50 in each groups) who underwent for elective chest, limb & abdominal surgeries under general anesthesia at the Department of Anaesthesiology, Government Medical College, Thrissur, between January 2021 and January 2022.100 patients will be divided into two equal groups – group B is betamethasone group, who will receive betamethasone 0.05% water miscible gel applied over ETT and group D is lignocaine group,who will receive lignocaine 2% water miscible jelly applied on ETT & In the post-anaesthesia care unit, a blinded anaesthesiologist will interview all patients on postoperative sore throat, cough, and hoarseness of voice at 1, 6, 12, and 24 hours after operation using the four point scales.

RESULTS: The severity of post-operative sore throat, severity of hoarseness and post extubation cough among the two groups showed Group D and Group B had most of them in minimal sore throat at 1-hour post op, but moderately sore throat was higher in group D. Similar pattern was seen in 6 hours, 12 hours and 24 hours; this was statistically significant.Hence Betamethasone (group B) usage for endotracheal intubation showed to be better than Lignocaine (group D) when compared to severity of post-operative sore throat, severity of hoarseness and post extubation cough.

CONCLUSION: The study's findings also show that, Betamethasone (group B) usage for endotracheal intubation showed to be better than Lignocaine (group D) when compared to severity of post-operative sore throat, severity of hoarseness and post extubation cough.

KEYWORDS: Intubation associated throat complications,Betamethasone, Lignocaine, ETT cuff.

INTRODUCTION

Tracheal intubation is often required during general anaesthesia to secure the airway and facilitate ventilation. Tracheal intubation is associated with an increase of polymorphonuclear cells in the tracheal tissue and plasma levels of interleukin-6, suggesting an inflammatory response to the presence of the endotracheal tube itself or to some aspect of the intubation process.The process of laryngoscopy and placement of tracheal tube is associated with postoperative throat complications such as sore throat, cough and hoarseness of voice. 1,2,3 The incidence of these throat complications vary between 15% and 94%.Although not typically incapacitating, these sequelae can be very discomforting and often a major source of patients' dissatisfaction post-operatively.Postoperative sore throat, cough, and hoarseness of voice is common,uncomfortable, distressing sequelae after tracheal intubation. It was postulated that these effects are because of irritation and inflammation of the airway.3 Although local anaesthetic jelly along with its lubricating properties limits the potential damage to the tracheal mucosa by suppressing bucking on the tracheal tube, its role in prevention of postoperative sore throat is inconclusive as it does not possess any intrinsic anti-inflammatory action.4,5

Postoperative throat complications following tracheal intubation are thought to result from a number of events. One mechanism is trauma to the pharyngotracheal mucosa following laryngoscopy and placement of endotracheal tube (ETT). Prolonged contact of the ETT with the vocal cords and posterior pharyngeal wall may also result in pathological changes such as epithelial loss,glottis haematoma and/or oedema, submucosal tear and contact granuloma. These,in addition to neuropraxia of the recurrent laryngeal nerve due to compression from excessive intracuff pressure have been implicated in the pathogenesis of postoperative hoarseness.

Several medications and non-pharmacological methods have shown to reduce the incidence of airway symptoms with variable success rate.These inconsistent results suggest the likelihood of multiple factors associated with these symptoms like endotracheal tube size, cuff design, duration of surgery, etc.Whatever the cause, the main mechanism postulated is irritation and inflammation of the airway.6,7 Although lidocaine is used for airway anaesthesia, its use for postoperative airway symptoms have shown variable results .8,9,10 Steroids are known for their anti-inflammatory action. Betamethasone gel is a long acting water soluble glucocorticoid that has been used topically for the treatment of inflammatory lesions of the oral mucosa. It should, thus, provide lubrication as well as anti-inflammatory effect if used for lubrication of the endotracheal tube.

Betamethasone is a synthetic glucocorticoid with metabolic,immunosuppressive and anti inflammatory activities. Betamethasone binds to specific intracellular glucocorticoid receptors and subsequently binds to DNA to modify gene expression. The synthesis of anti-inflammatory proteins is induced while the synthesis of certain inflammatory mediators is inhibited. As a result, there is an overall reduction in chronic inflammation and autoimmune reactions

Lignocaine is a synthetic amino-ethylamide with local anaesthetic property.Lignocaine stabilizes the neuronal membrane by binding to and inhibiting voltage gated sodium channels, thereby inhibiting the ionic fluxes required for the initiation and conduction of impulses and effecting local anaesthesia. The present study was undertaken to compare the effectiveness of application of an endotracheal tube with betamethasone gel and lignocaine jelly with using an unlubricated endotracheal tube in reducing the incidence and severity of postoperative sore throat, hoarseness and cough.

OBJECTIVES

Betamethasone gel or lignocaine jelly applied over ETT cuff are commonly used prophylactic methods for intubation assosciated throat complications in Govt medical college, Thrissur. The Present study aims to compare the effects of betamethasone gel and lignocaine jelly applied over endotracheal tube cuff as prophylaxis against intubation associated throat complications.

METHODS

After receiving approval from the institutional ethics committee and signed informed consent from the study participants, a prospective comparative study based in a hospital was carried out among 100 patients (50 in each groups) who underwent posted for elective chest, limb & abdominal surgeries under general anesthesia at the Department of Anaesthesiology, Government Medical College, Thrissur, between January 2021 and January 2022.100 patients will be divided into two equal groups – group B is betamethasone group, who will receive betamethasone 0.05% water miscible gel applied over ETT and group D is lignocaine group,who will receive lignocaine 2% water miscible jelly applied on ETT & In the post-anaesthesia care unit, a blinded anaesthesiologist will interview all patients on postoperative sore throat, cough, and hoarseness of voice at 1, 6, 12, and 24 hours after operation using the four point scales.

Inclusion Criteria

1. Patients of either sex ASA Grade l & ll
2. MMPC 1&2
3. Age between 20 & 60 years.
4. Body weight between 40 – 80 kg.
5. Intubated in a single attempt.
6. Patients undergoing elective general surgery,orthopaedic surgery& gynaecological surgeries
7. Duration of mechanical ventilation < 3hrs.

Exclusion Criteria

1. Patients not willing to participate in the study
2. Patients with history of drug allergy
3. Patient with an anticipated difficult airway
4. Patients with hypertension, cardiac, renal, hepatic, cerebral disease; peripheral vascular disease; bradycardia; patients on beta blockers; and obese, pregnant and nursing mothers.
5. Duration of mechanical ventilation > 3 hours

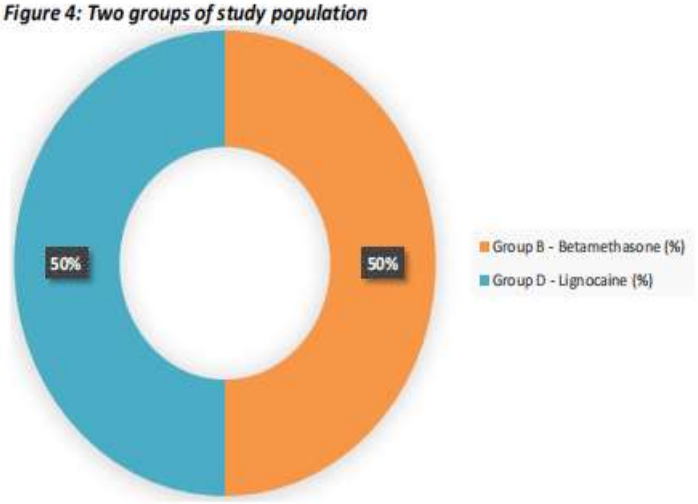
Statistical Methods

The data of study subjects and the outcome will be statistically analyzed and the appropriate statistical test, will be applied using the latest version of SPSS software. ‘p’ value less than 0.01 will be considered significant.

RESULTS

In this study the patients posted for elective chest, limb & abdominal surgeries under general anaesthesia. In total 50 each were included in 2 groups with betamethasone (Group B) and lignocaine (Group D). The results are as follows:

Figure 4: Two groups of study population



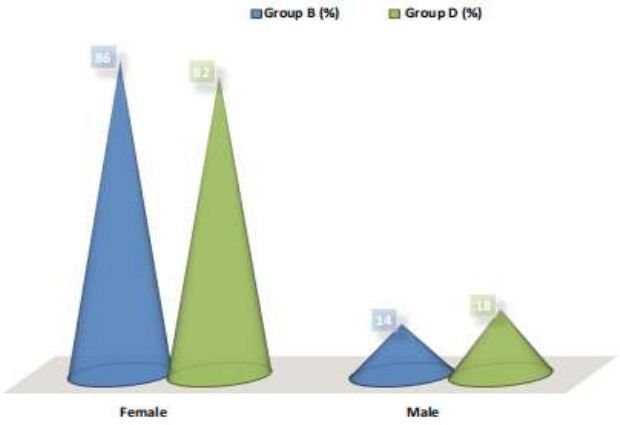
Gender distribution among the two groups

The gender distribution among the two groups showed females were higher in group B and males were higher in group D. As this difference was not statistically significant, hence gender is same in both groups

Table 1: Gender distribution among the two groups

Gender	Group B (n)	(%)	Group D (n)	(%)
Female	43	86.0	41	82.0
Male	7	14.0	9	18.0
Chi-square test value 0.298, d.f 1; p value 0.585				

Figure 5: Gender distribution among the two groups



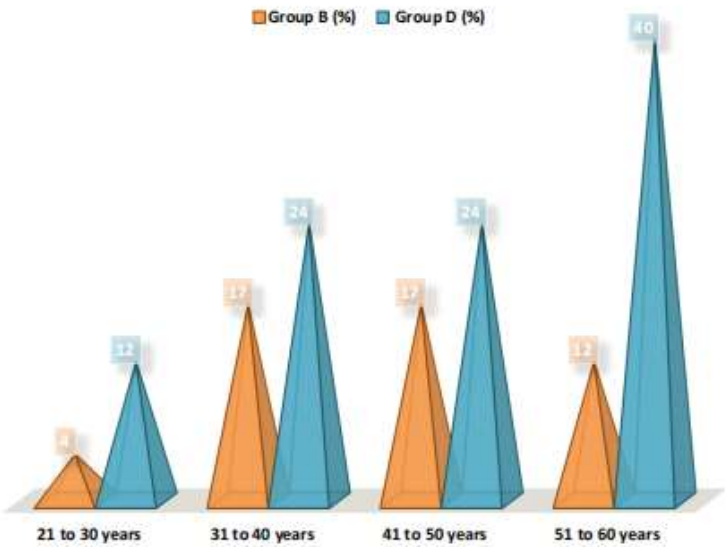
Age wise distribution among the two groups

The age distribution showed group B had higher number of people in 31 to 40 years and 41 to 50 years. The Group D had majority of the patients in the age group 51 to 60 years. As this differencewas not statistically significant, hence age groups are same in both groups.

Table 2: Age wise distribution among the two groups

Age groups (years)	Group B (n)	(%)	Group D (n)	(%)
21 to 30 years	4	8.0	6	12.0
31 to 40 years	17	34.0	12	24.0
41 to 50 years	17	34.0	12	24.0
51 to 60 years	12	24.0	20	40.0
Chi-square test value 4.124, d/f 3; p value 0.248				

Figure 6: Age wise distribution among the two groups



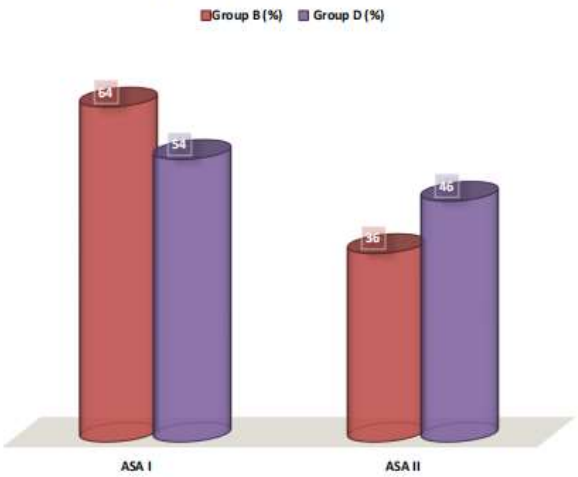
ASA classification among the two groups

The ASA classification was studied and ASA I was higher in Group B and similarly group D also had higher numbers than ASA II in both groups. As this difference was not statistically significant, hence ASA classification is same in both groups.

Table 3: ASA classification among the two groups

ASA classification	Group B (n)	(%)	Group D (n)	(%)
ASA I	32	64.0	27	54.0
ASA II	18	36.0	23	46.0
Chi-square test value 1.033, d.f 1; p value 0.309				

Figure 7: Age wise distribution among the two groups



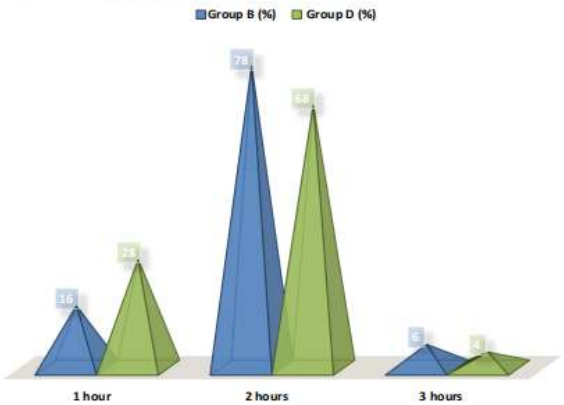
Duration of surgery among the two groups

The duration of surgery showed in both the groups nearly three forth had 2 hours of surgery, and only very few patients in both groups had 3 hours or more duration of surgery. As this difference was not statistically significant, hence age duration of surgery is same in both groups.

Table 4: Duration of surgery among the two groups

Duration of surgery	Group B (n)	(%)	Group D (n)	(%)
1 hour	8	16.0	14	28.0
2 hours	39	78.0	34	68.0
3 hours	03	06.0	02	04.0
Chi-square test value 2.179, d.f 2; p value 0.336				

Figure 8: Duration of surgery among the two groups



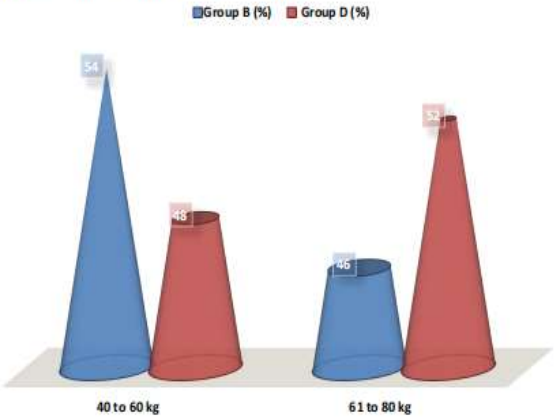
Patient weight among the two groups

The patient weights showed equal or similar number of patients in group B and group D with 40 to 60 kg and 61 to 80 kg. As this difference was not statistically significant, hence patient's weight is same in both groups

Table 5: Patient weight among the two groups

Patient weight	Group B (n)	(%)	Group D (n)	(%)
40 to 60 kg	27	54.0	24	48.0
61 to 80 kg	23	46.0	26	52.0
Chi-square test value 360, d.f 1; p value 0.548				

Figure 9: Patient weight among the two groups



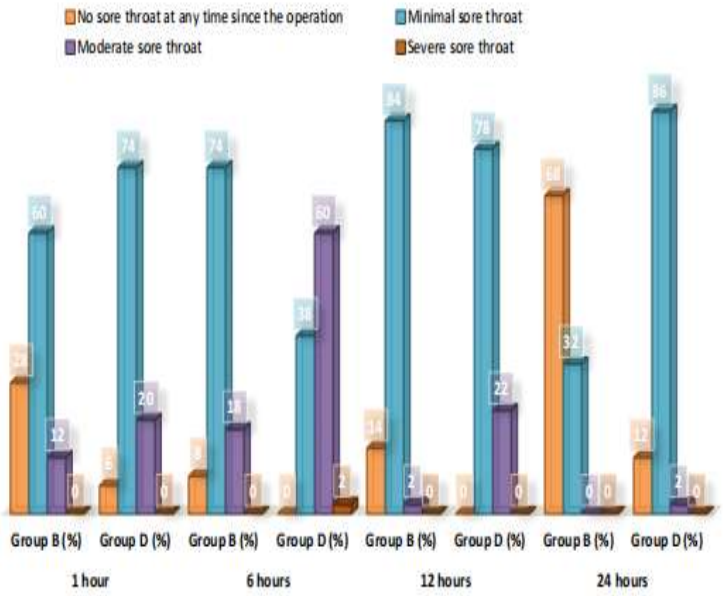
Severity of post-operative sore throat among the two groups

The severity of post-operative sore throat among the two groups showed Group D and Group B had most of them in minimal sore throat at 1-hour post op,but moderately sore throat was higher in group D. Similar pattern was seen in 6 hours, 12 hours and 24 hours; this was statistically significant.

Table 6: Severity of post-operative sore throat among the two groups

Severity of post-operative sore throat 1 hour	Group B (n)	(%)	Group D (n)	(%)	Fischer's exact
No sore throat at any time since the operation	14	28.0	3	6.0	
Minimal sore throat	30	60.0	37	74.0	*<0.001*
Moderate sore throat	6	12.0	10	20.0	
Severity of post-operative sore throat 6 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No sore throat at any time since the operation	4	8.0	0	0	
Minimal sore throat	37	74.0	19	38.0	*<0.001*
Moderate sore throat	9	18.0	30	60.0	
Severe sore throat	0	0	1	2.0	
Severity of post-operative sore throat 12 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No sore throat at any time since the operation	7	14.0	0	0	
Minimal sore throat	42	84.0	39	78.0	*<0.001*
Moderate sore throat	1	2.0	11	22.0	
No sore throat at any time since the operation	34	68.0	6	12.0	
Minimal sore throat	16	32.0	43	86.0	*<0.001*
Moderate sore throat	0	0	1	2.0	

Figure 10: Severity of post-operative sore throat among the two groups



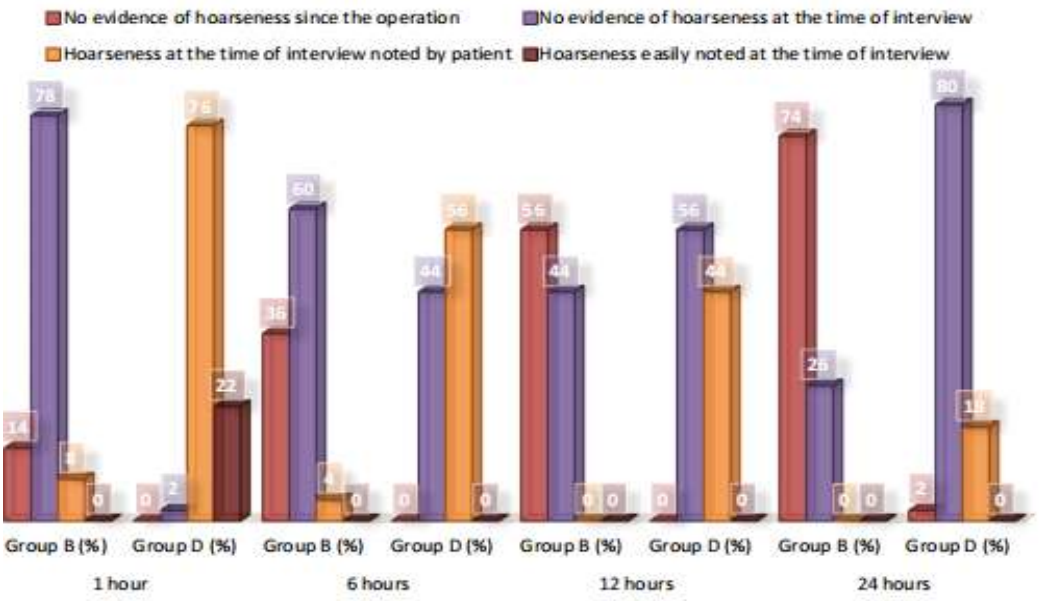
Severity of hoarseness among the two groups

The severity of hoarseness among the Group B and Group D showed at 1-hour group D had hoarseness at the time of interview noted by patient and group B had more patients with no evidence of hoarseness at the time of interview; this difference was statistically significant. At 6 hours, 12 hours and 24 hours a similar picture was noted, and this difference was statistically significant.

Table 7: Severity of hoarseness among the two groups

Severity of hoarseness 1 hour	Group B (n)	(%)	Group D (n)	(%)	Fischer's exact
No evidence of hoarseness since the operation	7	14.0	0	0	<0.001
No evidence of hoarseness at the time of interview	39	78.0	1	2.0	
Hoarseness at the time of interview noted by patient	4	8.0	38	76.0	
Hoarseness easily noted at the time of interview	0	0	11	22.0	
Severity of hoarseness 6 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No evidence of hoarseness since the operation	18	36	0	0	<0.001
No evidence of hoarseness at the time of interview	30	60	22	44	
Hoarseness at the time of interview noted by patient	2	4	28	56	
Severity of hoarseness 12 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No evidence of hoarseness since the operation	28	56.0	0	0	<0.001
No evidence of hoarseness at the time of interview	22	44.0	28	56.0	
Hoarseness at the time of interview noted by patient	0	0	22	44.0	
Severity of hoarseness 24 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No evidence of hoarseness since the operation	37	74.0	1	2.0	<0.001
No evidence of hoarseness at the time of interview	13	26.0	40	80.0	
Hoarseness at the time of interview noted by patient	0	0	9	18.0	

Figure 11: Severity of hoarseness among the two groups



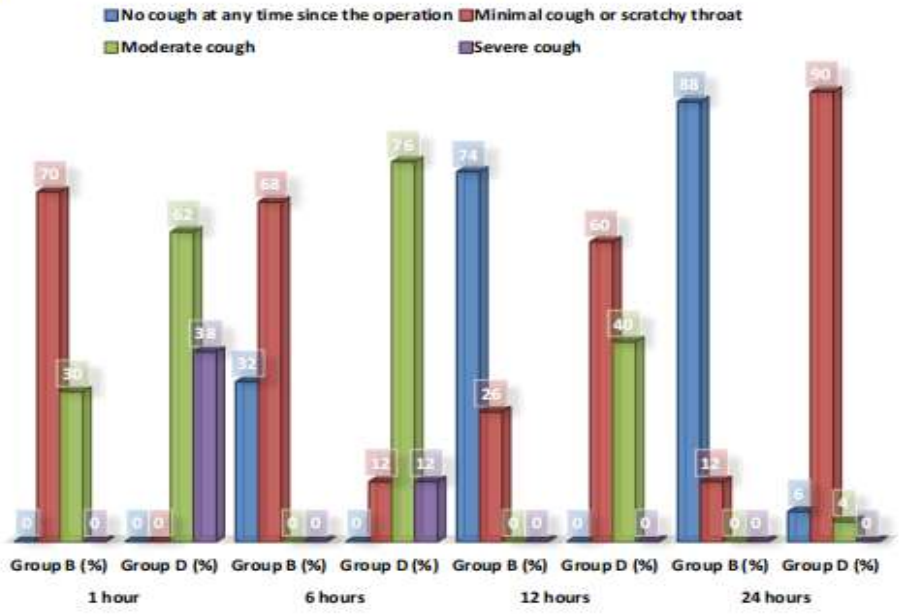
Post extubation cough among the two groups

The post extubation cough among the two groups showed the post extubation cough at 1 hour the group B had minimal cough & moderate cough however the Group D had more patients with moderate & severe cough; this difference was statistically significant. There was similar pattern see for post extubation cough at 6 hours, 12 hours and 24 hours which was statistically significant among the two groups.

Table 8: Post extubation cough among the two groups

Post extubation cough 1 hour	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
Minimal cough or scratchy throat	35	70.0	0	0	*<0.001*
Moderate cough	15	30.0	31	62.0	
Severe cough	0	0	19	38.0	
Post extubation cough 6 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No cough at any time since the operation	16	32.0	0	0	*<0.001*
Minimal cough or scratchy throat	34	68.0	6	12.0	
Moderate cough	0	0	38	76.0	
Severe cough	0	0	6	12.0	
Post extubation cough 12 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No cough at any time since the operation	37	74.0	0	0	*<0.001*
Minimal cough or scratchy throat	13	26.0	30	60.0	
Moderate cough	0	0	20	40.0	
Post extubation cough 24 hours	**Group B (n)**	**(%)**	**Group D (n)**	**(%)**	**Fischer's exact**
No cough at any time since the operation	44	88.0	3	6.0	*<0.001*
Minimal cough or scratchy throat	6	12.0	45	90.0	
Moderate cough	0	0	2	4.0	

Figure 12: Post extubation cough among the two groups



DISCUSSION

In this study the patients posted for elective chest, limb & abdominal surgeries under general anaesthesia. In total 50 each were included in 2 groups with betamethasone (Group B) and lignocaine (Group D). In our study the gender distribution, age distribution, ASA classification, duration of surgery and the patient weights showed equal or similar number of patients in group B and group D and was statistically non-significant, hence both groups had similar baseline characteristics. In the reviewed studies by P. A. Sumathi et al.67 had similar baseline characteristics which were similar in both groups. Parineeta Thapa et al.68 had a similar prospective, randomized, single-blind comparative study carried out among 120 ASA I and II patients aged 18–65 years undergoing elective surgery under general anaesthesia with endotracheal intubation. Adamu Muhammad Sarki et al.69 also had similar baseline characteristics.

In our study the severity of post-operative sore throat among the two groups showed Group D and Group B had most of them in minimal sore throat at 1-hour post op, but moderately sore throat was higher in group D. Similar pattern was seen in 6 hours, 12 hours and 24 hours; this was statistically significant. In this study the severity of hoarseness among the Group B and Group D showed at 1-hour group D had hoarseness at the time of interview noted by patient and group B had more patients with no evidence of hoarseness at the time of interview; this difference was statistically significant. At 6 hours, 12 hours and 24 hours a similar picture was noted, and this difference was statistically significant. In our study the post extubation cough among the two groups showed the post extubation cough at 1 hour the group B had minimal cough & moderate cough however the Group D had more patients with moderate & severe cough; this difference was statistically significant. There was similar pattern see for post extubation cough at 6 hours, 12 hours and 24 hours which was statistically significant among the two groups.

Similar pattern was seen in the reviewed studies by P. A. Sumathi et al.67 results showed in the first 24 h after surgery, the incidence of postoperative sore throat was 40, 100, and 100%; cough was 6, 40, and 28%; and hoarseness of voice was 4.1, 32.9, and 50%, for the betamethasone, lidocaine and control groups, respectively.

The incidence of postoperative sore throat, cough, and hoarseness of voice was significantly lower in the betamethasone group compared with the other two groups (P,0.05). It Concluded that a wide spread application of betamethasone gel on the tracheal tube decreases the incidence and severity of postoperative sore throat, cough, and hoarseness of voice. Another study by Parineeta Thapa et al.68 . At 24 hr following extubation, group B had the lowest incidence of postoperative sore throat among

the three groups (group B: 12.5% vs group L: 37.5% vs group C: 25%; p = 0.036). Severity of postoperative sore throat at 24 h was less with betamethasone (score 0: 87.5%, 1: 10%) compared with lidocaine (score 0: 62.5%, 1: 37.5%) and control (score 0:75%, 1: 20%) (p = 0.006). Observations at other times and of other variables were comparable. It concluded that Wide spread application of 0.05% betamethasone gel to lubricate the endotracheal tube significantly reduces the incidence and severity of sore throat at 24 h of extubation but not of hoarseness or cough. Adamu Muhammad Sarki et al.69 showed that the incidence and severity of sore throat, cough and hoarseness were then assessed by a blinded interviewer at the 6th, 24th and 48th h postoperative. Results were as follows**.** The highest incidence of throat complaints was recorded during the first evaluation at the 6th h postoperative. The incidence of sore throat was 36.7%, 66.7% and 80%; cough was 13.3%, 26.7% and 43.3%; and hoarseness was 23.3%, 30% and 46.7%, for the betamethasone, lidocaine and KY jelly groups, respectively.

Betamethasone gel demonstrated significant superiority over lidocaine and KY jellies in the prevention of sore throat (P = 0.002), cough (P = 0.03) and hoarseness (P = 0.03) throughout the study. Duration of tracheal intubation longer than 2 h was associated with significant increase in the incidence of throat complaints (P < 0.001). Another study showed a different results by Mahnaz Narimani et al.70 showed patients were assessed for postoperative sore throat, cough, and hoarseness at 1, 6, and 24 hours after surgery. Results were as follows. In the first hour after surgery, the patients who received lidocaine or betamethasone had a significantly greater incidence of sore throat than the patients who received distilled water (RR = 2.9). In the sixth hour after surgery, there was a better effect of distilled water on reducing the incidence of sore throat, but no significant differences between the three groups were seen 24 hours after surgery. The incidence of cough was significantly lower in the distilled water group (P < .02) except at the first and 24 hours postoperative when the incidence of cough was similar. The incidence of hoarseness was similar between the three groups at 1, 6, and 24 hours after surgery.

Another related study by Aatir Fayyaz et al.71 showed of the 120 patients, there were 60(50%) each in the two groups. The mean intubation time was 5.58+-1.31 hours in group 1and 5.43+-1.21 hours in group 2. Besides, 7(11.7%) patients developed mild sore throat and 3(5.0%) moderate sore throat in group 1,whereas 13(21.7%) patients developed mild sore throat, 7(11.6%) moderate and 2(3.3%) severe sore throat after one hour of extubation (p=0.04). After 6 hours, there were 2(3.3%) patients with moderate and 1(1.7%) with severe sore throat in group 1 compared to 8(13.3%) with moderate and 4(6.7%) with severe sore throat in group 2. After 24 hours,5(8.3%) patients developed mild and 2(3.3%) moderate sore throat in group 1 compared to 14(23.7%) patients with mild sore throat, 5(8.5%) with moderate and 1(1.7%) with severe throat in group 2. Generalized estimating equation analysis showed a significant positive association between application of lidocaine gel on endotracheal tube and severity of sore throat (p<0.001).

It concluded that local application of betamethasone gel was associated with reduced risk of post-operative sore throat as compared to local application of lidocaine gel on the endotracheal tube. Reviewed studies by Dr M. Raja et al.72 that in the post-anaesthesia care unit, all patients were interviewed on postoperative sore throat, cough, and hoarseness of voice at 0, 6, and 24 h after surgery. A wide spread application of betamethasone gel (B) on the endotracheal tube decreases the incidence and severity of postoperative sore throat, cough, and hoarseness of voice as compared to lignocaine group(L) and control group (c).

CONCLUSION

In our study the gender distribution, age distribution, ASA classification, duration of surgery and the patient weights showed equal or similar number of patients in group B and group D and was statistically nonsignificant, hence both groups had similar baseline characteristics.In this study the severity of post-operative sore throat, severity of hoarseness and post extubation cough among the two groups showed Group D and Group B had most of them in minimal sore throat at 1-hour post op, but moderately sore throat was higher in group D. Similar pattern was seen in 6 hours, 12 hours and

24 hours; this was statistically significant.Hence Betamethasone (group B) usage for endotracheal intubation showed to be better than Lignocaine (group D) when compared to severity of post-operative sore throat, severity of hoarseness and post extubation cough.

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