"CORRELATION OF CLINICAL SYMPTOMS AND LARYNGOSCOPIC SIGNS IN REFLUX LARYNGITIS" -A ONE YEAR CROSS-SECTIONAL STUDY IN A TERTIARY CARE CENTER, KLES DR. PRABHAKAR KORE HOSPITAL, BELAGAVI

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LIST OF ABBREVIATIONS

GERD	Gastro-oesophageal Reflux Disease
LPR	Lower Oesophageal Sphincture
UES	Upper Oesophageal Sphincture
RSI	Reflux Symptom Index
RFS	Reflux Finding Score
mm	Milimeters
IU	Intra-Uterine
URTI	Upper Respiratory Tract Infection
GE	Gastro-Oesophageal
LES	Lower Oesophageal Sphincture
WGO-OMGE	World Organization of Gastroenterology
mmHg	Milimeters of Mercury
cm	Centimeters
%	Percentage
PPI	Proton-Pump Inhibitor
IDL	Indirect Laryngoscopy
ENT	Ear Nose Throat
OPD	Out-Patient Department
COPD	Chronic Obstructive Pulmonary Disease
i.e.	id est (Latin; ‘that is’)
et al	Et alii (Latin; ‘and others’)

ABSTRACT

Background: The proximity of the larynx and proximal esophagus makes it susceptible to diseases that occur in these 2 areas, due to gastro-esophageal reflux disease (GERD). Unfortunately, there is a substantial percentage of medical professionals that are unaware of this. Patients with laryngopharyngeal reflux usually come to the ENT OPD with complains of hoarseness and Globus. The advent of fibreoptic flexible endoscopes has changed the scenario for diagnosis. The Reflux Symptom Index is used for clinical diagnosis and the Reflux Finding Score is used to assess the Laryngoscopic findings.

Objective: To assess the Correlation between the Clinical Symptoms and Laryngoscopic findings of Reflux Laryngitis using the Reflux Symptoms Index (RSI) and the Reflux Finding Score (RFS).

Materials & Methods: This is a cross-sectional study conducted in the department of Otorhinolaryngology of Dr. Prabhakar Kore Hospital, Belagavi, from January 2018 to December 2018. 75 patients were included in the study, who came to the OPD with typical and atypical findings of GERD. Their symptoms were scored using the Reflux Symptom Index (RSI) and all patients with abnormal RSI (>13) were subjected to laryngoscopy and the findings were assessed using the Reflux Finding Score.

Results: The study included 40 males and 35 females with mean age of patients being 40.96. The most common presenting complaint was heartburn, feeling of lump in the throat (Globus) and hoarseness. Among patients who underwent flexible fibreoptic laryngoscopic examination, 55 patients were found to have a significant score (RFS>7). The most common finding was erythema of laryngeal mucosa, posterior

commissure hypertrophy, vocal fold edema and partial ventricular obliteration. On comparing the two scores, they showed a strong correlation (p Value =0.007).

Conclusion: Laryngopharyngeal reflux / Reflux laryngitis being a diagnostic dilemma requires comprehensive evaluation of the symptoms first followed by laryngoscopic examination to assess the laryngeal changes. Our study concluded that RSI and RFS are easy, reproducible and complimentary scores that can be used to make a likely diagnosis of LPR.

Keywords: Laryngitis, Laryngopharyngeal Reflux, GERD

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INTRODUCTION

The proximity of the larynx to the upper end of esophagus makes it susceptible to diseases that occur in these areas, mainly due to reflux of gastric contents called gastroesophageal reflux disease (GERD). Unfortunately, there is a substantial percentage of medical professionals that are unaware of the problems that gastroesophageal reflux causes in these areas.[1]

Laryngopharyngeal reflux (LPR) is different to GERD and is caused by the retrograde passage of gastric contents from the upper oesophageal sphincter (UES).[2] The exposure causes injury to the mucosa and damage to the respiratory epithelium which causes mucous stasis, which inturn results in a lot of very troubling symptoms termed as laryngopharyngeal reflux.

The exact mechanism is unclear and it is said to occur either directly (microaspiration) or indirectly (vagal stimulation).[3,4]

Globus pharyngeus and hoarseness are the commonly described symptoms. Globus is usually described as 'sticking sensation in throat', whereas hoarseness is the reduced vocal quality and clarity. Dysphagia is described as difficulty in swallowing and it is important to differentiate this from obstructive causes of dysphagia.[1]

Hence, the diagnosis is unclear and fogged by non-specific symptoms and signs, and crossed over with differentials such as upper respiratory infection, asthma, vocal abuse, and allergy. Therefore, this disease is a conceptual dilemma.

It may cause various changes in oropharyngeal and laryngeal mucosa. The mucosal changes are evaluated during endoscopic examination, which makes laryngoscopic examination an important device for diagnosis of LPR.[3,5]

The **"Reflux Symptom Index"** is used to aid the clinical diagnosis[6] and the **"Reflux Finding Score"** is used to assess the Laryngoscopic findings.[7]

As there is a lack of such studies in India, this study aims at establishing diagnosis of Laryngopharyngeal Reflux among the people and helping the medical professionals to manage it efficiently.

OBJECTIVE

To assess the Correlation between the Clinical Symptoms and Laryngoscopic findings of Reflux Laryngitis using the Reflux Symptoms Index (RSI) and the Reflux Finding Score (RFS).

REVIEW OF LITERATURE

ANATOMY OF LARYNX

The larynx, in adults is situated opposite the 3rd to 6th cervical vertebrae. It is situated at the intersection of the food and air passages. It is made up of the cartilaginous skeletal framework connected by ligaments, membranes, and muscles. Its primary function is to serve as the "protector of the respiratory tract", it protects the lower airways, allowing only to air to pass and preventing food or foreign bodies from going into the trachea. It is also the organ of phonation and generates a high intrathoracic pressure for lifting and coughing. The average length, transverse diameter and antero-posterior diameter in male is 44mm, 43mm and 36mm and in females is 36mm, 41mm and 26mm respectively.[8] The epithelial lining of the larynx is continuous with the pharynx above and the trachea below.

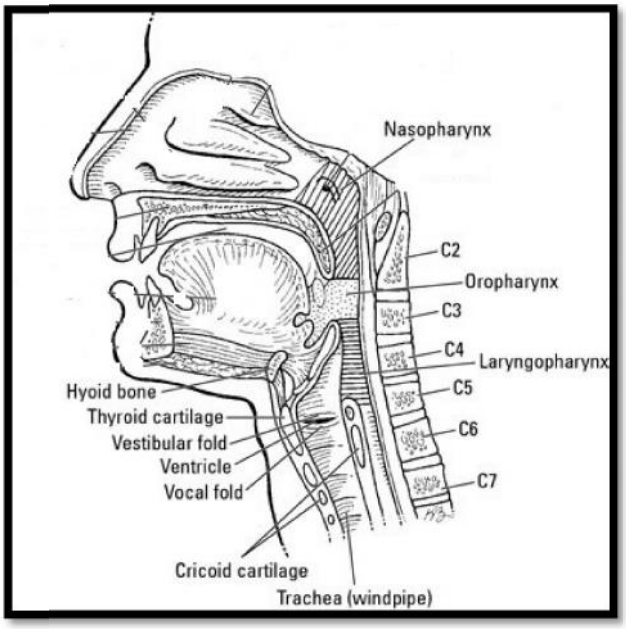


FIGURE 1:

EMBRYOLOGY

Laryngeal development starts in the 4th week of intra-uterine (IU) life, with the formation of the laryngotracheal groove.[8,9] This groove deepens and edges fuse thus forming the splanchnopleuric laryngotracheal tube, which starts caudally and proceeds cranially. However, at the cranial end the edges remain distinct opening into the pharynx through a slit like aperture. The developing tube is lined by endoderm. The epithelial lining develops from this. The cranial end forms trachea and larynx, and the caudal end, the bronchi with both the lung buds.

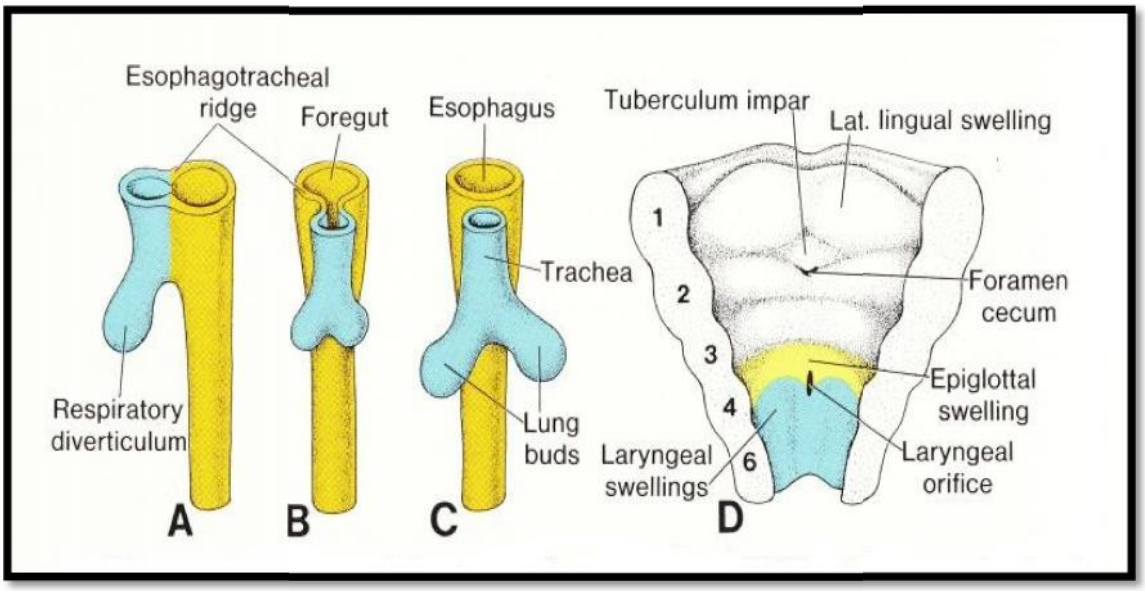


FIGURE 2

LARYNX AND TRACHEA

As said, the larynx starts developing at the proximal end of the laryngotracheal groove and on either side of this groove, the arytenoid swellings appear, which enlarge, approximate and form the hypobranchial eminence from where the epiglottis develops.[10]

Initially the opening is a narrow slit which becomes "T-shaped" due to the development of arytenoids and it stays approximated until the 3rd month IU life, later the lumen is restored.[11]

Primitive areyepiglottic fold is formed by upward growth of arytenoid swellings. These arytenoid swellings, during 2nd month of IU life differentiate into the arytenoids & corniculate cartilages, and the cuneiform cartilages develop in the aryepiglottic folds, which attach the arytenoids to the epiglottis.[12]

The "thyroid cartilage", develops as 2 lateral plates, from the ventral sides of the 4th branchial arch. The "cricoid cartilage" and "tracheal cartilages" develop during the week 6 of IU life from the 6th branchial arch.[8,10] The cartilages, muscles and vascular structures develops from the mesoderm of each pharyngeal arch with its respective afferent and efferent nerve supply.

The anatomical divisions are supraglottis, glottis and subglottis.[8]

1. The supraglottis has the epiglottis superiorly and the aryepiglottic folds laterally with the ventricular bands (false cords) inferiorly.
2. Naturally the false cords make the superior border of the glottis, which includes the true vocal cords, anterior and posterior commissure.
3. However, the division between the glottis and subglottis has always been disputed, some stating it starts just below the true cords and some stating it lies 5-10mm below. It later continues into the trachea and lungs.

FRAMEWORK

1. **Hyoid Bone:** The hyoid bone suspends the larynx. It is a "U-shaped" bone which gives attachment to the extrinsic muscles. It consists of body anteriorly, the greater cornua projects backwards on both sides and the lesser cornua are small cone like projections attached to the body of hyoid (FIGURE 3).[13]

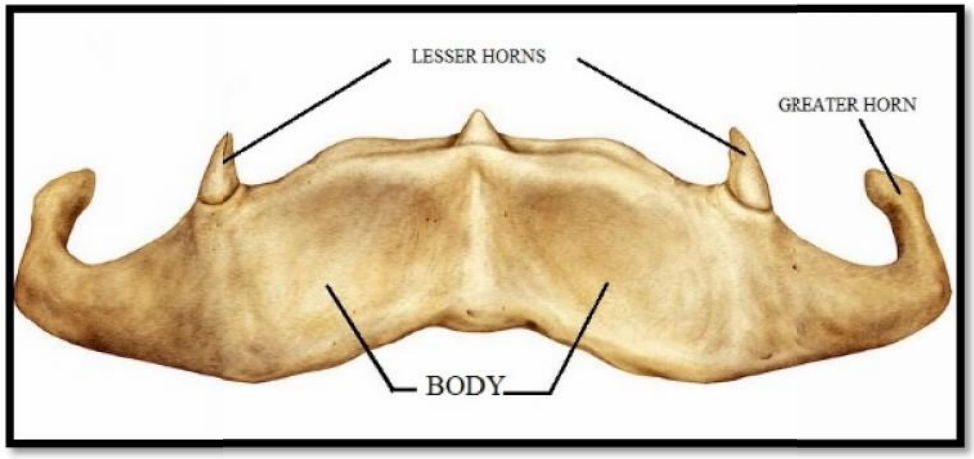


FIGURE 3

2. **Thyroid Cartilage:** It is a major structure in the larynx. The shape is "shield-like."[12,13,14,15] Formed by the union of the two quadrilateral laminae in the midline, which joins to form ,an angle of roughly 120 degrees in males and 90 degrees in females which explains the laryngeal prominence in males (the "Adam's apple") (FIGURE 4).[12]

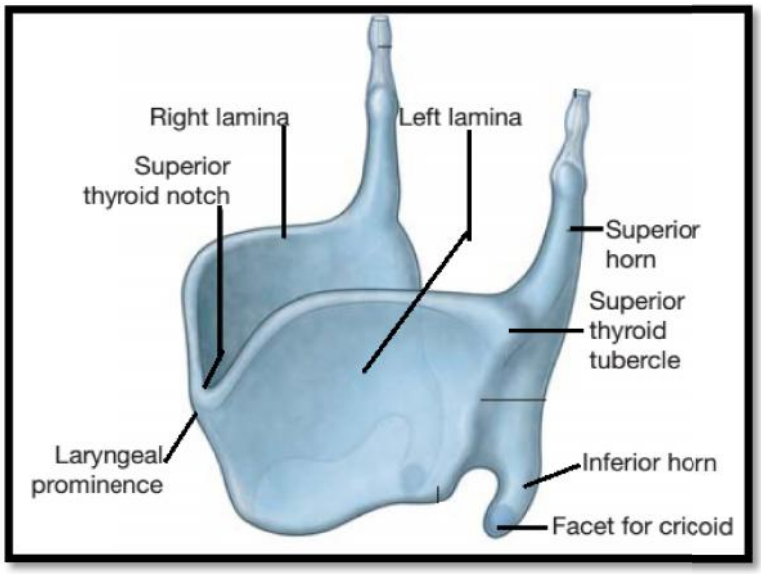


FIGURE 4

The vestibular ligament are attached to its inner surface and below them are attached the vocal ligaments. The greater and lesser horn are the posterior extensions from the thyroid lamina. The superior horn gives attachment to the lateral thyrohyoid ligament, and the inferior horn, at the cricothyroid joint, articulates with the cricoid. The movements are rotatory and results in lengthening and shortening of vocal cords (FIGURE 5).

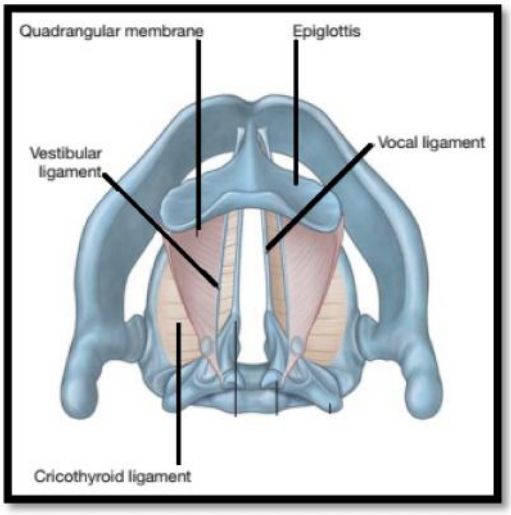


FIGURE 5

3. **Cricoid Cartilage:** The cricoid cartilage is said to be the inferior boundary of the larynx and helps support it. It is denser and sturdier and symbolizes the only "*complete cartilaginous ring*" in the airway.[12-15] The name comes from the Greek words "*krikos*" and "*eidos*", which means "*Shaped Like a Ring*", hence also called "signet ring shape".[8] (FIGURE 6) The larger portion is located posteriorly and also it articulates with the arytenoids postero-superiorly and the thyroid cartilage infero-lateral-anteriorly. It is attached to the thyroid cartilage by the cricothyroid membrane, an easily palpable avascular landmark.

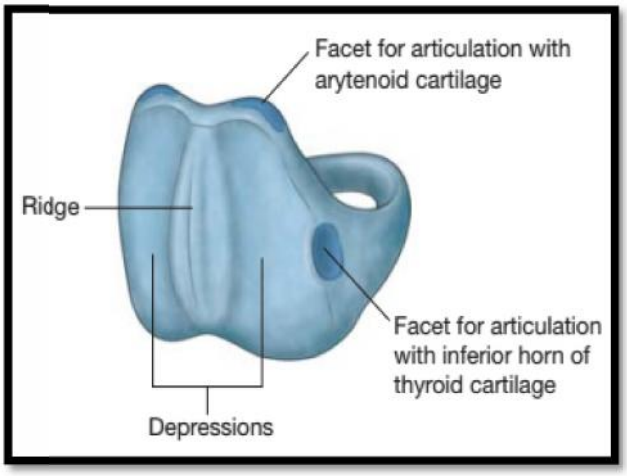


FIGURE 6 (posterior view)

- **Arytenoid Cartilages:** They are paired cartilages shaped like a "pyramid",[8,12] and lie at the posterior of the larynx. The flat medial surface is enclosed by a firm layer of mucoperichondrium and the concave base articulates with the posterior part of the cricoid cartilage (ball and socket joint) with three movements:
- Rocking or rotating
- Gliding, and
- Pivoting,

Which causes adduction and abduction of the cords. The lateral muscular process gives attachment to the intrinsic laryngeal muscles, lateral and posterior cricoarytenoids. The medial extension is called vocal process and the vocal ligaments extend from here till the midline of the inner aspect of the thyroid lamina (FIGURE 7).[12]

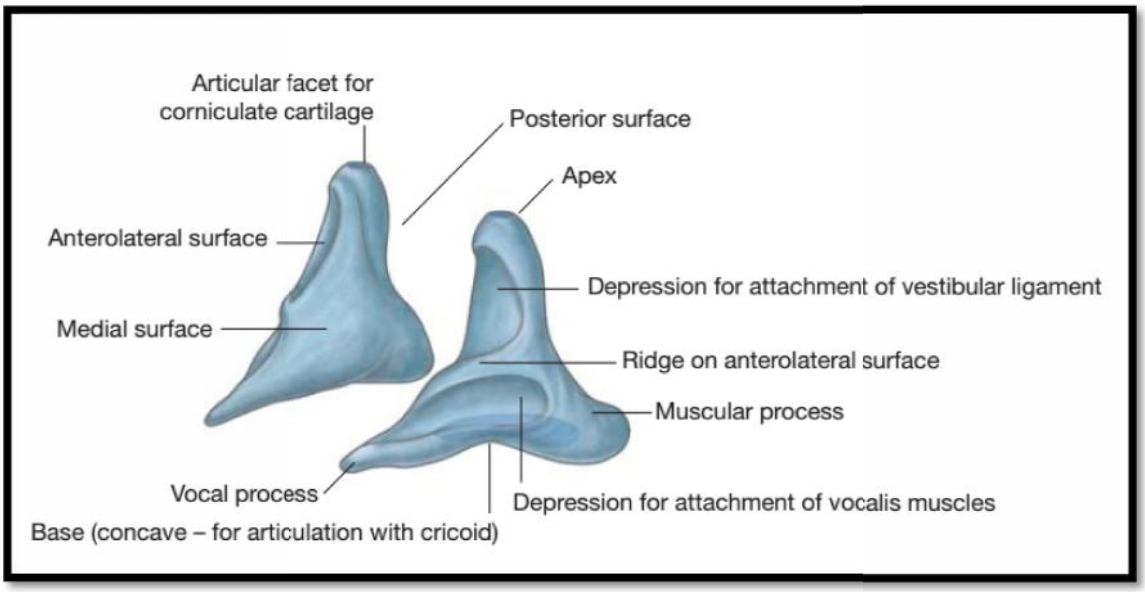


FIGURE 7

1. **Epiglottis:** It is a thin, leaf-lie elastic fibrocartilage projecting upwards, behind the tongue. Inferiorly it is connected with the thyroid cartilage by thyroepiglottic ligament and anteriorly by hyoepiglottic ligament to the hyoid bone. The pre-epiglottic space lies in-between these ligaments. The posterior surface has abundant small openings into which mucus glands open. The mucosa that shields the front of the epiglottis forms the median glossoepiglottic fold and the membrane that shields the pharynx forms the 2 lateral pharyngoepiglottic folds. The “pouch-like” areas found between these folds are the valleculae.[12-15]

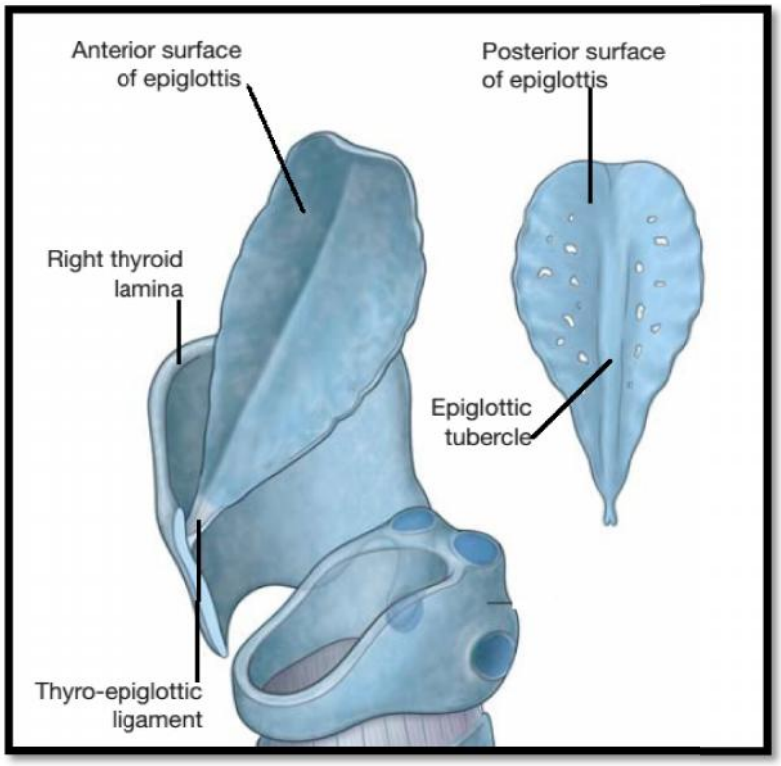


FIGURE 8

2. **Corniculate & Cuneiform cartilages:** There are a paired set of fibroelastic cartilages embedded in the aryepiglottic folds. The sesamoid cuneiform cartilages are cylindrical and lie anterosuperior to the corniculate. It may be seen as pale elevations through the mucosa while the corniculate are triangular and visible over the arytenoid. These both reinforce and support the aryepiglottic folds and help the arytenoids move.[8,12]

INTERIOR OF LARYNX

The internal anatomy consists of three parts which are separated by the false and true folds. The three parts include:

1. Vestibule,
2. Ventricle, and
3. Infraglottic cavity.

The *vestibular folds* are thick pinkish folds of mucus membrane, that encloses a band of fibrous tissue which is the vestibular ligament, fixed anteriorly to angle of thyroid cartilage.[12]

The *vocal folds* are paired structures extending from the center of the angle of thyroid cartilage to the vocal processes of the both the arytenoids.[12]

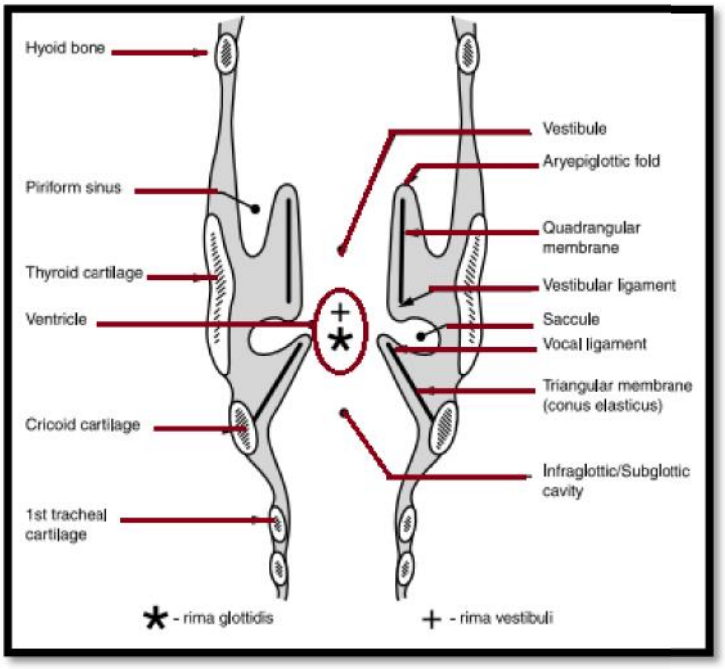


FIGURE 9

These mucosa-lined compartments outline two spaces:

1. Pre-epiglottic space and
2. Paraglottic space.

1. Vestibule

The vestibule extends from edge of the epiglottis to the false vocal cords being bound anteriorly by the epiglottis, laterally by the aryepiglottic folds, and posteriorly by the arytenoid and corniculate cartilages.[8] On visualizing, the anterior commissure

is almost always hidden, the vestibular folds are formed by mucosa overlying the vestibular ligament, as told before, and the submucosa contains numerous seromucinous glands with exocrine glands which produce secretions which provide protection and immunity for the vocal folds.[16]

Vocal folds: The anatomy of the vocal folds is complex. It is the structure between the vocal process and the anterior commissure, as told before. The vocal folds have a slit called the, "*rima glottides"* which is actually the glottis which can be divided into two halves by a horizontal line passing between the vocal processes into an intermembranous portion and an intercartilaginous portion.[8,17] The "vibratory portion" consists of three well-defined structural layer from superficial to deep which are

1. Epithelium
2. Lamina propria (three layers),
3. Vocalis muscle.

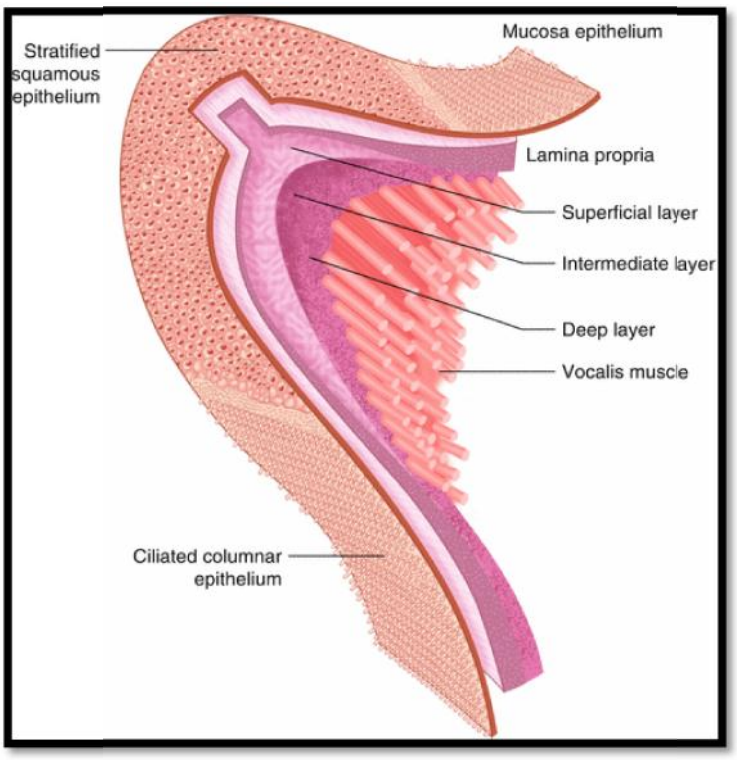


FIGURE 10

As described by Hirano, who gave the "Body-Cover concept",[18]

1. **The Cover** is the overlying epithelium and the superficial layer of the lamina propria, and
2. **The Body** is the vocalis muscle.

Between these two exists a transition zone composed of the intermediate which is elastic and a deep collagenous layer of the lamina propria.

2. Ventricle

Also called the, "*Sinus of Morgagni"* is a space between the false and true vocal folds.[8,12] It is often hidden during visualization of the larynx. At the anterior end of the ventricle there is a diverticulum known as the, "Saccule of Hilton".[19] The saccule is lined by mucous glands, which lubricates the vocal cords.

3. Infraglottic cavity

It extends down from the glottis to the inferior border of the cricoid cartilage which laterally forms the conus elasticus and walls of the cricoid cartilage.

Mucosa/Mucous Membranes of Larynx

The mucus membrane is a continuation of the pharyngeal mucosa superiorly and the tracheal mucosa inferiorly. It is loosely attached, hence becomes easily swollen. The *pseudostratified ciliated columnar* epithelium lines the vestibular folds and most of the larynx, whereas the *squamosal epithelium* lines the epiglottis, the aryepiglottic folds, and free edges of the vocal folds.[8]

INFLAMMATORY LESIONS OF LARYNX

LARYNGITIS

Definition and Etiology: Laryngitis is defined as "inflammation of, laryngeal structures commonly the laryngeal mucosa."[8]

It can be either acute or chronic. Acute laryngitis is a common condition affecting the vocal folds and supraglottis, secondary usually to upper respiratory tract infection (URTI), but can also be due to inhalational of toxic fumes, allergy or intubation.

Chronic laryngitis can either be infectious or non-infectious, the latter being more common, occurring secondary to smoking, voice abuse and/or esophageal reflux.

The association of gastro-esophageal reflux (GERD) with chronic laryngitis was given by Delahunty in 1972.[20] In a small case series of around 8 patients, barium swallow was used to detect GERD which when treated, the chronic laryngitis also was seen to settle. Therefore, GERD has a significant contribution, although the etiology of chronic laryngitis is dependent on number factors.

Clinical Presentation: There is an array of symptoms associated with chronic laryngitis among which alteration of voice quality (dysphonia), is the principal symptom. Normally the vocal cords move easily, causing vibrations and production of sound, but when the vocal cords become irritated and inflamed, swelling occurs, causing alteration of the vocal movements. As a result, voice becomes hoarse, 'rough' or faint. Symptoms also include, "sticking sensation" in throat (globus), difficulty in swallowing (dysphagia), persistent cough, constant clearing of throat and heartburn.

GASTRO-ESOPHAGEAL REFLUX DISEASE

Definition: The globally accepted definition of gastroesophageal reflux disease (GERD) is "a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complication."[21]

It is now prevalent around the world with a clear evidence of increasing prevalence in developing countries. Highest incident being in America, Australia and Northern Europe followed by Western and Southern Asia.

Pathophysiology: It is known to occur due to dysfunction at the gastro-esophageal (GE) junction that is, the lower oesophageal sphincter (LES).

Although GERD is multifactorial in etiology with potentially important modifying roles played by mucosal defensive factors, the effectiveness of esophageal acid clearance, and differences in the pH of refluxate, the key event in the pathogenesis of GERD is reflux of noxious substances from the stomach into the esophagus.

The antireflux barrier is an anatomically complex zone whose integrity has been attributed to LES pressure, extrinsic compression of the LES by the crural diaphragm, the intra-abdominal location of the LES, the phrenoesophageal ligament and maintenance of an acute angle of His.[22]

The antireflux barrier needs to be dynamic because it must guard against reflux in a variety of circumstances. The rate at which reflux events are incurred would then increase progressively as each of these protective mechanisms is compromised.

The three different prevailing opinions are that the dominant mechanism of reflux is by:[23]

1. Transient lower esophageal sphincter relaxations
2. As result of anatomic disruption of the diaphragmatic sphincter probably associated with a hiatal hernia, or
3. Simply a result of a hypotensive LES.

The vicinity of acid and pepsin secreting cells of the stomach to the GE junction, predisposes to early damage of the oesophageal mucosa (stratified squamous epithelium) which cannot withstand the acidic pH of the contents and is damaged easily.

The GE junction is designed to prevent the above, but this task is made challenging by a lot of factors.[24]

First factor is that the intra-abdominal pressure is much higher than the intra-thoracic pressure, during inspiration which forces gastric contents into oesophagus.

The LES also functions as a one-way valve which allows only liquid and food to pass from oesophagus to stomach simultaneously it prevents the gastric contents from coming back into the oesophagus.

Structure of Lower Oesophageal Sphincture

It comprises of 2 separate components.

First is the segment of circular smooth muscles at the lower end of oesophagus, which is approximately 3-4cm wide at the level of squamo-columnar

junction, called the "intrinsic sphincter" (FIGURE 11). It is maintained in a contracted state and relaxes only on swallowing.

Second component is the diaphragmatic crura which exerts a similar pressure adds to the pressure exerted by the intrinsic sphincter.

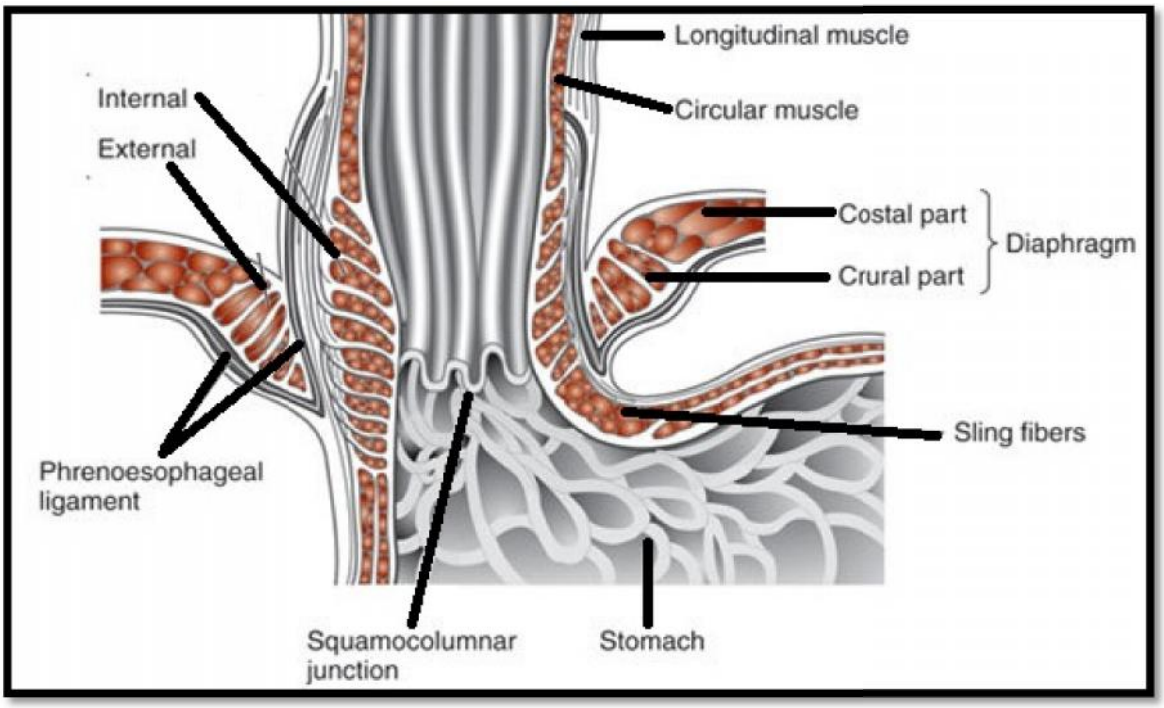


FIGURE 11

Therefore, the 4 physiological functions of LES are:[23]

1. It maintains pressure gradient to which ensures that gastric contents are not refluxed back into the oesophagus.
2. Prevents acid and pepsin from flowing back into oesophagus.
3. Acts as a one-way valve allowing only swallowed food to pass into the stomach.
4. Allows air to pass during transient LES relaxation.

Symptomatology[21]: GERD has a wide variety of clinical spectrum that are either symptom base or injury based which manifest separately or in combination.

TYPICAL SYMPTOMS	ATYPICAL SYMPTOMS
Heartburn	Nausea
Regurgitation	Belching
Hyper salivation/ water brash	Bloating
	Epigastric pain
	Vomiting
	Respiratory symptoms: non-productive chronic cough, wheeze
	ENT symptoms: hoarseness, pharyngeal pain, and globus.

TABLE 1

In 2006 a novel study was conducted which reviewed statements and articles published from 1980 onwards to develop a global definition for GERD.

The final document was validated by "World Organization of Gastroenterology (WGO-OMGE)" and first presented at the "World Congress of Gastroenterology" in Montreal.

This study stated that, "GERD can be classified into oesophageal and extra esophageal syndromes, with the extra esophageal syndromes being divided into established and proposed associations."[21]

GRADING: The Los Angeles Classification of GERD

Grade	Endoscopic description
A	One or more mucosal break <5 mm that does not extend between the tops of two mucosal folds
B	One or more mucosal break ≥5 mm that does not extend between the tops of two mucosal folds
C	One or more mucosal break that is continuous between the tops of two or more mucosal folds but that involves <75% of the circumference
D	One or more mucosal break that involves ≥75% of the esophageal circumference

TABLE 2

REFLUX LARYNGITIS SYNDROME

Definition: It is an extra esophageal manifestation of GERD.[12] The patients with reflux laryngitis usually present with history of heartburn/regurgitation only occasionally.

Symptoms: Majority of the patients present with atypical GERD symptoms,[23] which include:

1. Nausea
2. Epigastric pain
3. Chronic non-specific cough
4. Hoarseness of voice
5. Globus pharyngeus
6. Hawking sensation in throat
7. Nocturnal awakening

Structure of Upper Oesophageal Sphincture (UES)

It mainly comprises the cricopharyngeus part of inferior constrictor which encircles the entrance which is attached to each side of cricoid cartilage, continuous with circular muscle coat below. Therefore also called cricopharyngeal sphincter (FIGURE 12). It forms the first constriction, the pharyngo-oesophageal junction, 15cm from the upper incisors or at level of C6, with a luminal diameter of 1.5cm.[8] At rest it is tonically contracted, with a resting pressure of 45mmHg, thus protects from aspiration. Failure of the sphincter to maintain this tone, leads to cricopharyngeal dysfunction.

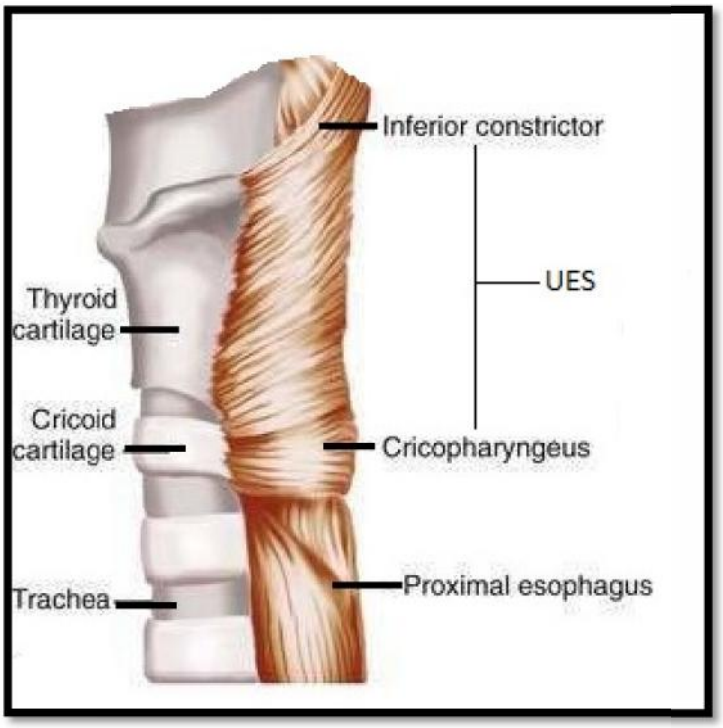


FIGURE 12

It is innervated by the pharyngeal plexus, which is supplied by 3 major nerves:

1. Vagus nerve through the pharyngoesophageal, superior laryngeal, and recurrent laryngeal branches
2. Glossopharyngeal nerve and
3. Sympathetic supply through the cranial cervical ganglion.

Pathophysiology: Possible mechanisms by which GERD triggers these symptoms include:

1. Direct stimulation of nerve endings responsible due to micro aspiration.[25]
2. Indirect stimulation by activation of neural pathway linking oesophagus to airway.[25]

DIRECT MECHANISM / MICROASPIRATION

Laryngopharyngeal reflux usually occurs due failure of UES which causes the refluxate to reach the larynx and pharynx along with a multifaceted mechanism of reduced laryngeal and pharyngeal reflexes.[26,27]

This is described as "microaspiration"[28,29,30] occurring due to impairment of the protective reflexes. However it can be debated that presence of excess refluxate in proximal oesophagus is a disposing factor. However in majority of the studies there is minimal correlation between the two.

INDIRECT MECHANISM/ VAGAL STIMULATION

The common vagal innervation of oesophagus and airway provides a conduit by which airway responses mainly bronchoconstriction and cough occurs along with

GERD called the "oesophago-bronchial reflex." [27],[29] However, the exact mechanism of how it occurs is not known and requires further evaluation.

However it can be postulated that the responses to oesophageal acid is a general visceral hypersensitivity reaction of oesophagus where the LES dysfunction causes multiple reflux events.[25,31]

LPR v/s GERD

GERD	LPR
Accompanied by esophagitis and/ or heartburn	Esophagitis or heartburn is rarely present
Reflux is nocturnal or in supine position	Reflux during daytime or in upright position
Abnormal esophageal motility and prolonged esophageal acid exposure	Intermittent episodes of reflux
Dysfunction of the lower esophageal sphincter	Dysfunction of the upper esophageal sphincter
Throat related symptoms are sometimes present	Leads to throat related symptoms and damage to the laryngopharyngeal epithelium

TABLE 3

REFLUX SYMPTOM INDEX (RSI)[6]

On the basis of the above etiology, LPR is said to be present in 56-60% of the patients who come with non-specific symptoms. Since there was no validated instrument/score that can be used to document the severity of these symptoms in LPR, in 2002 Peter C Belafsky et al developed the Reflux symptom index.

The Reflux symptom index in a self-administered, nine item outcome instrument for LPR. LPR symptoms differ from classic GERD symptoms. While

GERD commonly presents with heartburn and regurgitation, LPR symptoms include hoarseness of voice, globus pharyngeus, excessive clearing of throat, persistent cough and occasional post-nasal drip. Patients with LPR usually have mid-day reflux in upright position with good oesophageal motor function, while GERD patients have nocturnal reflex with oesophageal dysmotility.

As a result of this vast difference in etiology and other scores being lengthy, which rely on typical GERD symptoms, the RSI was developed for the otolaryngologists to assess LPR. It can be completed in less than a minute, it has a list of 9-symptoms which are graded as: "0 (no problem) to 5 (severe problem) with a maximum score of 45 points." (Table 4)

Reflux Symptom Index

Within the last MONTH, how did the following problems affect you?

0 = no problem, 5 = severe problem

1. Hoarseness or a problem with your voice	0 1 2 3 4 5
2. Clearing your throat	0 1 2 3 4 5
3. Excess throat mucous or postnasal drip	0 1 2 3 4 5
4. Difficulty swallowing food, liquids, or pills	0 1 2 3 4 5
5. Coughing after you ate or after lying down	0 1 2 3 4 5
6. Breathing difficulties or choking episodes	0 1 2 3 4 5
7. Troublesome or annoying cough	0 1 2 3 4 5
8. Sensations of something sticking in your throat or a lump in your throat	0 1 2 3 4 5
9. Heartburn, chest pain, indigestion, or stomach acid coming up	0 1 2 3 4 5
Total	

TABLE 4

Belafsky et al[6] conducted a study in 2002 to assess its validity and reliability on 23 patients which showed a significant change in the score pre-treatment to post treatment assessments. The upper confidence limits for 95% controls was 13.6 and hence 13 was considered as the lower limit, greater than which RSI was termed as "abnormal/significant."

REFLUX FINDING SCORE (RFS)[7]

The symptoms and manifestations of LPR are accompanied by certain physical findings in the larynx. In 2001 Peter C Belafsky et al formulated the reflux finding score as there was no validated instrument to document the laryngoscopic findings of LPR. They studied 40 patients in whom LPR was confirmed pH monitoring using a double probe, values of which were recorded pre-treatment and on 2, 4, 6 months after treatment which included a combination of dietary and lifestyle modifications along with antacids/H2 receptor antagonists/PPI.

The RFS contains 8-items based on the findings of flexible laryngoscopy. The score ranges from "0 (No abnormality) to 26 (Worst possible score)." The findings were derived from a pool of most common laryngeal findings of patients with LPR (Table 4).

The scale includes the following 8 items:

1. Subglottic edema
2. Ventricular obliteration
3. Erythema/Hyperemia
4. Vocal fold edema
5. Diffuse laryngeal edema
6. Posterior commissure hypertrophy

7. Granuloma/Granulation tissue
8. Thick endolaryngeal mucus

Reflux Finding Score		
Subglottic Edema	2 = present 0 = absent	
Ventricular Obliteration	2 = partial 4 = complete	
Erythema/Hyperemia	2 = arytenoids only 4 = diffuse	
Vocal Fold Edema	1 = mild 2 = moderate 3 = severe 4 = polypoid	
Diffuse Laryngeal Edema	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Posterior Commissure Hypertrophy	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Granuloma/Granulation	2 = present 0 = absent	
Thick Endolaryngeal Mucus	2 = present 0 = absent	
	Total:	

TABLE 5

In the study they conducted the mean RFS was 5.2, hence they concluded that a patient with RFS >7 definitely has LPR. Thus RFS standardized the laryngeal findings so that diagnosis is made easier for doctors and we can also evaluate improvement after treatment of patients with LPR.

The RFS is reproducible between different observers and with the same observers also. It is an easy and less time consuming score. Although each item is subjective, the overall score is reliable.

Components of RFS

i. Subglottic Edema : Kafmann first described it as "pseudosulcus vocalis" [7,12,32] in 1995.[33] It refers to "subglottic edema that extends from the anterior commissure to the posterior larynx." Differentiated from true sulcus which is limited at the vocal process and midpoint of the vocal folds contact zone, whereas pseudosulcus vocalis is seen to extend to the most posterior part of the larynx.

ii. Ventricular Obliteration: It is described as "swelling of the true and false vocal folds which causes the space between the two i.e. the ventricle to be poorly visualized." [7,12] It can be partial or complete.

FIGURE 13

iii. Hyperemia/ Erythema:[7,12] It is a non-specific finding, which considerably depends on the laryngoscope used for examination. The delicate changes are difficult to appreciate and may change depending on the quality of the scope, light source and monitor.

iv. Vocal fold Edema:[7] It is usually graded from 1-4:

1. If only slight swelling is present.
2. Moderate swelling which becomes perceptible.
3. Severe when there is sessile swelling of the cords.
4. Indicates polypoidal degeneration of the cords.

v. Diffuse laryngeal edema:[7] It is judged by "the size of the airway relative to the size of the larynx." The grades range from 1 to 4 with 1 being mild and 4 being obstructing.

vi. Posterior commissure Hypertrophy:[7,34] It is the most frequent finding and is graded as:

1. Mild: "Moustache like" appearance of the posterior commissure.
2. Moderate: When the swollen posterior commissure mucosa creates a line across the back of the larynx (FIGURE 14).
3. Severe: Where the posterior commissure is bulging into the airway.
4. Obstructive: When most of the airway is obliterated (FIGURE 15).

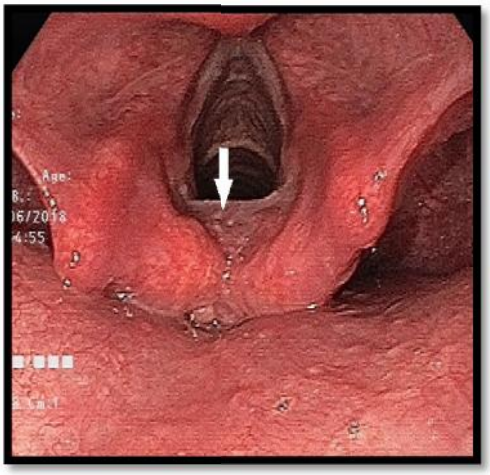


FIGURE 14

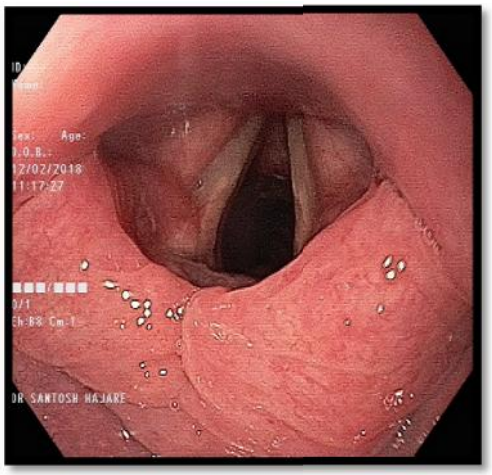


FIGURE15

vii. Granuloma/granulation tissue and endolaryngeal thick mucus can either be present or absent and is scored accordingly.[7]

VISUALIZATION OF LARYNX

LARYNGPSCOPY

It is a "medical procedure that is used to obtain a view of the vocal folds and the glottis."[35] It is also performed to facilitate intubation during resuscitation or for giving general anesthesia during surgical procedures.

It can be done in two ways:

1. Direct Laryngoscopy
2. Indirect Laryngoscopy

DIRECT LARYNGOSCOPY[36]

It is the visualization of the larynx using a direct light source. Carried out usually with the patient in supine position. The scope is introduced from the right side of the mouth and slided to the left which facilitates the movement of tongue keeping it out of sight. The blade is then placed either anterior or posterior to the epiglottis and in one quick forwards and upwards motion the epiglottis is lifted, to visualize the larynx. The procedure is extremely uncomfortable and never done on awake patients. This procedure is commonly done in a setting where resuscitation or general anesthesia is required. Many different types of laryngoscopes are available each having its unique use for different specialties. For the otolaryngologist this procedure is employed in diagnostic laryngoscopy by which even biopsy of suspected lesions can be taken.

INDIRECT LARYNGOSCOPY (IDL)[36]

It is visualization of the larynx by means other than using a direct light source (example a mirror/lense). This is the case with fibreoptic scopes and video laryngoscopes and mirrors/prisms which are used to enhance the video laryngosopes.

The Era of Mirrors and Reflections[37]

As a result of the natural anatomical constraints, visualization of larynx proved to be one of the most difficult but creative task for some of the cleverest innovators. Some of these early creators even risked their own life to figure out how to go about visualizing the larynx.

In 1743, the French surgeon André Levret (1703- 1780) introduced an angled-mirror for indirectly viewing the larynx. Though not refined, it arose over half a century before Philipp Bozzini's work.

In 1806 that Philipp Bozzini (1773-1809) described the principles for laryngoscopy. He used candlelight as a light source and a silver mirror to reflect that light through a speculum, through which he looked from a small hole in the center of the mirror.

Its various attachments allowed inspection of the female genetilia, the rectum and the upper airway but it was impossible to visualize the larynx. Regardless of proper principles his "Lichtleiter" did not gained reputation.

In 1825, the French physicist Charles Cagniard de la Tour (1777-1859), introduced a small mirror to the back of the throat, hoping to see the larynx with the aid of sunlight reflected by a second mirror. He only saw the epiglottis, but unfortunately did not publish his findings.

The use of an extended, angled speculum with double convex lenses was introduced on 1827 by John D. Fisher (1797-1850).

Also in 1827, Dr. Senn (Geneva) made a mirror for passing into oropharynx, with which he attempted to see the glottis. Senn's attempt failed because he did not have a light source.

In 1829, Benjamin Guy Babington (1794-1866) presented his "glottiscope" before the Hunterian Society.[38] It was a double-bladed rectangular stainless steel mirror attached to a long trunk and a tongue retractor united to it.

Sunlight from behind the patient would be the light source reflected with an ordinary glass held in the left hand, onto the laryngeal mirror introduced with the right hand, while the tongue depressor kept the tongue out of sight.

He used it on many patients, but his results were not recorded. Although his design made laryngoscopy possible the disadvantage was that it required two hands and did not have a practical source of light.

In 1840, Scottish surgeon Robert Liston (1794-1847) gave the technique of using a dentist's mirror carried to the back of the throat to examine the larynx.

In 1841 Friedrich Hofmann (1806-1886), described a concave mirror with a central aperture as an ideal instrument that allowed reflecting and focusing the light.

The breakthrough was given by Spanish singing teacher Manuel Patricio Rodriguez García (1805-1906) who made the discovery that is widely recognized as the "true" birth of laryngoscopy. He addressed this before the Seventh Session of the International Congress of Medicine in London in 1881.

He went on to examine and document his own, and other larynges in motion, and presented a paper on "Observations on the Human Voice" at the "Royal Society of London" on May 24, 1855.

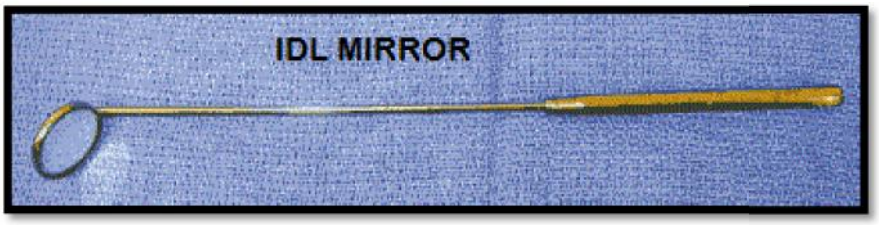


FIGURE 16

The Era of Scopes[39]

All previous observations of larynx had been performed under indirect vision (using mirrors) until 1895. Alfred Kirstein (1863–1922) in April 1895 (Germany) was the first describe direct visualization of the glottis. The death of Emperor Frederick III in 1888 motivated Kirstein to develop the "Autoscope."

He performed the first direct laryngoscopy in Berlin, using an esophagoscope which he modified and called it the "Autoscope."

In 1913, Chevalier Jackson reported the first to report successful use of a direct laryngoscope. He introduced a new blade with an inbuilt light source at the distal end. This blade also had a component through which the operator could slide in an endotracheal tube or bronchoscope.

Also in 1913, Henry Harrington Janeway (1873–1921) published results he had got using a laryngoscope he developed. Analogous to Jackson's device, Janeway's instrument had a distal light source, but the batteries for the light source were incorporated within the handle. Also the blade had a central notch to keep the

endotracheal tube in the center and the distal end was slightly curved for easy navigation.

Two types of laryngoscopic blades are commercially available, a curved and a straight blade. The curved Macintosh blade is the most frequently used blade. While the Miller straight blade is the most widely used in this category. Both blades are available in sizes "0(neonatal) to 4(adult)."

The Era of Fibreoptics

All the above instruments were designed specifically for anesthetist use. Out-patient examination was not possible by the otolaryngologists.

The transmission of a visual image through a flexible fibreoptic bundle was first reported in 1954.[40]

John Logie Baird (1888-1946), an electrical engineer, known for his work on the television, was also the pioneer in fibreoptic imaging. In 1926, he attempted to patent his work, "An improved method and Means of producing Optical Images."[41]

He advocated a "honeycomb" like assemblage of hollow rods which transmitted an image without requiring a lens/mirror. He advocated to make a structure of thin glass rods, which transmitted light by internal reflection and also could be flexible.

Much later in 1954, Hopkins, Kapany and van Heel published articles on the same, acknowledging Baird.

However in 1954 Basil Hirschowitz, a gastroenterologist, developed the flexible gastroscope. He presented his first commercially available flexible fibreoptic endoscope in 1961 with applications in surgery, anesthesia and visualization.

More than a decade later, Peter Murphy an anesthesiologist used the choledocoscope to aid nasao-tracheal intubation.[42]

The technology is based on optical characteristics. It states that "a very thin (8-25μm), flexible glass fiber that is capable of transmitting light over long distances." Insulation is given by glass layer with different optical densities which allows transmission by internal reflection. The image is formed by organized bundles of fibers with same angle at both ends of the scope. The light source is separately attached to provide illumination and a separate port is also available for suction, providing oxygen or passage of instruments for diagnostic procedures.

Recent evolutions have added a charge-coupled camera, which captures an image that is displayed on a monitor.

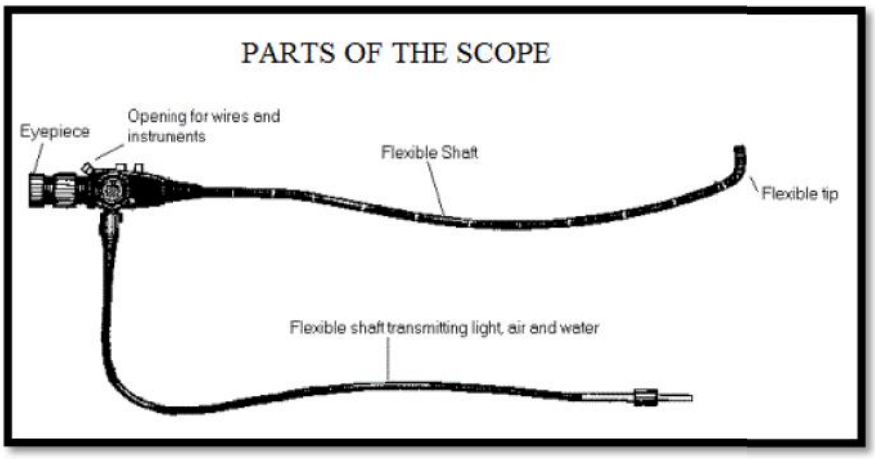


FIGURE 17

FIGURE 18

ADVANTAGES	DISADVANTAGES
Minimally invasive and safe	Learning curve is high
Visualization and intervention is easy	Scopes can be introduced only as far as its length
Differentiation of normal and diseased mucosa has high sensitivity	Functional diseases cannot be diagnosed
Larynx can be viewed dynamically	Distortion of periphery of image
Photographic and video documentation possible	High resolution advance systems are expensive
	Increased risk of injury and bleeding

TABLE 6

MATERIALS AND METHODS

Source of data: All cases who present to the OPD with typical and atypical symptoms (hoarseness, throat cleaning, cough, globus sensation, etc.) of GERD at, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum, for a period of 1year

Study Design: Cross-sectional study

Study Period: 1 year (January 2018 – December 2018)

Sample Size (n): 75

The minimum sample size formula based on prevalence is

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

Where P is the percentage of prevalence and d is the percentage likely difference in the prevalence. Zα is linked with the level of significance. For 5% level of the significance $z_\alpha = 1.96$.

With P=45%and d=25% the sample size is 75

SELECTION CRITERIA

INCLUSION CRITERIA:

1. All cases who present to the ENT OPD with typical and atypical symptoms (hoarseness, throat cleaning, dry cough, globus sensation, etc.) of GERD.
2. Patients between the ages of 20-60 years.

EXCLUSION CRITERIA:

1. Patients with history of chronic smoking or chronic alcoholics.
2. Patients with chronic cough associated with history of COPD / asthma.
3. Professional voice users or patients with history of voice abuse.
4. Patients with previous history of any upper GI or respiratory malignancy or previous radiotherapy for head and neck surgeries.
5. Patients with history of recent intubation, prolonged intubation or intubation injury.

METHODOLOGY:

1. Patients who report to the ENT OPD with atypical GERD symptoms will be subjected to detailed history taking and the symptoms will be noted.
2. The symptoms of the patients will be graded based on the "**Reflux Symptom Index"** to facilitate the clinical diagnosis. Any score > 13 (on a scale of 0 to 5, with maximum 45 points) is considered abnormal.
3. After this initial evaluation, patients will be subjected to Video Laryngoscopic Examination using a fiber optic endoscope, after spraying with local anesthetic agent to avoid gag reflex while examination, by the same examiner always, after explaining the procedure and taking consent.
4. Laryngoscopic changes of each patient will be noted methodically.
5. The Laryngoscopic Findings will be graded based on the **"Reflux Finding Score".** Any score > 7 (out of maximum 26) is considered significant.

RESULTS & ANALYSIS

My study included 75 patients, most of them (38.7%) were found to be in the age group of 30-40 years, with the rest of the age groups having similar number of patients. These included 40 males and 35 females, showing no significant sex predilection (TABLE 7 & 8; GRAPH 1 & 2)

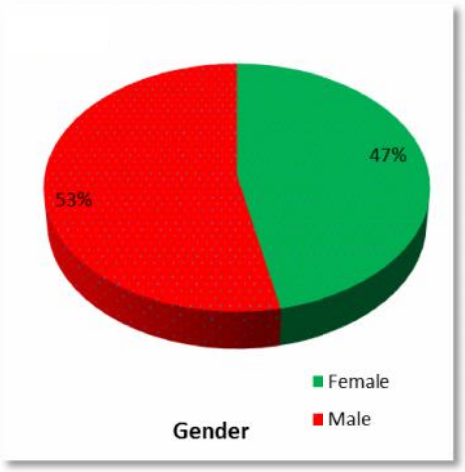
Table 7: Age distribution of patients studied

Age in years	No. of patients	%
<20	1	1.3
20-30	14	18.7
30-40	29	38.7
41-50	13	17.3
51-60	18	24.0
Total	75	100.0

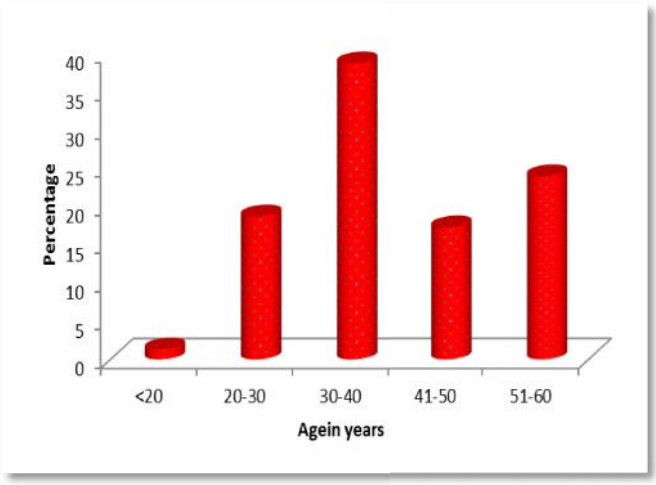
Table 8: Gender distribution of patients studied

Gender	No. of patients	%
Female	35	46.7
Male	40	53.3
Total	75	100.0

GRAPH 1



GRAPH 2

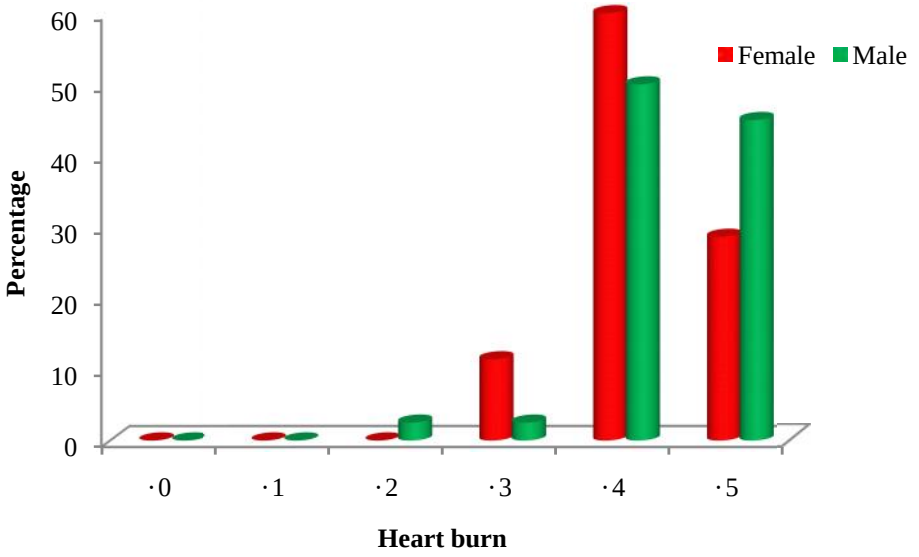


The average score of RSI 20.45(ranging from 17-24) (TABLE 9). Majority of the patients presented with heartburn (100%), feeling of lump in the throat and feeling of hoarseness of voice (97.3% and 56% respectively) (TABLE 10; GRAPH 3 to 5). All the patients with abnormal RSI were subjected to flexible fibreoptic laryngoscopy. All the patients were examined by the same clinician and the findings were scored using the RFS by the same examiner always.

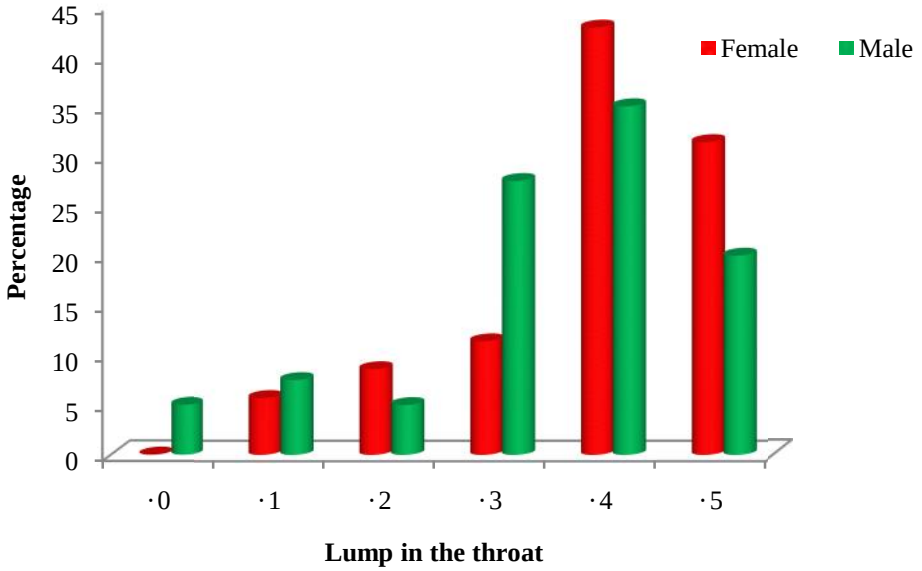
Table 9: Reflux symptom Index of patients studied in relation to significant findings

	Significant Findings		**Total**	**P value**
	No	**Yes**		
Reflex Symptom Index	19.15±3.75	20.93±3.37	20.45±3.54	0.054+

GRAPH 3



GRAPH 4



GRAPH 5

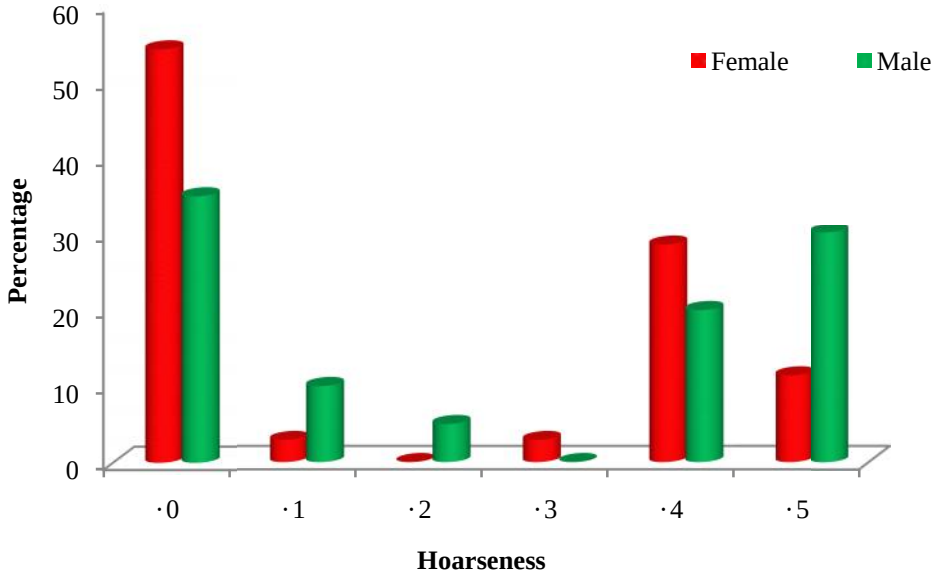


Table 10: Reflux symptom index (components) of patients studied in relation to significant findings

Reflux symptom index (components)	Significant Findings		Total	P value
	No	Yes		
Hoarseness	**0.95±1.73**	**2.64±2.16**	**2.19±2.18**	**0.002****
Lump in the throat	**4.05±0.89**	**3.45±1.36**	**3.61±1.27**	**0.073+**
Heart burn	**4.00±0.65**	**4.38±0.62**	**4.28±0.65**	**0.023***
Constant clearing of throat	3.15±1.14	3.55±1.00	3.44±1.04	0.148
Post nasal drip	0.95±1.28	1.31±1.23	1.21±1.24	0.272
Difficulty swallowing	2.50±2.19	2.31±1.90	2.36±1.97	0.713
Coughing on lying down	0.65±1.27	0.76±1.05	0.73±1.11	0.697
Chocking/difficulty breathing	0.00±0.00	0.15±0.68	0.11±0.58	0.343
Troublesome cough	2.90±1.68	2.47±1.65	2.59±1.66	0.328

After statistical analysis using Analysis of variance (ANOVA), Student t test (two tailed, independent) and Leven`s test, it was observed that erythema of hyperemia was the most common finding (98%), followed by posterior commissure hypertrophy (96%), vocal fold edema (93.3%) and partial ventricular obliteration (62.7%) (TABLE 11; GRAPHS 6 to 9). The RFS showed an average score ranging from 19-16 (TABLE 12).

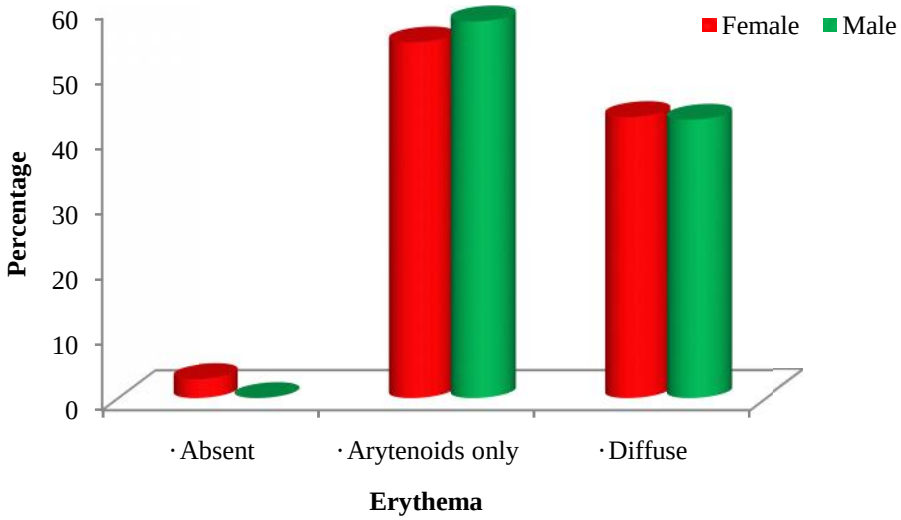
Table 11: Reflux finding score distribution of patients studied

Reflux finding score	Gender		Total (n=75)
	Female (n=35)	Male (n=40)	
Subglottic edema			
1. Absent	33(94.3%)	33(82.5%)	66(88%)
2. Present	2(5.7%)	7(17.5%)	9(12%)
Ventricular obliteration			
3. Absent	**6(17.1%)**	**2(5%)**	**8(10.7%)**
4. Partial	**23(65.7%)**	**24(60%)**	**47(62.7%)**
5. Complete	**6(17.1%)**	**14(35%)**	**20(26.7%)**
Erythema			
6. Absent	**1(2.9%)**	**0(0%)**	**1(1.3%)**
7. Arytenoids only	**19(54.3%)**	**23(57.5%)**	**42(56%)**
8. Diffuse	**15(42.9%)**	**17(42.5%)**	**32(42.7%)**
Vocal fold edema			
9. Absent	**4(11.4%)**	**1(2.5%)**	**5(6.7%)**
10. Mild	**14(40%)**	**14(35%)**	**28(37.3%)**
11. Moderate	**14(40%)**	**23(57.5%)**	**37(49.3%)**
12. Severe	**3(8.6%)**	**2(5%)**	**5(6.7%)**

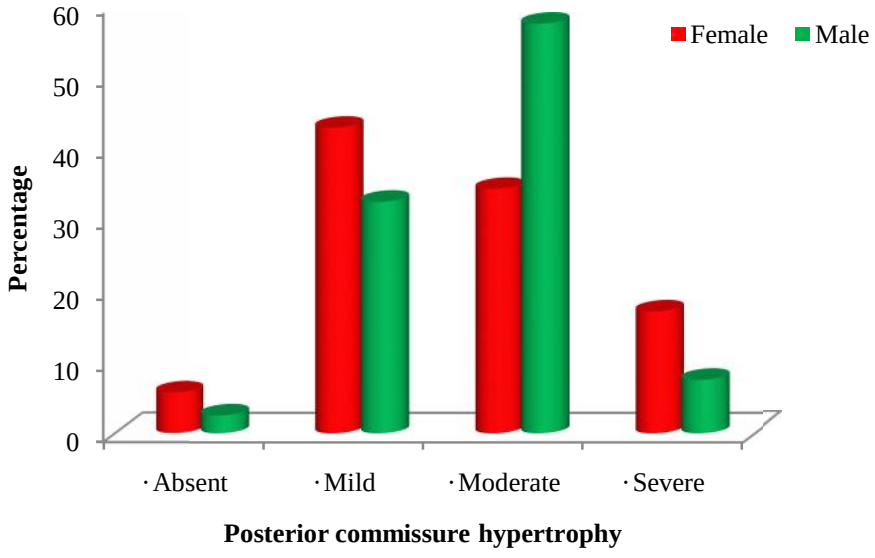
Diffuse laryngeal edema			
13. Absent	6(17.1%)	3(7.5%)	9(12%)
14. Mild	11(31.4%)	13(32.5%)	24(32%)
15. Moderate	14(40%)	18(45%)	32(42.7%)
16. Severe	4(11.4%)	6(15%)	10(13.3%)
Posterior commissure hypertrophy			
17. Absent	**2(5.7%)**	**1(2.5%)**	**3(4%)**
18. Mild	**15(42.9%)**	**13(32.5%)**	**28(37.3%)**
19. Moderate	**12(34.3%)**	**23(57.5%)**	**35(46.7%)**
20. Severe	**6(17.1%)**	**3(7.5%)**	**9(12%)**
Granulation			
21. Absent	32(91.4%)	36(90%)	68(90.7%)
22. Present	3(8.6%)	4(10%)	7(9.3%)
Thick endo-laryngeal mucus			
23. Absent	33(94.3%)	34(85%)	67(89.3%)
24. Present	2(5.7%)	6(15%)	8(10.7%)

Chi-Square/Fisher Exact Test

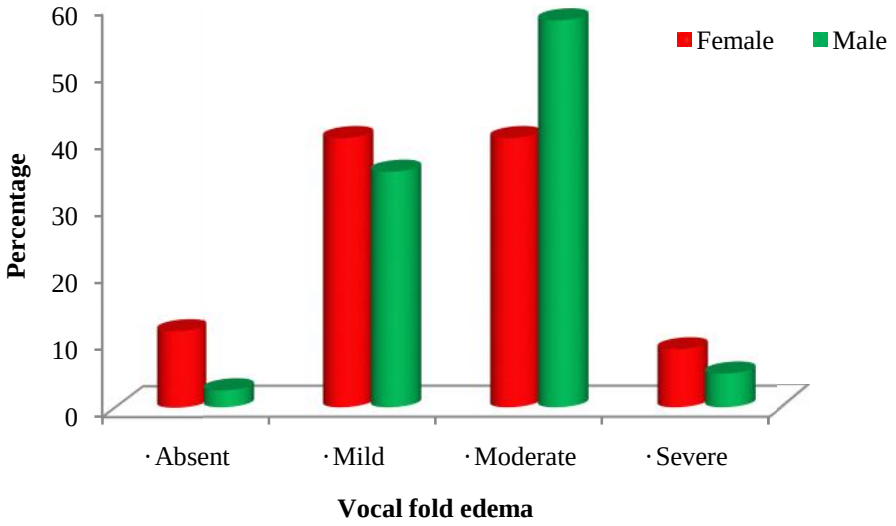
GRAPH 6



GRAPH 7



GRAPH 8



GRAPH 9

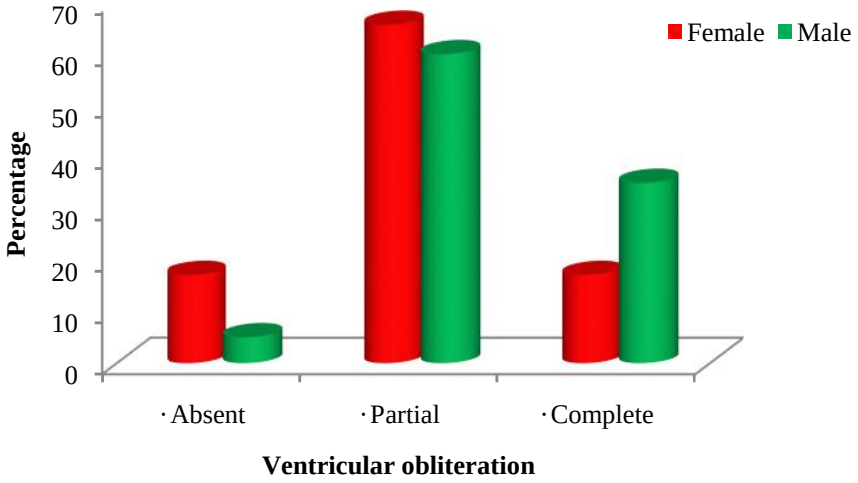


Table 12: Reflux Finding score of patients studied in relation to Significant findings

	Significant Findings		Total	P value
	No	Yes		
Reflux Finding Score	5.55±1.47	12.51±3.15	10.65±4.17	<0.001**

Table 13: Significant Findings distribution of patients studied

Significant Findings	No. of patients	%
No	20	26.7
Yes	55	73.3
Total	75	100.0

On comparing the two scores we found that when a patient has an abnormal RSI (>13) significant findings were noted on RFS (>7).Thus the two scores show strong correlation and can be used as a compliment to each other (p=0.007) and a likely diagnosis of LPR can be made (TABLE 14).

Table 14: Pearson correlation

Pair	r value	P value
Reflex Symptom Index **vs** Reflux Finding Score	0.307	0.007**

+ Suggestive significance (P value: 0.05<P<0.10)

*** Moderately significant (P value: 0.01<P á 0.05)**

**** Strongly significant (P value: Pá0.01)**

DISCUSSION

Laryngopharngeal reflux / Reflux laryngitis is a diagnostic dilemma, often presenting with non-specific symptoms to the ENT clinic. Although its mechanism of occurrence is not confirmed, certain symptoms and specific laryngoscopic findings may help in its diagnosis. To help the clinicians, Belfsky et al developed the RSI and RSF.

My study included 75 patients, most of them (38.7%) were found to be in the age group of 30-40 years, with the rest of the age groups having similar number of patients. These included 40 males and 35 females, showing no significant sex predilection.

RSI is a scoring system with 9 symptoms, out of which 100% of the patients (n=75) presented with heartburn. Among them 98% patients had non-specific complaints lie constant clearing of throat and feeling of lump in the throat i.e. globus and more than half of them (56%) had complains of hoarseness of voice.

The above symptoms can be accounted for by the direct and indirect mechanisms by which acid reflux takes place through the UES. Although the duration of exposure is short, the mucous membrane of the larynx is sensitive to even small amounts of acid exposure which causes inflammation and edema

In a study conducted done on 62 patients over 1 and a half years by U. Cesari et al[43] confirmed the estimated incidence of LPR in patients presenting with voice disorders reported in literature. The study concluded that “significant correlation between the severity of voice disorder and laryngoscopic findings exists.” This concurred with my study.

Also in a study done by Carlos Eduardo Dilen da Silva et al[44] over 8 months concluded that "the most common symptoms were dry cough, foreign body sensation in the throat and throat clearing." The same was also seen in my study.

In contrast to many studies, heartburn as seen in all the patients of my study, which added to the confusion between GERD and LPR. Also we found that 96% of patients did not complain of chocking/difficulty in breathing, inferring that patients are unlikely to have these symptom as a consequence of LPR.

To confirm the diagnosis patients with abnormal RSI underwent a fibreoptic laryngoscopic examination a findings were scored according to RFS. Out of 8 expected findings, 98% of patients were found to have erythema/hyperemia out of which 56% showed erythema of only the arytenoids.

Along with erythema 96% of patients had posterior commissure hypertrophy. 93.3% had vocal fold edema and only 62.7% of patients showed partial ventricular obliteration, which was similar to the study conducted by Carlos Dilen da Silva et al[44], which concluded that "there was statistically significant correlation between hoarseness and foreign body sensation with findings of posterior commissure hypertrophy."

The mean RSI in those with significant findings was 20.93 ± 3.37 which was found to be statistically significant (p value=0.054) indicating that those with an abnormal RSI are likely to have significant findings. The mean RFS was found to be 12.51±3.15 among with the patients with significant findings.

All the above analysis concludes that RSI v/s RFS are statistically significant (p value=0.007) which means that when a patient has an abnormal RSI (score>13) a positive RFS (score>7) a likely diagnosis of LPR can be made with the help of these two complimentary scores.

CONCLUSION

Laryngopharyngeal reflux / Reflux laryngitis being a diagnostic dilemma requires comprehensive evaluation of the symptoms first. In our study the RSI helped evaluate the symptoms, and all patients with abnormal RSI (>13) were included in our study (n=75).

We found that:

1. There was no significant sex predilection but majority of the patients were in age group 30-40 years.
2. Globus pharyngeus ("feeling of lump in throat") and hoarseness of voice were the most significant presenting complaints in patients with heartburn.
3. The mean RSI was found to be 20.45 ± 3.54

All these patients were subjected to flexible fibreoptic laryngoscopy, and the findings were scored using the RFS. We found that:

1. 82.7% (n=62) had a score above 7, suggesting that these patients had significant findings due to reflux.
2. The mean RFS was found to be 10.65 ± 4.17.
3. Erythema/Hyperemia, posterior commissure hypertrophy, vocal fold edema and partial ventricular obliteration were the most significant findings.

All the above findings have significant effect on the voice explaining the hoarseness. Erythema and posterior commissure hypertrophy explains the constant feeling of lump in the throat. Thus we can conclude that RSI and RFS are easy, quick, reproducible and complimentary scores that can be used to make a diagnosis of LPR.

SUMMARY

This study was done in the Department of Otorhinolaryngology and Head and Neck Surgery, Jawaharlal Nehru Medical College and KLES Dr.Prabhakar Kore Hospital from January 2018 to December 2018. The objective of the study was to assess the "Correlation between the clinical symptoms and laryngoscopic findings of Reflux Laryngitis using the Reflux Symptoms Index (RSI) and the Reflux Finding Score (RFS)."

Our study included 75 patients, who presented to the ENT-OPD with atypical symptoms of GERD. Their symptoms were assessed using the Reflux Symptom Index (RSI) and given a score out of 45. Any score above 13 was considered abnormal and all these patients were subjected to Flexible Laryngoscopy. The mean RSI of patients as found to be 20.45±3.54, with heartburn seen in 100% of patients along with feeling of lump in the throat (Globus) and hoarseness seen in 97.3% and 56% respectively.

The laryngoscopic findings recorded were scored using the Reflux Finding Score (RFS) and any score above 7 was considered as significant. The mean RFS was found to be 12.51±3.15. Erythema/Hyperemia was the most common finding (98%) followed by posterior commissure hypertrophy (96%), vocal fold edema (93.3%) and partial ventricular obliteration (62.7%).

The increased incidence in the association of gastroesophageal reflux (GERD) on laryngeal and pharyngeal disorders has ascended only in the past 30 years. Patients with typical GERD symptoms appeal to the gastroenterologist, whereas patients with atypical symptoms to the ENT specialists.

Thus, in our study we found that on comparing the two scores, that higher the RSI the more likely was the chance of having a significant score on RFS and thus more significant findings. The P value of 0.007 suggests that both the scores have significant correlation and complement each other and can easily be used by clinicians to diagnose Reflux Laryngitis.

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ANNEXURE - I - INFORMED CONSENT

TITLE: "CORRELATION OF CLINICAL SYMPTOMS AND LARYNGOSCOPIC SIGNS IN REFLUX LARYNGITIS - A ONE YEAR CROSS-SECTIONAL STUDY"

PRINCIPAL INVESTIGATOR: DR.

CO-INVESTIGATOR: DR.

INTRODUCTION AND PURPOSE: The present study is conducted among patients who are presenting with atypical GERD symptoms in ENT & HNS department in KLE's Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belgaum for assessing the Correlation of symptoms and laryngoscopic signs of Reflux Laryngitis. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE: If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed.

After getting inducted in the study, you will be evaluated. Complete detailed history will be taken and thereafter you will be undergoing Laryngoscopic examination on an out-patient basis under local anesthesia.

BENEFITS: Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS: Methods applied to do the study are safe. No adverse effects are expected.

COST OF PARTICIPATION: The cost of the Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY: The results of the study may be published in journals for scientific purposes. However your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY: You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS: The researcher may use the information gathered from this study for presentation in scientific meetings. However your identity will not be revealed.

QUERIES AND CONTACT: If you have any questions about rights as a research participant you can contact Dr. Roopa M Bellad Professor, Department of Pediatrics and Chairman, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects' research.

CONSENT SUMMARY: I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness (Relative):

Signature of the guide:

DATE :

ANNEXURE – II – ETHICAL CLEARANCE LETTER

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 62 **Date: 22/11/2017**

To,

PG student in ENT&HNS,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"CORRELATION OF CLINICAL SYMPTOMS AND LARYNGOSCOPIC SIGNS IN REFLUX LARYNGITIS – A ONE YEAR CROSS SECTIONAL STUDY IN A TERTIARY CARE CENTRE"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE - III - PROFORMA FOR DISSERTATION

"CORRELATION OF CLINICAL SYMPTOMS AND LARYNGOSCOPIC SIGNS IN REFLUX LARYNGITIS - A ONE YEAR CROSS-SECTIONAL STUDY"

Date:

O.P. No:

Name: Age:

Sex: Occupation:

Address: Phone No:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness:

Reflux Symptom Index

Within the last MONTH, how did the following problems affect you?

0 = no problem, 5 = severe problem

1. Hoarseness or a problem with your voice	0 1 2 3 4 5
2. Clearing your throat	0 1 2 3 4 5
3. Excess throat mucous or postnasal drip	0 1 2 3 4 5
4. Difficulty swallowing food, liquids, or pills	0 1 2 3 4 5
5. Coughing after you ate or after lying down	0 1 2 3 4 5
6. Breathing difficulties or choking episodes	0 1 2 3 4 5
7. Troublesome or annoying cough	0 1 2 3 4 5
8. Sensations of something sticking in your throat or a lump in your throat	0 1 2 3 4 5
9. Heartburn, chest pain, indigestion, or stomach acid coming up	0 1 2 3 4 5
Total	

Past History:

Personal History:

Family History:

I) General Physical Examination -

Vital signs:

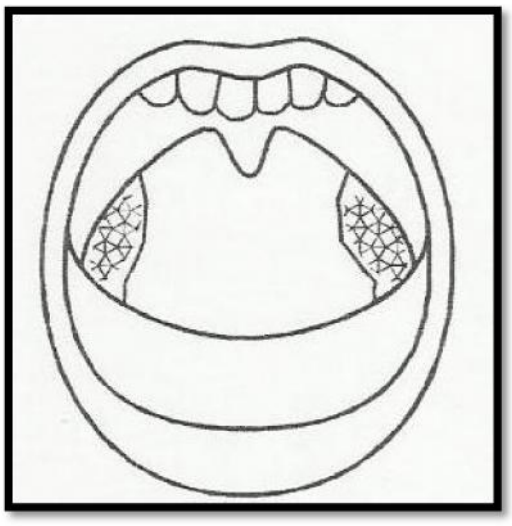
Blood Pressure

Pulse

Respiratory Rate

Pallor, icterus cyanosis, clubbing, lymphadenopathy, edema.

3.1 ORAL CAVITY and OROPHARYNX



3.2 FIBREOPTIC LARYNGOSCOPY (with photos)

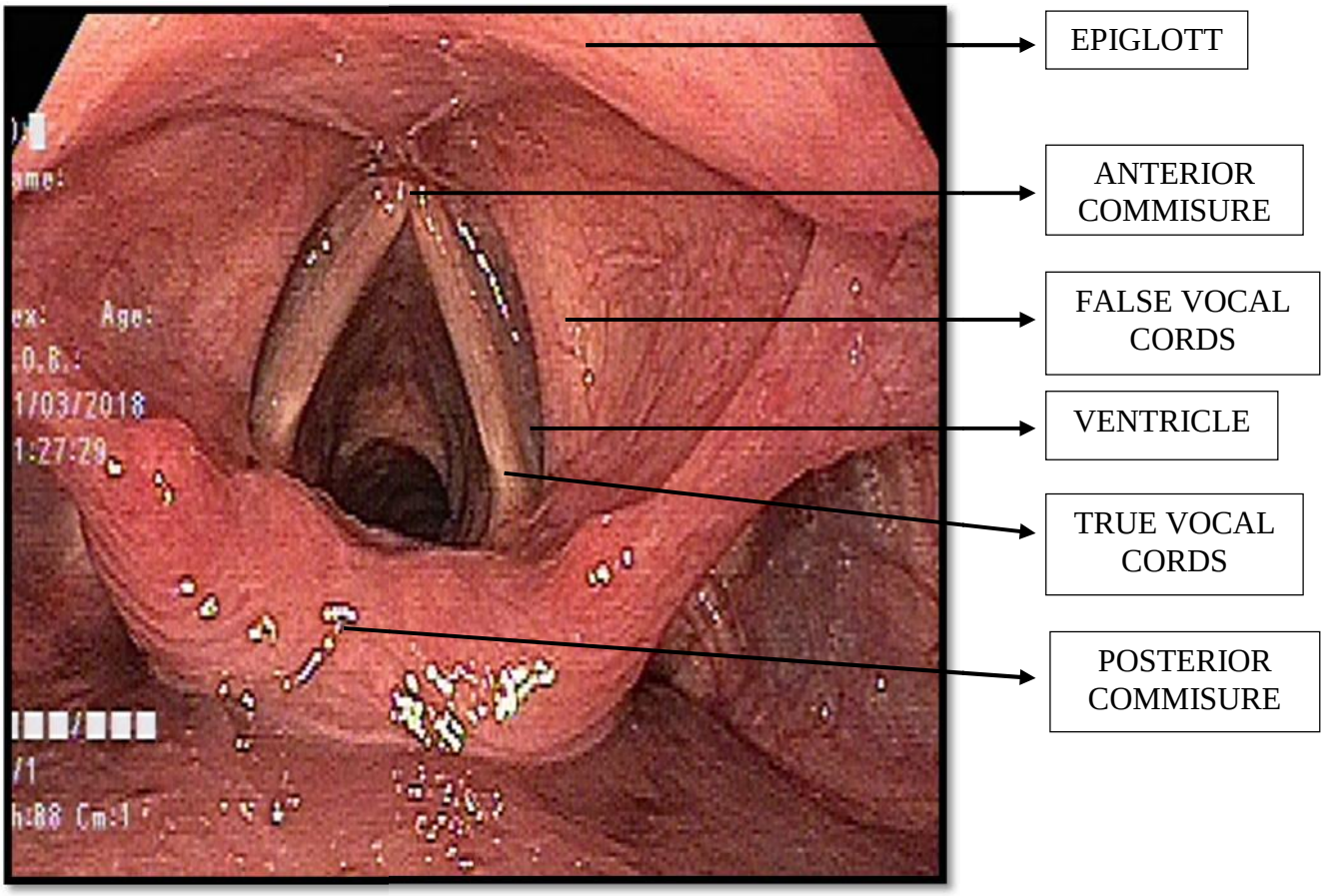
Reflux Finding Score

Subglottic Edema	2 = present 0 = absent	
Ventricular Obliteration	2 = partial 4 = complete	
Erythema/Hyperemia	2 = arytenoids only 4 = diffuse	
Vocal Fold Edema	1 = mild 2 = moderate 3 = severe 4 = polypoid	
Diffuse Laryngeal Edema	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Posterior Commissure Hypertrophy	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Granuloma/Granulation	2 = present 0 = absent	
Thick Endolaryngeal Mucus	2 = present 0 = absent	
	Total:	

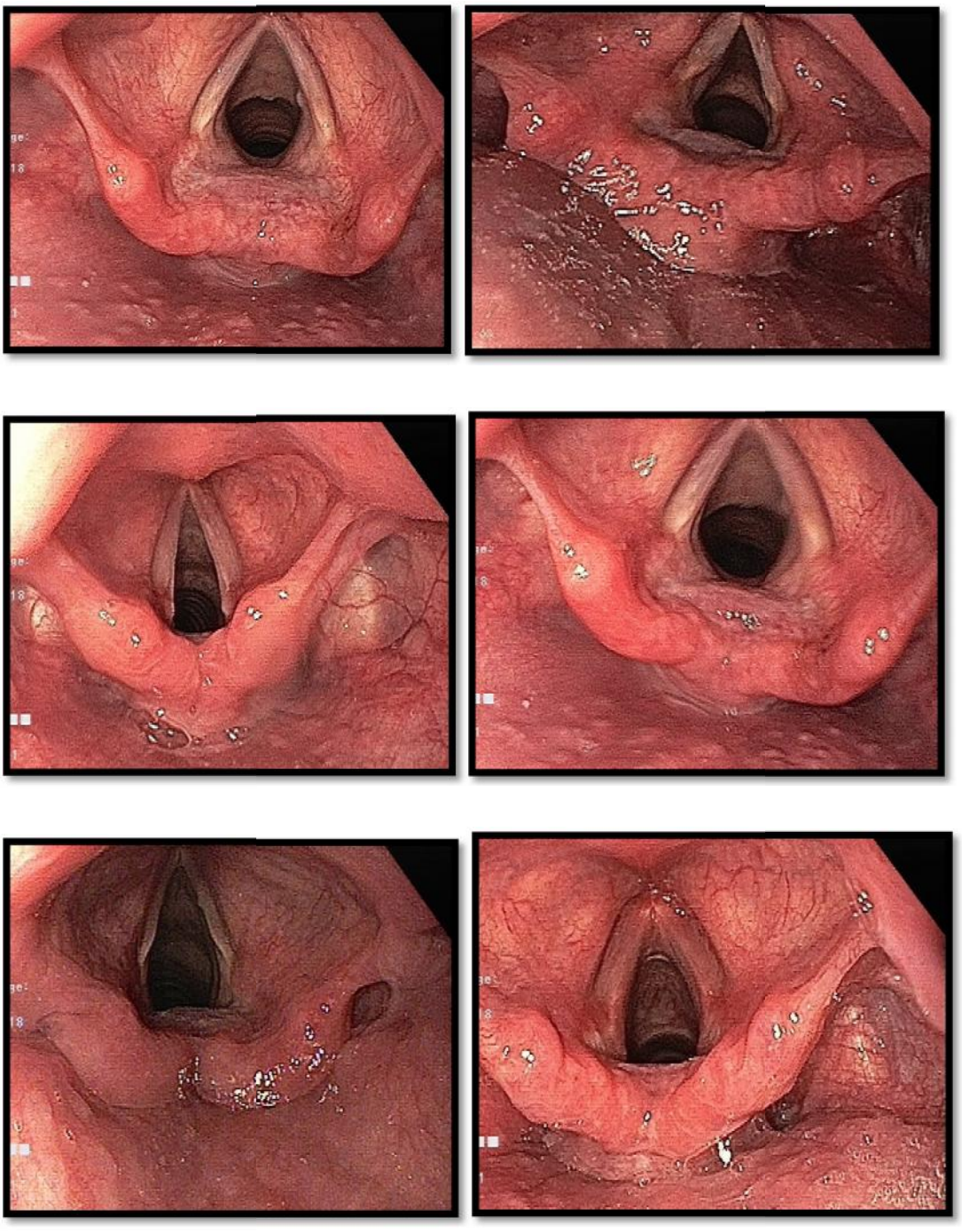
Diagnosis:

ANNNEXURE – IV- PHOTOGRAPHS

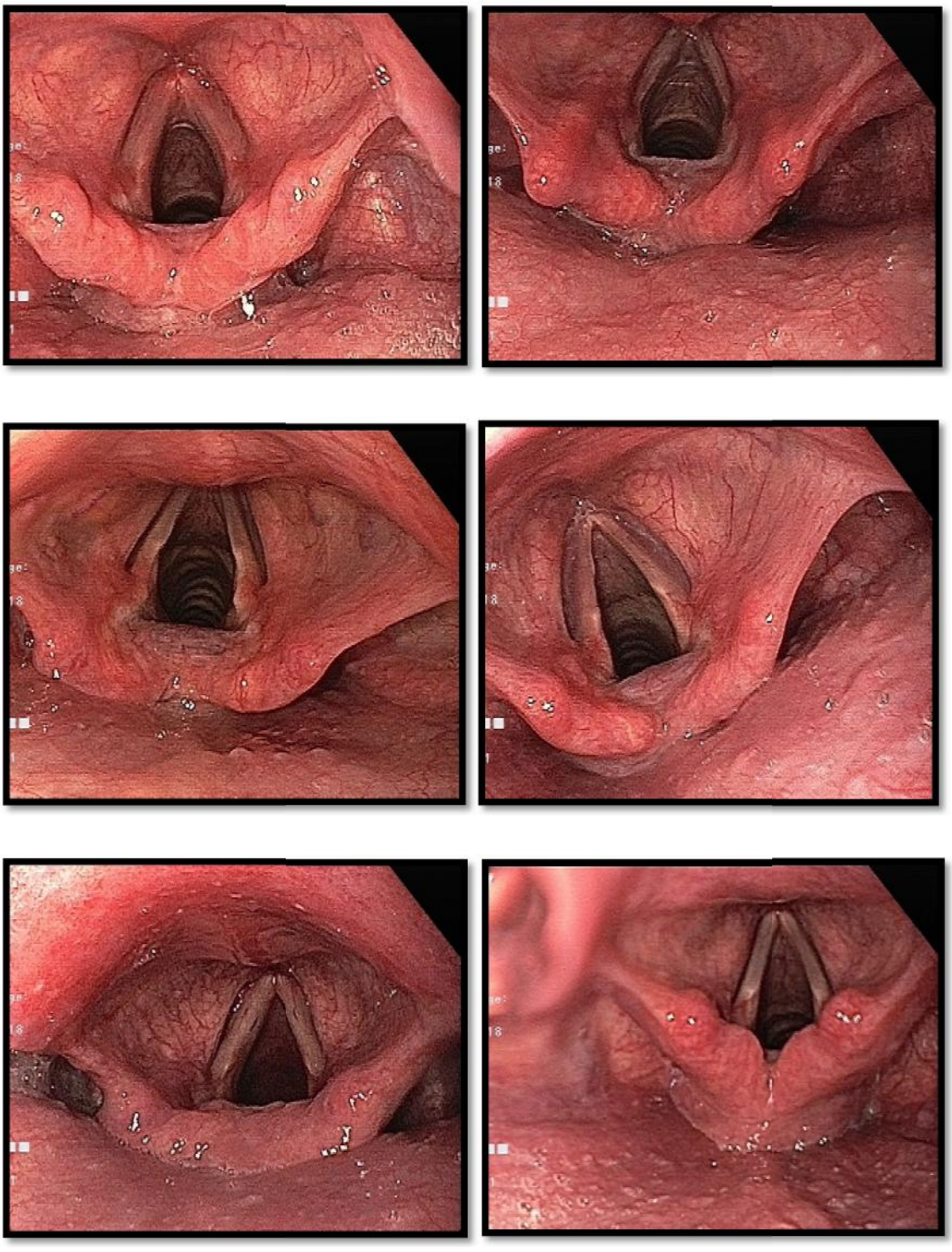
NORMAL PICTURE ON LARYNGOSCOPY

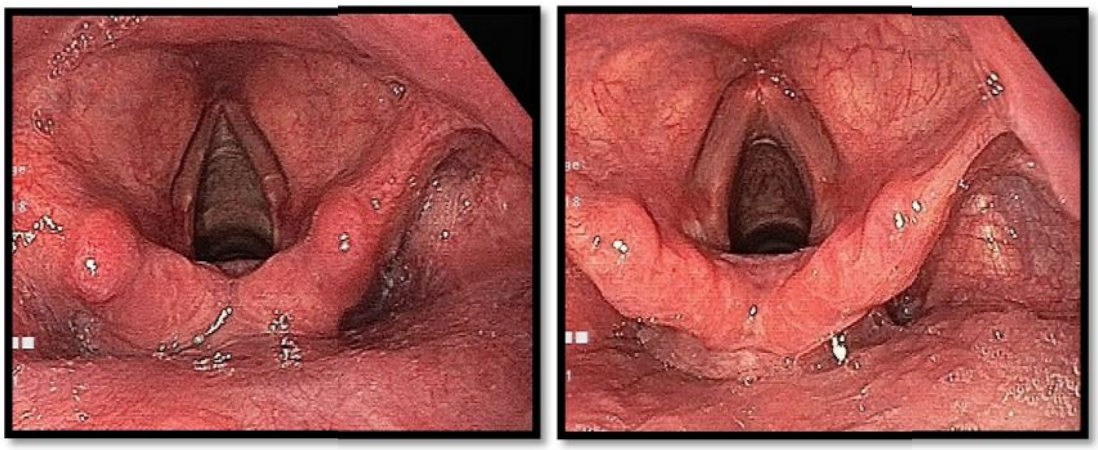


DIFFUSE LARYNGEAL OEDEMA

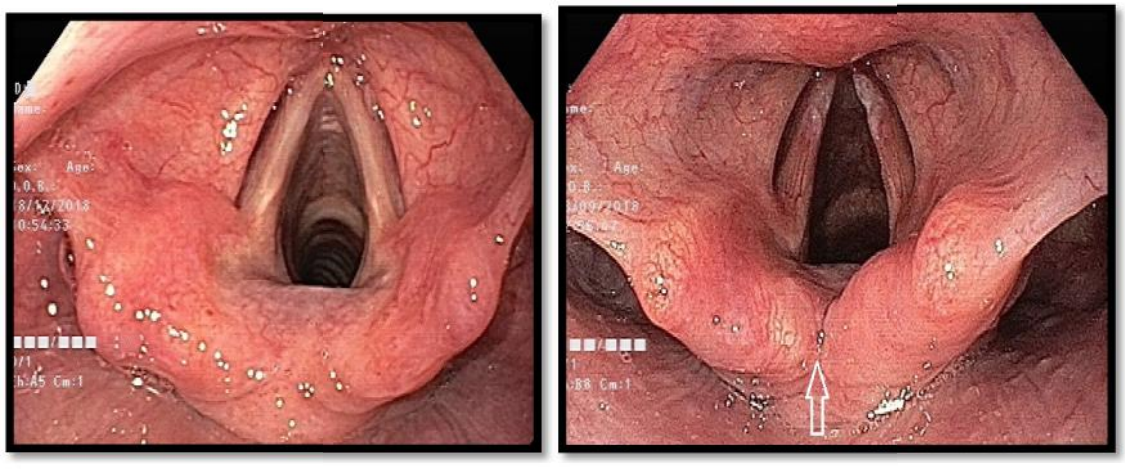


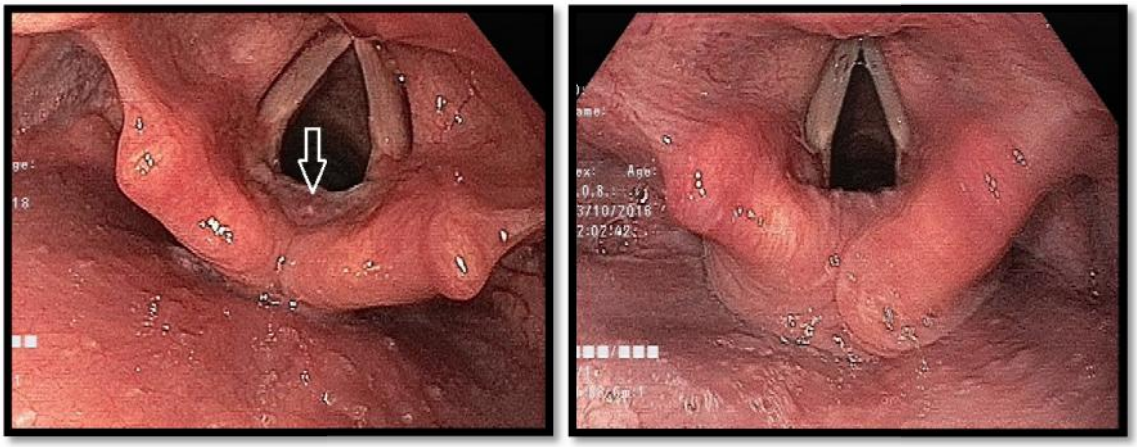
ERYTHEMA / HYPERAEMIA

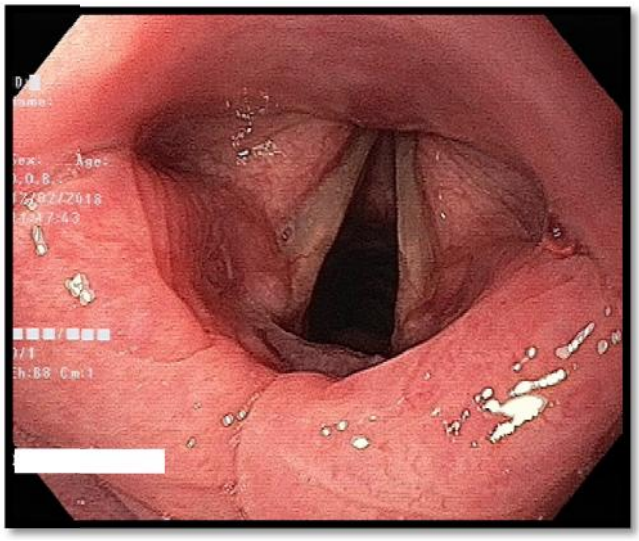




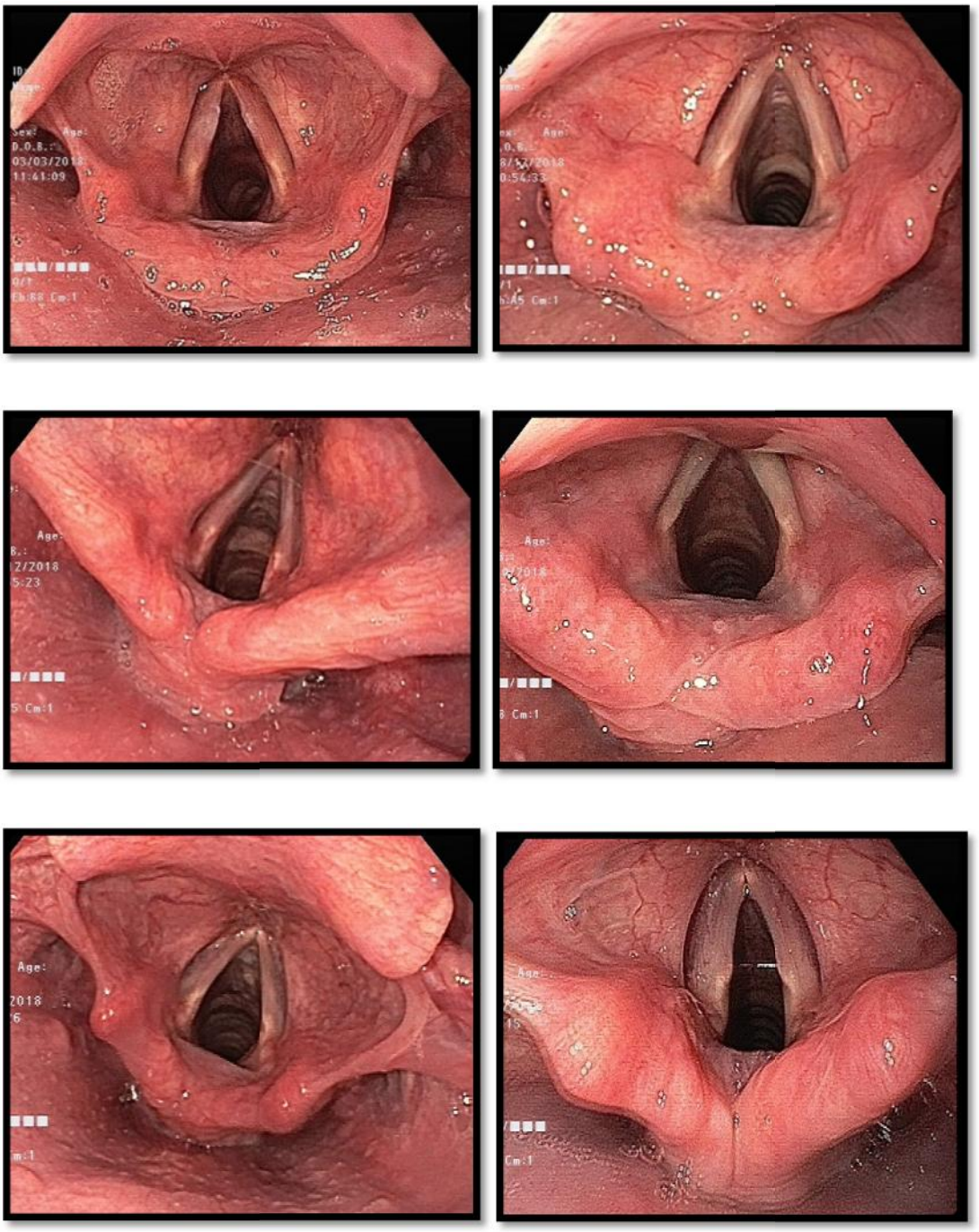
POSTERIOR COMMISURE HYPERTROPHY



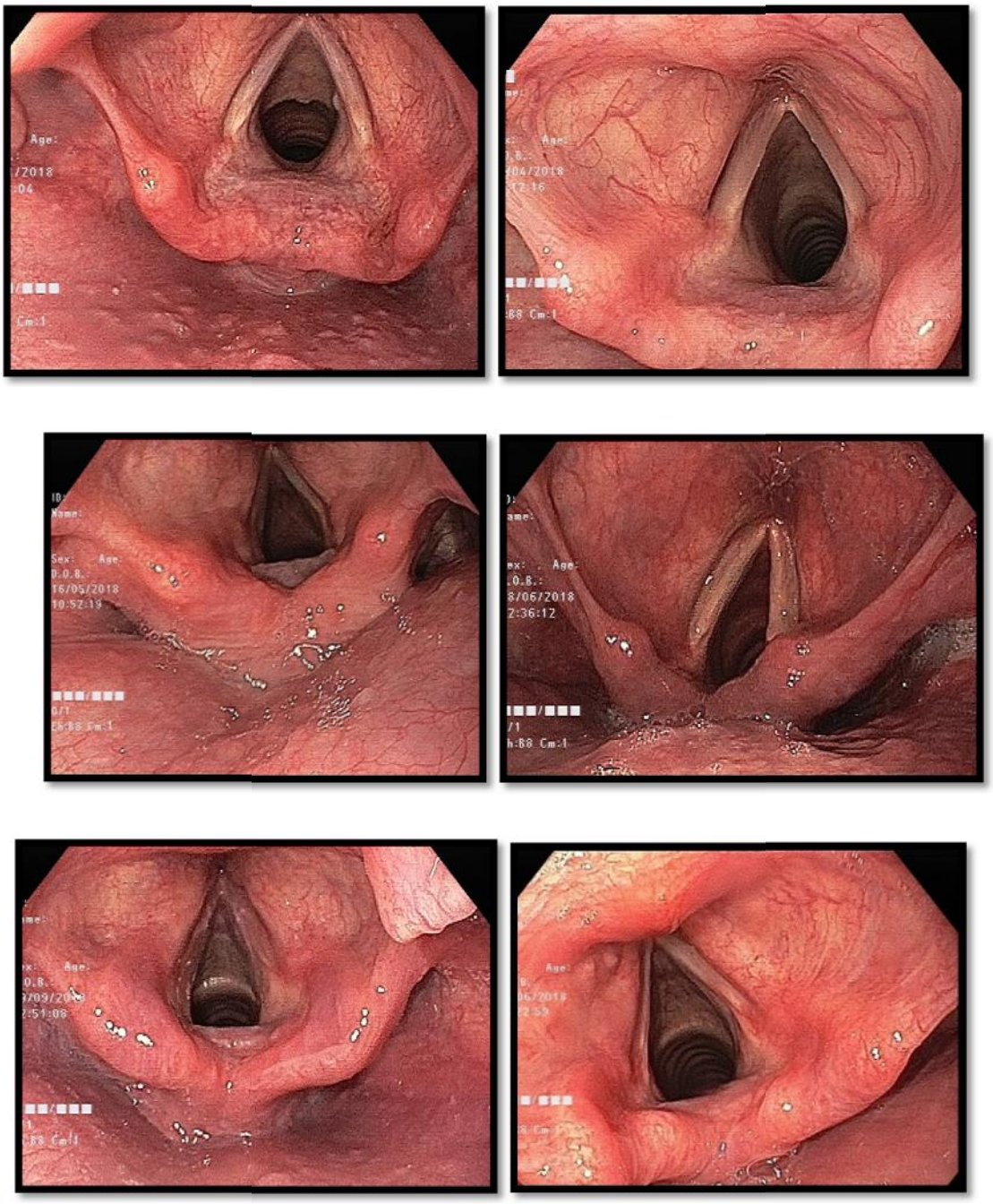


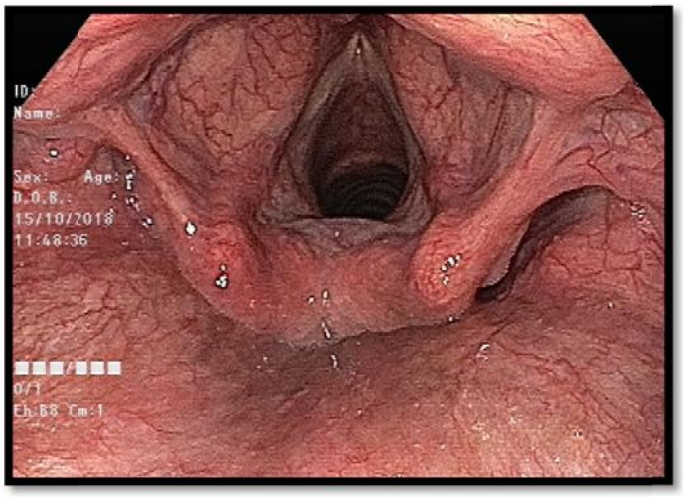


VOCAL FOLD OEDEMA

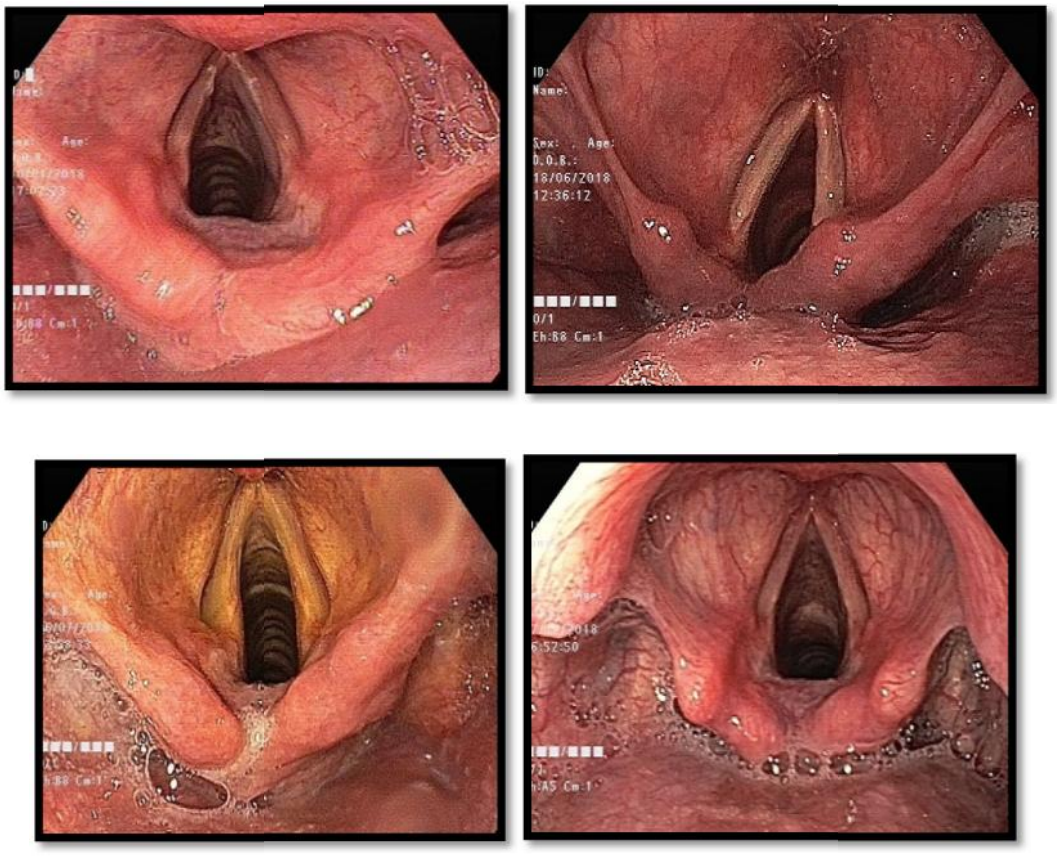


VENTRICULAR OBLITERATION

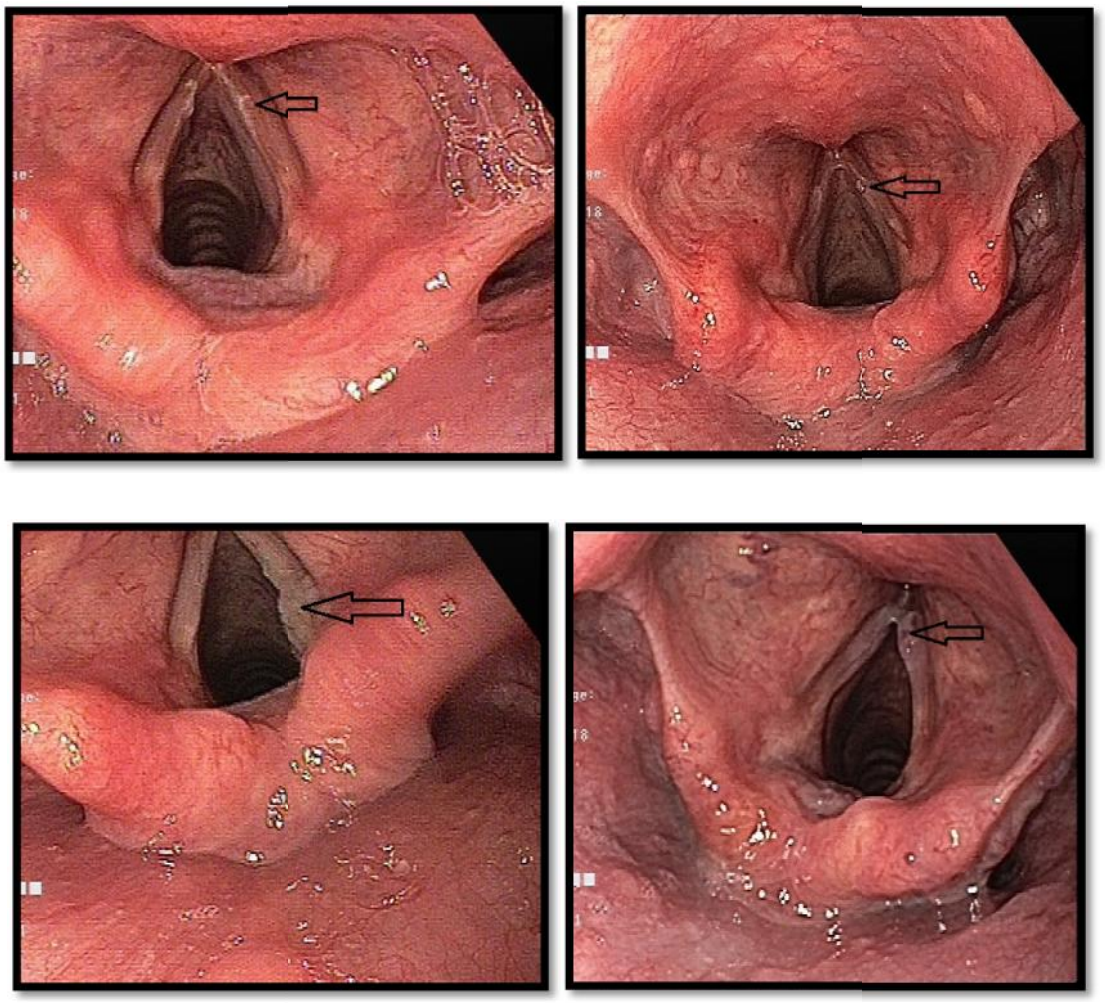




THICK ENDOLARYNGEAL MUCUS



GRANULATION



ANNEXRURE - V - KEY TO MASTER CHART

M	-	Male
F	-	Female
YES	-	Reflux finding score >7(Significant)
NO	-	Reflux finding score <7(Not significant)

AGE	SEX	REFLUX SYMPTOM INDEX (components)									TOTAL		REFLUX FINDING SCORE								TOTAL SCORE	SIGNIFICANCE
		HOARSENESS	CONSTANT CLEARING OF THROAT	POST NASAL DRIP	DIFFICULTY SWALLOWING	COUGHING ON LYING DOWN	CHOCKING/DIFFICULTY BREATHING	TROUBLESOME COUGH	LUMP IN THE THROAT	HEART BURN	NORMAL	ABNORMAL	SUBGLOTTIC EDEMA	VENTRICULAR OBLITERATION	ERYTHEMA	VOCAL FOLD EDEMA	DIFFUSE LARYNGEAL EDEMA	POSTERIOR COMMISURE HYPERTROPHY	GRANULATION	THICK ENDOLARYNGEAL MUCUS		
58	F	0	3	4	5	2	0	4	2	4		24	0	2	4	2	2	2	0	0	12	YES
37	M	4	3	1	3	3	0	2	4	4		24	2	2	4	2	1	2	0	0	13	YES
40	F	5	2	1	4	3	3	0	3	4		25	0	2	2	1	1	2	0	0	8	YES
35	M	5	3	4	4	1	0	3	4	5		29	0	2	4	2	2	2	0	0	12	YES
38	M	0	2	0	4	1	0	3	4	4		18	0	2	2	1	1	2	0	0	8	YES
42	F	0	4	1	0	0	0	4	4	3		16	0	2	2	2	1	1	0	0	8	YES
56	F	5	4	3	3	2	0	4	1	4		26	2	2	4	2	3	3	0	0	16	YES
55	M	5	4	1	4	0	0	3	4	5		26	2	4	4	2	3	3	0	0	20	YES
38	F	4	5	3	1	2	0	5	4	4		28	2	2	4	2	2	2	0	2	16	YES
60	F	4	4	1	2	0	0	4	4	5		24	0	2	2	1	2	1	0	0	8	YES
34	M	2	3	3	1	4	0	4	5	4		26	0	2	2	1	1	1	0	0	6	NO
26	F	0	3	1	4	0	0	4	4	4		20	0	2	2	1	0	1	0	0	6	NO
60	F	0	3	3	4	1	0	0	1	4		16	0	2	4	1	1	1	0	0	9	YES
50	F	0	4	0	0	0	0	3	4	4		15	0	0	2	1	0	1	0	0	4	NO
47	F	4	3	1	1	4	4	4	4	5		30	0	2	4	2	3	3	2	0	16	YES
32	F	0	4	1	3	0	0	4	5	5		22	0	2	2	2	2	1	0	0	9	YES
30	M	1	4	3	0	0	0	4	4	4		20	0	2	4	2	2	2	0	0	12	YES
40	M	1	2	0	0	0	0	3	4	5		15	0	2	2	2	2	2	0	0	10	YES
47	M	4	3	1	1	0	0	4	3	4		20	0	4	4	3	3	3	0	0	19	YES
59	M	4	3	1	0	0	0	3	4	4		19	2	2	2	2	2	2	0	0	12	YES
45	M	5	4	0	5	1	0	0	3	5		23	0	2	2	1	2	1	0	0	8	YES
45	M	4	3	3	4	4	0	0	1	4		22	0	2	2	2	3	3	0	0	12	YES
35	M	2	3	0	4	0	0	4	3	5		21	0	2	2	2	0	1	0	0	7	NO
55	F	0	3	1	4	0	0	3	4	4		19	0	2	2	1	1	1	0	0	9	YES
38	F	4	2	0	1	0	0	2	2	4		15	0	0	2	2	1	2	0	0	7	NO
60	M	0	4	3	4	0	0	2	3	3		19	0	4	2	2	2	2	0	0	12	YES
27	M	5	4	3	0	0	0	3	1	4		20	2	4	4	2	3	2	0	0	17	YES
55	F	0	3	3	5	1	0	3	4	4		23	0	2	0	1	1	1	0	0	5	NO
28	M	5	4	3	3	1	0	0	0	5		20	0	4	2	1	1	1	0	0	9	YES
45	M	4	4	3	1	1	0	4	2	4		23	0	4	4	2	2	2	0	2	16	YES
55	M	0	5	3	4	1	0	4	5	4		26	0	2	2	1	1	2	0	2	10	YES
28	M	0	3	1	1	0	0	4	5	5		19	0	2	2	1	1	2	0	0	8	YES
46	M	0	4	2	1	1	0	4	5	4		21	0	2	2	1	1	2	0	2	10	YES
41	F	4	3	3	3	0	0	4	4	4		25	0	4	4	3	3	3	0	2	19	YES
46	M	5	1	1	2	1	0	3	0	5		18	2	2	4	2	2	2	2	0	16	YES
41	M	5	4	1	1	1	0	3	1	4		20	2	2	4	2	2	1	0	0	13	YES
24	M	1	1	1	0	0	0	4	4	4		15	0	2	2	1	1	1	0	0	7	NO
25	F	4	2	1	0	0	0	3	4	4		18	0	2	4	1	2	2	0	0	11	YES
20	M	0	4	1	3	0	0	4	4	4		20	0	4	2	2	2	2	0	0	12	YES
30	F	0	4	1	5	4	0	4	4	4		26	0	2	2	1	1	1	0	0	7	NO
36	F	0	3	0	4	0	0	3	2	5		17	0	4	4	2	1	2	0	0	13	YES
36	M	4	1	3	0	0	0	3	3	4		18	0	4	2	2	2	2	0	2	14	YES
59	M	4	1	1	0	0	0	1	3	5		15	0	4	2	2	2	2	2	0	14	YES
60	F	0	4	3	4	0	0	4	4	4		23	0	2	2	1	1	1	0	0	7	NO
28	M	0	4	1	4	0	0	4	3	4		20	0	2	2	1	1	1	0	0	7	NO
40	M	5	4	0	0	0	0	0	4	5		18	0	4	4	2	3	2	0	0	15	YES
35	F	4	4	3	0	0	0	3	4	3		21	0	2	4	2	2	3	2	0	15	YES
38	F	1	4	0	3	0	0	5	4	4		20	0	4	2	2	2	3	0	0	13	YES
60	F	5	2	0	0	0	0	2	3	4		16	0	0	2	1	1	1	0	0	5	NO
38	M	0	4	1	5	1	0	0	4	5		20	0	2	4	1	2	2	0	0	11	YES
38	F	0	3	1	5	0	0	0	5	4		18	0	2	2	1	0	0	0	0	5	NO
58	M	0	4	4	0	0	0	5	4	5		22	0	2	2	1	0	0	0	0	5	NO
39	M	5	4	1	1	0	0	1	3	4		19	0	0	4	1	2	1	2	0	10	YES
44	M	1	4	0	5	1	0	0	4	5		20	0	4	4	3	3	2	0	2	18	YES
40	F	0	4	0	5	0	0	0	5	4		18	0	2	4	2	2	2	0	0	12	YES
55	M	0	4	1	5	1	0	0	4	5		20	0	4	4	2	2	2	0	0	14	YES
59	F	0	4	1	5	1	0	4	5	4		22	0	4	4	2	2	2	0	0	14	YES
35	M	5	4	1	0	0	0	3	3	5		21	0	2	2	2	1	2	0	0	9	YES
25	M	0	4	0	0	1	0	4	3	4		16	0	0	2	0	1	1	0	0	4	NO
55	F	4	4	0	0	1	0	0	5	5		19	0	4	4	3	3	2	0	0	16	YES
32	F	4	3	0	0	0	0	3	5	5		20	0	2	4	3	2	2	0	0	13	YES
30	F	0	4	1	0	2	0	5	4	5		21	0	2	2	0	0	1	0	0	5	NO
58	M	5	0	0	0	1	0	0	5	2		13	0	2	2	1	0	1	0	0	6	NO
19	F	0	4	0	3	0	0	0	5	4		16	0	0	2	0	0	1	0	0	3	NO
40	M	5	4	0	0	2	0	2	2	5		20	0	4	4	2	2	1	2	0	15	YES
38	F	0	4	0	5	0	0	3	5	4		21	0	0	2	0	0	0	0	0	2	NO
32	M	0	4	0	5	0	0	0	5	4		18	0	2	2	1	1	1	0	0	7	NO

AGE	SEX	REFLUX SYMPTOM INDEX (components)									TOTAL		REFLUX FINDING SCORE								TOTAL SCORE	SIGNIFICANCE
		HOARSENESS	CONSTANT CLEARING OF THROAT	POST NASAL DRIP	DIFFICULTY SWALLOWING	COUGHING ON LYING DOWN	CHOCKING/DIFFICULTY BREATHING	TROUBLESOME COUGH	LUMP IN THE THROAT	HEART BURN	NORMAL	ABNORMAL	SUBGLOTTIC EDEMA	VENTRICULAR OBLITERATION	ERYTHEMA	VOCAL FOLD EDEMA	DIFFUSE LARYNGEAL EDEMA	POSTERIOR COMMISURE HYPERTROPHY	GRANULATION	THICK ENDOLARYNGEAL MUCUS		
24	F	0	3	0	4	0	0	3	5	3		18	0	2	2	0	1	1	0	0	6	NO
34	F	3	5	0	3	0	0	3	5	3		22	0	2	4	2	2	2	0	0	12	YES
26	M	0	5	1	3	0	0	1	5	4		19	0	2	2	2	2	1	0	2	11	YES
35	M	0	5	0	0	0	0	5	3	5		18	0	2	4	2	1	2	0	0	11	YES
43	F	0	5	0	5	3	0	0	3	5		21	0	4	2	1	2	2	0	0	11	YES
35	F	5	5	0	4	1	0	1	5	5		26	0	0	4	2	2	3	0	0	11	YES
36	M	4	3	0	4	1	1	0	5	5		23	2	4	4	2	2	2	0	0	16	YES
36	F	4	3	1	0	0	0	3	3	5		19	0	2	2	1	2	1	2	0	10	YES