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Research Article

Comparative Study Between i-Scan and Conventional Flexible Laryngoscopy in the Diagnosis of Benign and Malignant Laryngeal Lesions

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Abstract

Background: Laryngeal squamous cell carcinoma is one of the most common head and neck cancer. Its early detection and diagnosis is essential in order to maximize cure rates and preserve its function. The in vivo diagnosis of benign, pre malignant and early glottic malignant lesions will help in management of the same with preservation of the function of larynx.

Objectives: 1) To study the sensitivity of i-SCAN in early diagnosis of premalignant and malignant glottic lesions. 2) Compare i-SCAN with conventional flexible laryngoscopy in diagnosis of benign, premalignant and malignant glottic lesions.

Methodology: Patient presenting with history of change in voice for greater than 3 weeks underwent flexible laryngoscopy in conventional mode and i-SCAN 1,2,3 modes. The lesions were categorized as benign, suspected malignant and malignant in both the modes. The excision and histopathological examination of the lesions was done. Considering histopathology as gold standard sensitivity of i-SCAN was determined. i-SCAN was compared with flexible laryngoscopy in conventional mode for diagnosis of glottic benign, premalignant and early malignant lesions.

Results: In the study 91.3% patients were male and most common age group was greater than 60 years. The sensitivity of i-SCAN in diagnosis of glottic benign, pre malignant and early malignant lesion is 85%. As compared to flexible laryngoscopy in conventional mode (sensitivity 62%), i-SCAN shows better results in in vivo diagnosis of glottic lesions.

Conclusion: There is a significant correlation of i-SCAN with histopathology for diagnosis of glottic lesions, the sensitivity of i-SCAN for the same being 85%. i-SCAN shows better results than flexible laryngoscopy in conventional mode for in vivo diagnosis of glottic benign, premalignant and early malignant lesions.

Keywords: Glottic; i-SCAN; Flexible Laryngoscopy; Histopathology; Benign; Premalignant; Malignant

Abbreviations

CIS: Carcinoma *in Situ*; WHO: World Health Organization; SCC: Squamous Cell Carcinoma; G: Grading; HPV: Human Papilloma Virus; AJCC: American Joint Committee on Cancer; PPV: Positive Predictive Value; NPV: Negative Predictive Value; NBI: Narrow Band Imaging; SE: Surface Enhancement; CE: Contrast Enhancement; TE: Tone Enhancement; EGD: Esophagogastroduodenoscopy; DCP: Diminutive Colonic Polyps; HDWL: High Definition White Light; RGB: Red Green Blue; ENT: Ear Nose Throat.

Introduction

Early and accurate diagnosis of laryngeal lesions is critical for optimal patient outcomes, especially in distinguishing benign from malignant pathology [1]. Conventional flexible laryngoscopy has long been the cornerstone of laryngeal examination, providing valuable morphological insights under white light. However, its limitations in detecting subtle mucosal and vascular changes often necessitate additional diagnostic tools or invasive biopsy for definitive diagnosis? [2].

The advent of advanced endoscopic imaging technologies, such as i-Scan, has introduced a new dimension to laryngeal visualization. i-Scan is a digital image enhancement technique that utilizes post-processing filters to improve mucosal surface contrast and vascular pattern recognition in real time [4]. By enhancing structural details and microvascular architecture, i-Scan holds promise in improving the sensitivity and specificity of laryngoscopic evaluations [5].

This comparative study aims to assess the diagnostic efficacy of i-Scan versus conventional flexible laryngoscopy in differentiating benign and malignant laryngeal lesions. Through this analysis, we seek to determine whether i-Scan provides a significant clinical advantage in early detection, lesion characterization, and decision-making for biopsy or treatment planning.

Materials and Methods

- **Study Site:** This study will be conducted at 'Deenanath Mangeshkar Hospital and Research Centre' (DMHRC), Erandwane, Pune - 411 004.
- **Study Population:** All patients with history of change in voice for greater than 3 weeks reporting to Otorhinolaryngology Department of Deenanath Mangeshkar Hospital, Pune fulfilling the inclusion criteria of the study between April 2018 and April 2019 shall be recruited and subjected to the study.
- **Study Design:** Observational Study
- **Sample size with Justification:** 41.

Based on literature sample size of 41 patients is needed to estimate the sensitivity for diagnosis of glottic malignant and premalignant lesions using i-SCAN, assuming it to be 83% (based on literature), with the allowable error of ±16.5%, with 5% level of significance (α, 95% CI) and 80% power.

Time frame to address the study: 12 months.

Inclusion criteria

Patients with history of change in voice for greater than 3 weeks and glottic benign/suspected malignant/malignant lesion on laryngoscopy.

Exclusion criteria

- Supraglottic or subglottic lesions.
- Diagnosed case of glottis malignancy and on active treatment for the same.
- Stage T2 lesion in which vocal cord mobility is affected, T3 and T 4 lesions.

Methodology

- Permission was taken for the Ethics and Scientific Committee of the Hospital.
- All the patients presenting to the OPD with complaint of hoarseness of voice for greater than 3 weeks and fit into the inclusion criteria were included in the study.
- First 46 patients were chosen for the study to due to logistical constraints, including limited time and resource availability. While this non-randomised sampling method may introduce selection bias, every consecutive patient who met the inclusion criteria during defined time window was enrolled until the sample size was reached. Efforts were made to minimize variability by standardizing the time of data collection (e.g., across different days of the week and clinic hours), thereby attempting to ensure a reasonably representative sample of the clinic population.
- Written informed consent would be taken. History of duration of change in voice was taken.

Procedure

- Patients were inspected under topical anaesthesia.
- Patients were examined in the upright position.
- Local anaesthesia xylocaine 10% (lidocaine hydrochloride) was sprayed intranasally and then transorally on the mucosa of the nasal cavity, oro- and hypopharynx, and the larynx.
- The examination in conventional mode was carried out, followed by the endoscopy in i SCAN in 3 modes.

In conventional mode the lesions were classified according to their endoscopic features into:

- Benign (smooth surface, well defined margins, polyp, nodule, cyst)
- Suspected malignant lesion (i.e. uneven or rough surface, slight protrusion or white patch on lesion).
- Malignant (protuberant or ulcerative tumour) [6,7]

In i-SCAN mode lesions were classified based on following scoring:

Surface	Score
Regular	1
Irregular surface	2
Protuberant or ulcerative growth	3
Margins	
Well-defined	1
Ill-defined	2
Vascularity	
Regular vessels	1
Few dilated and tortuous vessels in between regular vessels	2
Dilated and tortuous vessels micro vessels are dilated elongated and woven in appearance [8,9]	3

Based on above scoring i-SCAN scopy lesions would be labelled as

- 3-4 - Benign
- 5-6 - Suspected malignant or premalignant
- 7-8 – Malignant [9,10]

Under general anaesthesia Microlaryngoscopic Excision of the lesion was done and sent for histopathological examination. The histopathological report was considered as gold standard [11,12].

- Malignant: Carcinoma in situ and invasive cancer
- Pre-malignant: Squamous cell hyperplasia, Mild moderate or severe dysplasia
- Benign

The sensitivity of i-SCAN and Conventional laryngoscopy were determined using histopathology as gold standard and the results were compared.

Statistical methods

Sample size justification

Based on literature sample size of 41 patients is needed to estimate the sensitivity for diagnosis of glottic malignant and premalignant lesions using i-SCAN procedure, assuming it to be 83% (based on literature), with the allowable error of ±16.5%, with 5% level of significance (α, 95% CI) and 80% power.

Formula used to estimate Sample size

$$\text{Sample size (n)} = \frac{p\,(1-p)\,(z_{1-\alpha/2}+z_{1-\beta})^2}{(p-p0)^2}$$

Where,

· n is sample size

· p0 is the comparison value =0.83 (83% sensitivity of i-SCAN) &

· α is Type I error =5%; z_{α}=1.96 two sided, z_{α} =1.64 one sided

· β is Type II error, 1−β is power; $z_{1-\beta}$=0.84 for 1−β=80%

· Effect size= $(p-p_0)$ = ±0.165 16.5%)

Article cited for sample size estimation

Hoffman A, Basting N, Goetz M., *et al*. High-definition endoscopy with i-Scan and Lugol's solution for more precise detection of mucosal breaks in patients with reflux symptoms. Endoscopy. 2009;41(2):107–112.

Statistical Methods

Statistical analysis will be carried out with the help of SPSS (version 20) for Windows package (SPSS Science, Chicago, IL, USA).

The description of the data will be done in form of arithmetic mean +/- SD for quantitative data while in the form of frequencies (%) for qualitative (categorical) data. p-values of < 0.05 will be considered significant. For quantitative data, Mann-Whitney U test will be used to test statistical significance of difference between means of variables among two independent groups. To examine the associations between qualitative/ quantitative variables), chi-square test will be used if the number of elements in each cell are 5 or higher and Fisher's exact test, otherwise.

Image 1: Flexible fiberoptic laryngoscope.

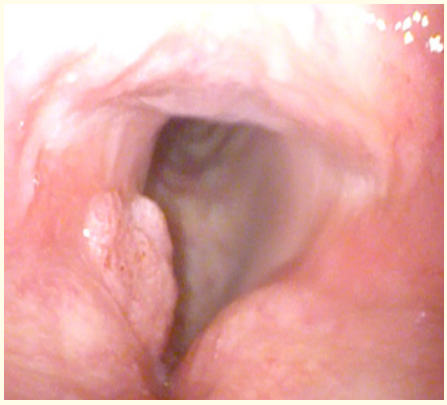

Image 2: Laryngoscopy in conventional mode.

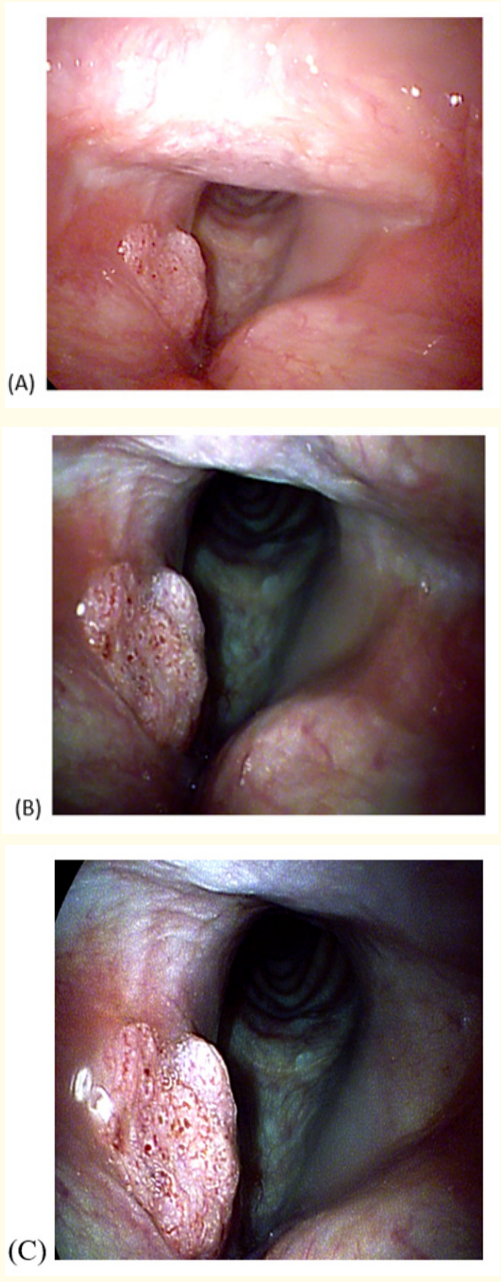

Image 3: (A) Laryngoscopy in i-SCAN 1 mode; (B) Laryngoscopy in i-SCAN 2 mode; (C) Laryngoscopy in i-SCAN 3 mode.

Observation and Results

Table 1: Distribution of patients on the basis of histopathological findings.

Histopathological findings	Number of patients	Percentage (%)
Benign	6	13.04
Pre malignant	14	30.43
Malignant	26	56.52
Total	46	100

Table 2: Distribution of patients on the basis of i-SCAN findings.

i-SCAN mode	Number of patients	Percentage (%)
Benign	8	17.39
Suspected/Pre malignant	15	32.61
Malignant	23	50
Total	46	100

Table 3: Comparison of i-SCAN with histopathology.

i-SCAN mode	Histopathology		Total
	Malignant	Benign/Pre malignant	
Malignant	22	1	23
Benign/Suspected	4	19	23
Total	26	20	46
Sensitivity	Specificity	PPV	NPV
85%	95%	96%	82.6%

Table 4: Comparison of i-SCAN with histopathology.

i-SCAN	Histopathology			Total	p-value
	Benign	Pre Malignant	Malignant		
Benign	6	1	1	8	< 0.001
Suspected/Pre Malignant	0	12	3	15	
Malignant	0	1	22	23	
Total	6	14	26	46	

p-value < 0.05 (Significant) Fisher's exact test used.

Thus there is statistically significant correlation between i-SCAN and histopathology.

Table 5: Distribution of patients on basis of flexible laryngoscopy in conventional mode.

Laryngoscopy in conventional Mode	Number of patients	Percentage (%)
Benign	14	30.43
Suspected/Pre malignant	19	41.3
Malignant	13	28.26
Total	46	100

Table 6: Comparison of laryngoscopy in conventional mode with histopathology.

Laryngoscopy in conventional method	Histopathology		Total
	Malignant	Benign/Pre Malignant	
Malignant	16	1	17
Benign/Suspected	10	19	29
Total	26	20	46
Sensitivity	Specificity	PPV	NPV
62%	95%	94%	66%

Discussion

Laryngeal tumor is the second most common head and neck tumor [1,2].

Among the laryngeal tumors, glottic tumors are commonest [3,4].

Early glottic carcinoma is the initial stage of laryngeal carcinoma which can be treated successfully with minimum morbidity and preservation of vocal function if diagnosed in early stages [5,6]. Early glottic carcinoma encompasses lesions ranging from carcinoma in situ to T2 lesions with normal cord mobility [7,8]. According to WHO 2005 classification the premalignant lesion range from squamous hyperplasia to dysplasia [9,10].

The patient usually presents with change in voice as an initial symptom.

Flexible fibreoptic naso-laryngoscopy is the standard method of assessment of larynx. It is useful for assessing the limits of a cancerous lesion, hidden areas of larynx such as anterior commissure ventricles, undersurface of vocal cord and subglottis [11,12].

At present white light laryngoscopy and biopsy is the standard diagnostic procedure in the assessment of laryngeal cancer and precancerous lesions. However, white light laryngoscopy has difficulty in identifying minute epithelial changes and directly differentiating benign from malignant tumors *in vivo* [13,14].

i-SCAN is a dynamic, software-based, image enhancement technology that provides the user an enhanced view of the texture of the mucosal surface and blood vessels [15,16]. i- SCAN has 3 algorithms surface enhancement, contrast enhancement and tone enhancement and there are 3 in built modes i-SCAN 1, i-SCAN 2 and i-SCAN 3 [17,18].

We conducted a prospective study in ENT department of Deenanath Mangeshkar Hospital from April 2022 to April 2023. Patient presenting with complaint of change in voice for greater than 3 weeks and having suspected glottis lesion on laryngoscopy were included in the study. First 46 cases were chosen for the study to prevent selection bias.

The patients underwent transnasal flexible laryngoscopy in conventional mode, i-SCAN 1, i-SCAN 2 and i-SCAN 3 mode. The patients underwent micro-laryngoscopic excision and the specimen was sent for histopathological examination. The histopathology was considered as gold standard.

Histopathologically the lesions were categorized as benign, premalignant and malignant.

In conventional mode and i-SCAN mode the lesions were categorized into benign, suspected malignant/premalignant and malignant based on endoscopic features.

The histopathological findings were correlated with endoscopic findings in conventional and i-SCAN mode.

The sensitivity of i-SCAN for diagnosis of glottic lesions was determined. i-SCAN was compared with laryngoscopy in conventional mode for diagnosis of glottic lesions.

Total 46 patients were included in the study, of which most common were in the age group of 60-70 years (26.09%), second most common age group was >70 years (24%) as seen in Table 1. The result is comparable to published data according to which carcinoma larynx is more common in age group above 60 years [19,20].

In the study 91.3% patients were male and 8.7 % patients were female. Male: Female ratio was 10.49 as described in Table 2. It is higher as compared to available literature. According to studies worldwide male to female ratio is 7.6 [21,22] whereas in India it is 4:1.

On Histopathology, 13% patients had benign lesion, 30% patients had premalignant lesion and 57% patients had malignant lesion as seen in Table 3.

In i-SCAN mode, 17% lesions were benign, 33% were suspected malignant and 50% lesions were malignant. i- SCAN mode had sensitivity 85%, Specificity 95%, positive predictive value 96% and NPV 82.6% in predicting glottis lesions as seen in Table 4. p value is < 0.01% thus there is a statistically significant correlation between i-SCAN findings and histopathology as described in Table.

There are various studies on utility of i-SCAN in detection of gastrointestinal lesions which have shown promising results. There is not enough literature available till date on use of i-SCAN in diagnosis of glottic lesions. Similiar study was performed to find the value of i-SCAN in diagnosis of vocal cord leukoplakia [23].

In the study using i-scan-enhanced endoscopy, abnormal vascular change with neoplastic neoangiogenesis was detected in most cases of malignant VC lesion severe dysplasia (64.3%), carcinoma in situ (50.0%) and invasive squamous cell carcinoma (73.4%). They concluded that i-SCAN is a useful optical technique for the diagnosis of VC leukoplakia and may be a promising diagnostic tool in the early detection of laryngeal cancer [24].

In a study a prospective randomized trial that used modified back to back colonoscopy to assess the efficacy of i-SCAN application during screening colonoscopy [25]. They compared i-SCAN with conventional white light endoscopy and the results of i-SCAN vs White light laryngoscopy were as follows accuracy, 88.1% vs 75.5%; P=0.29; sensitivity 86.5% vs 72.6%; P=0.02; specificity, 91.4% vs80.6%; P=0.04.

Another study investigated the used i-SCAN technology for prediction of polyp histology by 11 endoscopists across 550 images (396 adenomatous, 154 non adenomatous). Mean sensitivity, specificity and accuracy of i-SCAN for diagnosing adenomas were 79.3%, 85.7% and 81.1 % respectively [26].

A study, studied the utility of i-SCAN – enhanced endoscopy versus conventional WLE in 200 patients undergoing screening colonoscopy for prediction of histology from biopsy or resected samples. These investigators reported that i-SCAN detected significantly more patients with colorectal neoplasia (38%) compared with standard resolution endoscopy (13%). Furthermore, significantly more neoplastic (adenomatous and cancerous) lesions and more flat adenomas could be detected using i-SCAN and final histology could be predicted with high accuracy (98.6%) [27].

Another study compared NBI and i-SCAN for real-time histological prediction of diminutive colonic polyps (DCE) for polyp characterization by using the simple unified endoscopic classification. This study demonstrates similar diagnostic efficacy between NBI and the i-SCAN. The sensitivity, specificity, and overall diagnostic accuracies were 88.8%, 86.8%, and 87.8% in the NBI group and 94.6%, 86.4%, and 90.7% in the i-SCAN group (P .05) [28]. The results of our study are comparable with the above studies on i-SCAN.

On conventional mode, 31% patients had benign lesions, 41 % had suspected malignant lesions and 28% had malignant lesions. Thus for conventional mode, Sensitivity, Specificity, PPV and NPV were 62%, 95%, 54%and 66% respectively as seen in table 5 and 6. The results of our study were comparable to other studies.

According to a study which compared endoscopy with CT scan for diagnosis of laryngeal lesions concluded that diagnostic accuracy of white light endoscopy for detecting glottic mucosal invasion was as follows: sensitivity, 64%; specificity, 80%; PPV value, 94.1%; NPV, 30.7%; accu3racy 66% [29].

According to a study, which compared NBI with white light laryngoscopy concluded that sensitivity of white light laryngoscopy in detecting malignant lesions (carcinoma in situ or invasive carcinoma) was 68.9% [30].

The sensitivity of i-SCAN in diagnosis of glottic benign, premalignant and malignant lesions is 85% which is higher compared to laryngoscopy in conventional mode which is 62%. Thus laryngoscopy with i-SCAN mode shows better results in diagnosis of glottic lesions as compared to laryngoscopy in conventional mode. Till date no literature is available for comparison of the two modalities in diagnosis of glottic lesions.

The advantages of i-SCAN is that it is the inbuilt tool on the system and does not require separate examination, but merely a button to switch between conventional mode and various i-SCAN modes. The learning curve of i-SCAN is short. It helps in detection of vascularity of the lesion, and details of the mucosal surface and margins and *in vivo* diagnosis of the lesion.

The disadvantage is the cost and availability of the system. It is not easily available with all laryngologists [31-33].

Limitations

- There is not enough literature available on use of i-SCAN in laryngeal lesions for comparison with our study.
- The cost of the equipment, it cannot be afforded by all laryngologists.
- It is not easily available.
- Larger sample size would have given better results.

Conclusions

There is a significant correlation of i-SCAN with histopathology for diagnosis of glottic lesions, the sensitivity of i-SCAN for the same being 85%. i-SCAN shows better results than flexible laryngoscopy in conventional mode (sensitivity 62%) for *in vivo* diagnosis of glottic benign, premalignant and early malignant lesions.

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