



**SACCHARIN OR METHYLENE BLUE TEST - A SURGEON'S DILEMMA FOR
EUSTACHIAN TUBE EVALUATION.**

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ABSTRACT

Background: Saccharin and methylene blue tests have been used to assess the Eustachian tube function. Both have their advantages and disadvantages. Even after years of debate it is still not clear which test is superior to other. **Objective:** To evaluate which out of two i.e. the saccharin or methylene blue test is a better tool to assess Eustachian tube function. **Material and methods:** This observational study was conducted in the department of Otorhinolaryngology and Head and Neck Surgery of KLE University's Jawaharlal Nehru Medical College and KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2014 to December 2014. **Results:** 43 (78.2%) patients had normal saccharin test, 11(20%) patients had partial dysfunction while 1(1.2%) had gross dysfunction of eustachian tube. Mean saccharin clearance time was found to be 18 ± 5.44 min with range of 12.1 minutes to 47.4 minutes. Similar results were seen with methylene blue test. Mean duration for methylene blue test was found to be 8.3 ± 3.78 min with range of 4.1 minutes to 26 minutes. **Conclusion:** The saccharin test is an easy, simple, and cost-effective method because it does not require any sophisticated equipment, while methylene blue dye test has an added advantage of easy documentation.

KEYWORDS: Eustachian tube function, saccharin test, methylene blue test, Chronic Otitis Media.

INTRODUCTION

Eustachian tube function has been always at the forefront to understand various pathologies of middle ear. Eustachian tube function (ETF) has been measured by various methods like Valsalva's test, Toynbee test, Politzer's test, Eustachian tube catheterization to name a few. The tests like sonotubometry measures the middle ear pressure regulation function of Eustachian tube. Tests to assess the clearance and protective function of eustachian tube include mucociliary clearance using various materials like fluorescein dye, saccharin, glucose and methylene blue to name a few.

Saccharin is a nonnutritive sweetener that was discovered in 1879.^[1] It has property of being inert to respiratory epithelium that is it does not hamper physiological mucus clearance of sino-nasal mucosa. This property has been exploited to assess mucociliary function of nasal mucosa, without itself hampering it.

Methylene blue is a heterocyclic aromatic chemical compound with the chemical formula $C_{16}H_{18}N_3SCl$. It has various uses in chemistry and biology.

Methylene blue can be used to check patency of the dynamic conduit connecting the middle ear and nasopharynx, namely the Eustachian tube.

Eustachian tube function can be evaluated by various tests out of which saccharin test is a simple yet effective way for assessment of the same.

MATERIALS AND METHODS

An observational study was done wherein patients admitted in Department of ENT & HNS in KLEH & MRC, Belagavi were included. The study was done from January 2014 to December 2014. All patients admitted to IPD of ENT & HNS Department. All patients diagnosed with mucosal type Chronic Otitis Media (COM)) in inactive stage. Exclusion criteria was 1) Active COM mucosal 2) Squamosal COM (atticoantral), 3) Any type of mastoiditis, otomycosis and systemic diseases. 4) Patient with cleft palate and history of possible trauma. 5) Patients with history of previous middle ear surgery. The study was approved by the Ethical and Research Committee. A written informed consent was obtained and detailed history was taken. ENT examination was performed to rule out any associated pathology, any focus of infection, which could change the outcome of test. Assessment of ETF was done by Saccharin Test- wherein under microscopic control, one Saccharin pellet each of 12mg weight (ABOTT) (Picture 1) was placed in middle ear cavity through the perforation (Picture 2). The time required for the patient to taste saccharin was noted. If the patient did not taste saccharin within 45 minute, taste sensation was

tested. If taste sensation was intact, then response was taken as Gross dysfunction. If taste sensation was not intact, then response was taken as No response. Result of this test was classified into three groups: Less than 20 minutes as Normal; 20 to 45 minutes partial dysfunction; More than 45 minutes as gross dysfunction.^[2]



Picture 1: Saccharin pellets.



Picture 2: Saccharin pellet being placed in Middle ear through the perforation.

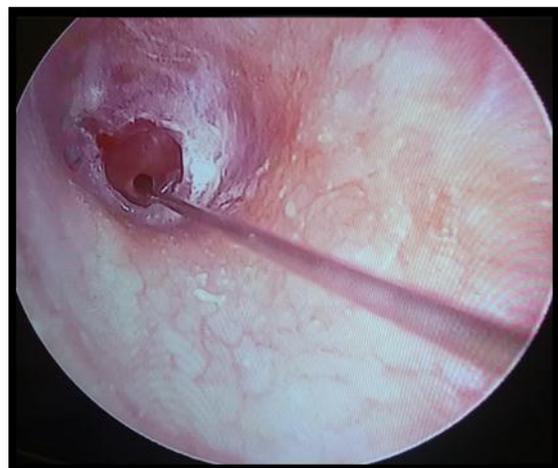
Methylene Blue Test

Two or Three drops of sterile methylene blue aqueous (SELKROM Product No.38883) (Picture 3) diluted in equal volume of saline were placed, under microscope/endoscopic control in the middle ear at eustachian tube opening through the perforation (Picture 4). With the help of Sinoscope (0° Nasal Endoscope), nasopharyngeal end of the Eustachian Tube was focused to look for the dye and the interval was noted. Less than 10 minutes taken as Normal; 10 to 20 minutes as Partial

dysfunction and more than 20 minutes as gross dysfunction.^[2]



Picture 3: Methylene Blue Dye used



Picture 4: Methylene blue dye placed in middle ear.

RESULTS AND DISCUSSION

There were 16 (29.1%) patients in the age group of 0-20 years, 34 (61.8%) patients in the age group of 20-40 years and 5 (9.1%) patients older than 40 years. Majority of the patients were males i.e. 61.8% compared to females 38.2% only. In this study, on performing Saccharin test 43 (78.2%) patients had normal eustachian tube function, 11(20%) patients had partial dysfunction while 1(1.2%) had gross dysfunction of eustachian tube. Mean saccharin clearance time was found to be 18 ± 5.44 min with range of 12.1 minutes to 47.4minutes. Similar results were seen with methylene blue test. Mean duration for methylene blue test was found to be 8.3 ± 3.78 min with range of 4.1 minutes to 26 minutes. The duration of tests had no significant relation in respect to age or sex.

Eustachian tube function (ETF) has been the center of focus as a prognostic factor because of the presumed primary role in pathogenesis of otitis media and in clearance of middle ear cavity.

In adults, it is about 36 mm in length, a size that is normally reached by the age of 7 years. It runs downwards from the middle ear at 45° and is turned forwards and medially. The tube can be considered to consist of two unequal cones, connected at their apices. The lateral third is bony and arises from the anterior wall of the tympanic cavity. This joins a medial cartilaginous part, which makes up two-thirds of the tubal length, just after its narrowest portion, called the isthmus.

The tube is lined with respiratory mucosa containing goblet cells and mucous glands, having a carpet of ciliated epithelium on its floor. At its nasopharyngeal end, the mucosa is truly respiratory, but in passing along the tube towards the middle ear, the number of goblet cells and glands decreases and the ciliary carpet becomes less profuse.

Abnormal or impaired eustachian tube functions may cause pathological changes in the middle ear. This in turn can lead to hearing loss and other complications of otitis media. These pathological changes include recurrent acute otitis media and otitis media with effusion. Chronic retraction of the tympanic membrane may also lead to middle ear atelectasis and subsequent adhesive otitis media. A retraction pocket of the tympanic membrane secondary to chronic eustachian tube dysfunction may eventually evolve into cholesteatoma and potentially serious complications.

Functions of eustachian tube can be broadly classified into three: 1) Pressure regulation-of middle ear, 2) Protective function, 3) Clearance function.

Despite pressure regulation function being the most important of the three physiologic functions of the eustachian tube for maintenance of optimal hearing, the protective and clearance functions are also important in maintaining the physiologic state. The clearance and drainage functions of the eustachian tube have been assessed by a variety of methods in the past. By means of radiographic techniques, the flow of contrast media from the middle ear (tympanic membrane not intact) into the nasopharynx has been assessed by Welin, Aschan, Compere, Parisier and Khilnani, Bluestone and colleagues, Ferber and Holmquist, and Honjo and colleagues.^[3-10] Rogers and colleagues instilled a solution of fluorescein into the middle ear and assessed the clearance function by subsequently examining the pharynx with an ultraviolet light.^[11] LaFaye and colleagues used a radioisotope technique to monitor the flow of saline solution down the eustachian tube.^[12]

Bauer assessed clearance by observing methylene blue in the pharynx after it had been instilled into the middle

ear.^[13] Elbrønd and Larsen assessed middle ear-eustachian tube mucociliary flow by determining the time that elapsed after saccharin had been placed on the mucous membrane of the middle ear until the subject reported tasting it.^[14]

Mucociliary clearance has been investigated for the past 50 years using a variety of methods. Clearance has been studied by instilling radiopaque material into the middle ears of children whose tympanic membranes were not intact. Following placement of foreign material in humans with perforations of the tympanic membrane, Sadé reported that the anterior half to two-thirds of the middle-ear cavity had the most active clearance properties. Such material will flow toward the middle ear portion of the eustachian tube and out the tube. This movement is related to ciliary activity that occurs in the eustachian tube and parts of the middle ear; these ciliated cells in the middle ear are increasingly more active as their location becomes more distal to the opening of the eustachian tube.^[15]

Methods used to assess mucociliary clearance function of the middle ear-Eustachian tube system in humans and animals.

Radiographic - Welin, 1947^[16], Compere, 1960.^[17]

Wittenborg and Neuhauser, 1963

Fluorescein - Rogers et al, 1962

Fluoroscopic with Contrast materials-
Bluestone in 1971

Methylene blue - Bauer, 1975

Saccharin - Elbrønd and Larsen, 1976

The age range of participants in this study was ranging from 12 to 64 years and mean age was 26.7 ± 10.18 years. In the current study 34 (61.8%) patients were males, while 21 (38.2%) were females. The male to female ratio was 1.6:1. In a similar study there were 45 (52.3%) males, while 41 (47.7%) were females.^[2]

Among the various tests used for mucociliary clearance, saccharin test has been widely accepted as the standard method. In the present study, on performing Saccharin test 43 (78.2%) patients had normal (less than 20 minutes) eustachian tube function, 11 (20%) patients had partial dysfunction (20-40min) while 1 (1.2%) had gross dysfunction of Eustachian tube.

Mean saccharin clearance time was found to be 18 ± 5.44 min with range of 12.1 minutes to 47.4 minutes.

Srivastav et al^[18] reported mucociliary function of the ET by mean of the saccharin test using a Sweetex tablet; they divided patients into two groups: 1) Saccharin clearance time ≤ 45 minutes, which indicates a patent ET; 2) Saccharin clearance time more than 45 minutes, indicates a blocked ET.

In our study we evaluated ETF by means of a similar technique using a Sweetex tablet, but we modified the

classification by considering both studies. Less than 20 minutes was considered normal ETF, 20 to 45 minutes as partial dysfunction, and more than 45 minutes as gross dysfunction.^[2] Elbrond *et al*^[14] used a saccharin crystal, which may be less soluble than the saccharin pellets used in our study. This probably explains the disparity in timings although the same method was used. Among the various tests used for Eustachian tube assessment, methylene blue dye test has been widely accepted as the standard method. In the present study, on performing methylene blue dye test 43 (78.2%) patients had normal (less than 10 minutes) eustachian tube function, 11 (20%) patients had partial dysfunction (10-20min) while 1 (1.2%) had gross dysfunction of Eustachian tube.

Mean time for methylene blue dye test was found to be 8.3 ± 3.78 min with range of 4.1 minutes to 26 minutes.

Despite various advanced techniques for assessing Eustachian tube function, the test is not performed in clinical practice by majority of clinicians. Various factors have been attributed in the ignorance of the same, most importantly the complexity to perform those tests and cost of performing it. ETF tests must be a part of the investigative repertoire in managing a case of COM. The saccharin test is an easy, simple and cost-effective method because it does not require any sophisticated equipment. It promises to be a useful diagnostic tool to assess the anatomical patency and mucociliary function of the ET. Moreover it's a great tool to demonstrate and document the same. The methylene blue dye test establishes the anatomical patency of the ET. The saccharin test establishes both the anatomical and physiological patency of the ET.

CONCLUSION

Despite various advanced techniques for assessing Eustachian tube function, the test is not performed in clinical practice by majority of otologists. Various factors have been attributed in the ignorance of the same, most importantly the complexity to perform those tests and cost of performing it. ETF tests must be a part of the investigative repertoire in managing a case of COM. The saccharin test is an easy, simple, and cost-effective method because it does not require any sophisticated equipment. It promises to be a useful diagnostic tool to assess the mucociliary function of the ET. Therefore, saccharin test is recommended as a part of routine pre-operative workup for all patients planned for tympanoplasty.

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